IOM 100-01 Chapter 3

20.5 - Blood Deductibles (Part A and Part B)
(Rev. 1, 09-11-02)

Program payment may not be made for the first 3 pints of whole blood or equivalent units of packed red cells received under Part A and Part B combined in a calendar year. However, blood processing (e.g., administration, storage) is not subject to the deductible.

The blood deductibles are in addition to any other applicable deductible and coinsurance amounts for which the patient is responsible.

The deductible applies only to the first 3 pints of blood furnished in a calendar year, even if more than one provider furnished blood.

20.5.1 - Part A Blood Deductible
(Rev. 1, 09-11-02)

Blood must be furnished on a Medicare covered day in a hospital or SNF to be counted under Part A. Blood furnished to an inpatient after benefits exhausted or before entitlement is not counted toward the combined deductible. Blood furnished during a lifetime extension election period is counted toward the combined A/B 3 pint total.

20.5.2 - Part B Blood Deductible
(Rev. 1, 09-11-02)

Blood is furnished on an outpatient basis or is subject to the Part B blood deductible and is counted toward the combined limit. It should be noted that payment for blood may be made to the hospital under Part B only for blood furnished in an outpatient setting. Blood is not covered for inpatient Part B services.

20.5.3 - Items Subject to Blood Deductibles
(Rev. 18, Issued: 03-04-05, Effective: 07-01-05, Implementation: 07-05-05)

The blood deductibles apply only to whole blood and packed red cells. The term whole blood means human blood from which none of the liquid or cellular components have been removed. Where packed red cells are furnished, a unit of packed red cells is considered equivalent to a pint of whole blood. Other components of blood such as platelets, fibrinogen, plasma, gamma globulin, and serum albumin are not subject to the blood deductible. However, these components of blood are covered as biologicals.

Refer to Pub. 100-04, Medicare Claims Processing Manual, Chapter 4, §231 regarding billing for blood and blood products under the Hospital Outpatient Prospective Payment System (OPPS).

20.5.4 - Obligations of the Beneficiary to Pay for or Replace Deductible Blood
(Rev. 1, 09-11-02)

A provider may charge the beneficiary or a third party its customary charge for whole blood or units of packed red cells which are subject to either the Part A or Part B blood deductible, unless the individual, another person, or a blood bank replaces the blood or arranges to have it replaced.

20.5.4.1—Replacement of Blood
(Rev. 1, 09-11-02)

For replacement purposes, a pint of whole blood is considered equivalent to a unit of packed red cells. A deductible pint of whole blood or unit of packed red cells is considered replaced when a medically acceptable pint or unit is given or offered to the provider or, at the provider’s request, to its blood supplier. Accordingly, where an individual or a blood bank offers blood as a replacement for a deductible pint or unit furnished a Medicare beneficiary, the provider may not charge the beneficiary for the blood, whether or not the provider or its blood supplier accepts the replacement offer. Thus a provider may not charge a beneficiary merely because it is the policy of the provider or its blood supplier not to accept blood from a particular source which has offered to replace blood on behalf of the beneficiary. However, a provider would not be barred from charging a beneficiary for deductible blood, if there is a reasonable basis for believing that replacement blood offered by or on behalf of the beneficiary would endanger the health of a recipient or that the prospective donor’s health would be endangered by making a blood donation. Once a provider accepts a pint of replacement blood from a beneficiary or another individual acting on his/her behalf, the blood is deemed to have been replaced, and, the beneficiary may not be charged for the blood, even though the replacement blood is later found to be unfit and has to be discarded.

When a provider accepts blood donated in advance, in anticipation of need by a specific beneficiary, whether the beneficiary’s own blood, that is, an autologous donation, or blood furnished by another individual or blood assurance group, such donations are considered replacement for pints or units subsequently furnished the beneficiary.

20.6—Part B Premium
(Rev. 96, Issued: 11-25-15, Effective: 01-01-16, Implementation: 01-04-16)

The Centers for Medicare and Medicaid Services (CMS) updates the Part B premium each year. These adjustments are made according to formulas set by statute. By law, the monthly Part B premium must be sufficient to cover 25 percent of the program’s costs, including the costs of maintaining a reserve against unexpected spending increases. The federal government pays the remaining 75 percent.

Below are the annual Part B premium amounts from Calendar Year (CY) 1996 to 2006. For these years, and years prior
to 1996, the Part B premium is a single established rate for all beneficiaries.

<table>
<thead>
<tr>
<th>Year</th>
<th>Part B Premium</th>
<th>Year</th>
<th>Part B Premium</th>
</tr>
</thead>
<tbody>
<tr>
<td>1996</td>
<td>$42.50</td>
<td>2002</td>
<td>$54.00</td>
</tr>
<tr>
<td>1997</td>
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<td>2003</td>
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</tr>
<tr>
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</tr>
<tr>
<td>2001</td>
<td>$50.00</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Beginning on January 1, 2007, the Part B premium is based on the income of the beneficiary. See the following Change Requests (CRs) for more information.

For 2013, see CR 8052 found on the “2012 Transmittals” page at http://www.cms.gov/Transmittals/2012Trans/list.asp
For 2014, see CR 8527 found on the “2013 Transmittals” page at http://www.cms.gov/Transmittals/2013Trans/list.asp
For 2016, see CR 9410 found on the ”2015 Transmittals” page at http://www.cms.gov/Transmittals/2015Trans/list.asp

Attachment A: Income Parameters for Determining Part B Premium

**Individual Income** = Beneficiaries who file an individual tax return (including those who are single, head of household, qualifying widow(er) with dependent child, or married filing separately who lived apart from their spouse for the entire taxable year)

**Joint Income (Married)** = Beneficiaries who are married and lived with their spouse at any time during the taxable year, and also file a joint tax return

**Married filing Separate** = Beneficiaries who are married and lived with their spouse at any time during the taxable year, but file a separate tax return from their spouse

### 30—Outpatient Mental Health Treatment Limitation

(Rev. 60, Issued: 10-30-09, Effective: 01-01-10, Implementation: 01-04-10)

Regardless of the actual expenses a beneficiary incurs in connection with the treatment of mental, psychoneurotic, and personality disorders while the beneficiary is not an inpatient of a hospital at the time such expenses are incurred, the amount of those expenses that may be recognized for Part B deductible and payment purposes is limited to 62.5 percent of the Medicare approved amount for those services. The limitation is called the outpatient mental health treatment limitation (the limitation). The 62.5 percent limitation has been in place since the inception of the Medicare Part B program and it will remain effective at this percentage amount until January 1, 2010. However, effective January 1, 2010, through January 1, 2014, the limitation will be phased out as follows:

- January 1, 2010–December 31, 2011, the limitation percentage is 68.75%. (Medicare pays 55% and the patient pays 45%).
- January 1, 2012–December 31, 2012, the limitation percentage is 75%. (Medicare pays 60% and the patient pays 40%).
- January 1, 2013–December 31, 2013, the limitation percentage is 81.25%. (Medicare pays 65% and the patient pays 35%).
- January 1, 2014–onward, the limitation percentage is 100%. (Medicare pays 80% and the patient pays 20%).

For additional details concerning the outpatient mental health treatment limitation, please see the Medicare Claims Processing Manual, Publication 100-04, chapter 9, section 60 and chapter 12, section 210.

### 40—Limitation on Physical Therapy, Occupational Therapy and Speech-Language Pathology Services

(Rev. 28; Issued: 08-12-05; Effective/Implementation: 09-12-05)

Coverage of outpatient physical therapy, occupational therapy, and speech-language pathology services under Part B has been limited in some years. For descriptions of these limitations see Pub 100-04, Chapter 5, §10.2.
Laboratory means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

100-02 Chapter 1

10—Covered Inpatient Hospital Services Covered Under Part A

Patients covered under hospital insurance are entitled to have payment made on their behalf for inpatient hospital services. (Inpatient hospital services do not include extended care services provided by hospitals pursuant to swing bed approvals. See Pub. 100-1, Chapter 8, §10.1, “Hospital Providers of Extended Care Services.”). However, both inpatient hospital and inpatient SNF benefits are provided under Part A - Hospital Insurance Benefits for the Aged and Disabled, of Title XVIII.

Additional information concerning the following topics can be found in the following manual chapters:

- Benefit periods is found in Chapter 3, “Duration of Covered Inpatient Services”;
- Copayment days is found in Chapter 2, “Duration of Covered Inpatient Services”;
- Lifetime reserve days is found in Chapter 5, “Lifetime Reserve Days”;
- Related payment information is housed in the Provider Reimbursement Manual.

Blood must be furnished on a day which counts as a day of inpatient hospital services to be covered as a Part A service and to count toward the blood deductible. Thus, blood is not covered under Part A and does not count toward the Part A blood deductible when furnished to an inpatient after the inpatient has exhausted all benefit days in a benefit period, or where the individual has elected not to use lifetime reserve days. However, where the patient is discharged on their first
day of entitlement or on the hospital's first day of participation, the hospital is permitted to submit a billing form with no accommodation charge, but with ancillary charges including blood.

The records for all Medicare hospital inpatient discharges are maintained in CMS for statistical analysis and use in determining future PPS DRG classifications and rates.

Non-PPS hospitals do not pay for noncovered services generally excluded from coverage in the Medicare Program. This may result in denial of a part of the billed charges or in denial of the entire admission, depending upon circumstance. In PPS hospitals, the following are also possible:

1. In appropriately admitted cases where a noncovered procedure was performed, denied services may result in payment of a different DRG (i.e., one which excludes payment for the noncovered procedure); or
2. In appropriately admitted cases that become cost outlier cases, denied services may lead to denial of some or all of an outlier payment.

The following examples illustrate this principle. If care is noncovered because a patient does not need to be hospitalized, the intermediary denies the admission and makes no Part A (i.e., PPS) payment unless paid under limitation on liability. Under limitation on liability, Medicare payment may be made when the provider and the beneficiary were not aware the services were not necessary and could not reasonably be expected to know that the services were not necessary. For detailed instructions, see the Medicare Claims Processing Manual, Chapter 30, “Limitation on Liability.” If a patient is appropriately hospitalized but receives (beyond routine services) only noncovered care, the admission is denied.

NOTE: The intermediary does not deny an admission that includes covered care, even if noncovered care was also rendered. Under PPS, Medicare assumes that it is paying for only the covered care rendered whenever covered services needed to treat and/or diagnose the illness were in fact provided.

If a noncovered procedure is provided along with covered nonroutine care, a DRG change rather than an admission denial might occur: If noncovered procedures are elevating costs into the cost outlier category, outlier payment is denied in whole or in part.

When the hospital is included in PPS, most of the subsequent discussion regarding coverage of inpatient hospital services is relevant only in the context of determining the appropriateness of admissions, which DRG, if any, to pay, and the appropriateness of payment for any outlier cases.

If a patient receives items or services in excess of, or more expensive than, those for which payment can be made, payment is made only for the covered items or services or for only the appropriate prospective payment amount. This provision applies not only to inpatient services, but also to all hospital services under Parts A and B of the program. If the items or services were requested by the patient, the hospital may charge him the difference between the amount customarily charged for the services requested and the amount customarily charged for covered services.

An inpatient is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. Generally, a patient is considered an inpatient if formally admitted as inpatient with the expectation that he or she will remain at least overnight and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight.

The physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient. Physicians should use a 24-hour period as a benchmark, i.e., they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis. However, the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting. Factors to be considered when making the decision to admit include such things as:

- The severity of the signs and symptoms exhibited by the patient;
- The medical predictability of something adverse happening to the patient;
- The need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and
- The availability of diagnostic procedures at the time when and at the location where the patient presents.

Admissions of particular patients are not covered or noncovered solely on the basis of the length of time the patient actually spends in the hospital. In certain specific situations coverage of services on an inpatient or outpatient basis is determined by the following rules:

**Minor Surgery or Other Treatment** - When patients with known diagnoses enter a hospital for a specific minor surgical procedure or other treatment that is expected to keep them in the hospital for only a few hours (less than 24), they are considered outpatients for coverage purposes regardless of: the hour they came to the hospital, whether they used a bed, and whether they remained in the hospital past midnight.

**Renal Dialysis** - Renal dialysis treatments are usually covered only as outpatient services but may under certain circumstances be covered as inpatient services depending on the patient's condition. Patients staying at home, who are ambulatory, whose conditions are stable and who come to the hospital for routine chronic dialysis treatments, and not for a diagnostic workup or a change in therapy, are considered outpatients. On the other hand, patients undergoing short-term dialysis until their kidneys recover from an acute illness (acute dialysis), or persons with borderline renal failure who develop acute renal failure every time they have an illness and require dialysis (episodic dialysis) are usually inpatients. A patient may begin dialysis as an inpatient and then progress to an outpatient status.

Under original Medicare, the Quality Improvement Organization (QIO), for each hospital is responsible for deciding, during review of inpatient admissions on a case-by-case...
basis, whether the admission was medically necessary. Medicare law authorizes the QIO to make these judgments, and the judgments are binding for purposes of Medicare coverage. In making these judgments, however, QIOs consider only the medical evidence which was available to the physician at the time an admission decision had to be made. They do not take into account other information (e.g., test results) which became available only after admission, except in cases where considering the post-admission information would support a finding that an admission was medically necessary.

Refer to Parts 4 and 7 of the QIO Manual with regard to initial determinations for these services. The QIO will review the swing bed services in these PPS hospitals as well.

**NOTE:** When patients requiring extended care services are admitted to beds in a hospital, they are considered inpatients of the hospital. In such cases, the services furnished in the hospital will not be considered extended care services, and payment may not be made under the program for such services unless the services are extended care services furnished pursuant to a swing bed agreement granted to the hospital by the Secretary of Health and Human Services.

### 10.1—Bed and Board

(Rev. 1, 10-01-03)

**A3-3101.1, HO-210.1**

### 10.1.1—Accommodations - General

(Rev. 1, 10-01-03)

**A3-3101.1.A, HO-210.1.A**

The program will pay the same amount for routine accommodations services whether the patient has a private room not medically necessary, a private room medically necessary (Medicare does not pay for deluxe accommodations in any case), a semiprivate room (2-, 3-, or 4-bed accommodations), or ward accommodations, if its ward accommodations are consistent with program purposes (see §10.1.6 below).

A provider having both private and semiprivate accommodations may nevertheless charge the patient a differential for a private room if:

- The private room is not medically necessary; and
- The patient (or relative or other person acting on their behalf) has requested the private room, and the provider informs them of the amount of charge at the time of the request.

The private room differential may not exceed the difference between the customary charge for the accommodations furnished and the most prevalent semiprivate accommodation rate at the time of the patient's admission.

Where the provider bills for a private room as a covered service, i.e., shows the charge for the room as a covered charge on the Form CMS-1450, the intermediary will deem the private room to be medically necessary. Where the provider, on the other hand, shows a private differential as a noncovered charge, the intermediary will assume that the private room is not medically necessary.

If the beneficiary (or their representative) protests a charge for the private room on the grounds that the privacy was medically necessary, such protest will, if not in written form, be reduced to writing and forwarded to the intermediary. If an intermediary receives many protests of this kind, the provider may need guidance on what constitutes medical necessity for privacy. If the protest is received after the claim is processed, it will be treated as a request for reconsideration.

If at any time in the course of development (or thereafter within the period when the determination is not administratively final), the provider acknowledges that the private room was medically necessary; the intermediary will make an immediate finding to this effect.

Where it is necessary to develop the medical necessity of a private room, the guidelines in subsections §§10.1.2 and 10.1.3 below will apply.

### 10.1.2—Medical Necessity - Need for Isolation

(Rev. 1, 10-01-03)


A private room is medically necessary where isolation of a beneficiary is required to avoid jeopardizing their health or recovery, or that of other patients who are likely to be alarmed or disturbed by the beneficiary’s symptoms or treatment or subjected to infection by the beneficiary’s communicable disease. For example, communicable diseases, heart attacks, cerebrovascular accidents, and psychotic episodes may require isolation of the patient for certain periods. (See §10.1.3 below concerning medical necessity not based on need for isolation).

In establishing the medical necessity for isolation, the date of the physician’s written statement is not controlling, nor is the presence of a written statement. The crucial question is whether a private room was ordered by the physician because it is necessary for the health of the patient himself or herself or of other patients. In the absence of such an order, a patient who requested the room with knowledge of the amount of the charge may be charged appropriately, even though a physician subsequently submits a statement that the room was medically necessary. There may be cases in which the physician’s written statement of medical necessity, though dated after admission or even after discharge, merely confirms an order made informally at or before the time the beneficiary was admitted to the private room (e.g., the physician made arrangements by phone for the patient’s admission, gave the diagnosis, and stated the beneficiary would need a private room). In such cases, assuming that the private room was medically necessary, the lack of a written statement by the physician, or the fact that the written statement was prepared after discharge, would not be controlling. The patient may not be charged.

### 10.1.3—Medical Necessity - Admission Required and Only Private Rooms Available

(Rev. 1, 10-01-03)


A private room is considered to be medically necessary even though the beneficiary’s condition does not require isolation
if he/she needs immediate hospitalization (i.e., the beneficiary's medical condition is such that hospitalization cannot be deferred) and the hospital has no semiprivate or ward accommodations available at the time of admission.

It need not be considered whether semiprivate or ward accommodations were available in some other accessible hospital. Where medical necessity exists, the provider may not charge the beneficiary a private room differential until semiprivate or ward accommodations become available. Thereafter, the provider may transfer the patient to the nonprivate accommodations, or allow them to continue occupancy of the private room, subject to an appropriate differential charge (described in §10.1.1 above) if they request the private room with knowledge of the amount of the charge.

If the admission could be deferred until semiprivate or ward accommodations become available, the beneficiary should be informed of the amount of the differential he/she must pay for a private room if he/she wishes to be admitted immediately. The beneficiary may be charged the specified differential if he/she has been admitted to the private room at their request (or at the request of their representative) with knowledge of the amount of the charge.

10.1.4—Charges for Deluxe Private Room (Rev. 1, 10-01-03)

A3-3101.1.D, HO-210.1.D

Beneficiaries found to need a private room (either because they need isolation for medical reasons or because they need immediate admission when no other accommodations are available) may be assigned to any of the provider's private rooms. They do not have the right to insist on the private room of their choice, but their preferences should be given the same consideration as if they were paying all provider charges themselves. The program does not, under any circumstances, pay for personal comfort items. Thus, the program does not pay for deluxe accommodations and/or services. These would include a suite, or a room substantially more spacious than is required for treatment, or specially equipped or decorated, or serviced for the comfort and convenience of persons willing to pay a differential for such amenities. If the beneficiary (or representative) requests such deluxe accommodations, the provider should advise that there will be a charge, not covered by Medicare, of a specified amount per day (not exceeding the differential defined in the next sentence); and may charge the beneficiary that amount for each day he/she occupies the deluxe accommodations. The maximum amount the provider may charge the beneficiary for such accommodations is the differential between the most prevalent private room rate at the time of admission and the customary charge for the room occupied. Beneficiaries may not be charged this differential if they (or their representative) do not request the deluxe accommodations.

The beneficiary may not be charged such a differential in private room rates if that differential is based on factors other than personal comfort items. Such factors might include differences between older and newer wings, proximity to lounge, elevators or nursing stations, desirable view, etc. Such rooms are standard 1-bed units and not deluxe rooms for purposes of these instructions, even though the provider may call them deluxe and have a higher customary charge for them. No additional charge may be imposed upon the beneficiary who is assigned to a room that may be somewhat more desirable because of these factors.

10.1.5—All Private Room Providers (Rev. 1, 10-01-03)

A3-3101.E, HO-210.1.E

If the patient is admitted to a provider which has only private accommodations, and no semiprivate or ward accommodations, medical necessity will be deemed to exist for the accommodations furnished. Beneficiaries may not be subjected to an extra charge for a private room in an all-private room provider.

10.1.6—Wards (Rev. 1, 10-01-03)

A3-3101.1.F, HO-210.1.F

The law contemplates that Medicare patients should not be assigned to ward accommodations except at the patient's request or for a reason consistent with the purposes of the health insurance program.

When ward accommodations are furnished at the patient's request or for a reason determined to be consistent with the program's purposes, payment will be based on the average per diem cost of routine services (see §10.1.1 above). Where ward accommodations are assigned for other reasons, the law provides what may be a substantial penalty (See §10.1.6.2 below).

Any request by the patient (or relative or other person responsible for his or her affairs) for ward accommodations must be obtained by the provider in writing and kept in its files.

10.1.6.1—Assignment Consistent With Program Purposes (Rev. 1, 10-01-03)

A3-3101.1.F.1, HO-210.1.F.1

It is considered to be consistent with the program's purposes to assign the patient to ward accommodations if all semiprivate accommodations are occupied, or the facility has no semiprivate accommodations. However, the patient must be moved to semiprivate accommodations if they become available during the stay.

Some hospitals have a policy of placing in wards all patients who do not have private physicians. Such a practice may be consistent with the purposes of the program if the intermediary determines that the ward assignment inures to the benefit of the patient. In making this determination, the principal consideration is whether the assignment is likely to result in better medical treatment of the patient (e.g., it facilitates necessary medical and nursing supervision and treatment). The intermediary should ask a provider having this policy to submit a statement describing how the assignments are made, their purpose, and the effect on the care of patients so assigned.

If the intermediary makes a favorable determination on a practice affecting all ward assignments of Medicare patients in the institution, a reference should be made on the appropriate billing form for patients to whom the hospital assigned a ward pursuant to such practice.
10.1.6.2—Assignment Not Consistent With Program Purposes
(Rev. 1, 10-01-03)
A3-3101.1.F.2, HO-210.1.F.2
It is not consistent with the purposes of the law to assign a patient ward accommodation based on their social or economic status, their national origin, race, or religion, or their entitlement to benefits as a Medicare patient, or any other such discriminatory reason. It is also inconsistent with the purposes of the law to assign patients to ward accommodations merely for the convenience or financial advantage of the institution. Additionally, under DRGs, there no longer is a reduction to payment or an adjustment to the end of year settlement.

10.1.7—Charges
(Rev. 1, 10-01-03)
Customary charges mean amounts which the hospital or skilled nursing facility is uniformly charging patients currently for specific services and accommodations. The most prevalent rate or charge is the rate that applies to the greatest number of semiprivate or private beds in the institution.

100-02 Chapter 6
10—Medical and Other Health Services Furnished to Inpatients of Participating Hospitals
(Rev. 182, Issued: 03-21-14, Effective: 10-01-13, Implementation: 04-21-14)
Payment may be made under Part B for physician services and for the nonphysician medical and other health services as provided in this section listed below when furnished by a participating hospital (either directly or under arrangements) to an inpatient of the hospital, but only if payment for these services cannot be made under Part A. This policy applies to all hospitals and critical access hospitals (CAHs) participating in Medicare, including those paid under a prospective payment system or alternative payment methodology such as State cost control systems, and to emergency hospital services furnished by nonparticipating hospitals. In this section, the term “hospital” includes all hospitals and CAHs, regardless of payment methodology, unless otherwise specified.

For services to be covered under Part A or Part B, a hospital must furnish nonphysician services to its inpatients directly or under arrangements (see chapter 16, §170 of this manual, “Inpatient Hospital or SNF Services Not Delivered Directly or Under Arrangement by the Provider”). A nonphysician service is one which does not meet the criteria defining physicians services specifically provided for in regulation at 42 CFR 415.102. Services “incident to” physicians’ services (except for the services of nurse anesthetists employed by anesthesiologists) are nonphysician services for purposes of this provision.

10.1 - Reasonable and Necessary Part A Hospital Inpatient Claim Denials
(Rev. 182, Issued: 03-21-14, Effective: 10-01-13, Implementation: 04-21-14)
If a Medicare Part A claim for inpatient hospital services is denied because the inpatient admission was not reasonable and necessary, or if a hospital determines under 42 CFR §482.30(d) or §485.641 after a beneficiary is discharged that the beneficiary’s inpatient admission was not reasonable and necessary, and if waiver of liability payment is not made, the hospital may be paid for the following Part B inpatient services that would have been reasonable and necessary if the beneficiary had been treated as a hospital outpatient rather than as an inpatient, provided the beneficiary is enrolled in Medicare Part B:

1) Part B services paid under the outpatient prospective payment system (OPPS), excluding observation services and hospital outpatient visits that require an outpatient status. Hospitals that are excluded from payment under the OPPS are instead paid under their alternative payment methodology (e.g., reasonable cost, all inclusive rate, or Maryland waiver) for the services that are otherwise payable under the OPPS.

2) The following services excluded from OPPS payment, that are instead paid under the respective Part B fee schedules or prospectively determined rates for which payment is made for these services when provided to hospital outpatients:
   a. Physical therapy services, speech-language pathology services, and occupational therapy services (see chapter 15, §§220 and 230 of this manual, “Covered Medical and Other Health Services.”).
   b. Ambulance services.
   c. Prosthetic devices, prosthetic supplies, and orthotic devices paid under the DMEPOS fee schedule (excludes implantable prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care) and replacement of such devices).
   d. Durametric equipment supplied by the hospital for the patient to take home, except durable medical equipment that is implantable.
   e. Certain clinical diagnostic laboratory services.
   f. Screening and diagnostic mammography services.
   g. Annual wellness visit providing personalized prevention plan services.

Hospitals may also be paid under Part B for services included in the payment window prior to the point of inpatient admission for outpatient services treated as inpatient services (see Pub. 100-04, Medicare Claims Processing Manual, Chapter 4, §10.12, “Payment Window for Outpatient Services Treated as Inpatient Services”), including services requiring an outpatient status. The hospital can only bill for services that it provided directly or under arrangement in accordance with Part B payment rules. Outpatient therapeutic services furnished at an entity that is wholly owned or wholly operated by the hospital and is not part of the hospital (such as a physician’s office), may not be billed by the hospital to Part B. Reference labs may be billed only if the referring laboratory does not bill for the laboratory test (see Pub. 100-04, Medicare Claims Processing Manual, Chapter 16, §40.1, “Laboratories Billing for Referred Tests”).

The services billed to Part B must be reasonable and necessary and must meet all applicable Part B coverage and payment conditions. Claims for Part B services submitted following a reasonable and necessary Part A claim denial or hospital utilization review determination must be filed no later than the close of the period ending 12 months or 1 calendar year after the date of service (see Pub. 100-04, Medicare Claims Processing Manual, Chapter 1, §70 “Time Limitations for Filing Part A and Part B Claims”). See Pub. 100-04, Medicare Claims Processing Manual, chapter 4, §240 for required bill types.
10.2 - Other Circumstances in Which Payment Cannot Be Made Under Part A

(Rev. 182, Issued: 03-21-14, Effective: 10-01-13, Implementation: 04-21-14)

Part B payment could be made to a hospital for the medical and other health services listed in this section for inpatients enrolled in Part B if:

- No Part A prospective payment is made at all for the hospital stay because of patient exhaustion of benefit days before or during the admission;
- The patient was not otherwise eligible for or entitled to coverage under Part A (see chapter 16, §180 of this manual for services received as a result of non-covered services).

Beginning in 2014, for hospitals paid under the OPPS these Part B inpatient services are separately payable under Part B, and are excluded from OPPS packaging if the primary service with which the service would otherwise be bundled is not a payable Part B inpatient service.

The following inpatient services are payable under the OPPS:

- Diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests;
- X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;
- Acute dialysis of a hospital inpatient with or without end stage renal disease (ESRD). The charge for hemodialysis is a charge for the use of a prosthetic device, billed in accordance with Pub. 100-04, Medicare Claims Processing Manual, Chapter 4, §200.2, “Hospital Dialysis Services for Patients With and Without End Stage Renal Disease (ESRD).”
- Screening pap smears;
- Influenza, pneumococcal pneumonia, and hepatitis B vaccines;
- Colorectal screening;
- Bone mass measurements;
- Prostate screening;
- Hemophilia clotting factors for hemophilia patients competent to use these factors without supervision;
- Immunosuppressive drugs;
- Oral anti-cancer drugs;
- Oral drug prescribed for use as an acute anti-emetic used as part of an anti-cancer chemotherapeutic regimen; and
- Epoetin Alfa (EPO) that is not covered under the ESRD benefit.

The following inpatient services are payable under the non-OPPS Part B fee schedules or prospectively determined rates listed:

- Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations (DMEPOS fee schedule);
- Prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of intraocular lens (DMEPOS fee schedule, except for implantable prosthetic devices paid at the applicable rate under Part B inpatient services into an entity that is wholly owned or wholly operated by the hospital and is not part of the hospital (such as a physician’s office), may not be billed by the hospital to Part B. Reference labs may be billed only if the referring laboratory does not bill for the laboratory test (see Pub. 100-04, Medicare Claims Processing Manual, Chapter 16, §40.1, “Laboratories Billing for Referred Tests”).

The services billed to Part B must be reasonable and necessary and must meet all applicable Part B coverage and payment conditions. Claims for these services must be filed no later than the close of the period ending 12 months or 1 calendar year after the date of service (see Pub. 100-04, Medicare Claims Processing Manual, Chapter 1, §70, “Time Limitations for Filing Part A and Part B Claims”). See Pub. 100-04, Medicare Claims Processing Manual, chapter 4, §240 for required bill types.

10.3—Hospital Inpatient Services Paid Only Under Part B

(Rev. 182, Issued: 03-21-14, Effective: 10-01-13, Implementation: 04-21-14)

The services listed in Chapter 15, §250 of this manual, “Medical and Other Health Services Furnished to Inpatients of Hospitals and Skilled Nursing Facilities,” when provided to a hospital inpatient, may be covered under Part B, even though the patient has Part A coverage for the hospital stay. This is because these services are covered under Part B and are not covered under Part A.

In all hospitals, all other services provided to a hospital inpatient must be treated as an inpatient hospital service to be paid for under Part A, if Part A coverage is available and the beneficiary is entitled to Part A. This is because every hospital must provide directly or arrange for any nonphysician service rendered to its inpatients, and a hospital can be paid under Part B for a service provided in this manner only if Part A coverage does not exist.

However, note that in order to have any Medicare coverage at all (Part A or Part B), any nonphysician service rendered to a hospital inpatient must be provided directly or arranged for by the hospital.

(Continued on page 10)
<table>
<thead>
<tr>
<th>Conditions</th>
<th>Review Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patient was transported by an approved supplier of ambulance services.</td>
<td>1. Ambulance suppliers are explained in greater detail in (§10.1.3)</td>
</tr>
<tr>
<td>2. The patient was suffering from an illness or injury, which contraindicated transportation by other means. (§10.2)</td>
<td>2. (a) The contractor presumes the requirement was met if the submitted documentation indicates that the patient: • Was transported in an emergency situation, e.g., as a result of an accident, injury or acute illness, or • Needed to be restrained to prevent injury to the beneficiary or others; or • Was unconscious or in shock; or • Required oxygen or other emergency treatment during transport to the nearest appropriate facility; or • Exhibits signs and symptoms of acute respiratory distress or cardiac distress such as shortness of breath or chest pain; or • Exhibits signs and symptoms that indicate the possibility of acute stroke; or • Had to remain immobile because of a fracture that had not been set or the possibility of a fracture; or • Was experiencing severe hemorrhage; or • Could be moved only by stretcher; or • Was bed-confined before and after the ambulance trip. (b) In the absence of any of the conditions listed in (a) above additional documentation should be obtained to establish medical need where the evidence indicates the existence of the circumstances listed below: (i) Patient's condition would not ordinarily require movement by stretcher, or (ii) The individual was not admitted as a hospital inpatient (except in accident cases), or (iii) The ambulance was used solely because other means of transportation were unavailable, or (iv) The individual merely needed assistance in getting from his room or home to a vehicle. (c) Where the information indicates a situation not listed in 2(a) or 2(b) above, refer the case to your supervisor.</td>
</tr>
<tr>
<td>3. The patient was transported from and to points listed below. (a) From patient's residence (or other place where need arose) to hospital or skilled nursing facility.</td>
<td>3. Claims should show the ZIP Code of the point of pickup. (a) • Condition met if trip began within the institution's service area as shown in the carrier's locality guide. • Condition met where the trip began outside the institution's service area if the institution was the nearest one with appropriate facilities.</td>
</tr>
<tr>
<td>NOTE: A patient's residence is the place where he or she makes his/her home and dwells permanently, or for an extended period of time. A skilled nursing facility is one, which is listed in the Directory of Medical Facilities as a participating SNF or as an institution which meets §1861(j)(1) of the Act. NOTE: A claim for ambulance service to a participating hospital or skilled nursing facility should not be denied on the grounds that there is a nearer nonparticipating institution having appropriate facilities.</td>
<td></td>
</tr>
<tr>
<td>(b) Skilled nursing facility to a hospital or hospital to a skilled nursing facility.</td>
<td>(b) • Condition met if the ZIP Code of the pickup point is within the service area of the destination as shown in the carrier's locality guide. • Condition met where the ZIP Code of the pickup point is outside the service area of the destination if the destination institution was the nearest appropriate facility.</td>
</tr>
<tr>
<td>(c) Hospital to hospital or skilled nursing facility to skilled nursing facility.</td>
<td>(c) Condition met if the discharging institution was not an appropriate facility and the admitting institution was the nearest appropriate facility.</td>
</tr>
<tr>
<td>(d) From a hospital or skilled nursing facility to patient's residence.</td>
<td>(d) • Condition met if patient's residence is within the institution's service area as shown in the carrier's locality guide. • Condition met where the patient's residence is outside the institution's service area if the institution was the nearest appropriate facility.</td>
</tr>
</tbody>
</table>
100-02 Chapter 10

20—Coverage Guidelines for Ambulance Service Claims

(Rev. 103; Issued: 02-20-09; Effective Date: 01-05-09; Implementation Date: 03-20-09)

B3-2125

Payment may be made for expenses incurred by a patient for ambulance service provided conditions 1, 2, and 3 in the left-hand column have been met. The right-hand column indicates the documentation needed to establish that the condition has been met. (See Conditions and Review Action on pages 8-9)

20.1—Mandatory Assignment Requirements

(Rev. 1, 10-01-03)

When an ambulance provider/supplier, or a third party under contract with the provider/supplier, furnishes a Medicare-covered ambulance service to a Medicare beneficiary and the service is not statutorily excluded under the particular circumstances, the provider/supplier must submit a claim to Medicare and accept assignment of the beneficiary’s right to payment from Medicare.

20.1.1—Managed Care Providers/Suppliers

(Rev. 103; Issued: 02-20-09; Effective Date: 01-05-09; Implementation Date: 03-20-09)

Mandatory assignment for ambulance services, in effect with the implementation of the ambulance fee schedule, applies to ambulance providers/suppliers under managed care as well as under fee-for-service. The ambulance fee schedule is effective for claims with a date of service on or after April 1, 2002.

Any provider or supplier without a contract establishing payment amounts for services provided to a beneficiary enrolled in a Medicare Advantage (MA) coordinated care plan or MA private fee-for-service plan must accept, as payment in full, the amounts that they could collect if the beneficiary were enrolled in original Medicare. The provider or supplier can collect from the MA plan enrollee the cost-sharing amount required under the MA plan, and collect the remainder from the MA organization.

20.1.2—Beneficiary Signature Requirements

(Rev. 190, Issued: 07-11-14, Effective: 08-12-14)

Medicare requires the signature of the beneficiary, or that of his or her representative, for both the purpose of accepting assignment and submitting a claim to Medicare. If the beneficiary is unable to sign because of a mental or physical condition, the following individuals may sign the claim form on behalf of the beneficiary: (1) The beneficiary’s legal guardian. (2) A relative or other person who receives social security or other governmental benefits on behalf of the beneficiary. (3) A relative or other person who arranges for the beneficiary’s treatment or exercises other responsibility for his or her affairs. (4) A representative of an agency or institution that did not furnish the services for which payment is claimed, but furnished other care, services, or assistance to the beneficiary. (5) A representative of the provider or of the nonparticipating hospital claiming payment for services it has furnished, if the provider or nonparticipating hospital is unable to have the claim signed in accordance with 42 CFR 424.36(b) (1 – 4). (6) A representative of the ambulance provider or supplier who is present during an emergency and/or nonemergency transport, provided that the ambulance provider or supplier maintains certain documentation in its records for at least 4 years from the date of service. A provider/supplier (or his/her employee) cannot request payment for services furnished except under circumstances fully documented to show that the beneficiary is unable to sign and that there is no other person who could sign.

Medicare does not require that the signature to authorize claim submission be obtained at the time of transport for the purpose of accepting assignment of Medicare payment for ambulance benefits. When a provider/supplier is unable to obtain the signature of the beneficiary, or that of his or her representative, at the time of transport, it may obtain this signature any time prior to submitting the claim to Medicare for payment. (Note: there is a 12 month period for filing a Medicare claim, depending upon the date of service.)
If the beneficiary/representative refuses to authorize the submission of a claim, including a refusal to furnish an authorizing signature, then the ambulance provider/supplier may not bill Medicare, but may bill the beneficiary (or his or her estate) for the full charge of the ambulance items and services furnished. If, after seeing this bill, the beneficiary/representative decides to have Medicare pay for these items and services, then a beneficiary/representative signature is required and the ambulance provider/supplier must afford the beneficiary/representative this option within the claims filing period.

100-02 Chapter 11

130 - Reserved
(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

100-02 Chapter 15

20.1 - Physician Expense for Surgery, Childbirth, and Treatment for Infertility
(Rev. 1, 10-01-03)

B3-2005.1
A. Surgery and Childbirth

Skilled medical management is covered throughout the events of pregnancy, beginning with diagnosis, continuing through delivery and ending after the necessary postnatal care. Similarly, in the event of termination of pregnancy, regardless of whether terminated spontaneously or for therapeutic reasons (i.e., where the life of the mother would be endangered if the fetus were brought to term), the need for skilled medical management and/or medical services is equally important as in those cases carried to full term. After the infant is delivered and is a separate individual, items and services furnished to the infant are not covered on the basis of the mother's eligibility.

Most surgeons and obstetricians bill patients an all-inclusive package charge intended to cover all services associated with the surgical procedure or delivery of the child. All expenses for surgical and obstetrical care, including preoperative/prenatal examinations and tests and post-operative/postnatal services, are considered incurred on the date of surgery or delivery, as appropriate. This policy applies whether the physician bills on a package charge basis, or itemizes the bill separately for these items.

Occasionally, a physician's bill may include charges for additional services not directly related to the surgical procedure or the delivery. Such charges are considered incurred on the date the additional services are furnished.

The above policy applies only where the charges are imposed by one physician or by a clinic on behalf of a group of physicians. Where more than one physician imposes charges for surgical or obstetrical services, all preoperative/prenatal and post-operative/postnatal services performed by the physician who performed the surgery or delivery are considered incurred on the date of the surgery or delivery. Expenses for services rendered by other physicians are considered incurred on the date they were performed.

B. Treatment for Infertility

Reasonable and necessary services associated with treatment for infertility are covered under Medicare. Infertility is a condition sufficiently at variance with the usual state of health to make it appropriate for a person who normally is expected to be fertile to seek medical consultation and treatment.

50—Drugs and Biologicals
(Rev. 1, 10-01-03)

B3-2049, A3-3112.4.B, HO-230.4.B

The Medicare program provides limited benefits for outpatient drugs. The program covers drugs that are furnished “incident to” a physician's service provided that the drugs are not usually self-administered by the patients who take them. Generally, drugs and biologicals are covered only if all of the following requirements are met:

- They meet the definition of drugs or biologicals (see §50.1);
- They are of the type that are not usually self-administered (see §50.2);
- They meet all the general requirements for coverage of items as incident to a physician's services (see §§50.1 and 50.3);
- They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice (see §50.4);
- They are not excluded as noncovered immunizations (see §50.4.2.2); and
- They have not been determined by the FDA to be less than effective. (See §50.4.4).

Medicare Part B does generally not cover drugs that can be self-administered, such as those in pill form, or are used for self-injection. However, the statute provides for the coverage of some self-administered drugs. Examples of self-administered drugs that are covered include blood-clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, osteoporosis drugs for certain homebound patients, and certain oral cancer drugs. (See §110.3 for coverage of drugs, which are necessary to the effective use of Durable Medical Equipment (DME) or prosthetic devices.)

50.1—Definition of Drug or Biological
(Rev. 1, 10-01-03)

B3-2049.1

Drugs and biologicals must be determined to meet the statutory definition. Under the statute §1861(t)(1), payment may be made for a drug or biological only where it is included, or approved for inclusion, in the latest official edition of the United States Pharmacopoeia National Formulary (USP-NF), the United States Pharmacopoeia-Drug Information (USP-DI), or the American Dental Association (AOA) Guide to Dental Therapeutics, except for those drugs and biologicals unfavorably evaluated in the ADA Guide to Dental Therapeutics. The inclusion of an item in the USP DI does not necessarily mean that the item is a drug or biological. The USP DI is a database of drug information developed by the U.S. Pharmacopoeia but maintained by Micromedex, which contains medically accepted uses for generic and brand name
drug products. Inclusion in such reference (or approval by a hospital committee) is a necessary condition for a product to be considered a drug or biological under the Medicare program, however, it is not enough. Rather, the product must also meet all other program requirements to be determined to be a drug or biological. Combination drugs are also included in the definition of drugs if the combination itself or all of the therapeutic ingredients of the combination are included, or approved for inclusion, in any of the above drug compendia.

Drugs and biologicals are considered approved for inclusion in a compendium if approved under the established procedure by the professional organization responsible for revision of the compendium.

50.2—Determining Self-Administration of Drug or Biological

The Medicare program provides limited benefits for outpatient prescription drugs. The program covers drugs that are furnished “incident to” a physician’s service provided that the drugs are not usually self-administered by the patients who take them. Section 112 of the Benefits, Improvements & Protection Act of 2000 (BIPA) amended sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act to redefine this exclusion. The prior statutory language referred to those drugs “which cannot be self-administered.” Implementation of the BIPA provision requires interpretation of the phrase “not usually self-administered by the patient”.

A—Policy

Fiscal intermediaries and carriers are instructed to follow the instructions below when applying the exclusion for drugs that are usually self-administered by the patient. Each individual contractor must make its own individual determination on each drug. Contractors must continue to apply the policy that not only the drug is medically reasonable and necessary for any individual claim, but also that the route of administration is medically reasonable and necessary. That is, if a drug is available in both oral and injectable forms, the injectable form of the drug must be medically reasonable and necessary as compared to using the oral form.

For certain injectable drugs, it will be apparent due to the nature of the condition(s) for which they are administered or the usual course of treatment for those conditions, they are, or are not, usually self-administered. For example, an injectable drug used to treat migraine headaches is usually self-administered. On the other hand, an injectable drug, administered at the same time as chemotherapy, used to treat anemia secondary to chemotherapy is not usually self-administered.

B—Administered

The term “administered” refers only to the physical process by which the drug enters the patient’s body. It does not refer to whether the process is supervised by a medical professional (for example, to observe proper technique or side-effects of the drug). Only injectable (including intravenous) drugs are eligible for inclusion under the “incident to” benefit. Other routes of administration including, but not limited to, oral drugs, suppositories, topical medications are all considered to be usually self-administered by the patient.

C—Usually

For the purposes of applying this exclusion, the term “usually” means more than 50 percent of the time for all Medicare beneficiaries who use the drug. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from coverage and the contractor may not make any Medicare payment for it. In arriving at a single determination as to whether a drug is usually self-administered, contractors should make a separate determination for each indication for a drug as to whether that drug is usually self-administered.

After determining whether a drug is usually self-administered for each indication, contractors should determine the relative contribution of each indication to total use of the drug (i.e., weighted average) in order to make an overall determination as to whether the drug is usually self-administered. For example, if a drug has three indications, is not self-administered for the first indication, but is self administered for the second and third indications, and the first indication makes up 40 percent of total usage, the second indication makes up 30 percent of total usage, and the third indication makes up 30 percent of total usage, then the drug would be considered usually self-administered.

Reliable statistical information on the extent of self-administration by the patient may not always be available. Consequently, CMS offers the following guidance for each contractor’s consideration in making this determination in the absence of such data:

1. Absent evidence to the contrary, presume that drugs delivered intravenously are not usually self-administered by the patient.
2. Absent evidence to the contrary, presume that drugs delivered by intramuscular injection are not usually self-administered by the patient. (Avonex, for example, is delivered by intramuscular injection, not usually self-administered by the patient.) The contractor may consider the depth and nature of the particular intramuscular injection in applying this presumption. In applying this presumption, contractors should examine the use of the particular drug and consider the following factors:
   A. Acute Condition — Is the condition for which the drug is used an acute condition? If so, it is less likely that a patient would self-administer the drug. If the condition were longer term, it would be more likely that the patient would self-administer the drug.
   B. Frequency of Administration — How often is the injection given? For example, if the drug is administered once per month, it is less likely to be self-administered by the patient. However, if it is administered once or more per week, it is likely that the drug is self-administered by the patient.

In some instances, carriers may have provided payment for one or perhaps several doses of a drug that would otherwise not be paid for because the drug is usually self-administered. Carriers may have exercised this discretion for limited coverage, for example, during a brief time when the patient is being trained under the supervision of a physician in the proper technique for self-administration. Medicare will no longer
pay for such doses. In addition, contractors may no longer pay for any drug when it is administered on an outpatient emergency basis, if the drug is excluded because it is usually self-administered by the patient.

D—Definition of Acute Condition

For the purposes of determining whether a drug is usually self-administered, an acute condition means a condition that begins over a short time period, is likely to be of short duration and/or the expected course of treatment is for a short, finite interval. A course of treatment consisting of scheduled injections lasting less than two weeks, regardless of frequency or route of administration, is considered acute. Evidence to support this may include Food and Drug Administration (FDA) approval language, package inserts, drug compendia, and other information.

E—By the Patient

The term “by the patient” means Medicare beneficiaries as a collective whole. The carrier includes only the patients themselves and not other individuals (that is, spouses, friends, or other care-givers are not considered the patient). The determination is based on whether the drug is self-administered by the patient a majority of the time that the drug is used on an outpatient basis by Medicare beneficiaries for medically necessary indications. The carrier ignores all instances when the drug is administered on an inpatient basis.

The carrier makes this determination on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis. In evaluating whether beneficiaries as a collective whole self-administer, individual beneficiaries who do not have the capacity to self-administer any drug due to a condition other than the condition for which they are taking the drug in question are not considered. For example, an individual afflicted with paralysis or advanced dementia would not have the capacity to self-administer any injectable drug, so such individuals would not be included in the population upon which the determination for self-administration by the patient was based. Note that some individuals afflicted with a less severe stage of an otherwise debilitating condition would be included in the population upon which the determination for “self-administered by the patient” was based; for example, an early onset of dementia.

F—Evidentiary Criteria

Contractors are only required to consider the following types of evidence: peer reviewed medical literature, standards of medical practice, evidence-based practice guidelines, FDA approved label, and package inserts. Contractors may also consider other evidence submitted by interested individuals or groups subject to their judgment.

Contractors should also use these evidentiary criteria when reviewing requests for making a determination as to whether a drug is usually self-administered, and requests for reconsideration of a pending or published determination.

Please note that prior to the August 1, 2002, one of the principal factors used to determine whether a drug was subject to the self-administered exclusion was whether the FDA label contained instructions for self-administration. However, CMS notes that under the new standard, the fact that the FDA label includes instructions for self-administration is not, by itself, a determining factor that a drug is subject to this exclusion.

G—Provider Notice of Noncovered Drugs

Contractors must describe on their Web site the process they will use to determine whether a drug is usually self-administered and thus does not meet the “incident to” benefit category. Contractors must publish a list of the injectable drugs that are subject to the self-administered exclusion on their Web site, including the data and rationale that led to the determination. Contractors will report the workload associated with developing new coverage statements in CAFM 21208.

Contractors must provide notice 45 days prior to the date that these drugs will not be covered. During the 45-day time period, contractors will maintain existing medical review and payment procedures. After the 45-day notice, contractors may deny payment for the drugs subject to the notice.

Contractors must not develop local medical review policies (LMRPs) for this purpose because further elaboration to describe drugs that do not meet the ‘incident to’ and the ‘not usually self-administered’ provisions of the statute are unnecessary. Current LMRPs based solely on these provisions must be withdrawn. LMRPs that address the self-administered exclusion and other information may be reissued absent the self-administered drug exclusion material. Contractors will report this workload in CAFM 21206. However, contractors may continue to use and write LMRPs to describe reasonable and necessary uses of drugs that are not usually self-administered.

H—Conferences Between Contractors

Contractors’ Medical Directors may meet and discuss whether a drug is usually self-administered without reaching a formal consensus. Each contractor uses its discretion as to whether or not it will participate in such discussions. Each contractor must make its own individual determinations, except that fiscal intermediaries may, at their discretion, follow the determinations of the local carrier with respect to the self-administered exclusion.

I—Beneficiary Appeals

If a beneficiary’s claim for a particular drug is denied because the drug is subject to the “self-administered drug” exclusion, the beneficiary may appeal the denial. Because it is a “benefit category” denial and not a denial based on medical necessity, an Advance Beneficiary Notice (ABN) is not required. A “benefit category” denial (i.e., a denial based on the fact that there is no benefit category under which the drug may be covered) does not trigger the financial liability protection provisions of Limitation On Liability (under §1879 of the Act). Therefore, physicians or providers may charge the beneficiary for an excluded drug.

J—Provider and Physician Appeals

A physician accepting assignment may appeal a denial under the provisions found in Chapter 29 of the Medicare Claims Processing Manual.

K—Reasonable and Necessary

Carriers and fiscal intermediaries will make the determination of reasonable and necessary with respect to the medical appropriateness of a drug to treat the patient’s condition. Contractors will continue to make the determination of whether the intravenous or injection form of a drug is appropriate as opposed to the oral form. Contractors will also continue to make the determination as to whether a physician’s office visit was reasonable and necessary. However, contractors should
not make a determination of whether it was reasonable and necessary for the patient to choose to have his or her drug administered in the physician's office or outpatient hospital setting. That is, while a physician's office visit may not be reasonable and necessary in a specific situation, in such a case an injection service would be payable.

L—Reporting Requirements

Each carrier, intermediary and Medicare Administrative Contractor (MAC) must report to CMS its complete list of injectable drugs that the contractor has determined are excluded when furnished incident to a physician's service on the basis that the drug is usually self-administered. The CMS expects that contractors will review injectable drugs on a rolling basis and update their list of excluded drugs as it is developed and no less frequently than annually. For example, contractors should not wait to publish this list until every drug has been reviewed. Contractors must enter their self-administered drug exclusion list to the Medicare Coverage Database (MCD). This database can be accessed at www.cms.hhs.gov/mcd. See Pub.100-08 Program Integrity Manual, Chapter 3, Section 3.3, “Policies and Guidelines Applied During Review”, for instructions on submitting these lists to the MCD.

M. Drugs Treated as Hospital Outpatient Supplies

In certain circumstances, Medicare pays for drugs that may be considered usually self-administered by the patient when such drugs function as supplies. This is the case when the drugs provided are an integral component of a procedure or are directly related to it, i.e., when they facilitate the performance of or recovery from a particular procedure. Except for the applicable copayment, hospitals may not bill beneficiaries for these types of drugs because their costs, as supplies, are packaged into the payment for the procedure with which they are used. Listed below are examples of when drugs are treated as supplies and hospitals should bill Medicare for the drug as a supply and not separately bill the beneficiary.

• Sedatives administered to a patient while he or she is in the preoperative area being prepared for a procedure.
• Mydriatic drops instilled into the eye to dilate the pupils, anti-inflammatory drops, antibiotic drops/ointments, and ocular hypotensives that are administered to a patient immediately before, during, or immediately following an ophthalmic procedure. This does not refer to the patient's eye drops that the patient uses pre-and postoperatively.
• Barium or low osmolar contrast media provided integral to a diagnostic imaging procedure.
• Topical solution used with photodynamic therapy furnished at the hospital to treat nonhyperkeratotic actinic keratosis lesions of the face or scalp.
• Antibiotic ointments such as bacitracin, placed on a wound or surgical incision at the completion of a procedure.

The following are examples of when a drug is not directly related or integral to a procedure, and does not facilitate the performance of or recovery from a procedure. Therefore the drug is not considered a packaged supply. In many of these cases the drug itself is the treatment instead of being integral or directly related to the procedure, or facilitating the performance of or recovery from a particular procedure.

• Drugs given to a patient for his or her continued use at home after leaving the hospital.
• Oral pain medication given to an outpatient who develops a headache while receiving chemotherapy administration treatment.
• Daily routine insulin or hypertension medication given preoperatively to a patient.
• A fentanyl patch or oral pain medication such as hydrocodone, given to an outpatient presenting with pain.
• A laxative suppository for constipation while the patient waits to receive an unrelated X-ray.

These two lists of examples may serve to guide hospitals in deciding which drugs are supplies packaged as a part of a procedure, and thus may be billed under Part B. Hospitals should follow CMS’ guidance for billing drugs that are packaged and paid as supplies, reporting coded and uncoded drugs with their charges under the revenue code associated with the cost center under which the hospital accumulates the costs for the drugs.

50.3—Incident-to Requirements

(Rev. 1, 10-01-03)
B3-2049.3

In order to meet all the general requirements for coverage under the incident-to provision, an FDA approved drug or biological must:

• Be of a form that is not usually self-administered;
• Must be furnished by a physician; and
• Must be administered by the physician, or by auxiliary personnel employed by the physician, and under the physician's personal supervision.

The charge, if any, for the drug or biological must be included in the physician's bill, and the cost of the drug or biological must represent an expense to the physician. Drugs and biologicals furnished by other health professionals may also meet these requirements. (See §§170, 180, 190 and 200 for specific instructions.)

Whole blood is a biological, which cannot be self-administered and is covered when furnished incident to a physician's services. Payment may also be made for blood fractions if all coverage requirements are satisfied and the blood deductible has been met.

50.4—Reasonableness and Necessity

(Rev. 1, 10-01-03)
B3-2049.4

50.4.1—Approved Use of Drug

(Rev. 1, 10-01-03)
B3-2049.4

Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. (See the Medicare Benefit Policy Manual, Chapter 16, “General Exclusions from Coverage.” §20.) Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, the program may pay for the use of an FDA approved drug or biological, if:

• It was injected on or after the date of the FDA’s approval;
• It is reasonable and necessary for the individual patient; and
• All other applicable coverage requirements are met.
The carrier, DMERC, or intermediary will deny coverage for drugs and biologicals which have not received final marketing approval by the FDA unless it receives instructions from CMS to the contrary. For specific guidelines on coverage of Group C cancer drugs, see the Medicare National Coverage Determinations Manual.

If there is reason to question whether the FDA has approved a drug or biological for marketing, the carrier or intermediary must obtain satisfactory evidence of FDA’s approval. Acceptable evidence includes:

- A copy of the FDA’s letter to the drug’s manufacturer approving the new drug application (NDA);
- A listing of the drug or biological in the FDA’s “Approved Drug Products” or “FDA Drug and Device Product Approvals”;
- A copy of the manufacturer’s package insert, approved by the FDA as part of the labeling of the drug, containing its recommended use;
- A copy of the manufacturer’s package insert, approved by the FDA as part of the labeling of the drug, containing its recommended use and any contraindications; or possible adverse reactions and recommended precautions in using it; or
- Information from the FDA’s Web site.

When necessary, the Regional Office (RO) may be able to help in obtaining information.

### 50.4.2—Unlabeled Use of Drug

(Rev. 1, 10-01-03)

B3-2049.3

An unlabeled use of a drug is a use that is not included as an indication on the drug’s label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. In the case of drugs used in an anti-cancer chemotherapeutic regimen, unlabeled uses are covered for a medically accepted indication as defined in §50.5.

These decisions are made by the contractor on a case-by-case basis.

### 50.4.3—Examples of Not Reasonable and Necessary

(Rev. 1, 10-01-03)

B3-2049.4

Determinations as to whether medication is reasonable and necessary for an individual patient should be made on the same basis as all other such determinations (i.e., with the advice of medical consultants and with reference to accepted standards of medical practice and the medical circumstances of the individual case). The following guidelines identify three categories with specific examples of situations in which medications would not be reasonable and necessary according to accepted standards of medical practice:

#### 1—Not for Particular Illness

Medications given for a purpose other than the treatment of a particular condition, illness, or injury are not covered (except for certain immunizations). Charges for medications, e.g., vitamins, given simply for the general good and welfare of the patient and not as accepted therapies for a particular illness are excluded from coverage.

#### 2—Injection Method Not Indicated

Medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration. For example, the accepted standard of medical practice for the treatment of certain diseases is to initiate therapy with parenteral penicillin and to complete therapy with oral penicillin. Carriers exclude the entire charge for penicillin injections given after the initiation of therapy if oral penicillin is indicated unless there are special medical circumstances that justify additional injections.

#### 3—Excessive Medications

Medications administered for treatment of a disease and which exceed the frequency or duration of injections indicated by accepted standards of medical practice are not covered. For example, the accepted standard of medical practice in the maintenance treatment of pernicious anemia is one vitamin B-12 injection per month. Carriers exclude the entire charge for injections given in excess of this frequency unless there are special medical circumstances that justify additional injections.

Carriers will supplement the guidelines as necessary with guidelines concerning appropriate use of specific injections in other situations. They will use the guidelines to screen out questionable cases for special review, further development, or denial when the injection billed for would not be reasonable and necessary. They will coordinate any type of drug treatment review with the Quality Improvement Organization (QIO).

If a medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the carrier excludes the entire charge (i.e., for both the drug and its administration). Also, carriers exclude from payment any charges for other services (such as office visits) which were primarily for the purpose of administering a noncovered injection (i.e., an injection that is not reasonable and necessary for the diagnosis or treatment of an illness or injury).

### 50.4.4—Payment for Antigens and Immunizations

(Rev. 1, 10-01-03)

#### 50.4.4.1—Antigens

(Rev. 186, Issued: 04-16-14, Effective: 01-01 01, Implementation: 05-12-14)

Payment may be made for a reasonable supply of antigens that have been prepared for a particular patient if: (1) the antigens are prepared by a physician who is a doctor of medicine or osteopathy, and (2) the physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen.

Antigens must be administered in accordance with the plan of treatment and by a doctor of medicine or osteopathy or by a properly instructed person (who could be the patient) under the supervision of the doctor. The associations of allergists that CMS consulted advised that a reasonable supply of antigens is considered to be not more than a 12-month supply of antigens that has been prepared for a particular patient at any one time. The purpose of the reasonable supply limitation is
to assure that the antigens retain their potency and effectiveness over the period in which they are to be administered to the patient. (See §§20.2 and 50.2.)

**50.4.4.2—Immunizations**

*(Rev. 202, Issued: 12-31-14, Effective: 09-19-14, Implementation: 02-02-15)*

Vaccinations or inoculations are excluded as immunizations unless they are directly related to the treatment of an injury or direct exposure to a disease or condition, such as antirabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin sera, or immune globulin. In the absence of injury or direct exposure, preventive immunization (vaccination or inoculation) against such diseases as smallpox, polio, diphtheria, etc., is not covered. However, pneumococcal, hepatitis B, and influenza virus vaccines are exceptions to this rule. (See items A, B, and C below.) In cases where a vaccination or inoculation is excluded from coverage, related charges are also not covered.

**A—Pneumococcal Pneumonia Vaccinations**

1. **Background and History of Coverage:**

Section 1861(s)(10)(A) of the Social Security Act and regulations at 42 CFR 410.57 authorize Medicare coverage under Part B for pneumococcal vaccine and its administration.

For services furnished on or after May 1, 1981 through September 18, 2014, the Medicare Part B program covered pneumococcal pneumonia vaccine and its administration when furnished in compliance with any applicable State law by any provider of services or any entity or individual with a supplier number.

Coverage included an initial vaccine administered only to persons at high risk of serious pneumococcal disease (including all people 65 and older; immunocompetent adults at increased risk of pneumococcal disease or its complications because of chronic illness; and individuals with compromised immune systems), with revaccination administered only to persons at highest risk of serious pneumococcal infection and those likely to have a rapid decline in pneumococcal antibody levels, provided that at least 5 years had passed since the previous dose of pneumococcal vaccine.

Those administering the vaccine did not require the patient to present an immunization record prior to administering the pneumococcal vaccine, nor should they feel compelled to review the patient’s complete medical record if it is not available. Instead, provided that the patient is competent, it is acceptable to rely on the patient’s verbal history to determine prior vaccination status.

Effective July 1, 2000, Medicare no longer required for coverage purposes that a doctor of medicine or osteopathy order the vaccine. Therefore, a beneficiary could receive the vaccine upon request without a physician’s order and without physician supervision.

2. **Coverage Requirements:**

Effective for claims with dates of service on and after September 19, 2014, an initial pneumococcal vaccine may be administered to all Medicare beneficiaries who have never received a pneumococcal vaccination under Medicare Part B. A second pneumococcal vaccine may be administered 1 year after the first vaccine was administered (i.e., 11 full months have passed following the month in which the last pneumococcal vaccine was administered).

Those administering the vaccine should not require the patient to present an immunization record prior to administering the pneumococcal vaccine, nor should they feel compelled to review the patient’s complete medical record if it is not available. Instead, provided that the patient is competent, it is acceptable to rely on the patient’s verbal history to determine prior vaccination status.

Medicare does not require for coverage purposes that a doctor of medicine or osteopathy order the vaccine. Therefore, the beneficiary may receive the vaccine upon request without a physician’s order and without physician supervision.

**B—Hepatitis B Vaccine**

Effective for services furnished on or after September 1, 1984, P.L. 98-369 provides coverage under Part B for hepatitis B vaccine and its administration, furnished to a Medicare beneficiary who is at high or intermediate risk of contracting hepatitis B. High-risk groups currently identified include (see exception below):

- ESRD patients;
- Hemophiliacs who receive Factor VIII or IX concentrates;
- Clients of institutions for the mentally retarded;
- Persons who live in the same household as a Hepatitis B Virus (HBV) carrier;
- Homosexual men
- Illicit injectable drug abusers; and
- Persons diagnosed with diabetes mellitus.

Intermediate risk groups currently identified include:

- Staff in institutions for the mentally retarded; and
- Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work.

**EXCEPTION:** Persons in both of the above-listed groups in paragraph B, would not be considered at high or intermediate risk of contracting hepatitis B, however, if there were laboratory evidence positive for antibodies to hepatitis B. (ESRD patients are routinely tested for hepatitis B antibodies as part of their continuing monitoring and therapy.)

For Medicare program purposes, the vaccine may be administered upon the order of a doctor of medicine or osteopathy, by a doctor of medicine or osteopathy, or by home health agencies, skilled nursing facilities, ESRD facilities, hospital outpatient departments, and persons recognized under the incident to physicians’ services provision of law.

A charge separate from the ESRD composite rate will be recognized and paid for administration of the vaccine to ESRD patients.

**C—Influenza Virus Vaccine**

Effective for services furnished on or after May 1, 1993, the Medicare Part B program covers influenza virus vaccine and its administration when furnished in compliance with any applicable State law by any provider of services or any entity or individual with a supplier number. Typically, these vaccines are administered once a flu season. Medicare does not require, for coverage purposes, that a doctor of medicine or osteopathy order the vaccine. Therefore, the beneficiary may receive the vaccine upon request without a physician’s order and without physician supervision.
50.4.5—Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen
(Rev. 212, Issued: 11-06-15, Effective: 08-12-15, Implementation: 02-10-16)

A. Overview

Effective January 1, 1994, off-label, medically accepted indications of Food and Drug Administration-(FDA) approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen are identified under the conditions described below. A regimen is a combination of anti-cancer agents clinically recognized for the treatment of a specific type of cancer. Off-label, medically accepted indications are supported in either one or more of the compendia or in peer-reviewed medical literature. The contractor may maintain its own subscriptions to the listed compendia or peer-reviewed publications to determine the medically accepted indication of drugs or biologicals used off-label in an anti-cancer chemotherapeutic regimen. Compendia documentation or peer-reviewed literature supporting off-label use by the treating physician may also be requested of the physician by the contractor.

B. Recent Revisions to the Compendia List

Do not deny coverage based solely on the absence of FDA-approved labeling for the use, if the use is supported by any of the following compendia and the use is not listed as unsupported, not indicated, not recommended, or equivalent terms, in any of the following compendia:

- Existing–American Hospital Formulary Service-Drug Information (AHFS-DI)
- Effective June 5, 2008 - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Effective June 10, 2008 - Micromedex DrugDex
- Effective July 2, 2008 - Clinical Pharmacology
- Effective August 12, 2015 – Lexi-Drugs

The listed compendia employ various rating and recommendation systems that may not be readily cross-walked from compendium to compendium. In general, a use is identified by a compendium as medically accepted if the:

1. indication is a Category 1 or 2A in NCCN, or Class I, Class Ha, or Class Ib in DrugDex; or,
2. narrative text in AHFS-DI or Clinical Pharmacology is supportive, or
3. indication is listed in Lexi-Drugs as "Use: Off-Label" and rated as "Evidence Level A"

A use is not medically accepted by a compendium if the:

1. indication is a Category 3 in NCCN or a Class III in DrugDex; or,
2. narrative text in AHFS or Clinical Pharmacology is "not supportive," or
3. indication is listed in Lexi-Drugs as "Use: Unsupported"

The complete absence of narrative text on a use is considered neither supportive nor nonsupportive.

C. Use Supported by Clinical Research That Appears in Peer-Reviewed Medical Literature

Contractors may also identify off-label uses that are supported by clinical research under the conditions identified in this section. Peer-reviewed medical literature may appear in scientific, medical, and pharmaceutical publications in which original manuscripts are published, only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication. In-house publications of entities whose business relates to the manufacture, sale, or distribution of pharmaceutical products are excluded from consideration. Abstracts (including meeting abstracts) are excluded from consideration.

In determining whether an off-label use is supported, the contractors will evaluate the evidence in published, peer-reviewed medical literature listed below. When evaluating this literature, they will consider (among other things) the following:

- Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence
- Whether the administered chemotherapy regimen is adequately represented in the published evidence.
- Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients.
- Whether the study is appropriate to address the clinical question. The contractor will consider:

  1. whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.);
  2. that non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and
  3. that case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

The contractor will use peer-reviewed medical literature appearing in the regular editions of the following publications, not to include supplement editions privately funded by parties with a vested interest in the recommendations of the authors.

- American Journal of Medicine;
- Annals of Internal Medicine;
- Annals of Oncology;
- Annals of Surgical Oncology;
- Biology of Blood and Marrow Transplantation;
- Blood;
- Bone Marrow Transplantation;
- British Journal of Cancer;
- British Journal of Hematology;
- British Medical Journal;
- Cancer;
- Clinical Cancer Research;
- Drugs;
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology);
- Gynecologic Oncology;
- International Journal of Radiation, Oncology, Biology, and Physics;
- The Journal of the American Medical Association;
- Journal of Clinical Oncology;
- Journal of the National Cancer Institute;
- Journal of the National Comprehensive Cancer Network (NCCN);
- Journal of Urology;
rirable characteristics:
this meeting, the MedCAC generated the following list of de-
drugs and biologicals in anti-cancer therapy. As a result of
use in the determination of medically- accepted indications of
advise CMS on the desirable characteristics of compendia for
2006. The goal of this session was to review the evidence and
oped by the MedCAC during a public session on March 30,
medication a list of desirable compendium characteristics out-
rating a list of desirable compendium characteristics out-
ded by the Medicare Evidence Development and Coverage
rating a list of desirable compendium characteristics out-
CMS increased the transparency of the process by incorpo-
ating a list of desirable compendium characteristics out-
line the Medicare Evidence Development and Coverage
Advisory Committee (MedCAC) as criteria for decision-making.
The list of desirable compendium characteristics was devel-
oped by the MedCAC during a public session on March 30,
6006. The goal of this session was to review the evidence and
advise CMS on the desirable characteristics of compendia for
use in the determination of medically-accepted indications of
drugs and biologicals in anti-cancer therapy. As a result of
this meeting, the MedCAC generated the following list of de-
sirable characteristics:

- Extensive breadth of listings,
- Quick processing from application for inclusion to listing,
- Detailed description of the evidence reviewed for every individual listing,
- Use of pre-specified published criteria for weighing evidence,
- Use of prescribed published process for making recommend-
dations,
- Publicly transparent process for evaluating therapies,
- Explicit "Not recommended" listing when validated evidence is appropriate,
- Explicit listing and recommendations regarding therapies, including sequential use or combination in relation to other therapies,
- Explicit "Equivocal" listing when validated evidence is equivocal, and,
- Process for public identification and notification of potential conflicts of interest of the compendia's parent and sibling organizations, reviewers, and committee members, with an established procedure to manage recognized conflicts.

Furthermore, the provisions discussed in section 182(b) of MIPPA bring more uniformity in compendia conflict of interest disclosure practices and allow the public the ability to monitor how these policies impact compendia off-label recommendations.

C. Process for Changing List of Compendia

CMS will provide an annual 30-day open request period starting January 15th for the public to submit requests for additions or deletions to the compendia list contained on the CMS Web site at http://www.cms.hhs.gov/CoverageGenInfo/02_compendia.asp.

Complete requests as defined in section 50.4.5.1.D will be posted to the Web site annually by March 15 for public notice and comment. The request will identify the requestor and the requested action CMS is being asked to make to the list. Public comments will be accepted for a 30-day period beginning on the day the request is posted on the Web site.

In addition to the annual process, CMS may generate a request for changes to the list at any time an urgent action is needed to protect the interests of the Medicare program and its beneficiaries.

D. Content of Requests

For a request to be considered complete, and therefore accepted for review, it must include the following information:

- The full name and contact information (including the mailing address, e-mail address, and telephone number) of the requestor. If the requestor is not an individual person, the information shall identify the officer or other representative who is authorized to act for the requestor on all matters related to the request.
- Full identification of the compendium that is the subject of the request, including name, publisher, edition if applicable, date of publication, and any other information needed for the accurate and precise identification of the specific compendium.
- A complete written copy of the compendium that is the subject of the request. If the complete compendium is available electronically, it may be submitted electronically in place of hard copy. If the compendium is available online, the requestor may provide CMS with electronic access by furnishing at no cost to the Federal Government sufficient accounts for the purposes and duration of the review of the application in place of hard copy.
- The specific action that the requestor wishes CMS to take, for example to add or delete a specific compendium.
• Detailed, specific documentation that the compendium that is the subject of the request does or does not comply with the conditions of this rule. Broad, nonspecific claims without supporting documentation cannot be efficiently reviewed; therefore, they will not be accepted.
• A publicly transparent process for evaluating therapies, which includes the following: (1) internal or external request for listing of a therapy recommendation, including criteria used to evaluate the request (the complete application), (2) listing of all the evidentiary materials reviewed or considered for inclusion in the compendium (3) listing of all individuals who substantively participated in the review and development of the request, and (4) minutes and voting records of meetings for the review and disposition of the request. The information from an internal or external request for inclusion of a therapy in a compendium are available to the public for a period of not less than 5 years, which includes availability on the compendium’s Web site for a period of not less than 3 years, coincident with the compendium’s publication.
• A publicly transparent process for identifying potential conflicts of interests that provides: (1) direct or indirect financial relationships, and (2) ownership or investment interests that exist between individuals or the spouse or minor child of individuals who have substantively participated in the development or disposition of compendia recommendations, and the manufacturer or seller of the drug or biological being reviewed by the compendium. This information shall be identified and made timely available in response to a public request for a period of not less than 5 years, which includes availability on the compendium’s Web site for a period of not less than 3 years, coincident with the compendium’s publication.

A request may have only a single compendium as its subject. This will provide greater clarity on the scope of the agency’s review of a given request. A requestor may submit multiple requests, each requesting a different action.

E. Submission of Requests
Requests must be in writing and submitted in one of the following two ways (no duplicates please):

• Electronic requests are encouraged to facilitate administrative efficiency. Each solicitation will include the electronic address for submissions.
• Hard copy requests can be sent to:
  Centers for Medicare & Medicaid Services
  Coverage and Analysis Group
  Mailstop C1–09–06
  7500 Security Boulevard
  Baltimore, MD, 21244

Allow sufficient time for hard copies to be received prior to the close of the open request period.

F. Review of Requests
CMS will consider a compendium’s attainment of the desirable characteristics specified in 50.4.5.1.B when reviewing requests. CMS may consider additional, reasonable factors in making a determination. For example, CMS may consider factors that are likely to impact the compendium’s suitability for this use, such as a change in compendium’s ownership or affiliation, and the standards applicable to the evidence considered by the compendium. CMS may consider that broad accessibility by the general public to the information contained in the compendium may assist beneficiaries, their treating physicians, or both, in choosing among treatment options. CMS will also consider a compendium’s grading of evidence used in making recommendations regarding off-label, uses, and the process by which the compendium grades the evidence. CMS may, at its discretion, combine and consider multiple requests that refer to the same compendium, even if those requests are for different actions. This facilitates administrative efficiency in the review of requests.

G. Publishing Review Results
CMS will publish decisions on the CMS Web site within 90 days after the close of the public comment period.

(This instruction was last reviewed by CMS in December 2009.)

50.4.6—Less Than Effective Drug
(Rev. 1, 10-01-03)
B3-2049.4.C.5
This is a drug that has been determined by the Food and Drug Administration (FDA) to lack substantial evidence of effectiveness for all labeled indications. Also, a drug that has been the subject of a Notice of an Opportunity for a Hearing (NOOH) published in the “Federal Register” before being withdrawn from the market, and for which the Secretary has not determined there is a compelling justification for its medical need, is considered less than effective. This includes any other drug product that is identical, similar, or related. Payment may not be made for a less than effective drug.

Because the FDA has not yet completed its identification of drug products that are still on the market, existing FDA efficacy decisions must be applied to all similar products once they are identified.

50.4.7—Denial of Medicare Payment for Compounded Drugs Produced in Violation of Federal Food, Drug, and Cosmetic Act
(Rev. 1, 10-01-03)
B3-2049.4.C.6
The Food and Drug Administration (FDA) has found that, from time to time, firms established as retail pharmacies engage in mass production of compounded drugs, beyond the normal scope of pharmaceutical practice, in violation of the Federal Food, Drug, and Cosmetic Act (FFDCA). By compounding drugs on a large scale, a company may be operating as a drug manufacturer within the meaning of the FFDCA, without complying with requirements of that law. Such companies may be manufacturing drugs which are subject to the new drug application (NDA) requirements of the FFDCA, but for which FDA has not approved an NDA or which are misbranded or adulterated. If the FDA has not approved the manufacturing and processing procedures used by these facilities, the FDA has no assurance that the drugs these companies are producing are safe and effective. The safety and effectiveness issues pertain to such factors as chemical stability, purity, strength, bioequivalency, and bioavailability.

Section 1862(a)(1)(A) of the Act requires that drugs must be reasonable and necessary in order to be covered under Medicare. This means, in the case of drugs, the FDA must approve them for marketing. Section 50.4.1 instructs carriers
and intermediaries to deny coverage for drugs that have not received final marketing approval by the FDA, unless instructed otherwise by CMS. The Medicare Benefit Policy Manual, Chapter 16, “General Exclusions from Coverage,” §180, instructs carriers to deny coverage of services related to the use of noncovered drugs as well. Hence, if DME or a prosthetic device is used to administer a noncovered drug, coverage is denied for both the nonapproved drug and the DME or prosthetic device.

In those cases in which the FDA has determined that a company is producing compounded drugs in violation of the FFDCA, Medicare does not pay for the drugs because they do not meet the FDA approval requirements of the Medicare program. In addition, Medicare does not pay for the DME or prosthetic device used to administer such a drug if FDA determines that a required NDA has not been approved or that the drug is misbranded or adulterated.

The CMS will notify the carrier when the FDA has determined that compounded drugs are being produced in violation of the FFDCA. The carrier does not stop Medicare payment for such a drug unless it is notified that it is appropriate to do so through a subsequent instruction. In addition, if the carrier or Regional Offices (ROs) become aware that other companies are possibly operating in violation of the FFDCA, the carrier or RO notifies:

Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Blvd.
Baltimore, MD 21244-1850

50.5.1—Immunosuppressive Drugs
(Rev. 1, 10-01-03)

A3-3112.4.B.3, HO-230.4.B.3, AB-01-10

Until January 1, 1995, immunosuppressive drugs were covered under Part B for a period of one year following discharge from a hospital for a Medicare covered organ transplant. The CMS interpreted the 1-year period after the date of the transplant procedure to mean 365 days from the day on which an inpatient is discharged from the hospital. Beneficiaries are eligible to receive additional Part B coverage within 18 months after the discharge date for drugs furnished in 1995; within 24 months for drugs furnished in 1996; within 30 months for drugs furnished in 1997; and within 36 months for drugs furnished after 1997.

For immunosuppressive drugs furnished on or after December 21, 2000, this time limit for coverage is eliminated.

Covered drugs include those immunosuppressive drugs that have been specifically labeled as such and approved for marketing by the FDA. (This is an exception to the standing drug policy which permits coverage of FDA approved drugs for nonlabeled uses, where such uses are found to be reasonable and necessary in an individual case.)

Covered drugs also include those prescription drugs, such as prednisone, that are used in conjunction with immunosuppressive drugs as part of a therapeutic regimen reflected in FDA approved labeling for immunosuppressive drugs. Therefore, antibiotics, hypertensives, and other drugs that are not directly related to rejection are not covered.

The FDA has identified and approved for marketing the following specifically labeled immunosuppressive drugs. They are:

- Sandimmune (cyclosporine), Sandoz Pharmaceutical;
- Imuran (azathioprine), Burroughs Wellcome;
- Atgam (antithymocyte globulin), Upjohn;
- Orthoclone OKT3 (Muromonab-CD3), Ortho Pharmaceutical;
- Prograf (tacrolimus), Fujisawa USA, Inc;
- Celicept (mycophenolate mefetil), Roche Laboratories;
- Daclizumab (Zenapax);
- Cyclophosphamide (Cytoxan);
- Prednisone; and
- Prednisolone.

The CMS expects contractors to keep informed of FDA additions to the list of the immunosuppressive drugs.

50.5.2—Erythropoietin (EPO)
(Rev. 1, 10-01-03)

A3-3112.4.B.4, HO-230.4.B.4

The statute provides that EPO is covered for the treatment of anemia for patients with chronic renal failure who are on dialysis. Coverage is available regardless of whether the drug is administered by the patient or the patient’s caregiver. EPO is a biologically engineered protein which stimulates the bone marrow to make red blood cells.

NOTE: Non-ESRD patients who are receiving EPO to treat anemia induced by other conditions such as chemotherapy or the drug zidovudine (commonly called AZT) must meet the coverage requirements in §50.

EPO is covered for the treatment of anemia for patients with chronic renal failure who are on dialysis when:

- It is administered in the renal dialysis facility; or
- It is self-administered in the home by any dialysis patient (or patient caregiver) who is determined competent to use the drug and meets the other conditions detailed below.

NOTE: Payment may not be made for EPO under the incident to provision when EPO is administered in the renal dialysis facility.

Also, in the office setting, reimbursement will be made for the administration charge only for non-ESRD patients receiving EPO.
50.5.2.1—Requirements for Medicare Coverage for EPO
(Rev. 1, 10-01-03)
B3-2049.5
Medicare covers EPO and items related to its administration for dialysis patients who use EPO in the home when the following conditions are met:

A—Patient Care Plan

A dialysis patient who uses EPO in the home must have a current care plan (a copy of which must be maintained by the designated backup facility for Method II patients) for monitoring home use of EPO that includes the following:

1. Review of diet and fluid intake for aberrations as indicated by hyperkalemia and elevated blood pressure secondary to volume overload;
2. Review of medications to ensure adequate provision of supplemental iron;
3. Ongoing evaluations of hematocrit and iron stores;
4. Reevaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume;
5. Method for physician and facility (including backup facility for Method II patients) follow-up on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results;
6. Training of the patient to identify the signs and symptoms of hypotension and hypertension; and
7. The decrease or discontinuance of EPO if hypertension is uncontrollable.

B—Patient Selection

The dialysis facility, or the physician responsible for all dialysis-related services furnished to the patient, must make a comprehensive assessment that includes the following:

1. Preselection Monitoring—The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.
2. Conditions the Patient Must Meet—The assessment must find that the patient meets the following conditions:
   a. Is a dialysis patient;
   b. Has a hematocrit (or comparable hemoglobin level) that is as follows:

   • For a patient who is initiating EPO treatment, no higher than 30 percent unless there is medical documentation showing the need for EPO despite a hematocrit (or comparable hemoglobin level) higher than 30 percent. Patients with severe angina, severe pulmonary distress, or severe hypertension may require EPO to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels.
   • For a patient who has been receiving EPO from the facility or the physician, between 30 and 36 percent.
   c. Is under the care of:

   • A physician who is responsible for all dialysis-related services and who prescribes the EPO and follows the drug labeling instructions when monitoring the EPO home therapy; and
   • A renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO therapy.
3. The assessment must find that the patient or a caregiver meets the following conditions:
   • Is trained by the facility to inject EPO and is capable of carrying out the procedure;
   • Is capable of reading and understanding the drug labeling; and
   • Is trained in, and capable of observing, aseptic techniques.

4. Care and Storage of Drug—The assessment must find that EPO can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child's having access to the drug and syringes.

C—Responsibilities of Physician or Dialysis Facility

The patient's physician or dialysis facility must:

• Develop a protocol that follows the drug label instructions;
• Make the protocol available to the patient to ensure safe and effective home use of EPO;
• Through the amounts prescribed, ensure that the drug on hand at any time does not exceed a 2-month supply;
• Maintain adequate records to allow quality assurance for review by the Network and State Survey Agencies. For Method II patients, current records must be provided to and maintained by the designated backup facility; and
• The dialysis facility must submit claims for EPO, if the facility provides it.

See the Medicare Claims Processing Manual, Chapter 11, “End Stage Renal Disease,” for instructions for billing and processing claims for EPO under Method 1 and Method 2. Note that hematocrit readings are required on claims. It is expected that the ESRD facility or hospital outpatient department will maintain the following information in each patient's medical record to permit the review of the medical necessity of EPO.

1. Diagnostic coding;
2. Most recent creatinine prior to initiation of EPO therapy;
3. Date of most recent creatinine prior to initiation of EPO therapy;
4. Most recent hematocrit (HCT) prior to initiation of EPO therapy;
5. Date of most recent hematocrit (HCT) prior to initiation of EPO therapy;
6. Dosage in units/kg;
7. Weight in kgs; and
8. Number of units administered.

50.5.2.2—Medicare Coverage of Epoetin Alfa (Procrit) for Preoperative Use
(Rev. 1, 10-01-03)
PM-AB-99-59, DATED 8/1/99
This instruction pertains exclusively to the preoperative surgical indication of the drug Procrit, in which it is administered to specific patients prior to surgery to reduce risk of transfusion. It does not affect Medicare policies related to other Food and Drug Administration (FDA) approved uses of Procrit. It is not a national coverage decision.

Procrit as Preventive Service
The carrier may determine that Procrit is covered for individuals who:
1. Are undergoing hip or knee surgery
2. Have an anemia with a hemoglobin between 10 and 13 mg/dL;
3. Are not a candidate for autologous blood transfusion;
4. Are expected to lose more than 2 units of blood; and
5. Have had a workup so that their anemia appears to be that of chronic disease.

The preoperative use of Procrit may be afforded to these individuals when carriers, exercising their discretion, determine that this treatment is reasonable and necessary. In other cases, Procrit is considered a preventive service and therefore not covered.

50.5.3—Oral Anti-Cancer Drugs

(Rev. 1, 10-01-03)
A3-3112.4.B.5, HO-230.4.B.5

Effective January 1, 1994, Medicare Part B coverage is extended to include oral anti-cancer drugs that are prescribed as anti-cancer chemotherapeutic agents providing they have the same active ingredients and are used for the same indications as anti-cancer chemotherapeutic agents which would be covered if they were not self-administered and they were furnished incident to a physician's service as drugs and biologicals.

For an oral anti-cancer drug to be covered under Part B, it must:

• Be prescribed by a physician or other practitioner licensed under State law to prescribe such drugs as anti-cancer chemotherapeutic agents;
• Be a drug or biological that has been approved by the Food and Drug Administration (FDA);
• Have the same active ingredients as a non-self-administrable anti-cancer chemotherapeutic drug or biological that is covered when furnished incident to a physician's service. The oral anti-cancer drug and the non-self-administrable drug must have the same chemical/generic name as indicated by the FDA’s “Approved Drug Products” (Orange Book), “Physician's Desk Reference” (PDR), or an authoritative drug compendium;
• Be used for the same indications, including unlabeled uses, as the non-self-administrable version of the drug; and
• Be reasonable and necessary for the individual patient.

50.5.4—Oral Anti-Nausea (Anti-Emetic) Drugs

(Rev. 185, Issued: 04-15-14, Effective: 05-29-13, Implementation: 07-07-14)

PM AB-97-26

Effective January 1, 1998, Medicare also covers self-administered anti-emetics which are necessary for the administration and absorption of the anti-neoplastic chemotherapeutic agents when a high likelihood of vomiting exists. The anti-emetic drug is covered as a necessary means for administration of the anti-neoplastic chemotherapeutic agents. Oral drugs prescribed for use with the primary drug, which enhance the anti-neoplastic effect of the primary drug or permit the patient to tolerate the primary anti-neoplastic drug in higher doses for longer periods, are not covered. Self-administered anti-emetics to reduce the side effects of nausea and vomiting brought on by the primary drug are not included beyond the administration necessary to achieve drug absorption.

Section 1861(s)(2) of the Social Security Act extends coverage to oral anti-emetic drugs that are used as full replacement for intravenous dosage forms of a cancer regimen under the following conditions:

• Coverage is provided only for oral drugs approved by the Food and Drug Administration (FDA) for use as anti-emetics;
• The oral anti-emetic must either be administered by the treating physician or in accordance with a written order from the physician as part of a cancer chemotherapy regimen;
• Oral anti-emetic drugs administered with a particular chemotherapy treatment must be initiated within 2 hours of the administration of the chemotherapeutic agent and may be continued for a period not to exceed 48 hours from that time;
• The oral anti-emetic drugs provided must be used as a full therapeutic replacement for the intravenous anti-emetic drugs that would have otherwise been administered at the time of the chemotherapy treatment.

Only drugs pursuant to a physician’s order at the time of the chemotherapy treatment qualify for this benefit. The dispensed number of dosage units may not exceed a loading dose administered within two hours of the treatment, plus a supply of additional dosage units not to exceed 48 hours of therapy.

Oral drugs that are not approved by the FDA for use as anti-emetics and which are used by treating physicians adjunctively in a manner incidental to cancer chemotherapy are not covered by this benefit and are not reimbursable within the scope of this benefit.

It is recognized that a limited number of patients will fail on oral anti-emetic drugs. Intravenous anti-emetics may be covered (subject to the rules of medical necessity) when furnished to patients who fail on oral anti-emetic therapy.

More than one oral anti-emetic drug may be prescribed and may be covered for concurrent use if needed to fully replace the intravenous drugs that otherwise would be given. See the Medicare National Coverage Determinations Manual, Publication 100-03, Chapter 1, Section 110.18, for detailed coverage criteria.

50.5.5—Hemophilia Clotting Factors

(Rev. 1, 10-01-03)
A3-3112.4.B.2, HO-230.4.B.2

Section 1861(s)(2)(I) of the Act provides Medicare coverage of blood clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision, and items related to the administration of such factors. Hemophilia, a blood disorder characterized by prolonged coagulation time, is caused by deficiency of a factor in plasma necessary for blood to clot. For purposes of Medicare Part B coverage, hemophilia encompasses the following conditions:

• Factor VIII deficiency (classic hemophilia);
• Factor IX deficiency (also termed plasma thromboplastin component (PTC) or Christmas factor deficiency); and
• Von Willebrand's disease.

Claims for blood clotting factors for hemophilia patients with these diagnoses may be covered if the patient is competent to use such factors without medical supervision.

The amount of clotting factors determined to be necessary to have on hand and thus covered under this provision is based on
the historical utilization pattern or profile developed by the contractor for each patient. It is expected that the treating source, e.g., a family physician or comprehensive hemophilia diagnostic and treatment center, have such information. From this data, the contractor is able to anticipate and make reasonable projections concerning the quantity of clotting factors the patient will need over a specific period of time. Unanticipated occurrences involving extraordinary events, such as automobile accidents or inpatient hospital stays, will change this baseline data and should be appropriately considered. In addition, changes in a patient’s medical needs over a period of time require adjustments in the profile.

50.6 – Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home

(Rev. 194, Issued: 09-03-14, Effective: Upon Implementation of ICD-10, Implementation: Upon Implementation of ICD-10)

Beginning for dates of service on or after January 1, 2004, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provides coverage of intravenous immune globulin (IVIG) for the treatment of primary immune deficiency diseases in the home (ICD-9 diagnosis codes 279.04, 279.05, 279.06, 279.12, and 279.2 or ICD-10-CM codes D80.0, D80.5, D81.0, D81.1, D81.2, D81.6, D81.7, D81.89, D81.9, D82.0, D83.0, D83.2, D83.3, or D83.9 if only an unspecified diagnosis is necessary). The Act defines “intravenous immune globulin” as an approved pooled plasma derivative for the treatment of primary immune deficiency disease. It is covered under this benefit when the patient has a diagnosed primary immune deficiency disease, it is administered in the home of a patient with a diagnosed primary immune deficiency disease, and the physician determines that administration of the derivative in the patient’s home is medically appropriate. The benefit does not include coverage for items or services related to the administration of the derivative. For coverage of IVIG under this benefit, it is not necessary for the derivative to be administered through a piece of durable medical equipment.

80—Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests

(Rev. 116, Issued: 12-11-09, Effective: 01-01-10, Implementation: 01-04-10)

This section describes the levels of physician supervision required for furnishing the technical component of diagnostic tests for a Medicare beneficiary who is not a hospital inpatient. For hospital outpatient diagnostic services, the supervision levels assigned to each CPT or Level II HCPCS code in the Medicare Physician Fee Schedule Relative Value File that is updated quarterly, apply as described below. For more information, see Chapter 6 (Hospital Services Covered Under Part B), §20.4 (Outpatient Diagnostic Services).

Section 410.32(b) of the Code of Federal Regulations (CFR) requires that diagnostic tests covered under §1861(s)(3) of the Act and payable under the physician fee schedule, with certain exceptions listed in the regulation, have to be performed under the supervision of an individual meeting the definition of a physician (§1861(r) of the Act) to be considered reasonable and necessary and, therefore, covered under Medicare. The regulation defines these levels of physician supervision for diagnostic tests as follows:

General Supervision—means the procedure is furnished under the physician’s overall direction and control, but the physician’s presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually performs the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

Direct Supervision—in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

Personal Supervision—means a physician must be in attendance in the room during the performance of the procedure.

One of the following numerical levels is assigned to each CPT or HCPCS code in the Medicare Physician Fee Schedule Database:

0 Procedure is not a diagnostic test or procedure is a diagnostic test which is not subject to the physician supervision policy.
1 Procedure must be performed under the general supervision of a physician.
2 Procedure must be performed under the direct supervision of a physician.
3 Procedure must be performed under the personal supervision of a physician.
4 Physician supervision policy does not apply when procedure is furnished by a qualified, independent psychologist or a clinical psychologist or furnished under the general supervision of a clinical psychologist; otherwise must be performed under the general supervision of a physician.
5 Physician supervision policy does not apply when procedure is furnished by a qualified audiologist; otherwise must be performed under the general supervision of a physician.
6 Procedure must be performed by a physician or by a physical therapist (PT) who is certified by the American Board of Physical Therapy Specialties (ABPTS) as a qualified electrophysiologic clinical specialist and is permitted to provide the procedure under State law.
6a Supervision standards for level 66 apply; in addition, the PT with ABPTS certification may supervise another PT but only the PT with ABPTS certification may bill.
7a Supervision standards for level 77 apply; in addition, the PT with ABPTS certification may supervise another PT but only the PT with ABPTS certification may bill.
9 Concept does not apply.
21 Procedure must be performed by a technician with certification under general supervision of a physician; otherwise must be performed under direct supervision of a physician.
22 Procedure may be performed by a technician with on-line real-time contact with physician.
66 Procedure must be performed by a physician or by a PT with ABPTS certification and certification in this specific procedure.
77 Procedure must be performed by a PT with ABPTS certification or by a PT without certification under direct supervision of a physician, or by a technician with certification under general supervision of a physician.
Nurse practitioners, clinical nurse specialists, and physician assistants are not defined as physicians under §1861(r) of the Act. Therefore, they may not function as supervisory physicians under the diagnostic tests benefit (§1861(s)(3) of the Act). However, when these practitioners personally perform diagnostic tests as provided under §1861(s)(2)(K) of the Act, §1861(s)(3) does not apply and they may perform diagnostic tests pursuant to State scope of practice laws and under the applicable State requirements for physician supervision or collaboration.

Because the diagnostic tests benefit set forth in §1861(s)(3) of the Act is separate and distinct from the incident to benefit set forth in §1861(s)(2) of the Act, diagnostic tests need not meet the incident to requirements. Diagnostic tests may be furnished under situations that meet the incident to requirements but this is not required. However, carriers must not scrutinize claims for diagnostic tests utilizing the incident to requirements.

80.1—Clinical Laboratory Services

(Rev. 79; Issued: 10-19-07; Effective: 01-01-03; Implementation: 11-19-07)

Section 1833 and 1861 of the Act provides for payment of clinical laboratory services under Medicare Part B. Clinical laboratory services involve the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as set forth at 42 CFR part 493. Section 1862(a)(1)(A) of the Act provides that Medicare payment may not be made for services that are not reasonable and necessary. Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 CFR 410.32(a), or by a qualified nonphysician practitioner, as described in 42 CFR 410.32(a)(3).

See section 80.6 of this manual for related physician ordering instructions.

See the Medicare Claims Processing Manual Chapter 16 for related claims processing instructions.

80.1.1—Certification Changes

(Rev. 1, 10-01-03)

B3-2070.1.E

Each page of the lists of approved specialties also includes a column “Certification Changed” in which the following codes are used:

“C” indicates a change in the laboratory’s approved certification since the preceding listing.

“A” discloses an accretion.

“TERM”—Laboratory not approved for payment after the indicated date which follows the code. The reason for termination also is given in the following codes:

1. Involuntary termination—no longer meets requirements

2. Voluntary withdrawal

3. Laboratory closed, merged with other interests, or organizational change

4. Ownership change with new ownership participating under different name

5. Ownership change with new owner not participating

6. Change in ownership—new provider number assigned

7. Involuntary termination—failure to abide by agreement

8. Former “emergency” hospital now fully participating

80.1.2—Carrier Contacts With Independent Clinical Laboratories

(Rev. 1, 10-01-03)

B3-2070.1.F

An important role of the carrier is as a communicant of necessary information to independent clinical laboratories. Experience has shown that the failure to inform laboratories of Medicare regulations and claims processing procedures may have an adverse effect on prosecution of laboratories suspected of fraudulent activities with respect to tests performed by, or billed on behalf of, independent laboratories. United States Attorneys often have to prosecute under a handicap or may simply refuse to prosecute cases where there is no evidence that a laboratory has been specifically informed of Medicare regulations and claims processing procedures.

Carriers must follow the Provider Education and Training (PET) guidelines to assure that laboratories are aware of Medicare regulations and the carrier’s policy when any changes are made in coverage policy or claims processing procedures. The PET guidelines require carriers to use various methods of communication (such as print, Internet, face-to-face instruction). Newsletters/bulletins that contain program and billing information must be produced at least quarterly and posted on the carrier Web site where duplicate copies may be obtained.

Some items which should be communicated to laboratories and responsibilities that laboratories are required to perform are:

- The requirements to have the same fee schedule for Medicare and private patients;
- To specify whether the tests are manual or automated;
- To document fully the medical necessity for pickup of specimens from a skilled nursing facility or a beneficiary’s home, and
- In cases when a laboratory service is referred from one independent laboratory to another independent laboratory, to identify the laboratory actually performing the test.

Additionally, when carrier professional relations representatives make personal contacts with particular laboratories, the representative should prepare and retain reports of contact indicating dates, persons present, and issues discussed. Finally, carriers should inform independent laboratories that the Medicare National Coverage Determinations Manual as well as other guidelines contained in the manual for determining medical necessity are on the Web site. Carriers should also publish local guidelines on its Web site; the carrier should not duplicate national instructions here. Timely paper or electronic communications concerning the Internet publications to independent laboratories new to the carrier’s service area are essential.
80.1.3—Independent Laboratory Service to a Patient in the Patient’s Home or an Institution

(Rev. 1, 10-01-03)

B3-2070.1.G

Where it is medically necessary for an independent laboratory to visit a patient to obtain a specimen, the service would be covered in the following circumstances:

1—Patient Confined to Home

If a patient is confined to the home or other place of residence used as his or her home (see §60.4.1 for the definition of a “homebound patient”), medical necessity would exist (e.g., where a laboratory technician draws a blood specimen). However, where the specimen is a type which would require only the services of a messenger and would not require the skills of a laboratory technician, e.g., urine or sputum, a specimen pickup service would not be considered medically necessary.

2—Place of Residence is an Institution

Medical necessity could also exist where the patient’s place of residence is an institution, including a skilled nursing facility that does not perform venipunctures. This would apply even though the institution meets the basic definition of a skilled nursing facility and would not ordinarily be considered a beneficiary’s home. (This policy is intended for independent laboratories only and does not expand the range of coverage of services to homebound patients under the incident to provision.) A trip by an independent laboratory technician to a facility (other than a hospital) for the purpose of performing a venipuncture is considered medically necessary only if:

a. The patient was confined to the facility; and
b. The facility did not have on duty personnel qualified to perform this service.

When facility personnel actually obtained and prepared the specimens for the independent laboratory to pick them up, the laboratory provides this pickup service as a service to the facility in the same manner as it does for physicians.

80.2—Psychological Tests and Neuropsychological Tests

(Rev. 85, Issued: 02-29-08, Effective: 01-01-06, Implementation: 12-28-06)

Medicare Part B coverage of psychological tests and neuropsychological tests is authorized under section 1861(s)(3) of the Social Security Act. Payment for psychological and neuropsychological tests is authorized under section 1842(b)(2) (A) of the Social Security Act. The payment amounts for the new psychological and neuropsychological tests (CPT codes 96105, 96110 and 96111) that are effective January 1, 2006, and are billed for tests administered by a technician or a computer reflect a site of service payment differential for the facility and non-facility settings. Additionally, there is no authorization for payment for diagnostic tests when performed on an “incident to” basis.

Under the diagnostic tests provision, all diagnostic tests are assigned a certain level of supervision. Generally, regulations governing the diagnostic tests provision require that only physicians can provide the assigned level of supervision for diagnostic tests. However, there is a regulatory exception to the supervision requirement for diagnostic psychological and neuropsychological tests in terms of who can provide the supervision. That is, regulations allow a clinical psychologist (CP) or a physician to perform the general supervision assigned to diagnostic psychological and neuropsychological tests.

In addition, nonphysician practitioners such as nurse practitioners (NPs), clinical nurse specialists (CNSs) and physician assistants (PAs) who personally perform diagnostic psychological and neuropsychological tests are excluded from having to perform these tests under the general supervision of a physician or a CP. Rather, NPs and CNSs must perform such tests under the requirements of their respective benefit instead of the requirements for diagnostic psychological and neuropsychological tests. Accordingly, NPs and CNSs must perform tests in collaboration (as defined under Medicare law at section 1861(aa)(6) of the Act) with a physician. PAs perform tests under the general supervision of a physician as required for services furnished under the PA benefit.

Furthermore, physical therapists (PTs), occupational therapists (OTs) and speech language pathologists (SLPs) are authorized to bill three test codes as “sometimes therapy” codes. Specifically, CPT codes 96105, 96110 and 96111 may be performed by these therapists. However, when PTs, OTs and SLPs perform these three tests, they must be performed under the general supervision of a physician or a CP.

Who May Bill for Diagnostic Psychological and Neuropsychological Tests

• CPs – see qualifications under chapter 15, section 160 of the Benefits Policy Manual, Pub. 100-02.
• Independently Practicing Psychologists (IPPs)
• PTs, OTs and SLPs – see qualifications under chapter 15, sections 220-230.6 of the Benefits Policy Manual, Pub. 100-02.

Psychological and neuropsychological tests performed by a psychologist (who is not a CP) practicing independently of an institution, agency, or physician’s office are covered when a physician orders such tests. An IPP is any psychologist who is licensed or certified to practice psychology in the State or jurisdiction where furnishing services or, if the jurisdiction does not issue licenses, if provided by any practicing psychologist. (It is CMS’ understanding that all States, the District of Columbia, and Puerto Rico license psychologists, but that some trust territories do not. Examples of psychologists, other than CPs, whose psychological and neuropsychological tests are covered under the diagnostic tests provision include, but are not limited to, educational psychologists and counseling psychologists.)

The carrier must secure from the appropriate State agency a current listing of psychologists holding the required credentials to determine whether the tests of a particular IPP are covered under Part B in States that have statutory licensure or certification. In States or territories that lack statutory licensing or certification, the carrier checks individual qualifications before provider numbers are issued. Possible
96102, 96103, 96110, and 96111 are appropriate for the range of CPT codes used to report psychological and neuropsychological tests. CPT codes 96116, 96118, 96119 and 96120 are appropriate for use when billing for psychological tests. CPT codes 96116, 96118, 96119 and 96120 are appropriate for use when billing for neuropsychological tests.

All of the tests under this CPT code range 96101-96120 are indicated as active codes under the physician fee schedule database and are covered if medically necessary.

**Payment and Billing Guidelines for Psychological and Neuropsychological Tests**

The technician and computer CPT codes for psychological and neuropsychological tests include practice expense, malpractice expense and professional work relative value units. Accordingly, CPT psychological test code 96101 should not be paid when billed for the same tests or services performed under psychological test codes 96102 or 96103, CPT neuropsychological test code 96118 should not be paid when billed for the same tests or services performed under neuropsychological test codes 96119 or 96120. However, CPT codes 96101 and 96118 can be paid separately on the rare occasion when billed on the same date of service for different and separate tests from 96102, 96103, 96119 and 96120.

Under the physician fee schedule, there is no payment for services performed by students or trainees. Accordingly, Medicare does not pay for services represented by CPT codes 96102 and 96119 when performed by a student or a trainee. However, the presence of a student or a trainee while the test is being administered does not prevent a physician, CP, IPP, NP, CNS or PA from performing and being paid for the psychological test under 96102 or the neuropsychological test under 96119.

### 80.3 - Audiology Services

(Rev. 132, Issued: 09-03-10, Effective: 09-30-10, Implementation: 09-30-10)

**References.**

- 1861(ll)(3) of the Social Security Act for the definition of audiology services.
- 1861(ll)(4)(B) of the Social Security Act for qualifications of audiologists.
- 42 CFR 410.32(b) for the physician supervision requirements for diagnostic tests.
- Pub. 100-04, chapter 12, section 30.3 for coding and billing information related to audiological services and aural rehabilitation.
- Pub. 100-02, chapter 15, sections 220 and 230 for the physical therapy and speech-language pathology policies relative to aural rehabilitation and balance, section 60 for services incident to a physician’s service, and section 80.6 for policies relevant to ordering for diagnostic tests.
- Pub. 100-02, chapter 16, section 100 for hearing aid policies.
- A list of audiology services is found at: www.cms.gov/therapyservices.

**A. Benefit**

Hearing and balance assessment services are generally covered as “other diagnostic tests” under section 1861(s)(3) of the Social Security Act. Hearing and balance assessment services furnished to an outpatient of a hospital are covered as “diagnostic services” under section 1861(s)(2)(C).

As defined in the Social Security Act, section 1861(ll)(3), the term “audiology services” specifically means such hearing and balance assessment services furnished by a qualified audiologist as the audiologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), as would otherwise be covered if furnished by a physician.
Herein after in this section, hearing and balance assessment services are termed “audiology services,” regardless of whether they are furnished by an audiologist, physician, nonphysician practitioner (NPP), or hospital.

Because audiology services are diagnostic tests, when furnished by a physician in an office or hospital outpatient department, they must be furnished under the appropriate level of supervision of a physician as established in 42 CFR 410.32(b)(1) and 410.28(e). However, as specified in 42 CFR 410.32(b)(2)(ii) or (v), respectively, they are exempted from physician supervision when they are personally furnished by a qualified audiologist or performed by a nurse practitioner or clinical nurse specialist authorized to perform the tests under applicable State laws.

Audiological diagnostic testing refers to tests of the audiological and vestibular systems, e.g., hearing, balance, auditory processing, tinnitus and diagnostic programming of certain prosthetic devices, performed by qualified audioligists.

Audiological diagnostic tests are not covered under the benefit for services incident to a physician's service (described in Pub. 100-02, chapter 15, section 60), because they have their own benefit as "other diagnostic tests". See Pub. 100-04, chapter 13 for general diagnostic test policies.

Audiology services, like all other services, should be reported under the most specific HCPCS code that describes the service that was furnished and in accordance with all CPT guidance and Medicare national and local contractor instructions.

B. Orders

Audiology tests are covered as “other diagnostic tests” under section 1861(s)(3) or 1861(s)(2)(C) of the Act in the physician's office or hospital outpatient settings, respectively, when a physician (or an NPP, as applicable) orders such testing for the purpose of obtaining information necessary for the physician's diagnostic medical evaluation or to determine the appropriate medical or surgical treatment of a hearing deficit or related medical problem. See section 80.6 of this chapter for policies regarding the ordering of diagnostic tests.

If a beneficiary undergoes diagnostic testing performed by an audiologist without a physician order, the tests are not covered even if the audiologist discovers a pathologic condition.

When a qualified physician orders a qualified technician (see definition in subsection D of this section) to furnish an appropriate audiology service, that order must specify which test is to be furnished by the technician under the direct supervision of a physician. Only that test may be provided on that order by the technician.

When the qualified physician or NPP orders diagnostic audiological tests by an audiologist without naming specific tests, the audiologist may select the appropriate battery of tests.

C. Coverage and Payment for Audiology Services

Diagnostic services furnished by a qualified audiologist meeting the requirements in section 80.3.1 of this chapter or physicians and NPPs as described in section 80.6 are covered and payable under the MPFS as “other diagnostic tests.”

Services furnished in a hospital outpatient department are covered and payable under the hospital Outpatient Prospective Payment System (OPPS) or other payment methodology applicable to the provider furnishing the services.

Coverage and, therefore, payment for audiological diagnostic tests is determined by the reason the tests were performed, rather than by the diagnosis or the patient’s condition. Under any Medicare payment system, payment for audiological diagnostic tests is not allowed by virtue of their exclusion from coverage in section 1862(a)(7) of the Social Security when:

- The type and severity of the current hearing, tinnitus or balance status needed to determine the appropriate medical or surgical treatment is known to the physician before the test; or
- The test was ordered for the specific purpose of fitting or modifying a hearing aid.

Payment of audiological diagnostic tests is allowed for other reasons and is not limited, for example, by:

- Any information resulting from the test, for example:
  - Confirmation of a prior diagnosis;
  - Post-evaluation diagnoses; or
  - Treatment provided after diagnosis, including hearing aids, or
  - The type of evaluation or treatment the physician anticipates before the diagnostic test; or
  - Timing of re-evaluation. Re-evaluation is appropriate at a schedule dictated by the ordering physician when the information provided by the diagnostic test is required; for example, to determine changes in hearing, to evaluate the appropriate medical or surgical treatment or to evaluate the results of treatment. For example, re-evaluation may be appropriate, even when the evaluation was recent, in cases where the hearing loss, balance or tinnitus may be progressive or fluctuating, the patient or caregiver complains of new symptoms, or treatment (such as medication or surgery) may have changed the patient’s audiological condition with or without awareness by the patient.

Examples of appropriate reasons for ordering audiological diagnostic tests that could be covered include, but are not limited to:

- Evaluation of suspected change in hearing, tinnitus, or balance;
- Evaluation of the cause of disorders of hearing, tinnitus, or balance;
- Determination of the effect of medication, surgery, or other treatment;
- Reevaluation to follow-up changes in hearing, tinnitus, or balance that may be caused by established diagnoses that place the patient at probable risk for a change in status including, but not limited to: otosclerosis, atelectatic tympanic membrane, tympanosclerosis, cholesteatoma, resolving middle ear infection, Menière's disease, sudden idiopathic sensorineural hearing loss, autoimmune inner ear disease, acoustic neuroma, demyelinating diseases, ototoxicity secondary to medications, or genetic vascular and viral conditions;
- Failure of a screening test (although the screening test is not covered);
- Diagnostic analysis of cochlear or brainstem implant and programming; and
- Audiology diagnostic tests before and periodically after implantation of auditory prosthetic devices.

If a physician refers a beneficiary to an audiologist for testing related to signs or symptoms associated with hearing loss,
balance disorder, tinnitus, ear disease, or ear injury, the audiologist's diagnostic testing services should be covered even if the only outcome is the prescription of a hearing aid.

D. Qualified Professionals. See section 80.3.1 of this chapter for the qualifications of audiologists. See section 80.6 of this chapter for the qualifications of physicians and NPPs who may furnish diagnostic tests.

2. Qualified Technicians or Other Qualified Staff. References to technicians in this section include other qualified clinical staff. The qualifications for technicians vary locally and may also depend on the type of test, the patient, and the level of participation of the physician who is directly supervising the test. Therefore, an individual must meet qualifications appropriate to the service furnished as determined by the contractor to whom the claim is billed. If it is necessary to determine whether the individual who furnished the labor for appropriate audiology services is qualified, contractors may request verification of any relevant education and training that has been completed by the technician, which shall be available in the records of the clinic or facility.

Depending on the qualifications determined by the contractor, individuals who are also hearing instrument specialists, students of audiology, or other health care professionals may furnish the labor for appropriate audiology services under direct physician supervision when these services are billed by physicians or hospital outpatient departments.

E. Documentation for Audiology Services.

1. Documentation for Orders (Reasons for Tests). The reason for the test should be documented either on the order, on the audiological evaluation report, or in the patient's medical record. (See subsection C. of this section concerning reasons for tests.)

2. Documenting skilled services. When the medical record is subject to medical review, it is necessary that the record contains sufficient information so that the contractor may determine that the service qualifies for payment. For example, documentation should indicate that the test was ordered, that the reason for the test results in coverage, and that the test was furnished to the patient by a qualified individual. Records that support the appropriate provision of an audiological diagnostic test shall be made available to the contractor on request.

F. Audiological Treatment.

There is no provision in the law for Medicare to pay audiologists for therapeutic services. For example, vestibular treatment, auditory rehabilitation treatment and auditory processing treatment, and canalith repositioning, while they are generally within the scope of practice of audiologists, are not those hearing and balance assessment services that are defined as audiology services in 1861(l)(3) of the Social Security Act, and therefore, shall not be billed by audiologists to Medicare. Services for the purpose of hearing aid evaluation and fitting are not covered regardless of how they are billed. Services identified as "always" therapy in Pub. 100-04 chapter 5, section 20 may not be billed by hospitals, physicians, NPPs, or audiologists when provided by audiologists. (See also Pub 100-04, chapter 12, section 30.3.)

Treatment related to hearing may be covered under the speech-language pathology benefit when the services are provided by speech-language pathologists. Treatment related to balance (e.g., services described by "always therapy" codes 97001-97004, 97110, 97112, 97116, and 97750) may be covered under the physical therapy or occupational therapy benefit when the services are provided by therapists or their assistants, where appropriate. Covered therapy services incident to a physician's service must conform to policies in sections 60, 220 and 230 of this chapter. Audiological treatment provided under the benefits for physical therapy and speech-language pathology services may also be personally provided and billed by physicians and NPPs when the services are within their scope of practice and consistent with State and local laws.

For example, aural rehabilitation and signed communication training may be payable according to the benefit for speech-language pathology services or as speech-language pathology services incident to a physician's or NPP's service. Treatment for balance disorders may be payable according to the benefit for physical therapy services or as a physical therapy service incident to the services of a physician or NPP. See the policies in this chapter; sections 220 and 230 for details.

G. Assignment. Nonhospital entities billing for the audiologist's services may accept assignment under the usual procedure or, if not accepting assignment, may charge the patient and submit a nonassigned claim on their behalf.

H. Opt Out and Mandatory Claims Submissions.

The opt out law does not define "physician" or "practitioner" to include audiologists; therefore, they may not opt out of Medicare and provide services under private contracts. See section 40.4 of this chapter for details.

When a physician or supplier furnishes a service that is covered by Medicare, then it is subject to the mandatory claim submission provisions of section 1848(g)(4) of the Social Security Act. Therefore, if an audiologist charges or attempts to charge a beneficiary any remuneration for a service that is covered by Medicare, then the audiologist must submit a claim to Medicare.

I. Non-Audiology Services Furnished by Audiologists.

Audiologists may be qualified to furnish all or part of some diagnostic tests or treatments that are not defined as audiology services under the MPFS, such as non-auditory evoked potentials or cerumen removal. Audiologists may not bill Medicare for services that are not audiology services according to Medicare's definition (see list at: www.cms.gov/therapyservices). However, the labor for the Technical Component (TC) of certain other diagnostic tests or treatment services may qualify to be billed when furnished by audiologists under physician supervision when all the appropriate policies are followed.

When furnishing services that are not on the Medicare list of audiology services, the audiologist may or may not be working within the scope of practice of an audiologist according to State law. The audiologist furnishing the service must have the qualifications that are ordinarily required of any person providing that service. Consult the following policies for details:

- Policies for physical therapy, occupational therapy, and speech-language pathology services are in sections 220 and 230 of this chapter and in Pub. 100-04, chapter 5, sections 10 and 20.
- Policies for services furnished incident to physicians' services in the physician's office are in section 60 of this chapter.
• Policies for therapeutic services furnished incident to physicians’ services in the hospital outpatient setting are in chapter 6, section 20.5, of this manual.
• Policies for diagnostic tests in the physician’s office are in section 80 of this chapter.
• Policies for diagnostic tests furnished in the hospital outpatient setting are in chapter 6, section 20.4, of this manual.

Therapeutic or treatment services that are not audiology services and are not “always” therapy (according to the policy in Pub.100-04, chapter 5, section 20) and are furnished by audiologists may be billed incident to the services of a physician when all other appropriate requirements are met.

In addition, the TC or facility services for diagnostic tests that are not audiology services may be billed by physicians or hospital outpatient departments when provided by qualified personnel (who may be audiologists), and physicians and hospital outpatient departments may bill for these diagnostic tests when provided by those qualified personnel under the specified level of physician supervision for the diagnostic test.

80.3.1 - Definition of Qualified Audiologist
(Rev. 84; Issued: 02-29-08; Effective: 04-01-08; Implementation: 04-07-08)

Audiological tests require the skills of an audiologist and shall be furnished by qualified audiologists, or, in States where it is allowed by State and local laws, by a physician or non-physician practitioner. Medicare is not authorized to pay for these services when performed by audiological aides, assistants, technicians, or others who do not meet the qualifications below. In cases where it is not clear, the Medicare contractor shall determine whether a service is an audiological service that requires the skills of an audiologist and whether the qualifications for an audiologist have been met.

Section 1861(l)(3) of the Act, provides that a qualified audiologist is an individual with a master’s or doctoral degree in audiology. Therefore, a Doctor of Audiology (AuD) 4th year student with a provisional license from a State does not qualify unless he or she also holds a master’s or doctoral degree in audiology. In addition, a qualified audiologist is an individual who:

• Is licensed as an audiologist by the State in which the individual furnishes such services, or
• In the case of an individual who furnishes services in a State which does not license audiologists has:
  • Successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), and
  • Performed not less than 9 months of supervised full-time audiology services after obtaining a master’s or doctoral degree in audiology or a related field, and
  • Successfully completed a national examination in audiology approved by the Secretary.

If it is necessary to determine whether a particular audiologist is qualified under the above definition, the carrier should check references. Carriers in States that have statutory licensure or certification should secure from the appropriate State agency a current listing of audiologists holding the required credentials. Additional references for determining an audiologist’s professional qualifications are the national directory published annually by the American Speech-Language-Hearing Association and records and directories, which may be available from the State Licensing Authority.

80.4—Coverage of Portable X-Ray Services Not Under the Direct Supervision of a Physician
(Rev. 1, 10-01-03)
B3-2070.4

80.4.1—Diagnostic X-Ray Tests
(Rev. 1, 10-01-03)
B3-2070.4.A

Diagnostic x-ray services furnished by a portable x-ray supplier are covered under Part B when furnished in a place or residence used as the patient’s home and in nonparticipating institutions. These services must be performed under the general supervision of a physician, the supplier must meet FDA certification requirements, and certain conditions relating to health and safety (as prescribed by the Secretary) must be met.

Diagnostic portable x-ray services are also covered under Part B when provided in participating SNFs and hospitals, under circumstances in which they cannot be covered under hospital insurance, i.e., the services are not furnished by the participating institution directly or under arrangements that provide for the institution to bill for the services. (See §250 for Part B services furnished to inpatients of participating and nonparticipating institutions.)

80.4.2—Applicability of Health and Safety Standards
(Rev. 1, 10-01-03)
B3-2070.4.B

The health and safety standards apply to all suppliers of portable x-ray services, except physicians who provide immediate personal supervision during the administration of diagnostic x-ray services. Payment is made only for services of approved suppliers who have been found to meet the standards. Notice of the coverage dates for services of approved suppliers are given to carriers by the RO.

When the services of a supplier of portable x-ray services no longer meet the conditions of coverage, physicians having an interest in the supplier’s certification status must be notified. The notification action regarding suppliers of portable x-ray equipment is the same as required for decertification of independent laboratories, and the procedures explained in §80.1.3 are followed.

80.4.3—Scope of Portable X-Ray Benefit
(Rev. 71, Issued: 05-25-07, Effective: N/A; Implementation: July 2, 2007)

In order to avoid payment for services, which are inadequate or hazardous to the patient, the scope of the covered portable x-ray benefit is defined as:

• Skeletal films involving the extremities, pelvis, vertebral column, or skull;
• Chest films which do not involve the use of contrast media (except routine screening procedures and tests in connection with routine physical examinations);
• Abdominal films which do not involve the use of contrast media; and
• Diagnostic mammograms if the approved portable x-ray supplier, as defined in 42 CFR part 486, subpart C, meets the certification requirements of section 354 of the Public Health Services Act, as implemented by 21 CFR part 900, subpart B.
80.4.4—Exclusions From Coverage as Portable X-Ray Services

(Rev. 1, 10-01-03)

B3-2070.4.D

Procedures and examinations which are not covered under the portable x-ray provision include the following:

• Procedures involving fluoroscopy;
• Procedures involving the use of contrast media;
• Procedures requiring the administration of a substance to the patient or injection of a substance into the patient and/or special manipulation of the patient;
• Procedures which require special medical skill or knowledge possessed by a doctor of medicine or doctor of osteopathy or which require that medical judgment be exercised;
• Procedures requiring special technical competency and/or special equipment or materials;
• Routine screening procedures; and
• Procedures which are not of a diagnostic nature.

80.4.5—Electrocardiograms

(Rev. 1, 10-01-03)

B3-2070.4.F

The taking of an electrocardiogram tracing by an approved supplier of portable x-ray services may be covered as an "other diagnostic test." The health and safety standards referred to in §80.4.2 are applicable to such diagnostic EKG services, e.g., the technician must meet the personnel qualification requirements in the conditions for coverage of portable x-ray services.

80.5—Bone Mass Measurements (BMMs)

(Rev.70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

80.5.1—Background

(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

On June 24, 1998, CMS published an Interim Final Rule with Comment Period (IFC) in the Federal Register entitled "Medicare Coverage of and Payment for Bone Mass Measurements." This IFC implemented section 4106 of the Balanced Budget Act of 1997 by establishing conditions for coverage and frequency standards thereby providing uniform coverage under Medicare Part B. It was effective July 1, 1998.

On December 1, 2006, CMS published the CY 2007 Physician Fee Schedule final rule. This rule implemented several changes effective January 1, 2007, which are reflected below.

80.5.2—Authority

(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

Definitions can be found in sections 1861(s)(15) and (rr)(1) of the Social Security Act (the Act). Conditions for coverage and frequency standards can be found in 42 CFR 410.31. Denials as not reasonable and necessary can be found at §1862(a)(1)(A) of the Act, 42 CFR 410.31(e), and 42 CFR 411.15(k).

80.5.3—Definition

(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

BMM means a radiologic, radioisotopic, or other procedure that meets all of the following conditions:

• Is performed to identify bone mass, detect bone loss, or determine bone quality.
• Is performed with either a bone densitometer (other than single-photon or dual-photon absorptiometry) or a bone somatometer system that has been cleared for marketing for BMM by the Food and Drug Administration (FDA) under 21 CFR part 807, or approved for marketing under 21 CFR part 814.
• Includes a physician’s interpretation of the results.

80.5.4—Conditions for Coverage

(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

Medicare covers BMM under the following conditions:

1. Is ordered by the physician or qualified nonphysician practitioner who is treating the beneficiary following an evaluation of the need for a BMM and determination of the appropriate BMM to be used.

A physician or qualified nonphysician practitioner treating the beneficiary for purposes of this provision is one who furnishes a consultation or treats a beneficiary for a specific medical problem, and who uses the results in the management of the patient. For the purposes of the BMM benefit, qualified nonphysician practitioners include physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives.

2. Is performed under the appropriate level of physician supervision as defined in 42 CFR 410.32(b).

3. Is reasonable and necessary for diagnosing and treating the condition of a beneficiary who meets the conditions described in §80.5.6.

4. In the case of an individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy, is performed with a dual-energy x-ray absorptiometry system (axial skeleton).

5. In the case of any individual who meets the conditions of 80.5.6 and who has a confirmatory BMM, is performed by a dual-energy x-ray absorptiometry system (axial skeleton). A confirmatory baseline BMM is not covered if the initial BMM was not performed by a dual-energy x-ray absorptiometry system (axial skeleton).

80.5.5—Frequency Standards

(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

Medicare pays for a screening BMM once every 2 years (at least 23 months have passed since the month the last covered BMM was performed).

When medically necessary, Medicare may pay for more frequent BMMs. Examples include, but are not limited to, the following medical circumstances:

• Monitoring beneficiaries on long-term glucocorticoid (steroid) therapy of more than 3 months.
• Confirming baseline BMMs to permit monitoring of beneficiaries in the future.
80.5.6—Beneficiaries Who May Be Covered
(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

To be covered, a beneficiary must meet at least one of the five conditions listed below:

1. A woman who has been determined by the physician or qualified nonphysician practitioner treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history and other findings.

NOTE: Since not every woman who has been prescribed estrogen replacement therapy (ERT) may be receiving an “adequate” dose of the therapy, the fact that a woman is receiving ERT should not preclude her treating physician or other qualified treating nonphysician practitioner from ordering a bone mass measurement for her. If a BMM is ordered for a woman following a careful evaluation of her medical need, however, it is expected that the ordering treating physician (or other qualified treating nonphysician practitioner) will document in her medical record why he or she believes that the woman is estrogen-deficient and at clinical risk for osteoporosis.

2. An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture.

3. An individual receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to an average of 5.0 mg of prednisone, or greater, per day, for more than 3 months.

4. An individual with primary hyperparathyroidism.

5. An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.

80.5.7—Noncovered BMMs
(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

The following BMMs are noncovered under Medicare because they are not considered reasonable and necessary under section 1862(a)(1)(A) of the Act.

• Single photon absorptiometry (effective January 1, 2007).
• Dual photon absorptiometry (established in 1983).

80.5.8—Claims Processing
(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

For instructions concerning payment methodology, HCPCS coding, and Medicare summary notice and remittance advice messages, see chapter 13, section 140 of Pub. 100-04, Medicare Claims Processing Manual.

80.5.9—National Coverage Determinations (NCDs)
(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

In addition to these conditions for coverage, CMS may determine through the NCD process that additional BMM systems are reasonable and necessary under section 1862(a)(1) of the Act for monitoring and confirming baseline BMMs.

80.6—Requirements for Ordering and Following Orders for Diagnostic Tests
(Rev. 80; Issued: 01-11-08; Effective: 01-01-03; Implementation: 11-19-07)

The following sections provide instructions about ordering diagnostic tests and for complying with such orders for Medicare payment.

NOTE: Unless specified, these sections are not applicable in a hospital setting.

80.6.1—Definitions
(Rev. 94, Issued: 08-29-08, Effective: 01-01-03, Implementation: 09-30-08)

Diagnostic Test

A “diagnostic test” includes all diagnostic x-ray tests, all diagnostic laboratory tests, and other diagnostic tests furnished to a beneficiary.

Treating Physician

A “treating physician” is a physician, as defined in §1861(r) of the Social Security Act (the Act), who furnishes a consultation or treats a beneficiary for a specific medical problem, and who uses the results of a diagnostic test in the management of the beneficiary’s specific medical problem.

A radiologist performing a therapeutic interventional procedure is considered a treating physician. A radiologist performing a diagnostic interventional or diagnostic procedure is not considered a treating physician.

Treating Practitioner

A “treating practitioner” is a nurse practitioner, clinical nurse specialist, or physician assistant, as defined in §1861(s)(2)(K) of the Act, who furnishes, pursuant to State law, a consultation or treats a beneficiary for a specific medical problem, and who uses the result of a diagnostic test in the management of the beneficiary’s specific medical problem.

Testing Facility

A “testing facility” is a Medicare provider or supplier that furnishes diagnostic tests. A testing facility may include a physician or a group of physicians (e.g., radiologist, pathologist), a laboratory, or an independent diagnostic testing facility (IDTF).

Order

An “order” is a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary. The order may conditionally request an additional diagnostic test for a particular beneficiary if the result of the initial diagnostic test ordered yields to a certain value determined by the treating physician/practitioner (e.g., if test X is negative, then perform test Y). An order may be delivered via the following forms of communication:

• A written document signed by the treating physician/practitioner, which is hand-delivered, mailed, or faxed to the testing facility; NOTE: No signature is required on orders for clinical diagnostic tests paid on the basis of the clinical laboratory fee schedule, the physician fee schedule, or for physician pathology services;
80.6.2—Interpreting Physician Determines a Different Diagnostic Test is Appropriate

(Rev. 80; Issued: 01-11-08; Effective: 01-01-03; Implementation: 11-19-07)

When an interpreting physician, e.g., radiologist, cardiologist, family practitioner, general internist, neurologist, obstetrician, gynecologist, ophthalmologist, thoracic surgeon, vascular surgeon, at a testing facility determines that an ordered diagnostic radiology test is clinically inappropriate or suboptimal, and that a different diagnostic test should be performed (e.g., an MRI should be performed instead of a CT scan because of the clinical indication), the interpreting physician/testing facility may not perform the unordered test until a new order from the treating physician/practitioner has been received. Similarly, if the result of an ordered diagnostic test is normal and the interpreting physician believes that another diagnostic test should be performed (e.g., a renal sonogram was normal and based on the clinical indication, the interpreting physician believes an MRI will reveal the diagnosis), an order from the treating physician must be received prior to performing the unordered diagnostic test.

80.6.3—Rules for Testing Facility to Furnish Additional Tests

(Rev. 80; Issued: 01-11-08; Effective: 01-01-03; Implementation: 11-19-07)

If the testing facility cannot reach the treating physician/practitioner to change the order or obtain a new order and documents this in the medical record, then the testing facility may furnish the additional diagnostic test if all of the following criteria apply:

• The testing center performs the diagnostic test ordered by the treating physician/practitioner;
• The interpreting physician at the testing facility determines and documents that, because of the abnormal result of the diagnostic test performed, an additional diagnostic test is medically necessary;
• Delaying the performance of the additional diagnostic test would have an adverse effect on the care of the beneficiary;
• The result of the test is communicated to and is used by the treating physician/practitioner in the treatment of the beneficiary; and
• The interpreting physician at the testing facility documents in his/her report why additional testing was done.

EXAMPLE:
The last cut of an abdominal CT scan with contrast shows a mass requiring a pelvic CT scan to further delineate the mass; (b) a bone scan reveals a lesion on the femur requiring plain films to make a diagnosis.

80.6.4—Rules for Testing Facility Interpreting Physician to Furnish Different or Additional Tests

(Rev. 80; Issued: 01-11-08; Effective: 01-01-03; Implementation: 11-19-07)

The following applies to an interpreting physician of a testing facility who furnishes a diagnostic test to a beneficiary who is not a hospital inpatient or outpatient. The interpreting physician must document accordingly in his/her report to the treating physician/practitioner:

Test Design

Unless specified in the order, the interpreting physician may determine, without notifying the treating physician/practitioner, the parameters of the diagnostic test (e.g., number of radiographic views obtained, thickness of tomographic sections acquired, use or non-use of contrast media).

Clear Error

The interpreting physician may modify, without notifying the treating physician/practitioner, an order with clear and obvious errors that would be apparent to a reasonable layperson, such as the patient receiving the test (e.g., x-ray of wrong foot ordered).

Patient Condition

The interpreting physician may cancel, without notifying the treating physician/practitioner, an order because the beneficiary's physical condition at the time of diagnostic testing will not permit performance of the test (e.g., a barium enema cannot be performed because of residual stool in colon on scout KUB; 170.5PA/LAT of the chest cannot be performed because the patient is unable to stand). When an ordered diagnostic test is cancelled, any medically necessary preliminary or scout testing performed is payable.

80.6.5—Surgical/Cytopathology Exception

(Rev. 80; Issued: 01-11-08; Effective: 01-01-03; Implementation: 11-19-07)

This exception applies to an independent laboratory's pathologist or a hospital pathologist who furnishes a pathology service to a beneficiary who is not a hospital inpatient or outpatient, and where the treating physician/practitioner does not specifically request additional tests the pathologist may need to perform. When a surgical or cytopathology specimen is sent to the pathology laboratory, it typically comes in a labeled container with a requisition form that reveals the patient demographics, the name of the physician/practitioner, and a clinical impression and/or brief history. There is no specific order from the surgeon or the treating physician/practitioner for a certain type of pathology service. While the pathologist will generally perform some type of examination or interpretation on the cells or tissue, there may be additional tests, such as special stains, that the pathologist may need to perform, even though they have not been specifically requested by the treating physician/practitioner. The pathologist may perform such additional tests under the following circumstances:

• These services are medically necessary so that a complete and accurate diagnosis can be reported to the treating physician/practitioner;
• The results of the tests are communicated to and are used by the treating physician/practitioner in the treatment of the beneficiary; and
• The pathologist documents in his/her report why additional testing was done.

EXAMPLE:
A lung biopsy is sent by the surgeon to the pathology department and the pathologist finds a granuloma which is suspicious for tuberculosis. The pathologist cultures the granuloma, sends it to bacteriology, and requests smears for acid fast bacilli (tuberculosis). The pathologist is expected to determine the need for these studies so that the surgical pathology examination and interpretation can be completed and the definitive diagnosis reported to the treating physician for use in treating the beneficiary.

100—Surgical Dressings, Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations

(Rev. 1, 10-01-03)
B3-2079, A3-3110.3, HO-228.3

Surgical dressings are limited to primary and secondary dressings required for the treatment of a wound caused by, or treated by, a surgical procedure that has been performed by a physician or other health care professional to the extent permissible under State law. In addition, surgical dressings required after debridement of a wound are also covered, irrespective of the type of debridement, as long as the debridement was reasonable and necessary and was performed by a health care professional acting within the scope of his/her legal authority when performing this function. Surgical dressings are covered for as long as they are medically necessary.

Primary dressings are therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin. Secondary dressing materials that serve a therapeutic or protective function and that are needed to secure a primary dressing are also covered. Items such as adhesive tape, roll gauze, bandages, and disposable compression material are examples of secondary dressings. Elastic stockings, support hose, foot coverings, leather and artificial leather, knee supports, surgical leggings, gauntlets, and pressure garments for the arms and hands are examples of items that are not ordinarily covered as surgical dressings. Some items, such as transparent film, may be used as a primary or secondary dressing.

If a physician, certified nurse midwife, physician assistant, nurse practitioner, or clinical nurse specialist applies surgical dressings as part of a professional service that is billed to Medicare, the surgical dressings are considered incident to the professional services of the health care practitioner. When surgical dressings are not covered incident to the services of a health care practitioner and are obtained by the patient from a supplier (e.g., a drugstore, physician, or other health care practitioner that qualifies as a supplier) on an order from a physician or other health care professional authorized under State law or regulation to make such an order, the surgical dressings are covered separately under Part B.

Splints and casts, and other devices used for reductions of fractures and dislocations are covered under Part B of Medicare. This includes dental splints.

110—Durable Medical Equipment—General

(Rev. 1, 10-01-03)
B3-2100, A3-3113, HO-235, HHA-220

Expenses incurred by a beneficiary for the rental or purchase of durable medical equipment (DME) are reimbursable if the following three requirements are met:

• The equipment meets the definition of DME (§110.1);
• The equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his or her malformed body member (§110.1); and
• The equipment is used in the patient's home.

The decision whether to rent or purchase an item of equipment generally resides with the beneficiary, but the decision on how to pay rests with CMS. For some DME, program payment policy calls for lump sum payments and in others for periodic payment. Where covered DME is furnished to a beneficiary by a supplier of services other than a provider of services, the DMERC makes the reimbursement. If a provider of services furnishes the equipment, the intermediary makes the reimbursement. The payment method is identified in the annual fee schedule update furnished by CMS.

The CMS issues quarterly updates to a fee schedule file that contains rates by HCPCS code and also identifies the classification of the HCPCS code within the following categories.

<table>
<thead>
<tr>
<th>Category Code</th>
<th>Definition</th>
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<tbody>
<tr>
<td>IN</td>
<td>Inexpensive and Other Routinely Purchased Items</td>
</tr>
<tr>
<td>FS</td>
<td>Frequently Serviced Items</td>
</tr>
<tr>
<td>CR</td>
<td>Capped Rental Items</td>
</tr>
<tr>
<td>GX</td>
<td>Oxygen and Oxygen Equipment</td>
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<tr>
<td>DS</td>
<td>Ostomy, Tracheostomy &amp; Urological Items</td>
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<td>SD</td>
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<td>PO</td>
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<td>SU</td>
<td>Supplies</td>
</tr>
<tr>
<td>TE</td>
<td>Transcutaneous Electrical Nerve Stimulators</td>
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</tbody>
</table>

The DMERCs, carriers, and intermediaries, where appropriate, use the CMS files to determine payment rules. See the Medicare Claims Processing Manual, Chapter 20, “Durable Medical Equipment, Surgical Dressings and Casts, Orthotics and Artificial Limbs, and Prosthetic Devices,” for a detailed description of payment rules for each classification.

Payment may also be made for repairs, maintenance, and delivery of equipment and for expendable and nonreusable items essential to the effective use of the equipment subject to the conditions in §110.2.

See the Medicare Benefit Policy Manual, Chapter 11, “End Stage Renal Disease,” for hemodialysis equipment and supplies.

110.1—Definition of Durable Medical Equipment


Durable medical equipment is equipment which:

• Can withstand repeated use;
• Is primarily and customarily used to serve a medical purpose;
• Generally is not useful to a person in the absence of an illness or injury; and
• Is appropriate for use in the home.
All requirements of the definition must be met before an item can be considered to be durable medical equipment.

The following describes the underlying policies for determining whether an item meets the definition of DME and may be covered.

A—Durability

An item is considered durable if it can withstand repeated use, i.e., the type of item that could normally be rented. Medical supplies of an expendable nature, such as incontinent pads, lamb's wool pads, catheters, ace bandages, elastic stockings, surgical facemasks, irrigating kits, sheets, and bags are not considered “durable” within the meaning of the definition. There are other items that, although durable in nature, may fall into other coverage categories such as supplies, braces, prosthetic devices, artificial arms, legs, and eyes.

B—Medical Equipment

Medical equipment is equipment primarily and customarily used for medical purposes and is not generally useful in the absence of illness or injury. In most instances, no development will be needed to determine whether a specific item of equipment is medical in nature. However, some cases will require development to determine whether the item constitutes medical equipment. This development would include the advice of local medical organizations (hospitals, medical schools, medical societies) and specialists in the field of physical medicine and rehabilitation. If the equipment is new on the market, it may be necessary, prior to seeking professional advice, to obtain information from the supplier or manufacturer explaining the design, purpose, effectiveness and method of using the equipment in the home as well as the results of any tests or clinical studies that have been conducted.

1. Equipment Presumptively Medical—Items such as hospital beds, wheelchairs, hemodialysis equipment, iron lungs, respirators, intermittent positive pressure breathing machines, medical regulators, oxygen tents, crutches, canes, trapeze bars, walkers, inhalators, nebulizers, commodes, suction machines, and traction equipment presumptively constitute medical equipment. (Although hemodialysis equipment is covered as a prosthetic device ($120), it also meets the definition of DME, and reimbursement for the rental or purchase of such equipment for use in the beneficiary’s home will be made only under the provisions for payment applicable to DME. See the Medicare Benefit Policy Manual, Chapter 11, “End Stage Renal Disease,” §38.1, for coverage of home use of hemodialysis.) NOTE: There is a wide variety in types of respirators and suction machines. The DME MACs medical staff should determine whether the apparatus specified in the claim is appropriate for home use.

2. Equipment Presumptively Nonmedical—Equipment which is primarily and customarily used for a non-medical purpose may not be considered “medical” equipment for which payment can be made under the medical insurance program. This is true even though the item has some remote medically related use. For example, in the case of a cardiac patient, an air conditioner might possibly be used to lower room temperature to reduce fluid loss in the patient and to restore an environment conducive to maintenance of the proper fluid balance. Nevertheless, because the primary and customary use of an air conditioner is a nonmedical one, the air conditioner cannot be deemed to be medical equipment for which payment can be made.

Other devices and equipment used for environmental control or to enhance the environmental setting in which the beneficiary is placed are not considered covered DME. These include, for example, room heaters, humidifiers, dehumidifiers, and electric air cleaners. Equipment which basically serves comfort or convenience functions or is primarily for the convenience of a person caring for the patient, such as elevators, stairway elevators, and posture chairs, do not constitute medical equipment. Similarly, physical fitness equipment (such as an exercise cycle), first-aid or precautionary-type equipment (such as preset portable oxygen units), self-help devices (such as safety grab bars), and training equipment (such as Braille training texts) are considered nonmedical in nature.

3. Special Exception Items—Specified items of equipment may be covered under certain conditions even though they do not meet the definition of DME because they are not primarily and customarily used to serve a medical purpose and/or are generally useful in the absence of illness or injury. These items would be covered when it is clearly established that they serve a therapeutic purpose in an individual case and would include:

a. Gel pads and pressure and water mattresses (which generally serve a preventive purpose) when prescribed for a patient who had bed sores or there is medical evidence indicating that they are highly susceptible to such ulceration;

b. Heat lamps for a medical rather than a soothing or cosmetic purpose, e.g., where the need for heat therapy has been established.

In establishing medical necessity for the above items, the evidence must show that the item is included in the physician's course of treatment and a physician is supervising its use.

NOTE: The above items represent special exceptions and no extension of coverage to other items should be inferred.

C—Necessary and Reasonable

Although an item may be classified as DME, it may not be covered in every instance. Coverage in a particular case is subject to the requirement that the equipment be necessary and reasonable for treatment of an illness or injury, or to improve the functioning of a malformed body member. These considerations will bar payment for equipment which cannot reasonably be expected to perform a therapeutic function in an individual case or will permit only partial therapeutic function in an individual case or will permit only partial payment when the type of equipment furnished substantially exceeds that required for the treatment of the illness or injury involved.

See the Medicare Claims Processing Manual, Chapter 1, “General Billing Requirements,” §60, regarding the rules for providing advanced beneficiary notices (ABNs) that advise beneficiaries, before items or services actually are furnished, when Medicare is likely to deny payment for them. ABNs allow beneficiaries to make an informed consumer decision about receiving items or services for which they may have to pay out-of-pocket and to be more active participants in their own health care treatment decisions.
1. **Necessity for the Equipment**—Equipment is necessary when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member. In most cases the physician's prescription for the equipment and other medical information available to the DME MACs will be sufficient to establish that the equipment serves this purpose.

2. **Reasonableness of the Equipment**—Even though an item of DME may serve a useful medical purpose, the DME MAC or A/B MAC (A) must also consider to what extent, if any, it would be reasonable for the Medicare program to pay for the item prescribed. The following considerations should enter into the determination of reasonableness:

   1. Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment?
   2. Is the item substantially more costly than a medically appropriate and realistically feasible alternative pattern of care?
   3. Does the item serve essentially the same purpose as equipment already available to the beneficiary?

3. **Payment Consistent With What is Necessary and Reasonable**—Where a claim is filed for equipment containing features of an aesthetic nature or features of a medical nature which are not required by the patient's condition or where there exists a reasonably feasible and medically appropriate alternative pattern of care which is less costly than the equipment furnished, the amount payable is based on the rate for the equipment or alternative treatment which meets the patient's medical needs.

   The acceptance of an assignment binds the supplier-assignee to accept the payment for the medically required equipment or service as the full charge and the supplier-assignee cannot charge the beneficiary the differential attributable to the equipment actually furnished.

4. **Establishing the Period of Medical Necessity**—Generally, the period of time an item of durable medical equipment will be considered to be medically necessary is based on the physician's estimate of the time that his or her patient will need the equipment. See the Medicare Program Integrity Manual, Chapters 5 and 6, for medical review guidelines.

**D—Definition of a Beneficiary's Home**

For purposes of rental and purchase of DME a beneficiary's home may be his/her own dwelling, an apartment, a relative's home, a home for the aged, or some other type of institution (such as an assisted living facility, or an intermediate care facility for individuals with intellectual disabilities (ICF/IID)). However, an institution may not be considered a beneficiary's home if it:

- Meets at least the basic requirement in the definition of a hospital, i.e., it is primarily engaged in providing by or under the supervision of physicians, to inpatients, diagnostic and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, and sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons; or
- Meets at least the basic requirement in the definition of a skilled nursing facility, i.e., it is primarily engaged in providing to inpatients skilled nursing care and related services for patients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

Thus, if an individual is a patient in an institution or distinct part of an institution which provides the services described in the bullets above, the individual is not entitled to have separate Part B payment made for rental or purchase of DME. This is because such an institution may not be considered the individual's home. The same concept applies even if the patient resides in a bed or portion of the institution not certified for Medicare.

If the patient is at home for part of a month and, for part of the same month is in an institution that cannot qualify as his or her home, or is outside the U.S., monthly payments may be made for the entire month. Similarly, if DME is returned to the provider before the end of a payment month because the beneficiary died in that month or because the equipment became unnecessary in that month, payment may be made for the entire month.

110.2—Repairs, Maintenance, Replacement, and Delivery


Under the circumstances specified below, payment may be made for repair, maintenance, and replacement of medically required DME, including equipment which had been in use before the user enrolled in Part B of the program. However, do not pay for repair, maintenance, or replacement of equipment in the frequent and substantial servicing or oxygen equipment payment categories. In addition, payments for repair and maintenance may not include payment for parts and labor covered under a manufacturer's or supplier's warranty.

**A—Repairs**

To repair means to fix or mend and to put the equipment back in good condition after damage or wear. Repairs to equipment which a beneficiary owns are covered when necessary to make the equipment serviceable. However, do not pay for repair of previously denied equipment or equipment in the frequent and substantial servicing or oxygen equipment payment categories. If the expense for repairs exceeds the estimated expense of purchasing or renting another item of equipment for the remaining period of medical need, no payment can be made for the amount of the excess. (See subsection C where claims for repairs suggest malicious damage or culpable neglect.)

Since renters of equipment recover from the rental charge the expenses they incur in maintaining in working order the equipment they rent out, separately itemized charges for repair of rented equipment are not covered. This includes items in the frequent and substantial servicing, oxygen equipment, capped rental, and inexpensive or routinely purchased payment categories which are being rented.

A new Certificate of Medical Necessity (CMN) and/or physician's order is not needed for repairs.

For replacement items, see Subsection C below.
B—Maintenance

Routine periodic servicing, such as testing, cleaning, regulating, and checking of the beneficiary's equipment, is not covered. The owner is expected to perform such routine maintenance rather than a retailer or some other person who charges for maintenance. Normally, purchasers of DME are given operating manuals which describe the type of servicing an owner may perform to properly maintain the equipment. It is reasonable to expect that beneficiaries will perform this maintenance. Thus, hiring a third party to do such work is for the convenience of the beneficiary and is not covered. However, more extensive maintenance which, based on the manufacturers' recommendations, is to be performed by authorized technicians, is covered as repairs for medically necessary equipment which a beneficiary owns. This might include, for example, breaking down sealed components and performing tests which require specialized testing equipment not available to the beneficiary. Do not pay for maintenance of purchased items that require frequent and substantial servicing or oxygen equipment.

Since renters of equipment recover from the rental charge the expenses they incur in maintaining in working order the equipment they rent out, separately itemized charges for maintenance of rented equipment are generally not covered. Payment may not be made for maintenance of rented equipment other than the maintenance and servicing fee established for capped rental items. For capped rental items which have reached the 13-month rental cap, contractors pay claims for maintenance and servicing fees after 6 months have passed from the end of the final paid rental month or from the end of the period the item is no longer covered under the supplier's or manufacturer's warranty, whichever is later. See the Medicare Claims Processing Manual, Chapter 20, “Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS),” for additional instruction and an example.

A new CMN and/or physician's order is not needed for covered maintenance.

In cases where one or more monthly rental payments have been made in accordance with 42 CFR 414.229 for a capped rental DME item, medical necessity for the equipment has been established. In cases where one or more rental payments have been made for an item classified as capped rental DME, and the supplier transfers title to the equipment prior to the end of a 13-month period of continuous use per 42 CFR 414.230, Medicare payment may be made for reasonable and necessary maintenance and servicing of the beneficiary-owned DME. Under the regulations at 42 CFR 414.210(e)(1), reasonable and necessary charges for maintenance and servicing are those made for parts and labor not otherwise covered under a manufacturer's or supplier's warranty. Charges for routine maintenance and servicing would not be covered. Charges for maintenance and servicing that exceed the purchase price of the equipment (i.e., the capped rental monthly fee multiplied by 10) would not be reasonable and necessary and should be denied.

C—Replacement

Replacement refers to the provision of an identical or nearly identical item. Situations involving the provision of a different item because of a change in medical condition are not addressed in this section.

Equipment which the beneficiary owns or is a capped rental item may be replaced in cases of loss or irreparable damage. Irreparable damage refers to a specific accident or to a natural disaster (e.g., fire, flood). A physician's order and/or new Certificate of Medical Necessity (CMN), when required, is needed to reaffirm the medical necessity of the item.

Irreparable wear refers to deterioration sustained from day-to-day usage over time and a specific event cannot be identified. Replacement of equipment due to irreparable wear takes into consideration the reasonable useful lifetime of the equipment. If the item of equipment has been in continuous use by the patient on either a rental or purchase basis for the equipment's useful lifetime, the beneficiary may elect to obtain a new piece of equipment. Replacement may be reimbursed when a new physician order and/or new CMN, when required, is needed to reaffirm the medical necessity of the item.

The reasonable useful lifetime of durable medical equipment is determined through program instructions. In the absence of program instructions, A/B MACs (B) may determine the reasonable useful lifetime of equipment, but in no case can it be less than 5 years. Computation of the useful lifetime is based on when the equipment is delivered to the beneficiary, not the age of the equipment. Replacement due to wear is not covered during the reasonable useful lifetime of the equipment. During the reasonable useful lifetime, Medicare does cover repair up to the cost of replacement (but not actual replacement) for medically necessary equipment owned by the beneficiary. (See subsection A.)

Charges for the replacement of oxygen equipment, items that require frequent and substantial servicing or inexpensive or routinely purchased items which are being rented are not covered.

Cases suggesting malicious damage, culpable neglect, or wrongful disposition of equipment should be investigated and denied where the “DME MACs determines that it is unreasonable to make program payment under the circumstances, DME MACs refer such cases to the program integrity specialist in the RO.

D—Delivery

Payment for delivery of DME whether rented or purchased is generally included in the fee schedule allowance for the item. See Pub. 100-04, Medicare Claims Processing Manual, Chapter 20, “Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS),” for the rules that apply to making reimbursement for exceptional cases.

110.3—Coverage of Supplies and Accessories

(Rev. 1, 10-01-03)

B3-2100.5, A3-3113.4, HO-235.4, HHA-220.5

Payment may be made for supplies, e.g., oxygen, that are necessary for the effective use of durable medical equipment. Such supplies include those drugs and biologicals which must be put directly into the equipment in order to achieve the therapeutic benefit of the durable medical equipment or to assure the proper functioning of the equipment, e.g., tumor chemotherapy agents used with an infusion pump or heparin used with a home dialysis system. However, the coverage of such drugs or biologicals does not preclude the need for a determination that the drug or biological itself is reasonable and necessary for treatment of the illness or injury or to improve the functioning of a malformed body member.

In the case of prescription drugs, other than oxygen, used in conjunction with durable medical equipment, prosthetic, orthotics, and supplies (DMEPOS) or prosthetic devices, the
entity that dispenses the drug must furnish it directly to the patient for whom a prescription is written. The entity that dispenses the drugs must have a Medicare supplier number, must possess a current license to dispense prescription drugs in the State in which the drug is dispensed, and must bill and receive payment in its own name. A supplier that is not the entity that dispenses the drugs cannot purchase the drugs used in conjunction with DME for resale to the beneficiary. Reimbursement may be made for replacement of essential accessories such as hoses, tubes, mouthpieces, etc., for necessary DME, only if the beneficiary owns or is purchasing the equipment.

110.4—Miscellaneous Issues Included in the Coverage of Equipment

(Rev. 1, 10-01-03)

B3-2100.6, A3-3113.5, HO-235.5, HHA-220.6

Payment can be made for the purchase of DME even though rental payments may have been made for prior months. This could occur where, because of a change in his/her condition, the beneficiary feels that it would be to his/her advantage to purchase the equipment rather than to continue to rent it.

A beneficiary may sell or otherwise dispose of equipment for which they have no further use, for example, because of recovery from the illness or injury that gave rise to the need for the equipment. (There is no authority for the program to repossess the equipment.) If after such disposal there is again medical need for similar equipment, payment can be made for the rental or purchase of that equipment.

However, where an arrangement is motivated solely by a desire to create artificial expenses to be met by the program and to realize a profit thereby, such expenses would not be covered under the program. The resolution of questions involving the disposition and subsequent acquisition of durable medical equipment must be made on a case-by-case basis.

Cases where it appears that there has been an attempt to create an artificial expense and realize a profit thereby should be developed and when appropriate declined. After adjudication the DMERC would refer such cases to the program integrity specialist in the RO.

When payments stop because the beneficiary’s condition has changed and the equipment is no longer medically necessary, the beneficiary is responsible for the remaining noncovered charges. Similarly, when payments stop because the beneficiary dies, the beneficiary’s estate is responsible for the remaining noncovered charges.

Contractors do not get involved in issues relating to ownership or title of property.

110.5—Incurred Expense Dates for Durable Medical Equipment

(Rev. 1, 10-01-03)

A3-3113.7.B, HO-235.7.B, B3-3011

The date of service on the claim must be the date that the beneficiary or authorized representative received the DMEPOS item. If the date of delivery is not specified on the bill, the contractor should assume, in the absence of evidence to the contrary, that the date of purchase was the date of delivery.

For mail order DMEPOS items, the date of service on the claim must be the shipping date.

The date of service on the claim must be the date that the DMEPOS item(s) was received by the nursing facility if the supplier delivered it or the shipping date if the supplier utilized a delivery/shipping service.

An exception to the preceding statements concerning the date of service on the claim occurs when items are provided in anticipation of discharge from a hospital or nursing facility. If a DMEPOS item is delivered to a patient in a hospital up to two days prior to discharge to home and it is for the benefit of the patient for purposes of fitting or training of the patient on its use, the supplier should bill the date of service on the claim as the date of discharge to home and should use POS = 12.

See the Medicare Program Integrity Manual, Chapter 5, “Items and Services Having Special DMERC Review Considerations,” for additional information pertaining to the date of service on the claim. Also see the Medicare Claims Processing Manual, Chapter 20, “Durable Medical Equipment, Surgical dressings and Casts, Orthotics and Artificial Limbs, and Prosthetic Devices,” for additional DME billing and claims processing information.

110.6—Determining Months for Which Periodic Payments May Be Made for Equipment Used in an Institution

(Rev. 1, 10-01-03)

A3-3113.7.D, HO-235.7.C

If a patient uses equipment subject to the monthly payment rule in an institution, which does not qualify as his or her home, the used months during which the beneficiary was institutionalized are not covered.

110.7—No Payment for Purchased Equipment Delivered Outside the United States or Before Beneficiary’s Coverage Began

(Rev. 1, 10-01-03)

A3-3113.7.C

In the case of equipment subject to the lump sum payment rules, the beneficiary must have been in the United States and must have had Medicare coverage at the time the item was delivered. Therefore, where an item of durable medical equipment paid for as a lump sum was delivered to an individual outside the United States or before his or her coverage period began, the entire expense of the item would be excluded from coverage. Payment cannot be made in such cases even though the individual later uses the item inside the United States or after his or her coverage begins.

If the individual is outside the U.S. for more than 30 days and then returns to the U.S., the DMERC determines medical necessity as in an initial case before resuming payments.

120—Prosthetic Devices

(Rev. 1, 10-01-03)

B3-2130, A3-3110.4, HO-228.4, A3-3111, HO-229

A—General

Prosthetic devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue), or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ are covered when furnished on a physician’s order. This does not require...
NOTE: Medicare does not cover a prosthetic device dispensed to a patient prior to the time at which the patient undergoes the procedure that makes necessary the use of the device. For example, the carrier does not make a separate Part B payment for an intraocular lens (IOL) or pacemaker that a physician, during an office visit prior to the actual surgery, dispenses to the patient for his or her use. Dispensing a prosthetic device in this manner raises health and safety issues. Moreover, the need for the device cannot be clearly established until the procedure that makes its use possible is successfully performed. Therefore, dispensing a prosthetic device in this manner is not considered reasonable and necessary for the treatment of the patient’s condition.

Colostomy (and other ostomy) bags and necessary accouterments required for attachment are covered as prosthetic devices. This coverage also includes irrigation and flushing equipment and other items and supplies directly related to ostomy care, whether the attachment of a bag is required.

Accessories and/or supplies which are used directly with an enteral or parenteral device to achieve the therapeutic benefit of the prosthesis or to assure the proper functioning of the device may also be covered under the prosthetic device benefit subject to the additional guidelines in the Medicare National Coverage Determinations Manual.

Covered items include catheters, filters, extension tubing, infusion bottles, pumps (either food or infusion), intravenous (I.V.) pole, needles, syringes, dressings, tape, Heparin Sodium (parenteral only), volumetric monitors (parenteral only), and parenteral and enteral nutrient solutions. Baby food and other regular grocery products that can be blended and used with the enteral system are not covered. Note that some of these items, e.g., a food pump and an I.V. pole, qualify as DME. Although coverage of the enteral and parenteral nutritional therapy systems is provided on the basis of the prosthetic device benefit, the payment rules relating to lump sum or monthly payment for DME apply to such items.

The coverage of prosthetic devices includes replacement of and repairs to such devices as explained in subsection D.

Finally, the Benefits Improvement and Protection Act of 2000 amended §1834(b)(1) of the Act by adding a provision (1834-h)(1)(G)(i) that requires Medicare payment to be made for the replacement of prosthetic devices which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the replacement device, or replacement part of such a device, is necessary.

Payment may be made for the replacement of a prosthetic device that is an artificial limb, or replacement part of a device if the ordering physician determines that the replacement device or part is necessary because of any of the following:

1. A change in the physiological condition of the patient;
2. An irrepairable change in the condition of the device, or in a part of the device; or
3. The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.

This provision is effective for items replaced on or after April 1, 2001. It supersedes any rule that provided a 5-year or other replacement rule with regard to prosthetic devices.

B—Prosthetic Lenses

The term “internal body organ” includes the lens of an eye. Prostheses replacing the lens of an eye include post-surgical lenses customarily used during convalescence from eye surgery in which the lens of the eye was removed. In addition, permanent lenses are also covered when required by an individual lacking the organic lens of the eye because of surgical removal or congenital absence. Prosthetic lenses obtained on or after the beneficiary’s date of entitlement to supplementary medical insurance benefits may be covered even though the surgical removal of the crystalline lens occurred before entitlement.

1. Prosthetic Cataract Lenses—One of the following prosthetic lenses or combinations of prosthetic lenses furnished by a physician (see §30.4 for coverage of prosthetic lenses prescribed by a doctor of optometry) may be covered when determined to be reasonable and necessary to restore essentially the vision provided by the crystalline lens of the eye:
   • Prosthetic bifocal lenses in frames;
   • Prosthetic lenses in frames for near vision, and prosthetic lenses in frames for far vision; or
   • When a prosthetic contact lens(es) for far vision is prescribed (including cases of binocular and monocular aphakia), make payment for the contact lens(es) and prosthetic lenses in frames for near vision to be worn at the same time as the contact lens(es), and prosthetic lenses in frames to be worn when the contacts have been removed.
Lenses which have ultraviolet absorbing or reflecting properties may be covered, in lieu of payment for regular (untinted) lenses, if it has been determined that such lenses are medically reasonable and necessary for the individual patient.

Medicare does not cover cataract sunglasses obtained in addition to the regular (untinted) prosthetic lenses since the sunglasses duplicate the restoration of vision function performed by the regular prosthetic lenses.

2. Payment for Intraocular Lenses (IOLs) Furnished in Ambulatory Surgical Centers (ASCs)—Effective for services furnished on or after March 12, 1990, payment for intraocular lenses (IOLs) inserted during or subsequent to cataract surgery in a Medicare certified ASC is included with the payment for facility services that are furnished in connection with the covered surgery.

Refer to the Medicare Claims Processing Manual, Chapter 14, “Ambulatory Surgical Centers,” for more information.

3. Limitation on Coverage of Conventional Lenses—
   One pair of conventional eyeglasses or conventional contact lenses furnished after each cataract surgery with insertion of an IOL is covered.

C—Dentures

Dentures are excluded from coverage. However, when a denture or a portion of the denture is an integral part (built-in) of a covered prosthesis (e.g., an obturator to fill an opening in the palate), it is covered as part of that prosthesis.

D—Supplies, Repairs, Adjustments, and Replacement

Supplies are covered that are necessary for the effective use of a prosthetic device (e.g., the batteries needed to operate an artificial larynx). Adjustment of prosthetic devices required by wear or by a change in the patient’s condition are covered when ordered by a physician.

Adjustments, repairs and replacements are covered even when the item had been in use before the user enrolled in Part B of the program so long as the device continues to be medically required.

140—Therapeutic Shoes for Individuals with Diabetes

Coverage of therapeutic shoes (depth or custom-molded) along with inserts for individuals with diabetes is available as of May 1, 1993. These diabetic shoes are covered if the requirements as specified in this section concerning certification and prescription are fulfilled. In addition, this benefit provides for a pair of diabetic shoes even if only one foot suffers from diabetic foot disease. Each shoe is equally equipped so that the affected limb, as well as the remaining limb, is protected. Claims for therapeutic shoes for diabetics are processed by the Durable Medical Equipment Regional Carriers (DMERCs).

Therapeutic shoes for diabetics are not DME and are not considered DME nor orthotics, but a separate category of coverage under Medicare Part B. (See §1861(s)(12) and §1833(o) of the Act.)

A. Definitions

The following items may be covered under the diabetic shoe benefit:

1. Custom-Molded Shoes

   Custom-molded shoes are shoes that:
   
   • Are constructed over a positive model of the patient’s foot;
   • Are made from leather or other suitable material of equal quality;
   • Have removable inserts that can be altered or replaced as the patient’s condition warrants; and
   • Have some form of shoe closure.

2. Depth Shoes

   Depth shoes are shoes that:
   
   • Have a full length, heel-to-toe filler that, when removed, provides a minimum of 3/16 inch of additional depth used to accommodate custom-molded or customized inserts;
   • Are made from leather or other suitable material of equal quality;
   • Have some form of shoe closure; and
   • Are available in full and half sizes with a minimum of three widths so that the sole is graded to the size and width of the upper portions of the shoes according to the American standard last sizing schedule or its equivalent. (The American standard last sizing schedule is the numerical shoe sizing system used for shoes sold in the United States.)
3. Inserts

Inserts are total contact, multiple density, removable inlays that are directly molded to the patient’s foot or a model of the patient’s foot and that are made of a suitable material with regard to the patient’s condition.

B. Coverage

1. Limitations

For each individual, coverage of the footwear and inserts is limited to one of the following within one calendar year:

- No more than one pair of custom-molded shoes (including inserts provided with such shoes) and two additional pairs of inserts; or
- No more than one pair of depth shoes and three pairs of inserts (not including the noncustomized removable inserts provided with such shoes).

2. Coverage of Diabetic Shoes and Brace

Orthopedic shoes, as stated in the Medicare Claims Processing Manual, Chapter 20, “Durable Medical Equipment, Surgical Dressings and Casts, Orthotics and Artifical Limbs, and Prosthetic Devices,” generally are not covered. This exclusion does not apply to orthopedic shoes that are an integral part of a leg brace. In situations in which an individual qualifies for both diabetic shoes and a leg brace, these items are covered separately. Thus, the diabetic shoes may be covered if the requirements for this section are met, while the brace may be covered if the requirements of §130 are met.

3. Substitution of Modifications for Inserts

An individual may substitute modification(s) of custom-molded or depth shoes instead of obtaining a pair(s) of inserts in any combination. Payment for the modification(s) may not exceed the limit set for the inserts for which the individual is entitled. The following is a list of the most common shoe modifications available, but it is not meant as an exhaustive list of the modifications available for diabetic shoes:

- **Rigid Rocker Bottoms** - These are exterior elevations with apex positions for 51 percent to 75 percent distance measured from the back end of the heel. The apex is a narrowed or pointed end of an anatomical structure. The apex must be positioned behind the metatarsal heads and tapered off sharply to the front tip of the sole. Apex height helps to eliminate pressure at the metatarsal heads. Rigidity is ensured by the steel in the shoe. The heel of the shoe tapers off in the back in order to cause the heel to strike in the middle of the heel;

- **Roller Bottoms (Sole or Bar)** - These are the same as rocker bottoms, but the heel is tapered from the apex to the front tip of the sole;

- **Metatarsal Bars** - An exterior bar is placed behind the metatarsal heads in order to remove pressure from the metatarsal heads. The bars are of various shapes, heights, and construction depending on the exact purpose;

- **Wedges (Posting)** - Wedges are either of hind foot, fore foot, or both and may be in the middle or to the side. The function is to shift or transfer weight bearing upon standing or during ambulation to the opposite side for added support, stabilization, equalized weight distribution, or balance; and

- **Offset Heels** - This is a heel flanged at its base either in the middle, to the side, or a combination, that is then extended upward to the shoe in order to stabilize extreme positions of the hind foot. Other modifications to diabetic shoes include, but are not limited to flared heels, Velcro closures, and inserts for missing toes.

4. Separate Inserts

Inserts may be covered and dispensed independently of diabetic shoes if the supplier of the shoes verifies in writing that the patient has appropriate footwear into which the insert can be placed. This footwear must meet the definitions found above for depth shoes and custom-molded shoes.

C. Certification

The need for diabetic shoes must be certified by a physician who is a doctor of medicine or a doctor of osteopathy and who is responsible for diagnosing and treating the patient’s diabetic systemic condition through a comprehensive plan of care. This managing physician must:

- Document in the patient’s medical record that the patient has diabetes;
- Certify that the patient is being treated under a comprehensive plan of care for diabetes, and that the patient needs diabetic shoes; and
- Document in the patient’s record that the patient has one or more of the following conditions:
  - Peripheral neuropathy with evidence of callus formation;
  - History of pre-ulcerative calluses;
  - History of previous ulceration;
  - Foot deformity;
  - Previous amputation of the foot or part of the foot; or
  - Poor circulation.

D. Prescription

Following certification by the physician managing the patient’s systemic diabetic condition, a podiatrist or other qualified physician who is knowledgeable in the fitting of diabetic shoes and inserts may prescribe the particular type of footwear necessary.

E. Furnishing Footwear

The footwear must be fitted and furnished by a podiatrist or other qualified individual such as a pedorthist, an orthotist, or a prosthetist. The certifying physician may not furnish the diabetic shoes unless the certifying physician is the only qualified individual in the area. It is left to the discretion of each carrier to determine the meaning of “in the area.”

150—Dental Services

(Rev. 1, 10-01-03)

B3-2136

As indicated under the general exclusions from coverage, items and services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting the teeth are not covered. “Structures directly supporting the teeth” means the periodontium, which includes the gingivae, dentogingival junction, periodontal membrane, cementum of the teeth, and alveolar process.

In addition to the following, see Pub 100-01, the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, Definitions and Pub 3, the Medicare National Coverage Determinations Manual for specific services which may
be covered when furnished by a dentist. If an otherwise noncovered procedure or service is performed by a dentist as incident to and as an integral part of a covered procedure or service performed by the dentist, the total service performed by the dentist on such an occasion is covered.

**EXAMPLE 1:**
The reconstruction of a ridge performed primarily to prepare the mouth for dentures is a noncovered procedure. However, when the reconstruction of a ridge is performed as a result of and at the same time as the surgical removal of a tumor (for other than dental purposes), the totality of surgical procedures is a covered service.

**EXAMPLE 2:**
Medicare makes payment for the wiring of teeth when this is done in connection with the reduction of a jaw fracture.

The extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease is also covered. This is an exception to the requirement that to be covered, a noncovered procedure or service performed by a dentist must be an incident to and an integral part of a covered procedure or service performed by the dentist. Ordinarily, the dentist extracts the patient’s teeth, but another physician, e.g., a radiologist, administers the radiation treatments.

When an excluded service is the primary procedure involved, it is not covered, regardless of its complexity or difficulty. For example, the extraction of an impacted tooth is not covered. Similarly, an alveoplasty (the surgical improvement of the shape and condition of the alveolar process) and a frenectomy are excluded from coverage when either of these procedures is performed in connection with an excluded service, e.g., the preparation of the mouth for dentures. In a like manner, the removal of a tumor (a bony protuberance of the hard palate) may be a covered service. However, with rare exception, this surgery is performed in connection with an excluded service, i.e., the preparation of the mouth for dentures. Under such circumstances, Medicare does not pay for this procedure.

Dental splints used to treat a dental condition are excluded from coverage under §1862(a)(12) of the Act. On the other hand, if the treatment is determined to be a covered medical condition (i.e., dislocated upper/lower jaw joints), then the splint can be covered.

Whether such services as the administration of anesthesia, diagnostic x-rays, and other related procedures are covered depends upon whether the primary procedure being performed by the dentist is itself covered. Thus, an x-ray taken in connection with the reduction of a fracture of the jaw or facial bone is covered. However, a single x-ray or x-ray survey taken in connection with the care or treatment of teeth or the periodontium is not covered.

Medicare makes payment for a covered dental procedure no matter where the service is performed. The hospitalization or nonhospitalization of a patient has no direct bearing on the coverage or exclusion of a given dental procedure.

Payment may also be made for services and supplies furnished incident to covered dental services. For example, the services of a dental technician or nurse who is under the direct supervision of the dentist or physician are covered if the services are included in the dentist’s or physician’s bill.

**150.1—Treatment of Temporomandibular Joint (TMJ) Syndrome**

(Rev. 1, 10-01-03)

**PASS memo Read.014**

There are a wide variety of conditions that can be characterized as TMJ, and an equally wide variety of methods for treating these conditions. Many of the procedures fall within the Medicare program’s statutory exclusion that prohibits payment for items and services that have not been demonstrated to be reasonable and necessary for the diagnosis and treatment of illness or injury (§1862(a)(1) of the Act). Other services and appliances used to treat TMJ fall within the Medicare program’s statutory exclusion at §1862(a)(12), which prohibits payment “for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth....” For these reasons, a diagnosis of TMJ on a claim is insufficient. The actual condition or symptom must be determined.

**200—Nurse Practitioner (NP) Services**

(Rev. 75, Issued: 08-17-07, Effective: 11-19-07, Implementation: 11-19-07)

Effective for services rendered after January 1, 1998, any individual who is participating under the Medicare program as a nurse practitioner (NP) for the first time ever, may have his or her professional services covered if he or she meets the qualifications listed below, and he or she is legally authorized to furnish NP services in the State where the services are performed. NPs who were issued billing provider numbers prior to January 1, 1998, may continue to furnish services under the NP benefit.

Payment for NP services is effective on the date of service, that is, on or after January 1, 1998, and payment is made on an assignment-related basis only.

**A. Qualifications for NPs**

In order to furnish covered NP services, an NP must meet the conditions as follows:

- Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law; and be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; or
- Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner by December 31, 2000.

The following organizations are recognized national certifying bodies for NPs at the advanced practice level:

- American Academy of Nurse Practitioners;
- American Nurses Credentialing Center;
- National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties;
- Pediatric Nursing Certification Board (previously named the National Certification Board of Pediatric Nurse Practitioners and Nurses);
- Oncology Nurses Certification Corporation;
- AACP Certification Corporation; and
- National Board on Certification of Hospice and Palliative Nurses.
The NPs applying for a Medicare billing number for the first time on or after January 1, 2001, must meet the requirements as follows:

- Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law; and
- Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners.

The NPs applying for a Medicare billing number for the first time on or after January 1, 2003, must meet the requirements as follows:

- Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law;
- Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; and
- Possess a master's degree in nursing.

**B. Covered Services**

Coverage is limited to the services an NP is legally authorized to perform in accordance with State law (or State regulatory mechanism established by State law).

### 1. General

The services of an NP may be covered under Part B if all of the following conditions are met:

- They are the type that are considered physician's services if furnished by a doctor of medicine or osteopathy (MD/DO);
- They are performed by a person who meets the definition of an NP (see subsection A);
- The NP is legally authorized to perform the services in the State in which they are performed;
- They are performed in collaboration with an MD/DO (see subsection D); and
- They are not otherwise precluded from coverage because of one of the statutory exclusions. (See subsection C.2.)

### 2. Incident To

If covered NP services are furnished, services and supplies furnished incident to the services of the NP may also be covered if they would have been covered when furnished incident to the services of an MD/DO as described in §60.

### C. Application of Coverage Rules

#### 1. Types of NP Services That May Be Covered

State law or regulation governing an NP's scope of practice in the State in which the services are performed applies. Consider developing a list of covered services based on the State scope of practice. Examples of the types of services that NPs may furnish include services that traditionally have been reserved to physicians, such as physical examinations, minor surgery, setting casts for simple fractures, interpreting x-rays, and other activities that involve an independent evaluation or treatment of the patient's condition. Also, if authorized under the scope of their State license, NPs may furnish services billed under all levels of evaluation and management codes and diagnostic tests if furnished in collaboration with a physician.

See §60.2 for coverage of services performed by NPs incident to the services of physicians.

### 2. Services Otherwise Excluded From Coverage

The NP services may not be covered if they are otherwise excluded from coverage even though an NP may be authorized by State law to perform them. For example, the Medicare law excludes from coverage routine foot care, routine physical checkups, and services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. Therefore, these services are precluded from coverage even though they may be within an NP's scope of practice under State law.

### D. Collaboration

Collaboration is a process in which an NP works with one or more physicians (MD/DO) to deliver health care services, with medical direction and appropriate supervision as required by the law of the State in which the services are furnished. In the absence of State law governing collaboration, collaboration is to be evidenced by NPs documenting their scope of practice and indicating the relationships that they have with physicians to deal with issues outside their scope of practice.

The collaborating physician does not need to be present with the NP when the services are furnished or to make an independent evaluation of each patient who is seen by the NP.

### E. Direct Billing and Payment

Direct billing and payment for NP services may be made to the NP.

### F. Assignment

Assignment is mandatory.

230—Practice of Physical Therapy, Occupational Therapy, and Speech-Language Pathology

(Rev. 63, Issued: 12-29-06, Effective: 01-01-07, Implementation: on or before 01-29-07)

#### A. Group Therapy Services

Contractors pay for outpatient physical therapy services (which includes outpatient speech-language pathology services) and outpatient occupational therapy services provided simultaneously to two or more individuals by a practitioner as group therapy services (97150). The individuals can be, but need not be performing the same activity. The physician or therapist involved in group therapy services must be in constant attendance, but one-on-one patient contact is not required.

#### B. Therapy Students

### 1. General

Only the services of the therapist can be billed and paid under Medicare Part B. The services performed by a student are not reimbursed even if provided under “line of sight” supervision of the therapist; however, the presence of the student “in the room” does not make the service unbillable. Pay for the direct (one-to-one) patient contact services of the physician or therapist provided to Medicare Part B patients. Group therapy services performed by a therapist or physician may be billed when a student is also present “in the room”.

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EXAMPLES:
Therapists may bill and be paid for the provision of services in the following scenarios:

- The qualified practitioner is present and in the room for the entire session. The student participates in the delivery of services when the qualified practitioner is directing the service, making the skilled judgment, and is responsible for the assessment and treatment.
- The qualified practitioner is present in the room guiding the student in service delivery when the therapy student and the therapy assistant student are participating in the provision of services, and the practitioner is not engaged in treating another patient or doing other tasks at the same time.
- The qualified practitioner is responsible for the services and as such, signs all documentation. (A student may, of course, also sign but it is not necessary since the Part B payment is for the clinician’s service, not for the student’s services).

2. Therapy Assistants as Clinical Instructors
Physical therapist assistants and occupational therapy assistants are not precluded from serving as clinical instructors for therapy students, while providing services within their scope of work and performed under the direction and supervision of a licensed physical or occupational therapist to a Medicare beneficiary.

3. Services Provided Under Part A and Part B
The payment methodologies for Part A and B therapy services rendered by a student are different. Under the MPFS (Medicare Part B), Medicare pays for services provided by physicians and practitioners that are specifically authorized by statute. Students do not meet the definition of practitioners under Medicare Part B. Under SNF PPS, payments are based upon the case mix or Resource Utilization Group (RUG) category that describes the patient. In the rehabilitation groups, the number of therapy minutes delivered to the patient determines the RUG category. Payment levels for each category are based upon the costs of caring for patients in each group rather than providing specific payment for each therapy service as is done in Medicare Part B.

230.1—Practice of Physical Therapy
(Rev. 179, Issued: 01-14-14, Effective: 01-07-14, Implementation: 01-07-14)

A—General
Physical therapy services are those services provided within the scope of practice of physical therapists and necessary for the diagnosis and treatment of impairments, functional limitations, disabilities or changes in physical function and health status. (See Pub. 100-03, the Medicare National Coverage Determinations Manual, for specific conditions or services.) For descriptions of aquatic therapy in a community center pool see section 220C of this chapter.

B—Qualified Physical Therapist Defined
Reference: 42CFR484.4

The new personnel qualifications for physical therapists were discussed in the 2008 Physician Fee Schedule. See the Federal Register of November 27, 2007, for the full text. See also the correction notice for this rule, published in the Federal Register on January 15, 2008.

The regulation provides that a qualified physical therapist (PT) is a person who is licensed, if applicable, as a PT by the state in which he or she is practicing unless licensure does not apply, has graduated from an accredited PT education program and passed a national examination approved by the state in which PT services are provided. The phrase, “by the state in which practicing” includes any authorization to practice provided by the same state in which the service is provided, including temporary licensure, regardless of the location of the entity billing the services. The curriculum accreditation is provided by the Commission on Accreditation in Physical Therapy Education (CAPTE) or, for those who graduated before CAPTE, curriculum approval was provided by the American Physical Therapy Association (APTA). For internationally educated PTs, curricula are approved by a credentials evaluation organization either approved by the APTA or identified in 8 CFR 212.15(e) as it relates to PTs. For example, in 2007, 8 CFR 212.15(e) approved the credentials evaluation provided by the Federation of State Boards of Physical Therapy (FSBPT) and the Foreign Credentialing Commission on Physical Therapy (FCCPT).

The requirements above apply to all PTs effective January 1, 2010, if they have not met any of the following requirements prior to January 1, 2010.

Physical therapists whose current license was obtained on or prior to December 31, 2009, qualify to provide PT services to Medicare beneficiaries if they:

- graduated from a CAPTE approved program in PT on or before December 31, 2009 (examination is not required); or,
- graduated on or before December 31, 2009, from a PT program outside the U.S. that is determined to be substantially equivalent to a U.S. program by a credentials evaluating organization approved by either the APTA or identified in 8 CFR 212.15(e) and also passed an examination for PTs approved by the state in which practicing.

Or, PTs whose current license was obtained before January 1, 2008, may meet the requirements in place on that date (i.e., graduation from a curriculum approved by either the APTA, the Committee on Allied Health Education and Accreditation of the American Medical Association, or both).

Or, PTs meet the requirements who are currently licensed and were licensed or qualified as a PT on or before December 31, 1977, and had 2 years appropriate experience as a PT, and passed a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

Or, PTs meet the requirements if they are currently licensed and before January 1, 1966, they were:

- admitted to membership by the APTA; or
- admitted to registration by the American Registry of Physical Therapists; or
- graduated from a 4-year PT curriculum approved by a State Department of Education; or
- licensed or registered and prior to January 1, 1970, they had 15 years of fulltime experience in PT under the order and direction of attending and referring doctors of medicine or osteopathy.

Or, PTs meet requirements if they are currently licensed and they were trained outside the U.S. before January 1, 2008, and after 1928 graduated from a PT curriculum.
approved in the country in which the curriculum was located, if that country had an organization that was a member of the World Confederation for Physical Therapy, and that PT qualified as a member of the organization.

For outpatient PT services that are provided incident to the services of physicians/NPPs, the requirement for PT licensure does not apply; all other personnel qualifications do apply. The qualified personnel providing PT services incident to the services of a physician/NPP must be trained in an accredited PT curriculum. For example, a person who, on or before December 31, 2009, graduated from a PT curriculum accredited by CAPTE, but who has not passed the national examination or obtained a license, could provide Medicare outpatient PT therapy services incident to the services of a physician/NPP if the physician assumes responsibility for the services according to the incident to policies. On or after January 1, 2010, although licensure does not apply, both education and examination requirements that are effective January 1, 2010, apply to qualified personnel who provide PT services incident to the services of a physician/NPP.

C—Services of Physical Therapy Support Personnel

Reference: 42CFR 484.4

Personnel Qualifications. The new personnel qualifications for physical therapist assistants (PTA) were discussed in the 2008 Physician Fee Schedule. See the Federal Register of November 27, 2007, for the full text. See also the correction notice for this rule, published in the Federal Register on January 15, 2008.

The regulation provides that a qualified PTA is a person who is licensed as a PTA unless licensure does not apply, is registered or certified, if applicable, as a PTA by the state in which practicing; or graduated, and graduated from an approved curriculum for PTAs, and passed a national examination for PTAs. The phrase, “by the state in which practicing” includes any authorization to practice provided by the same state in which the service is provided, including temporary licensure, regardless of the location or the entity billing for the services. Approval for the curriculum is provided by CAPTE or, if internationally or military trained PTAs apply, approval will be through a credentialing body for the curriculum for PTAs identified by either the American Physical Therapy Association or identified in 8 CFR 212.15(e). A national examination for PTAs is, for example the one furnished by the Federation of State Boards of Physical Therapy. These requirements above apply to all PTAs effective January 1, 2010, if they have not met any of the following requirements prior to January 1, 2010.

Those PTAs also qualify who, on or before December 31, 2009, are licensed, registered, or certified as a PTA and met one of the following requirements:

1. Is licensed or otherwise regulated in the state in which practicing; or
2. In states that have no licensure or other regulations, or where licensure does not apply, PTAs have:
   • graduated on or before December 31, 2009, from a 2-year college-level program approved by the APTA or CAPTE; and
   • effective January 1, 2010, those PTAs must have both graduated from a CAPTE approved curriculum and passed a national examination for PTAs; or

PTAs may also qualify if they are licensed, registered or certified as a PTA, if applicable and meet requirements in effect before January 1, 2008, that is,

• they have graduated before January 1, 2008, from a 2 year college level program approved by the APTA; or
• on or before December 31, 1977, they were licensed or qualified as a PTA and passed a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

Services. The services of PTAs used when providing covered therapy benefits are included as part of the covered service. These services are billed by the supervising physical therapist. PTAs may not provide evaluation services, make clinical judgments or decisions or take responsibility for the service. They act at the direction and under the supervision of the treating physical therapist and in accordance with state laws. A physical therapist must supervise PTAs. The level and frequency of supervision differs by setting (and by state or local law). General supervision is required for PTAs in all settings except private practice (which requires direct supervision) unless state practice requirements are more stringent, in which case state or local requirements must be followed. See specific settings for details. For example, in clinics, rehabilitation agencies, and public health agencies, 42CFR485.713 indicates that when a PTA provides services, either on or off the organization’s premises, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days or more frequently if required by state or local laws or regulation.

The services of a PTA shall not be billed as services incident to a physician/NPP’s service, because they do not meet the qualifications of a therapist.

The cost of supplies (e.g., theraband, hand putty, electrodes) used in furnishing covered therapy care is included in the payment for the HCPCS codes billed by the physical therapist, and are, therefore, not separately billable. Separate coverage and billing provisions apply to items that meet the definition of brace in §130.

Services provided by aides, even if under the supervision of a therapist, are not therapy services in the outpatient setting and are not covered by Medicare. Although an aide may help the therapist by providing unskilled services, those services that are unskilled are not covered by Medicare and shall be denied as not reasonable and necessary if they are billed as therapy services.

D—Application of Medicare Guidelines to PT Services

This subsection will be used in the future to illustrate the application of the above guidelines to some of the physical therapy modalities and procedures utilized in the treatment of patients.

230.2—Practice of Occupational Therapy

(Rev. 179, Issued: 01-14-14, Effective: 01-07-14, Implementa
tion: 01-07-14)

A—General

Occupational therapy services are those services provided within the scope of practice of occupational therapists and necessary for the diagnosis and treatment of impairments, functional disabilities or changes in physical function and health status. (See Pub. 100-03, the Medicare National Coverage Determinations Manual, for specific conditions or services.)
Occupational therapy is medically prescribed treatment concerned with improving or restoring functions which have been impaired by illness or injury or, where function has been permanently lost or reduced by illness or injury, to improve the individual's ability to perform those tasks required for independent functioning. Such therapy may involve:

- The evaluation, and reevaluation as required, of a patient's level of function by administering diagnostic and prognostic tests;
- The selection and teaching of task-oriented therapeutic activities designed to restore physical function; e.g., use of woodworking activities on an inclined table to restore shoulder, elbow, and wrist range of motion lost as a result of burns;
- The planning, implementing, and supervising of individualized therapeutic activity programs as part of an overall "active treatment" program for a patient with a diagnosed psychiatric illness; e.g., the use of sewing activities which require following a pattern to reduce confusion and restore reality orientation in a schizophrenic patient;
- The planning and implementing of therapeutic tasks and activities to restore sensory-integrative function; e.g., providing motor and tactile activities to increase sensory input and improve response for a stroke patient with functional loss resulting in a distorted body image;
- The teaching of compensatory technique to improve the level of independence in the activities of daily living, for example:
  - Teaching a patient who has lost the use of an arm how to pare potatoes and chop vegetables with one hand;
  - Teaching an upper extremity amputee how to functionally utilize a prosthesis;
  - Teaching a stroke patient new techniques to enable the patient to perform feeding, dressing, and other activities as independently as possible; or
  - Teaching a patient with a hip fracture/hip replacement techniques of standing tolerance and balance to enable the patient to perform such functional activities as dressing and homemaking tasks.
- The designing, fabricating, and fitting of orthotics and self-help devices; e.g., making a hand splint for a patient with rheumatoid arthritis to maintain the hand in a functional position or constructing a device which would enable an individual to hold a utensil and feed independently; or
- Vocational and prevocational assessment and training, subject to the limitations specified in item B below.

Only a qualified occupational therapist has the knowledge, training, and experience required to evaluate and, as necessary, reevaluate a patient's level of function, determine whether an occupational therapy program could reasonably be expected to improve, restore, or compensate for lost function and, where appropriate, recommend to the physician/NPP a plan of treatment.

**B—Qualified Occupational Therapist Defined**

Reference: 42CFR484.4

The new personnel qualifications for occupational therapists (OT) were discussed in the 2008 Physician Fee Schedule. See the Federal Register of November 27, 2007, for the full text. See also the correction notice for this rule, published in the Federal Register on January 15, 2008.

The regulation provides that a qualified OT is an individual who is licensed, if licensure applies, or otherwise regulated, if applicable, as an OT by the state in which practicing, and graduated from an accredited education program for OTs, and is eligible to take or has passed the examination for OTs administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT). The phrase, "by the state in which practicing" includes any authorization to practice provided by the same state in which the service is provided, including temporary licensure, regardless of the location of the entity billing the services. The education program for U.S. trained OTs is accredited by the Accreditation Council for Occupational Therapy Education (ACOTE). The requirements above apply to all OTs effective January 1, 2010, if they have not met any of the following requirements prior to January 1, 2010.

The OTs may also qualify if on or before December 31, 2009:

- they are licensed or otherwise regulated as an OT in the state in which practicing (regardless of the qualifications they met to obtain that licensure or regulation); or
- when licensure or other regulation does not apply, OTs have graduated from an OT education program accredited by ACOTE and are eligible to take, or have successfully completed the NBCOT examination for OTs.

Also, those OTs who met the Medicare requirements for OTs that were in 42CFR484.4 prior to January 1, 2008, qualify to provide OT services for Medicare beneficiaries if:

- on or before January 1, 2008, they graduated an OT program approved jointly by the American Medical Association and the AOTA, or
- they are eligible for the National Registration Examination of AOTA or the National Board for Certification in OT.

Also, they qualify who on or before December 31, 1977, had 2 years of appropriate experience as an occupational therapist, and had achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

Those educated outside the U.S. may meet the same qualifications for domestic trained OTs. For example, they qualify if they were licensed or otherwise regulated by the state in which practicing on or before December 31, 2009. Or they are qualified if they:

- graduated from an OT education program accredited as substantially equivalent to a U.S. OT education program by ACOTE, the World Federation of Occupational Therapists, or a credentialing body approved by AOTA; and
- passed the NBCOT examination for OT; and
- Effective January 1, 2010, are licensed or otherwise regulated, if applicable as an OT by the state in which practicing.

For outpatient OT services that are provided incident to the services of physicians/NPPs, the requirement for OT licensure does not apply; all other personnel qualifications do apply. The qualified personnel providing OT services incident to the services of a physician/NPP must be trained in an accredited OT curriculum. For example, a person who, on or before December 31, 2009, graduated from an OT curriculum accredited by ACOTE and is eligible to take or has successfully completed the entry-level certification examination for OTs developed and administered by NBCOT, could provide Medicare outpatient OT services incident to the services of a
physician/NPP if the physician assumes responsibility for the services according to the incident to policies. On or after January 1, 2010, although licensure does not apply, both education and examination requirements that are effective January 1, 2010, apply to qualified personnel who provide OT services incident to the services of a physician/NPP.

C—Services of Occupational Therapy Support Personnel

Reference: 42CFR 484.4

The new personnel qualifications for occupational therapy assistants were discussed in the 2008 Physician Fee Schedule. See the Federal Register of November 27, 2007, for the full text. See also the correction notice for this rule, published in the Federal Register on January 15, 2008.

The regulation provides that an occupational therapy assistant is a person who is licensed, unless licensure does not apply, or otherwise regulated, if applicable, as an OTA by the state in which practicing, and graduated from an OTA education program accredited by ACOTE and is eligible to take or has successfully completed the NBCOT examination for OTAs. The phrase, “by the state in which practicing” includes any authorization to practice provided by the same state in which the service is provided, including temporary licensure, regardless of the location of the entity billing the services.

If the requirements above are not met, an OTA may qualify if, on or before December 31, 2009, the OTA is licensed or otherwise regulated as an OTA; or, after January 1, 2010, has also completed an education program accredited by ACOTE and passed the NBCOT examination for OTAs.

OTAs who qualified under the policies in effect prior to January 1, 2008, continue to qualify to provide OT directed and supervised OTA services to Medicare beneficiaries. Therefore, OTAs qualify who after December 31, 1977, and on or before December 31, 2007:

• completed certification requirements to practice as an OTA established by a credentialing organization approved by AOTA; and
• after January 1, 2010, have also completed an education program accredited by ACOTE and passed the NBCOT examination for OTAs.

Those OTAs who were educated outside the U.S. may meet the same requirements as domestically trained OTAs. Or, if educated outside the U.S. on or after January 1, 2008, they must have graduated from an OTA program accredited as substantially equivalent to OTA entry level education in the U.S. by ACOTE, its successor organization, or the World Federation of Occupational Therapists or a credentialing body approved by AOTA. In addition, they must have passed an exam for OTAs administered by NBCOT.

Services. The services of OTAs used when providing covered therapy benefits are included as part of the covered service. These services are billed by the supervising occupational therapist. OTAs may not provide evaluation services, make clinical judgments or decisions or take responsibility for the service. They act at the direction and under the supervision of the treating occupational therapist and in accordance with state laws.

An occupational therapist must supervise OTAs. The level and frequency of supervision differs by setting (and by state or local law). General supervision is required for OTAs in all settings except private practice (which requires direct supervision) unless state practice requirements are more stringent, in which case state or local requirements must be followed. See specific settings for details. For example, in clinics, rehabilitation agencies, and public health agencies, 42CFR485.713 indicates that if an OTA provides services, either on or off the organization’s premises, those services are supervised by a qualified occupational therapist who makes an onsite supervisory visit at least once every 30 days or more frequently if required by state or local laws or regulation.

The services of an OTA shall not be billed as services incident to a physician/NPP’s service, because they do not meet the qualifications of a therapist.

The cost of supplies (e.g., looms, ceramic tiles, or leather) used in furnishing covered therapy care is included in the payment for the HCPCS codes billed by the occupational therapist and are, therefore, not separately billable. Separate coverage and billing provisions apply to items that meet the definition of brace in §130 of this manual.

Services provided by aides, even if under the supervision of a therapist, are not therapy services in the outpatient setting and are not covered by Medicare. Although an aide may help the therapist by providing unskilled services, those services that are unskilled are not covered by Medicare and shall be denied as not reasonable and necessary if they are billed as therapy services.

D—Application of Medicare Guidelines to Occupational Therapy Services

Occupational therapy may be required for a patient with a specific diagnosed psychiatric illness. If such services are required, they are covered assuming the coverage criteria are met. However, where an individual’s motivational needs are not related to a specific diagnosed psychiatric illness, the meeting of such needs does not usually require an individualized therapeutic program. Such needs can be met through general activity programs or the efforts of other professional personnel involved in the care of the patient. Patient motivation is a proper function of all health disciplines, which is interwoven with other functions performed by such personnel for the patient. Accordingly, since the special skills of an occupational therapist are not required, an occupational therapy program for individuals who do not have a specific diagnosed psychiatric illness is not to be considered reasonable and necessary for the treatment of an illness or injury. Services furnished under such a program are not covered.

Occupational therapy may include vocational and prevocational assessment and training. When services provided by an occupational therapist are related solely to specific employment opportunities, work skills, or work settings, they are not reasonable or necessary for the diagnosis or treatment of an illness or injury and are not covered. However, carriers and intermediaries exercise care in applying this exclusion,
because the assessment of level of function and the teaching of compensatory techniques to improve the level of function, especially in activities of daily living, are services which occupational therapists provide for both vocational and nonvocational purposes. For example, an assessment of sitting and standing tolerance might be nonvocational for a mother of young children or a retired individual living alone, but could also be a vocational test for a sales clerk. Training an amputee in the use of prosthesis for telephoning is necessary for everyday activities as well as for employment purposes. Major changes in lifestyle may be mandatory for an individual with a substantial disability. The techniques of adjustment cannot be considered exclusively vocational or nonvocational.

230.3——Practice of Speech-Language Pathology

(Rev. 106, Issued: 04-24-09, Effective: 07-01-09, Implementation: 07-06-09)

A——GENERAL

Speech-language pathology services are those services provided within the scope of practice of speech-language pathologists and necessary for the diagnosis and treatment of speech and language disorders, which result in communication disabilities and for the diagnosis and treatment of swallowing disorders (dysphagia), regardless of the presence of a communication disability. (See Pub. 100-03, chapter 1, §170.3) See section 230.4 of this chapter for benefit policies on speech-language pathologists in private practice (SLPP). See Pub. 100-08, Medicare Program Integrity Manual, chapter 10, section 12.4.14 for policy on enrollment in an SLPP.

B——Qualified Speech-Language Pathologist Defined

A qualified speech-language pathologist for program coverage purposes meets one of the following requirements:

• The education and experience requirements for a Certificate of Clinical Competence in (speech-language pathology or audiology) granted by the American Speech-Language Hearing Association; or
• Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

For outpatient speech-language pathology services that are provided incident to the services of physicians/NPPs, the requirement for speech-language pathology licensure does not apply; all other personnel qualifications do apply. Therefore, qualified personnel providing speech-language pathology services incident to the services of a physician/NPP must meet the above qualifications.

C——Services of Speech-Language Pathology Support Personnel

Services of speech-language pathology assistants are not recognized for Medicare coverage. Services provided by speech-language pathology assistants, even if they are licensed to provide services in their states, will be considered unskilled services and denied as not reasonable and necessary if they are billed as therapy services.

Services provided by aides, even if under the supervision of a therapist, are not therapy services and are not covered by Medicare. Although an aide may help the therapist by providing unskilled services, those services are not covered by Medicare and shall be denied as not reasonable and necessary if they are billed as therapy services.

D——Application of Medicare Guidelines to Speech-Language Pathology Services

1——Evaluation Services

Speech-language pathology evaluation services are covered if they are reasonable and necessary and not excluded as routine screening by §1862(a)(7) of the Act. The speech-language pathologist employs a variety of formal and informal speech, language, and dysphagia assessment tests to ascertain the type, causal factor(s), and severity of the speech and language or swallowing disorders. Reevaluation of patients for whom speech, language, and swallowing were previously contraindicated is covered only if the patient exhibits a change in medical condition. However, monthly reevaluations; e.g., a Western Aphasia Battery, for a patient undergoing a rehabilitative speech-language pathology program, are considered a part of the treatment session and shall not be covered as a separate evaluation for billing purposes. Although hearing screening by the speech-language pathologist may be part of an evaluation, it is not billable as a separate service.

2——Therapeutic Services

The following are examples of common medical disorders and resulting communication deficits, which may necessitate active rehabilitative therapy. This list is not all-inclusive:

Cerebrovascular disease such as cerebral vascular accidents presenting with dysphagia, aphasia/dysphasia, apraxia, and dysarthria;
Neurological disease such as Parkinsonism or Multiple Sclerosis with dysarthria, dysphagia, inadequate respiratory volume/control, or voice disorder;
Laryngeal carcinoma requiring laryngectomy resulting in aphonia.

3——Impairments of the Auditory System

The terms, aural rehabilitation, auditory rehabilitation, auditory processing, lipreading and speech reading are among the terms used to describe covered services related to perception and comprehension of sound through the auditory system. See Pub. 100-04, chapter 12, section 30.3 for billing instructions. For example:

• Auditory processing evaluation and treatment may be covered and medically necessary. Examples include but are not limited to services for certain neurological impairments or the absence of natural auditory stimulation that results in impaired ability to process sound. Certain auditory processing disorders require diagnostic audiological tests in addition to speech-language pathology evaluation and treatment.
• Evaluation and treatment for disorders of the auditory system may be covered and medically necessary, for example, when it has been determined by a speech-language pathologist in collaboration with an audiologist that the hearing impaired beneficiary’s current amplification options (hearing aid, other amplification device or cochlear implant) will not sufficiently meet the patient’s functional communication needs. Audiologists and speech-language pathologists both evaluate beneficiaries for disorders of the auditory system using different skills and techniques, but only speech-language pathologists may provide treatment.

Assessment for the need for rehabilitation of the auditory system (but not the vestibular system) may be done by a speech language pathologist. Examples include but are not limited to: evaluation of comprehension and production of
language in oral, signed or written modalities, speech and voice production, listening skills, speech reading, communications strategies, and the impact of the hearing loss on the patient/client and family.

Examples of rehabilitation include but are not limited to treatment that focuses on comprehension, and production of language in oral, signed or written modalities; speech and voice production, auditory training, speech reading, multimodal (e.g., visual, auditory-visual, and tactile) training, communication strategies, education and counseling. In determining the necessity for treatment, the beneficiary’s performance in both clinical and natural environment should be considered.

4—Dysphagia

Dysphagia, or difficulty in swallowing, can cause food to enter the airway, resulting in coughing, choking, pulmonary problems, aspiration, or inadequate nutrition and hydration with resultant weight loss, failure to thrive, pneumonia, and death. It is most often due to complex neurological and/or structural impairments including head and neck trauma, cerebrovascular accident, neuromuscular degenerative diseases, head and neck cancer, dementias, and encephalopathies. For these reasons, it is important that only qualified professionals with specific training and experience in this disorder provide evaluation and treatment.

The speech-language pathologist performs clinical and instrumental assessments and analyzes and integrates the diagnostic information to determine candidacy for intervention as well as appropriate compensations and rehabilitative therapy techniques. The equipment that is used in the examination may be fixed, mobile, or portable. Professional guidelines recommend that the service be provided in a team setting with a physician/NPP who provides supervision of the radiological examination and interpretation of medical conditions revealed in it.

Swallowing assessment and rehabilitation are highly specialized services. The professional rendering care must have education, experience, and demonstrated competencies. Competencies include but are not limited to: identifying abnormal upper aero-digestive tract structure and function; conducting an oral, pharyngeal, laryngeal and respiratory function examination as it relates to the functional assessment of swallowing; recommending methods of oral intake and risk precautions; and developing a treatment plan employing appropriate compensations and therapy techniques.

230.4—Services Furnished by a Therapist in Private Practice (TPP)

(Rev. 179, Issued: 01-14-14, Effective: 01-07-14, Implementation: 01-07-14)

A—General

See section 220 of this chapter for definitions. Therapist refers only to a qualified physical therapist, occupational therapist or speech-language pathologist. TPP refers to therapists in private practice (qualified physical therapists, occupational therapists and speech-language pathologists).

In order to qualify to bill Medicare directly as a therapist, each individual must be enrolled as a private practitioner and employed in one of the following practice types: an unincorporated solo practice, unincorporated partnership, unincorporated group practice, physician/NPP group or groups that are not professional corporations, if allowed by state and local law. Physician/NPP group practices may employ TPP if state and local law permits this employee relationship.

For purposes of this provision, a physician/NPP group practice is defined as one or more physicians/NPPs enrolled with Medicare who may bill as one entity. For further details on issues concerning enrollment, see the provider enrollment Web site at www.cms.hhs.gov/MedicareProviderSupEnroll and Pub. 100-08, Medicare Program Integrity Manual, chapter 15, section 15.4.4.9.

Private practice also includes therapists who are practicing therapy as employees of another supplier, of a professional corporation or other incorporated therapy practice. Private practice does not include individuals when they are working as employees of an institutional provider.

Services should be furnished in the therapist’s or group’s office or in the patient’s home. The office is defined as the location(s) where the practice is operated, in the state(s) where the therapist (and practice, if applicable) is legally authorized to furnish services, during the hours that the therapist engages in the practice at that location. If services are furnished in a private practice office space, that space shall be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. For descriptions of aquatic therapy in a community center pool see section 220C of this chapter.

Therapists in private practice must be approved as meeting certain requirements, but do not execute a formal provider agreement with the Secretary.

If therapists who have their own National Provider Identifier (NPI) are employed by therapist groups, physician/NPP groups, or groups that are not professional organizations, the requirement that therapy space be owned, leased, or rented may be satisfied by the group that employs the therapist. Each therapist employed by a group should enroll as a TPP.

When therapists with a Medicare NPI provide services in the physician’s/NPP’s office in which they are employed, and bill using their NPI for each therapy service, then the direct supervision requirement for enrolled staff apply.

When the therapist who has a Medicare PIN/NPI is employed in a physician’s/NPP’s office the services are ordinarily billed as services of the therapist, with the therapist identified on the claim as the supplier of services. However, services of the therapist who has a Medicare NPI may also be billed by the physician/NPP as services incident to the physician’s/NPP’s service. (See §230.5 for rules related to therapy services incident to a physician.) In that case, the physician/NPP is the supplier of service, the NPI of the supervising physician/NPP is reported on the claim with the service and all the rules for both therapy services and incident to services (§230.5) must be followed.

B—Private Practice Defined


The contractor considers a therapist to be in private practice if the therapist maintains office space at his or her own expense and furnishes services only in that space or the patient’s home. Or, a therapist is employed by another supplier and furnishes services in facilities provided at the expense of that supplier.

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The therapist need not be in full-time private practice but must be engaged in private practice on a regular basis; i.e., the therapist is recognized as a private practitioner and for that purpose has access to the necessary equipment to provide an adequate program of therapy.

The therapy services must be provided either by or under the direct supervision of the TPP. Each TPP in a practice should be enrolled as a Medicare provider. If a physical or occupational therapist is not enrolled, the services of that therapist must be directly supervised by an enrolled physical or occupational therapist. Direct supervision requires that the supervising private practice therapist be present in the office suite at the time the service is performed. These direct supervision requirements apply only in the private practice setting and only for physical therapists and occupational therapists and their assistants. In other outpatient settings, supervision rules differ. The services of support personnel must be included in the therapist’s bill. The supporting personnel, including other therapists, must be W-2 or 1099 employees of the TPP or other qualified employer.

Coverage of outpatient therapy under Part B includes the services of a qualified TPP when furnished in the therapist’s office or the beneficiary’s home. For this purpose, “home” includes an institution that is used as a home, but not a hospital, CAH or SNF. (Federal Register Nov. 2, 1998, pg 58869).

C—Assignment

Reference: Nov. 2, 1998 Federal Register, pg. 58863
See also Pub. 100-04 chapter 1, §30.2.

When physicians, NPPs or TPP obtain provider numbers, they have the option of accepting assignment (participating) or not accepting assignment (nonparticipating). In contrast, providers, such as outpatient hospitals, SNFs, rehabilitation agencies, and CORFs, do not have the option. For these providers, assignment is mandatory.

If physicians/NPPs or TPPs accept assignment (are participating), they must accept the Medicare Physician Fee Schedule amount as payment. Medicare pays 80% and the patient is responsible for 20%. In contrast, if they do not accept assignment, Medicare will only pay 95% of the fee schedule amount. However, when these services are not furnished on an assignment-related basis, the limiting charge applies. (See §1848(g)(2)(c) of the Act.)

NOTE: Services furnished by a therapist in the therapist’s office under arrangements with hospitals in rural communities and public health agencies (or services provided in the beneficiary’s home under arrangements with a provider of outpatient physical or occupational therapy services) are not covered under this provision. See section 230.6.

230.5—Physical Therapy, Occupational Therapy and Speech-Language Pathology Services Provided Incident to the Services of Physicians and Non-Physician Practitioners (NPP)

(Rev. 179, Issued: 01-14-14, Effective: 01-07-14, Implementation: 01-07-14)

References: §1861(s)(2)(A) of the Act
42 CFR 410.10(b)
42 CFR 410.26
Pub. 100-02, ch. 15, § 60.

The Benefit. Therapy services have their own benefit under §1861 of the Social Security Act and shall be covered when provided according to the standards and conditions of the benefit described in Medicare manuals. The statute 1862(a)(20) requires that payment be made for a therapy service billed by a physician/NPP only if the service meets the standards and conditions—other than licensing—that would apply to a therapist. (For example, see coverage requirements in Pub. 100-08, Chapter 13, §13.5.1(C), Pub. 100-04, Chapter 5, and also the requirements of this manual, §220 and §230.

Incident to a Therapist. There is no coverage for services provided incident to the services of a therapist. Although PTAs and OTAs work under the supervision of a therapist and their services may be billed by the therapist, their services are covered under the benefit for therapy services and not by the benefit for services incident to a physician/NPP. The services furnished by PTAs and OTAs are not incident to the therapist’s service.

Qualifications of Auxiliary Personnel. Therapy services appropriately billed incident to a physician’s/NPP’s service shall be subject to the same requirements as therapy services that would be furnished by a physical therapist, occupational therapist or speech-language pathologist in any other outpatient setting with one exception. When therapy services are performed incident to a physician’s/NPP’s service, the qualified personnel who perform the service do not need to have a license to practice therapy, unless it is required by state law. The qualified personnel must meet all the other requirements except licensure. Qualifications for therapists are found in 42CFR484.4 and in section 230.1, 230.2, and 230.3 of this manual. In effect, these rules require that the person who furnishes the service to the patient must, at least, be a graduate of a program of training for one of the therapy services as described above. Regardless of any state licensing that allows other health professionals to provide therapy services, Medicare is authorized to pay only for services provided in a physician’s office.) If the PT or OT is not enrolled, Medicare shall not pay for the services of a PTA or OTA billed incident to the physician’s service, because they do not meet the qualification standards in 42CFR484.4.

Therapy services provided and billed incident to the services of a physician/NPP also may not be billed incident to a physician’s/NPP’s service. However, if a PT and PTA (or an OT and OTA) are both employed in a physician’s office, the services of the PTA, when directly supervised by the PT or the services of the OTA, when directly supervised by the OT may be billed by the physician group as PT or OT services using the PIN/NPI of the enrolled PT (or OT). (See Section 230.4 for private practice rules on billing services performed in a physician’s office.) If the PT or OT is not enrolled, Medicare shall not pay for the services of a PTA or OTA billed incident to the physician’s service, because they do not meet the qualification standards in 42CFR484.4.

Therapy services provided and billed incident to the services of a physician/NPP also must meet all incident-to requirements in §60 of this chapter. Where the policies have different requirements, the more stringent requirement shall be met.

For example, when therapy services are billed as incident to a physician/NPP services, the requirement for direct supervision by the physician/NPP and other incident to requirements
must be met, even though the service is provided by a licensed therapist who may perform the services unsupervised in other settings.

The mandatory assignment provision does not apply to therapy services furnished by a physician/NPP or “incident to” a physician/NPP’s service. However, when these services are not furnished on an assignment-related basis, the limiting charge applies.

For emphasis, following are some of the standards that apply to therapy services billed incident-to the services of a physician/NPP in the physician/NPP’s office or the beneficiary’s residence.

A. Therapy services provided to the beneficiary must be covered and payable outpatient rehabilitation services as described, for example, in this section as well as Pub. 100-08, Chapter 13, §13.5.1.

B. Therapy services must be provided by, or under the direct supervision of a physician (a doctor of medicine or osteopathy) or NPP who is legally authorized to practice therapy services by the state in which he or she performs such function or action. Direct supervision requirements are the same as in 42CFR410.32(b) (3). The supervisor must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician/NPP must be present in the same room in the office where the service is performed.

C. The services must be of a level of complexity that require that they be performed by a therapist or under the direct supervision of the therapist, physician/NPP who is licensed to perform them. Services that do not require the performance or supervision of the therapist, physician/NPP are not considered reasonable or necessary therapy services even if they are performed or supervised by a physician/NPP or other qualified professional.

D. Services must be furnished under a plan of treatment as in §220.1.2 of this chapter. The services provided must relate directly to the physician/NPP service to which it is incident.

230.6—Therapy Services Furnished Under Arrangements With Providers and Clinics

(Rev. 36, Issued: 06-24-05, Effective: 06-06-05, Implementation: 06-06-05)

References: See also Pub. 100-01, chapter 5, §10.3.

A—General

For rules regarding services provided under arrangement, see Pub. 100-01, chapter 5, §10.3.

A provider may have others furnish outpatient therapy (physical therapy, occupational therapy, or speech-language pathology) services through arrangements under which receipt of payment by the provider for the services discharges the liability of the beneficiary or any other person to pay for the service.

However, it is not intended that the provider merely serve as a billing mechanism for the other party. For such services to be covered the provider must assume professional responsibility for the services.

The provider’s professional supervision over the services requires application of many of the same controls that are applied to services furnished by salaried employees. The provider must:

• Accept the patient for treatment in accordance with its admission policies;
• Maintain a complete and timely clinical record on the patient which includes diagnosis, medical history, orders, and progress notes relating to all services received;
• Maintain liaison with the attending physician/NPP with regard to the progress of the patient and to assure that the required plan of treatment is periodically reviewed by the physician/NPP;
• Secure from the physician/NPP the required certifications and recertifications; and
• Ensure that the medical necessity of such service is reviewed on a sample basis by the agency’s staff or an outside review group.

In addition, when a provider provides outpatient services under an arrangement with others, such services must be furnished in accordance with the terms of a written contract, which provides for retention by the provider of responsibility for and control and supervision of such services. The terms of the contract should include at least the following:

• Provide that the therapy services are to be furnished in accordance with the plan of care established according to Medicare policies for therapy plans of care in Section 220.1.2 of this chapter;
• Specify the geographical areas in which the services are to be furnished;
• Provide that contracted personnel and services meet the same requirements as those which would be applicable if the personnel and services were furnished directly by the provider;
• Provide that the therapist will participate in conferences required to coordinate the care of an individual patient;
• Provide for the preparation of treatment records, with progress notes and observations, and for the prompt incorporation of such into the clinical records of the clinic;
• Specify the financial arrangements. The contracting organization or individual may not bill the patient or the health insurance program; and
• Specify the period of time the contract is to be in effect and the manner of termination or renewal.

B—Special Rules for Hospitals

A hospital may bill Medicare for outpatient therapy (physical therapy, occupational therapy, or speech-language pathology) services that it furnishes to its outpatients either directly or under arrangements in the hospital’s outpatient department. If a hospital furnishes medically necessary therapy services in its outpatient department to individuals who are registered as its outpatients, those services must be billed directly by the hospital using bill type 13X or 85X for critical access hospitals. Note that services provided to residents of a Medicare-certified SNF may not be billed by the hospital as services to its outpatients.

• When a hospital sends its therapists to the home of an individual who is registered as an outpatient of the hospital but who is unable, for medical reasons, to come to the hospital to receive medically necessary therapy services, the services must meet the requirements applicable to outpatient hospital therapy services, as set forth in the regula-
In certain settings and under certain circumstances, hospitals may bill for those services directly using bill type 13X or 85X for critical access hospitals.

- If a hospital sends its therapists to provide therapy services to individuals who are registered as its outpatients and who are residing in the non-certified part of a SNF, or in another residential setting (e.g., a group home, assisted living facility or domiciliary care home), the hospital may bill for the services as hospital outpatient services if the services meet the requirements applicable to outpatient hospital therapy services, as set forth in the regulations and applicable Medicare manuals.

- A hospital may make an arrangement with another entity such as an Outpatient Rehab Facility (Rehabilitation Agency) or a private practice, to provide therapy services to individuals who are registered as outpatients of the hospital. These services must meet the requirements applicable to services furnished under arrangements and the requirements applicable to the outpatient hospital therapy services as set forth in the regulations and applicable Medicare manuals. The hospital uses bill type 13X or 85X for critical access hospitals to bill for the services that another entity furnishes under arrangement to its outpatients.

- Where the provider is a public health agency or a hospital in a rural community, it may enter into arrangements to have outpatient physical therapy services furnished in the private office of a qualified physical therapist if the agency or hospital does not have the capacity to provide on its premises all of the modalities of treatment, tests, and measurements that are included in an adequate outpatient physical therapy program and the services and modalities which the public health agency or hospital cannot provide on its premises are not available on an outpatient basis in another accessible certified facility.

- In certain settings and under certain circumstances, hospitals may not bill Medicare for therapy services as services of the hospital:

  - If a hospital sends its therapists to provide therapy services to patients of another hospital, including a patient at an inpatient rehabilitation facility or a long term care facility, the services must be furnished under arrangements made with the hospital sending the therapists by the hospital having the patients and billed as hospital services by the facility whose patients are treated. These services would be subject to existing hospital bundling rules and would be paid under the payment method applicable to the hospital at which the individuals are patients.

  - A hospital may not send its therapists to provide therapy services to individuals who are receiving services from an HHA under a home health plan of care and bill for the therapy services as hospital outpatient services. For patients under a home health plan of care, payment for therapy services (unless provided by physicians/NPPs) is included or bundled into Medicare's episodic payment to the HHA, and those services must be billed by the HHA under the HHA consolidated billing rules. For patients receiving HHA services under an HHA plan of care, therapy services must be furnished directly or under arrangements made by the HHA, and only the HHA may bill for those services.

  - If a hospital sends its therapists to provide services under arrangements made by a SNF to residents of the Medicare-certified part of a SNF, SNF consolidated billing rules apply. For arrangements specific to SNF Part A, see Pub. 100-04, chapter 6, §10.4. This means that therapy services furnished to SNF residents in the Medicare-certified part of a SNF cannot be billed by any entity other than the SNF. Therefore, a hospital may not bill Medicare for PT/OT/SLP services furnished to residents of a Medicare-certified part of a SNF by its therapists as services of the hospital.

  NOTE: If the SNF resident is in a covered Part A stay, the therapy services would be included in the SNF’s global PPS per diem payment for the covered Part A stay itself. If the resident is in a noncovered stay (Part A benefits exhausted, no prior qualifying hospital stay, etc.), but remains in the Medicare-certified part of a SNF, the SNF would submit the Part B therapy bill to its fiscal intermediary.

<table>
<thead>
<tr>
<th>SNF Setting</th>
<th>Consolidated Billing Rules Apply?</th>
<th>Hospital May Bill For Outpatient Services?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare Part A or B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Covered/PPS Resident in Medicare-certified part of a SNF</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Medicare Part B Resident in Medicare-certified part of a SNF</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Not a Resident in Medicare-certified part of a SNF</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

- A hospital may not send therapy staff to provide therapy services in non-residential health care settings and bill for the services as if they were provided at the hospital, even if the hospital owns the other facility or entity. Examples of such non-residential settings include CORFs, rehabilitation agencies, ORFs and offices of physicians/NPPs or other practitioners, such as physical therapists. For example, services furnished to patients of a CORF must be billed as CORF services and not as outpatient hospital services. Even if a CORF contracts with a hospital to furnish services to CORF patients, the hospital may not bill Medicare for the services as hospital outpatient services. However, the CORF could have the hospital furnish services to its patients under arrangements, in which case the CORF would bill for the services.

Psychiatric hospitals are treated the same as other hospitals for the purpose of therapy billing.

290—Foot Care

(Rev. 1, 10-01-03)

A3-3158, B3-2323, HO-260.9, B3-4120.1

A—Treatment of Subluxation of Foot

Subluxations of the foot are defined as partial dislocations or displacements of joint surfaces, tendons ligaments, or muscles of the foot. Surgical or nonsurgical treatments under
taken for the sole purpose of correcting a subluxed structure in the foot as an isolated entity are not covered.

However, medical or surgical treatment of subluxation of the ankle joint (talo-crural joint) is covered. In addition, reasonable and necessary medical or surgical services, diagnosis, or treatment for medical conditions that have resulted from or are associated with partial displacement of structures is covered. For example, if a patient has osteoarthritis that has resulted in a partial displacement of joints in the foot, and the primary treatment is for the osteoarthritis, coverage is provided.

**B—Exclusions from Coverage**

The following foot care services are generally excluded from coverage under both Part A and Part B. (See §290.F and §290.G for instructions on applying foot care exclusions.)

1. **Treatment of Flat Foot** — The term “flat foot” is defined as a condition in which one or more arches of the foot have flattened out. Services or devices directed toward the care or correction of such conditions, including the prescription of supportive devices, are not covered.

2. **Routine Foot Care** — Except as provided above, routine foot care is excluded from coverage. Services that normally are considered routine and not covered by Medicare include the following:
   - The cutting or removal of corns and calluses;
   - The trimming, cutting, clipping, or debriding of nails; and
   - Other hygienic and preventive maintenance care, such as cleaning and soaking the feet, the use of skin creams to maintain skin tone of either ambulatory or bedfast patients, and any other service performed in the absence of localized illness, injury, or symptoms involving the foot.

3. **Supportive Devices for Feet** — Orthopedic shoes and other supportive devices for the feet generally are not covered. However, this exclusion does not apply to such a shoe if it is an integral part of a leg brace, and its expense is included as part of the cost of the brace. Also, this exclusion does not apply to therapeutic shoes furnished to diabetics.

**C—Exceptions to Routine Foot Care Exclusion**

1. **Necessary and Integral Part of Otherwise Covered Services** — In certain circumstances, services ordinarily considered to be routine may be covered if they are performed as a necessary and integral part of otherwise covered services, such as diagnosis and treatment of ulcers, wounds, or infections.

2. **Treatment of Warts on Foot** — The treatment of warts (including plantar warts) on the foot is covered to the same extent as services provided for the treatment of warts located elsewhere on the body.

3. **Presence of Systemic Condition** — The presence of a systemic condition such as metabolic, neurologic, or peripheral vascular disease may require scrupulous foot care by a professional that in the absence of such condition(s) would be considered routine (and, therefore, excluded from coverage). Accordingly, foot care that would otherwise be considered routine may be covered when systemic condition(s) result in severe circulatory embarrassment or areas of diminished sensation in the individual's legs or feet. (See subsection A.)

In these instances, certain foot care procedures that otherwise are considered routine (e.g., cutting or removing corns and calluses, or trimming, cutting, clipping, or debriding nails) may pose a hazard when performed by a nonprofessional person on patients with such systemic conditions. (See §290.G for procedural instructions.)

4. **Mycotic Nails** — In the absence of a systemic condition, treatment of mycotic nails may be covered.

The treatment of mycotic nails for an ambulatory patient is covered only when the physician attending the patient's mycotic condition documents that (1) there is clinical evidence of mycosis of the toenail, and (2) the patient has marked limitation of ambulation, pain, or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.

The treatment of mycotic nails for a nonambulatory patient is covered only when the physician attending the patient's mycotic condition documents that (1) there is clinical evidence of mycosis of the toenail, and (2) the patient suffers from pain or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.

For the purpose of these requirements, documentation means any written information that is required by the carrier in order for services to be covered. Thus, the information submitted with claims must be substantiated by information found in the patient's medical record. Any information, including that contained in a form letter, used for documentation purposes is subject to carrier verification in order to ensure that the information adequately justifies coverage of the treatment of mycotic nails.

**D—Systemic Conditions That Might Justify Coverage**

Although not intended as a comprehensive list, the following metabolic, neurologic, and peripheral vascular diseases (with synonyms in parentheses) most commonly represent the underlying conditions that might justify coverage for routine foot care.

- Diabetes mellitus*
- Arteriosclerosis obliterans (A.S.O., arteriosclerosis of the extremities, occlusive peripheral arteriosclerosis)
- Buerger's disease (thromboangiitis obliterans)
- Chronic thrombophlebitis*
- Peripheral neuropathies involving the feet—
  - Associated with malnutrition and vitamin deficiency*  
    - Malnutrition (general, pellagra)
  - Alcoholism
  - Malabsorption (celiac disease, tropical sprue)
  - Pernicious anemia
  - Associated with carcinoma*
  - Associated with diabetes mellitus*
  - Associated with drugs and toxins*
  - Associated with multiple sclerosis*
  - Associated with uremia (chronic renal disease)*
  - Associated with traumatic injury
  - Associated with leprosy or neurosyphilis
Associated with hereditary disorders
   Hereditary sensory radicular neuropathy
   Angiokeratoma corporis diffusum (Fabry's)
   Amyloid neuropathy

When the patient's condition is one of those designated by an asterisk (*), routine procedures are covered only if the patient is under the active care of a doctor of medicine or osteopathy who documents the condition.

E—Supportive Devices for Feet

Orthopedic shoes and other supportive devices for the feet generally are not covered. However, this exclusion does not apply to such a shoe if it is an integral part of a leg brace, and its expense is included as part of the cost of the brace. Also, this exclusion does not apply to therapeutic shoes furnished to diabetics.

F—Presumption of Coverage

In evaluating whether the routine services can be reimbursed, a presumption of coverage may be made where the evidence available discloses certain physical and/or clinical findings consistent with the diagnosis and indicative of severe peripheral involvement. For purposes of applying this presumption the following findings are pertinent:

Class A Findings
   Nontraumatic amputation of foot or integral skeletal portion thereof.

Class B Findings
   Absent posterior tibial pulse;
   Advanced trophic changes as: hair growth (decrease or absence) nail changes (thickening) pigmentedary changes (discoloration) skin texture (thick, shiny) skin color (rubor or redness) (Three required); and
   Absent dorsalis pedis pulse.

Class C Findings
   Claudication;
   Temperature changes (e.g., cold feet);
   Edema;
   Paresthesias (abnormal spontaneous sensations in the feet); and
   Burning.

The presumption of coverage may be applied when the physician rendering the routine foot care has identified:

1. A Class A finding;
2. Two of the Class B findings; or
3. One Class B and two Class C findings.

Cases evidencing findings falling short of these alternatives may involve podiatric treatment that may constitute covered care and should be reviewed by the intermediary's medical staff and developed as necessary.

For purposes of applying the coverage presumption where the routine services have been rendered by a podiatrist, the contractor may deem the active care requirement met if the claim or other evidence available discloses that the patient has seen an M.D. or D.O. for treatment and/or evaluation of the complicating disease process during the 6-month period prior to the rendition of the routine-type services. The intermediary may also accept the podiatrist's statement that the diagnosing and treating M.D. or D.O. also concurs with the podiatrist's findings as to the severity of the peripheral involvement indicated.

Services ordinarily considered routine might also be covered if they are performed as a necessary and integral part of otherwise covered services, such as diagnosis and treatment of diabetic ulcers, wounds, and infections.

G—Application of Foot Care Exclusions to Physician's Services

The exclusion of foot care is determined by the nature of the service. Thus, payment for an excluded service should be denied whether performed by a podiatrist, osteopath, or a doctor of medicine, and without regard to the difficulty or complexity of the procedure.

When an itemized bill shows both covered services and noncovered services not integrally related to the covered service, the portion of charges attributable to the noncovered services should be denied. (For example, if an itemized bill shows surgery for an ingrown toenail and also removal of calluses not necessary for the performance of toe surgery, any additional charge attributable to removal of the calluses should be denied.)

In reviewing claims involving foot care, the carrier should be alert to the following exceptional situations:

1. Payment may be made for incidental noncovered services performed as a necessary and integral part of, and secondary to, a covered procedure. For example, if trimming of toenails is required for application of a cast to a fractured foot, the carrier need not allocate and deny a portion of the charge for the trimming of the nails. However, a separately itemized charge for such excluded service should be disallowed. When the primary procedure is covered the administration of anesthesia necessary for the performance of such procedure is also covered.

2. Payment may be made for initial diagnostic services performed in connection with a specific symptom or complaint if it seems likely that its treatment would be covered even though the resulting diagnosis may be one requiring only noncovered care.

The name of the M.D. or D.O. who diagnosed the complicating condition must be submitted with the claim. In those cases, where active care is required, the approximate date the beneficiary was last seen by such physician must also be indicated.

NOTE: Section 939 of P.L. 96-499 removed "warts" from the routine foot care exclusion effective July 1, 1981.

Relatively few claims for routine-type care are anticipated considering the severity of conditions contemplated as the basis for this exception. Claims for this type of foot care should not be paid in the absence of convincing evidence that nonprofessional performance of the service would have been hazardous for the beneficiary because of an underlying systemic disease. The mere statement of a diagnosis such as those mentioned in §D above does not of itself indicate the
severity of the condition. Where development is indicated to
verify diagnosis and/or severity the carrier should follow ex-
isting claims processing practices which may include review
of carrier's history and medical consultation as well as physi-
cian contacts.

The rules in §290.F concerning presumption of coverage also
apply.

Codes and policies for routine foot care and supportive de-
vices for the feet are not exclusively for the use of podiatrists.
These codes must be used to report foot care services regard-
less of the specialty of the physician who furnishes the ser-
vices. Carriers must instruct physicians to use the most ap-
propriate code available when billing for routine foot care.

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10—General Exclusions From Coverage

(Rev. 198, Issued: 11-06-14, Effective: 01-01-15, Implementa-
tion: 01-05-15)

No payment can be made under either the hospital insurance
or supplementary medical insurance program for certain items and services, when the following conditions exist:

- Not reasonable and necessary (§20);
- Not legal obligation to pay for or provide (§40);
- Paid for by a governmental entity (§80);
- Not provided within United States (§60);
- Resulting from war (§70);
- Personal comfort (§80);
- Routine services and appliances (§90);
- Custodial care (§110);
- Cosmetic surgery (§120);
- Charges by immediate relatives or members of household
  (§130);
- Dental services (§140);
- Paid or expected to be paid under workers’ compensation
  (§150);
- Nonphysician services provided to a hospital inpatient that
  were not provided directly or arranged for by the hospital
  (§170);
- Services Related to and Required as a Result of Services
  Which are not Covered Under Medicare (§180);
- Excluded foot care services and supportive devices for feet
  (§30); or
- Excluded investigational devices (See Chapter 14).

20—Services Not Reasonable and Necessary

(Rev. 1, 10-01-03)

A3-3151, HO-260.1, B3-2303, AB-00-52 - 6/00

Items and services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to im-
prove the functioning of a malformed body member are not
covered, e.g., payment cannot be made for the rental of a
special hospital bed to be used by the patient in their home
unless it was a reasonable and necessary part of the patient’s
treatment. See also §80.

A healthcare item or service for the purpose of causing, or
assisting to cause, the death of any individual (assisted
suicide) is not covered. This prohibition does not apply to the
provision of an item or service for the purpose of alleviating
pain or discomfort, even if such use may increase the risk of
death, so long as the item or service is not furnished for the
specific purpose of causing death.

90—Routine Services and Appliances

(Rev. 186, Issued: 04-16-14, Effective: 01-01 01, Implementa-
tion: 05-12-14)

Routine physical checkups; eyeglasses, contact lenses, and eye
examinations for the purpose of prescribing, fitting, or chang-
ing eyeglasses; eye refractions by whatever practitioner and
for whatever purpose performed; hearing aids and examina-
tions for hearing aids; and immunizations are not covered.

The routine physical checkup exclusion applies to (a) exami-
inations performed without relationship to treatment or diagnosis
for a specific illness, symptom, complaint, or injury; and (b)
examinations required by third parties such as insurance com-
panies, business establishments, or Government agencies.

The routine physical checkup exclusion does not apply to the
following services (as noted in section 42 CFR 411.15(a)(1)):

- Screening mammography,
- Colorectal cancer screening tests,
- Screening pelvic exams,
- Prostate cancer screening tests,
- Glaucoma screening exams,
- Ultrasound screening for abdominal aortic aneurysms (AAA),
- Cardiovascular disease screening tests,
- Diabetes screening tests,
- Screening electrocardiogram,
- Initial preventive physical examinations,
- Annual wellness visits providing personalized prevention
  plan services, and
- Additional preventive services that meet the criteria speci-
  fied in 42 CFR 410.64.

If the claim is for a diagnostic test or examination performed
solely for the purpose of establishing a claim under title IV of
Public Law 91-173, “Black Lung Benefits,” the service is not
covered under Medicare and the claimant should be advised
to contact their Social Security office regarding the filing of a
claim for reimbursement under the “Black Lung” program.

The exclusions apply to eyeglasses or contact lenses, and eye
examinations for the purpose of prescribing, fitting, or chang-
ing eyeglasses or contact lenses for refractive errors. The ex-
clusions do not apply to physicians’ services (and services in-
cident to a physicians’ service) performed in conjunction with
an eye disease, as for example, glaucoma or cataracts, or to
post-surgical prosthetic lenses which are customarily used
during convalescence from eye surgery in which the lens of the
eye was removed, or to permanent prosthetic lenses required
by an individual lacking the organic lens of the eye, whether
by surgical removal or congenital disease. Such prosthetic lens
is a replacement for an internal body organ - the lens of the
eye. (See the Medicare Benefit Policy Manual, Chapter 15,
“Covered Medical and Other Health Services,” §120).

Expenses for all refractive procedures, whether performed by
an ophthalmologist (or any other physician) or an optome-
trist and without regard to the reason for performance of the
refraction, are excluded from coverage.
A. Immunizations

Vaccinations or inoculations are excluded as immunizations unless they are either:

- Directly related to the treatment of an injury or direct exposure to a disease or condition, such as antirabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin sera, or immune globulin. (In the absence of injury or direct exposure, preventive immunization (vaccination or inoculation) against such diseases as smallpox, polio, diphtheria, etc., is not covered.); or
- Specifically covered by statute, as described in the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §50.4.4.2.

B. Antigens

Prior to the Omnibus Reconciliation Act of 1980, a physician who prepared an antigen for a patient could not be reimbursed for that service unless the physician also administered the antigen to the patient. Effective January 1, 1981, payment may be made for a reasonable supply of antigens that have been prepared for a particular patient even though they have not been administered to the patient by the same physician who prepared them if:

- The antigens are prepared by a physician who is a doctor of medicine or osteopathy, and
- The physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen.

A reasonable supply of antigens is considered to be not more than a 12-week supply of antigens that has been prepared for a particular patient at any one time. The purpose of the reasonable supply limitation is to assure that the antigens retain their potency and effectiveness over the period in which they are to be administered to the patient. (See the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §50.4.4.1)

100 - Hearing Aids and Auditory Implants

(Rev. 39; Issued: 11-10-05; Effective: 11-10-05; Implementation: 12-12-05)

Section 1862(a)(7) of the Social Security Act states that no payment may be made under part A or part B for any expenses incurred for items or services “where such expenses are for . . . hearing aids or examinations therefor. . . .” This policy is further reiterated at 42 CFR 411.15(d) which specifically states that “hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids” are excluded from coverage.

Hearing aids are amplifying devices that compensate for impaired hearing. Hearing aids include air conduction devices that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound. They also include bone conduction devices that provide mechanical energy to the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.

Certain devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery.

The following are prosthetic devices:

- Cochlear implants and auditory brain stem implants, i.e., devices that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays.
- Osseointegrated implants, i.e., devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer.

Medicare contractors deny payment for an item of service that is associated with any hearing aid as defined above. See §180 for policy for the medically necessary treatment of complications of implantable hearing aids, such as medically necessary removals of implantable hearing aids due to infection.

110 - Custodial Care

(Rev. 1, 10-01-03)

A3-3159, HO-260.10, HO-261, B3-2326

Custodial care is excluded from coverage. Custodial care serves to assist an individual in the activities of daily living, such as assistance in walking, getting in and out of bed, bathing, dressing, feeding, and using the toilet, preparation of special diets, and supervision of medication that usually can be self-administered. Custodial care essentially is personal care that does not require the continuing attention of trained medical or paramedical personnel. In determining whether a person is receiving custodial care, the intermediary or carrier considers the level of care and medical supervision required and furnished. It does not base the decision on diagnosis, type of condition, degree of functional limitation, or rehabilitation potential.

Institutional care that is below the level of care covered in a SNF is custodial care. (See the Medicare Benefit Policy Manual, Chapter 8, “Coverage of Extended Care (SNF) Services Under Hospital Insurance,” §30.) Some examples of custodial care in hospitals and SNFs are:

- A stroke patient who is ambulatory, has no bladder or bowel involvement, no serious associated or secondary illnesses and does not require medical or paramedical care but requires only the assistance of an aide in feeding, dressing, and bathing;
- A cardiac patient who is stable and compensated and has reasonable cardiac reserve and no associated illnesses, but who because of advanced age has difficulty in managing alone in the home, and requires assistance in meeting the activities of daily living; and
- A senile patient who has diabetes which remains stabilized as long as someone sees to it that the patient takes oral medication and sticks to a prescribed diet.

Even if a patient’s stay in a hospital or SNF is determined to be custodial, some individual services may still be covered under Part B if they are reasonable and necessary. For example, periodic visits by a physician to their patient are covered under Part B if such services are reasonable and necessary to the treatment of the patient’s illness or injury even
though a finding has been made that the care being furnished the patient in the hospital of SNF is custodial care and, therefore, not covered. Similarly, such a finding of custodial care does not preclude payment for a Part B claim for ancillary services which are medically necessary (see the Medicare Benefit Policy Manual, Chapter 1, “Covered Medical and Other Health Services,” §250). (See the Medicare Benefit Policy Manual, Chapter 6, “Hospital Services Covered Under Part B,” §10, and Chapter 8, §80.)

110.1 - Custodial Care Under a Hospice Program
(Rev. 1, 10-01-03)
A3-3159.1

Care furnished to an individual who has elected the hospice care option is custodial only if it is not reasonable and necessary for the palliation or management of the terminal illness or related conditions. (See the Medicare Benefit Policy Manual, Chapter 9, “Coverage of Hospice Services Under Hospital Insurance,” §40.)

140—Dental Services Exclusion
(Rev. 1, 10-01-03)
A3-3162, HO-260.13, B3-2336

Items and services in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth are not covered. Structures directly supporting the teeth mean the periodontium, which includes the gingivae, dentogingival junction, periodontal membrane, cementum, and alveolar process. However, payment may be made for certain other services of a dentist. (See the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §150.)

The hospitalization or nonhospitalization of a patient has no direct bearing on the coverage or exclusion of a given dental procedure.

When an excluded service is the primary procedure involved, it is not covered regardless of its complexity or difficulty. For example, the extraction of an impacted tooth is not covered. Similarly, an alveoplasty (the surgical improvement of the shape and condition of the alveolar process) and a frenectomy are excluded from coverage when either of these procedures is performed in connection with an excluded service, e.g., the preparation of the mouth for dentures. In like manner, the removal of the torus palatinus (a bony protuberance of the hard palate) could be a covered service. However, with rare exception, this surgery is performed in connection with an excluded service, i.e., the preparation of the mouth for dentures. Under such circumstances, reimbursement is not made for this purpose.

The extraction of teeth to prepare the jaw for radiation treatments of neoplastic disease is also covered. This is an exception to the requirement that to be covered, a noncovered procedure or service performed by a dentist must be an incidental to and an integral part of a covered procedure or service performed by the dentist. Ordinarily, the dentist extracts the patient’s teeth, but another physician, e.g., a radiologist, administers the radiation treatments.

Whether such services as the administration of anesthesia, diagnostic x-rays, and other related procedures are covered depends upon whether the primary procedure being performed by the dentist is covered. Thus, an x-ray taken in connection with the reduction of a fracture of the jaw or facial bone is covered. However, a single x-ray or x-ray survey taken in connection with the care or treatment of teeth or the periodontium is not covered.

See also the Medicare Benefit Policy Manual, Chapter 1, “Inpatient Hospital Services,” §70, and Chapter 15, “Covered Medical and Other Health Services,” §150 for additional information on dental services.

100-03 Chapter 1, Part 1

20.8—Cardiac Pacemakers (Various Effective Dates Below)

Cardiac pacemakers are self-contained, battery-operated units that send electrical stimulation to the heart. They are generally implanted to alleviate symptoms of decreased cardiac output related to abnormal heart rate and/or rhythm. Pacemakers are generally used for persistent, symptomatic second- or third-degree atrioventricular (AV) block and symptomatic sinus bradycardia.

Cardiac pacemakers are covered as prosthetic devices under the Medicare program, subject to the following conditions and limitations. While cardiac pacemakers have been covered under Medicare for many years, there were no specific guidelines for their use other than the general Medicare requirement that covered services be reasonable and necessary for the treatment of the condition. Services rendered for cardiac pacing on or after the effective dates of this instruction are subject to these guidelines, which are based on certain assumptions regarding the clinical goals of cardiac pacing. While some uses of pacemakers are relatively certain or unambiguous, many other uses require considerable expertise and judgment.

Consequently, the medical necessity for permanent cardiac pacing must be viewed in the context of overall patient management. The appropriateness of such pacing may be conditional on other diagnostic or therapeutic modalities having been undertaken. Although significant complications and adverse side effects of pacemaker use are relatively rare, they cannot be ignored when considering the use of pacemakers for dubious medical conditions, or marginal clinical benefit.

These guidelines represent current concepts regarding medical circumstances in which permanent cardiac pacing may be appropriate or necessary. As with other areas of medicine, advances in knowledge and techniques in cardiology are expected. Consequently, judgments about the medical necessity and acceptability of new uses for cardiac pacing in new classes of patients may change as more conclusive evidence becomes available. This instruction applies only to permanent cardiac pacemakers, and does not address the use of temporary, non-implanted pacemakers.

The two groups of conditions outlined below deal with the necessity for cardiac pacing for patients in general. These are intended as guidelines in assessing the medical necessity for pacing therapies, taking into account the particular circumstances in each case. However, as a general rule, the two groups of current medical concepts may be viewed as representing:
Group I: Single-Chamber Cardiac Pacemakers - a) conditions under which single chamber pacemaker claims may be considered covered without further claims development; and b) conditions under which single-chamber pacemaker claims would be denied unless further claims development shows that they fall into the covered category, or special medical circumstances exist of the sufficiency to convince the Medicare Administrative Contractor (MAC) that the claim should be paid.

Group II: Dual-Chamber Cardiac Pacemakers - a) conditions under which dual-chamber pacemaker claims may be considered covered without further claims development, and b) conditions under which dual-chamber pacemaker claims would be denied unless further claims development shows that they fall into the covered categories for single- and dual-chamber pacemakers, or special medical circumstances exist sufficient to convince the MAC that the claim should be paid.

The Centers for Medicare & Medicaid Services (CMS) opened the National Coverage Determination (NCD) on Cardiac Pacemakers to afford the public an opportunity to comment on the proposal to revise the language contained in the instruction. The revisions transfer the focus of the NCD from the actual pacemaker implantation procedure itself to the reasonable and necessary medical indications that justify cardiac pacing. This is consistent with our findings that pacemaker implantation is no longer considered routinely harmful or an experimental procedure.

Group I: Single-Chamber Cardiac Pacemakers (Effective March 16, 1983)

A. Nationally Covered Indications

Conditions under which cardiac pacing is generally considered acceptable or necessary, provided that the conditions are chronic or recurrent and not due to transient causes such as acute myocardial infarction, drug toxicity, or electrolyte imbalance. (In cases where there is a rhythm disturbance, if the rhythm disturbance is chronic or recurrent, a single episode of a symptom such as syncope or seizure is adequate to establish medical necessity.)

1. Acquired complete (also referred to as third-degree) AV heart block.
2. Congenital complete heart block with severe bradycardia (in relation to age), or significant physiological deficits or significant symptoms due to the bradycardia.
3. Second-degree AV heart block of Type II (i.e., no progressive prolongation of P-R interval prior to each blocked beat. P-R interval indicates the time taken for an impulse to travel from the atria to the ventricles on an electrocardiogram).
4. Second-degree AV heart block of Type I (i.e., progressive prolongation of P-R interval prior to each blocked beat) with significant symptoms due to hemodynamic instability associated with the heart block.
5. Sinus bradycardia associated with major symptoms (e.g., syncope, seizures, congestive heart failure (CHF)); or substantial sinus bradycardia (heart rate less than 50) associated with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
6. In selected and few patients, sinus bradycardia of lesser severity (heart rate 50-59) with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
7. Sinus bradycardia is the consequence of long-term necessary drug treatment for which there is no acceptable alternative when accompanied by significant symptoms (e.g., syncope, seizures, CHF, dizziness, or confusion). The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
8. Sinus node dysfunction with or without tachyarrhythmias or AV conduction block (i.e., the bradyarrhythmia-tachycardia syndrome, sino-atrial block, sinus arrest) when accompanied by significant symptoms (e.g., syncope, seizures, CHF, dizziness, or confusion).
9. Sinus node dysfunction with or without symptoms when there are potentially lifethreatening ventricular arrhythmias or tachycardia secondary to the bradycardia (e.g., numerous premature ventricular contractions, couplets, runs of premature ventricular contractions, or ventricular tachycardia).
10. Bradycardia associated with supraventricular tachycardia (e.g., atrial fibrillation, atrial flutter, or paroxysmal atrial tachycardia) with high-degree AV block which is unresponsive to appropriate pharmacological management and when the bradycardia is associated with significant symptoms (e.g., syncope, seizures, CHF, dizziness, or confusion).
11. The occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.
12. Bifascicular or trifascicular block accompanied by syncope which is attributed to transient complete heart block after other plausible causes of syncope have been reasonably excluded.
13. Prophylactic pacemaker use following recovery from acute myocardial infarction (MI) during which there was temporary complete (third-degree) and/or Mobitz Type II second-degree AV block in association with bundle branch block.
14. In patients with recurrent and refractory ventricular tachycardia, “overdrive pacing” (pacing above the basal rate) to prevent ventricular tachycardia. (Effective May 9, 1985)
15. Second-degree AV heart block of Type I with the QRS complexes prolonged.

B. Nationally Non-Covered Indications

Conditions which, although used by some physicians as a basis for permanent cardiac pacing, are considered unsupported by adequate evidence of benefit and therefore should not generally be considered appropriate uses for single-chamber pacemakers in the absence of the above indications. MACs should review claims for pacemakers with these indications to determine the need for further claims development prior to denying the claim, since additional claims development may be required. The object of such further development is to establish whether the particular claim actually meets the conditions in a) above. In claims where this is not the case or where such an event appears unlikely, the MAC may deny the claim:

1. Syncope of undetermined cause.
2. Sinus bradycardia without significant symptoms.
3. Sino-atrial block or sinus arrest without significant symptoms.
4. Prolonged P-R intervals with atrial fibrillation (without third-degree AV block) or with other causes of transient ventricular pause.
5. Bradycardia during sleep.
6. Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent AV block.
7. Asymptomatic second-degree AV block of Type I unless the QRS complexes are prolonged or electrophysiological studies have demonstrated that the block is at or beyond the level of the His bundle (a component of the electrical conduction system of the heart).

Effective October 1, 2001
8. Asymptomatic bradycardia in post-MI patients about to initiate long-term beta-blocker drug therapy.

C. Other

All other indications for single-chamber cardiac pacing for which CMS has not specifically indicated coverage remain nationally non-covered, except for Category B Investigational Device Exemption (IDE) clinical trials, or as routine costs of single-chamber cardiac pacing associated with clinical trials, in accordance with section 310.1 of the NCD Manual.

Group II: Dual-Chamber Cardiac Pacemakers - (Effective May 9, 1985)

A. Nationally Covered Indications

Conditions under dual-chamber cardiac pacing are considered acceptable or necessary in the general medical community unless conditions 1 and 2 under Group II, B., are present:

1. Patients in whom single-chamber (ventricular pacing) at the time of pacemaker insertion elicits a definite drop in blood pressure, retrograde conduction, or discomfort.
2. Patients in whom the pacemaker syndrome (atrial ventricular asynchrony), with significant symptoms, has already been experienced with a pacemaker that is being replaced.
3. Patients in whom even a relatively small increase in cardiac efficiency will importantly improve the quality of life, e.g., patients with CHF despite adequate other medical measures.
4. Patients in whom the pacemaker syndrome can be anticipated, e.g., in young and active people, etc.

Dual-chamber pacemakers may also be covered for the conditions as listed in Group I, A., if the medical necessity is sufficiently justified through adequate claims development. Expert physicians differ in their judgments about what constitutes appropriate criteria for dual-chamber pacemaker use. The judgment that such a pacemaker is warranted in the patient meeting accepted criteria must be based upon the individual needs and characteristics of that patient, weighing the magnitude and likelihood of anticipated benefits against the magnitude and likelihood of disadvantages to the patient.

B. Nationally Non-Covered Indications

Whenever the following conditions (which represent overriding contraindications) are present, dual-chamber pacemakers are not covered:

1. Ineffective atrial contractions (e.g., chronic atrial fibrillation or flutter, or giant left atrium.

2. Frequent or persistent supraventricular tachycardias, except where the pacemaker is specifically for the control of the tachycardia.
3. A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged, e.g., the occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.
4. Prophylactic pacemaker use following recovery from acute MI during which there was temporary complete (third-degree) and/or Type II second-degree AV block in association with bundle branch block.

C. Other

All other indications for dual-chamber cardiac pacing for which CMS has not specifically indicated coverage remain nationally non-covered, except for Category B IDE clinical trials, or as routine costs of dual-chamber cardiac pacing associated with clinical trials, in accordance with section 310.1 of the NCD Manual.

20.8.1—Cardiac Pacemaker Evaluation Services

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation:

Medicare covers a variety of services for the post-implant follow-up and evaluation of implanted cardiac pacemakers. The following guidelines are designed to assist Medicare Administrative Contractors (MACs) in identifying and processing claims for such services.

NOTE: These new guidelines are limited to lithium battery-powered pacemakers, because mercury-zinc battery-powered pacemakers are no longer being manufactured and virtually all have been replaced by lithium units. MACs still receiving claims for monitoring such units should continue to apply the guidelines published in 1980 to those units until they are replaced.

There are two general types of pacemakers in current use—single-chamber pacemakers which sense and pace the ventricles of the heart, and dual-chamber pacemakers which sense and pace both the atria and the ventricles. These differences require different monitoring patterns over the expected life of the units involved. One fact of which MACs should be aware is that many dual-chamber units may be programmed to pace only the ventricles; this may be done either at the time the pacemaker is implanted or at some time afterward. In such cases, a dual-chamber unit, when programmed or reprogrammed for ventricular pacing, should be treated as a single-chamber pacemaker in applying screening guidelines.

The decision as to how often any patient’s pacemaker should be monitored is the responsibility of the patient’s physician who is best able to take into account the condition and circumstances of the individual patient. These may vary over time, requiring modifications of the frequency with which the patient should be monitored. In cases where monitoring is done by some entity other than the patient’s physician, such as a commercial monitoring service or hospital outpatient department, the physician's prescription for monitoring is required and should be periodically renewed (at least annually) to assure that the frequency of monitoring is proper for the patient. Where a patient is monitored both during
clinic visits and transtelephonically, the MAC should be sure
to include frequency data on both types of monitoring in
evaluating the reasonableness of the frequency of monitoring
services received by the patient. Since there are over 200
pacemaker models in service at any given point, and a variety
of patient conditions that give rise to the need for pacemaker-
s, the question of the appropriate frequency of monitoring
is a complex one. Nevertheless, it is possible to develop guide-
lines within which the vast majority of pacemaker monitoring
will fall and MACs should do this, using their own data
and experience, as well as the frequency guidelines which
follow, in order to limit extensive claims development to
those cases requiring special attention.

20.8.1.1—Transtelephonic Monitoring of Cardiac Pacemakers
(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation:
of ICD-10, Implementation: Upon Implementation of ICD-10)
A—General
Transtelephonic monitoring of pacemakers is furnished by
commercial suppliers, hospital outpatient departments, and
physicians’ offices.

Telephone monitoring of cardiac pacemakers as described
below is medically efficacious in identifying early signs of
possible pacemaker failure, thus reducing the number of sud-
den pacemaker failures requiring emergency replacement.
All systems that monitor the pacemaker rate (bpm) in both
the free-running and/or magnetic mode are effective in de-
tecting subclinical pacemaker failure due to battery deple-
tion. More sophisticated systems are also capable of detect-
ing internal electronic problems within the pulse generator
itself and other potential problems. In the case of dual cham-
ber pacemakers in particular, such monitoring may detect
failure of synchronization of the atria and ventricles, and the
need for adjustment and reprogramming of the device.

NOTE: The transmitting device furnished to the patient is
simply one component of the diagnostic system, and
is not covered as durable medical equipment. Those
engaged in transtelephonic pacemaker monitoring
should reflect the costs of the transmitters in setting
their charges for monitoring.

B—Definition of Transtelephonic Monitoring
In order for transtelephonic monitoring services to be cov-
ered, the services must consist of the following elements:

• A minimum 30-second readable strip of the pacemaker in
  the free-running mode;
• Unless contraindicated, a minimum 30-second readable
  strip of the pacemaker in the magnetic mode; and
• A minimum 30 seconds of readable ECG strip.

C—Frequency Guidelines for Transtelephonic Monitoring
The guidelines below constitute a system which Medicare
Administrative Contractors (MACs) should use, in conjunc-
tion with their knowledge of local medical practices, to screen
claims for transtelephonic monitoring prior to payment. It is
important to note that they are not recommendations with
respect to a minimum frequency for such monitorings, but
rather a maximum frequency (within which payment may be
made without further claims development). As with previous
guidelines, more frequent monitorings may be covered in
cases where MACs are satisfied that such monitorings are
medically necessary; e.g., based on the condition of the pa-
tient, or with respect to pacemakers exhibiting unexpected
defects or premature failure. MACs should seek written
justification for more frequent monitorings from the patient’s
physician and/or any monitoring service involved.

These guidelines are divided into two broad categories—
Guideline I which will apply to the majority of pacemakers
now in use, and Guideline II which will apply only to pace-
maker systems (pacemaker and leads) for which sufficient
long-term clinical information exists to assure that they meet
the standards of the Inter-Society Commission for Heart Dis-
ease Resources (ICHD) for longevity and end-of-life decay. (The
ICHD standards are: (1) 90% cumulative survival at 5 years
following implant; and (2) an end-of-life decay of less than a
50% drop of output voltage and less than 20 percent deviation
of magnet rate, or a drop of 5 beats per minute or less, over a
period of 3 months or more.) MACs should consult with their
medical advisers and other appropriate individuals and orga-
nizations (such as the North American Society of Pacing and
Electrophysiology which publishes product reliability infor-
mation) should questions arise over whether a pacemaker
system meets the ICHD standards.

The two groups of guidelines are then further broken down into
two general categories—single-chamber and dual-chamber
pacemakers. MACs should be aware that the frequency with
which a patient is monitored may be changed from time to
time for a number of reasons, such as a change in the patient’s
overall condition, a reprogramming of the patient’s pacemaker,
the development of better information on the pacemaker’s
longevity or failure mode, etc. Consequently, changes in the
proper set of guidelines may be required. MACs should inform
physicians and monitoring services to alert MACs to any
changes in the patient’s monitoring prescription that might
necessitate changes in the screening guidelines applied to that
patient. (Of particular importance is the reprogramming of a
dual-chamber pacemaker to a single-chamber mode of opera-
tion. Such reprogramming would shift the patient from the
appropriate dual-chamber guideline to the appropriate single-
chamber guideline.)

Guideline I

1. Single-chamber pacemakers
   1st month—every 2 weeks.
   2nd through 36th month—every 8 weeks.
   37th month to failure—every 4 weeks.

2. Dual-chamber pacemaker
   1st month—every 2 weeks.
   2nd through 6th month—every 4 weeks.
   7th through 36th month—every 8 weeks.
   37th month to failure—every 4 weeks.

Guideline II

1. Single-chamber pacemakers
   1st month—every 2 weeks.
   2nd through 48th month—every 12 weeks.
   49th through 72nd month—every 8 weeks.
   Thereafter—every 4 weeks.

2. Dual-chamber pacemaker
   1st month—every 2 weeks.
   2nd through 30th month—every 12 weeks.
   31st through 48th month—every 8 weeks.
   Thereafter—every 4 weeks.
D—Pacemaker Clinic Services

1. General

Pacemaker monitoring is also covered when done by pacemaker clinics. Clinic visits may be done in conjunction with transtelephonic monitoring or as a separate service; however, the services rendered by a pacemaker clinic are more extensive than those currently possible by telephone. They include, for example, physical examination of patients and reprogramming of pacemakers. Thus, the use of one of these types of monitoring does not preclude concurrent use of the other.

2. Frequency Guidelines

As with transtelephonic pacemaker monitoring, the frequency of clinic visits is the decision of the patient’s physician, taking into account, among other things, the medical condition of the patient. However, MACs can develop monitoring guidelines that will prove useful in screening claims. The following are recommendations for monitoring guidelines on lithium-battery pacemakers:

- For single-chamber pacemakers—twice in the first 6 months following implant, then once every 12 months.
- For dual-chamber pacemakers—twice in the first 6 months, then once every 6 months.

20.8.2—Self-Contained Pacemaker Monitors

(Rev. 1, 10-03-03)

CIM 60-7

Self-contained pacemaker monitors are accepted devices for monitoring cardiac pacemakers. Accordingly, program payment may be made for the rental or purchase of either of the following pacemaker monitors when a physician for a patient prescribes it with a cardiac pacemaker:

A—Digital Electronic Pacemaker Monitor

This device provides the patient with an instantaneous digital readout of his pacemaker pulse rate. Use of this device does not involve professional services until there has been a change of five pulses (or more) per minute above or below the initial rate of the pacemaker; when such change occurs, the patient contacts his physician.

B—Audible/Visible Signal Pacemaker Monitor

This device produces an audible and visible signal which indicates the pacemaker rate. Use of this device does not involve professional services until a change occurs in these signals; at such time, the patient contacts his physician.

NOTE: The design of the self-contained pacemaker monitor makes it possible for the patient to monitor his pacemaker periodically and minimizes the need for regular visits to the outpatient department of the provider.

Therefore, documentation of the medical necessity for pacemaker evaluation in the outpatient department of the provider should be obtained where such evaluation is employed in addition to the self-contained pacemaker monitor used by the patient in his home.

Cross-reference: §20.8.1

20.8.3—Single Chamber and Dual Chamber Permanent Cardiac Pacemakers

(Rev. 187, Issued: 12-10-15, Effective: 08-13-13, Issued: 01-13-16)

A. General

Permanent cardiac pacemakers refer to a group of self-contained, battery operated, implanted devices that send electrical stimulation to the heart through one or more implanted leads. They are often classified by the number of chambers of the heart that the devices stimulate (pulse or depolarize). Single chamber pacemakers typically target either the right atrium or right ventricle. Dual chamber pacemakers stimulate both the right atrium and the right ventricle.

The implantation procedure is typically performed under local anesthesia and requires only a brief hospitalization. A catheter is inserted into the chest and the pacemaker’s leads are threaded through the catheter to the appropriate chamber(s) of the heart. The surgeon then makes a small “pocket” in the pad of the flesh under the skin on the upper portion of the chest wall to hold the power source. The pocket is then closed with stitches.

The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to conclude that implanted permanent cardiac pacemakers, single chamber or dual chamber, are reasonable and necessary for the treatment of non-reversible symptomatic bradycardia due to sinus node dysfunction and second and/or third degree atrioventricular block. Symptoms of bradycardia are symptoms that can be directly attributable to a heart rate less than 60 beats per minute (for example: syncope, seizures, congestive heart failure, dizziness, or confusion).

B. Nationally Covered Indications

The following indications are covered for implanted permanent single chamber or dual chamber cardiac pacemakers:

1. Documented non-reversible symptomatic bradycardia due to sinus node dysfunction, and
2. Documented non-reversible symptomatic bradycardia due to second degree and/or third degree atrioventricular block.

C. Nationally Non-Covered Indications

The following indications are non-covered for implanted permanent single chamber or dual chamber cardiac pacemakers:

1. Reversible causes of bradycardia such as electrolyte abnormalities, medications or drugs, and hypothermia,
2. Asymptomatic first degree atrioventricular block,
3. Asymptomatic sinus bradycardia,
4. Asymptomatic sino-atrial block or asymptomatic sinus arrest,
5. Ineffective atrial contractions (e.g., chronic atrial fibrillation or flutter, or giant left atrium) without symptomatic bradycardia,
6. Asymptomatic second degree atrioventricular block of Mobitz Type I unless the QRS complexes are prolonged or electrophysiological studies have demonstrated that the block is at or beyond the level of the His Bundle (a component of the electrical conduction system of the heart),
7. Syncope of undetermined cause,
8. Bradycardia during sleep,
9. Right bundle branch block with left axis deviation (and
other forms of fascicular or bundle branch block) without
syncope or other symptoms of intermittent atrioven-
tricular block,
10. Asymptomatic bradycardia in post-myocardial infarct-
ion patients about to initiate long-term beta-blocker
drug therapy,
11. Frequent or persistent supraventricular tachycardias,
except where the pacemaker is specifically for the con-
trol of tachycardia, and
12. A clinical condition in which pacing takes place only in-
termittently and briefly, and which is not associated
with a reasonable likelihood that pacing needs will be-
come prolonged.

D. Other

A/B MACs will determine coverage under section 1862(a)(1)(A)
of the Social Security Act for any other indications for the
implantation and use of single chamber or dual chamber car-
diac pacemakers that are not specifically addressed in this
national coverage determination.

(This NCD last reviewed August 2013.)

20.9—Artificial Hearts And Related Devices (Various Effective
Dates Below)

(Rev. 172, Issued: 08-29-14, Effective: 10-30-13, Implementa-
tion: 09-30-14)

A. General

An artificial heart is a biventricular replacement device which
requires removal of a substantial part of the native heart,
including both ventricles. Removal of this device is not com-
patible with life, unless the patient has a heart transplant.

B. Nationally Covered Indications

1. Bridge-to-transplant (BTT) (effective for services per-
formed on or after May 1, 2008)

An artificial heart for bridge-to-transplantation (BTT) is cov-
ered when performed under coverage with evidence develop-
ment (CED) when a clinical study meets all of the criteria
listed below. The clinical study must address at least one of
the following questions:

• Were there unique circumstances such as expertise avail-
able in a particular facility or an unusual combination of
conditions in particular patients that affected their out-
comes?
• What will be the average time to device failure when the
device is made available to larger numbers of patients?
• Do results adequately give a reasonable indication of the
full range of outcomes (both positive and negative) that
might be expected from more widespread use?

The clinical study must meet all of the criteria stated in Sec-
section D of this policy.

The above information should be mailed to:

Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services (CMS)
Re: Artificial Heart
Mailstop C1-09-06
7500 Security Blvd.
Baltimore, MD 21244-1850

Clinical studies that are determined by CMS to meet the
above requirements will be listed on the CMS Web site at:
http://www.cms.gov/Medicare/Coverage/Coverage-with-
Evidence-Development/Artificial-Hearts.html.

2. Destination therapy (DT) (effective for services performed
on or after May 1, 2008)

An artificial heart for destination therapy (DT) is covered
when performed under CED when a clinical study meets all of
the criteria listed below. The clinical study must address at
least one of the following questions:

• Were there unique circumstances such as expertise avail-
able in a particular facility or an unusual combination of
conditions in particular patients that affected their out-
comes?
• What will be the average time to device failure when the
device is made available to larger numbers of patients?
• Do results adequately give a reasonable indication of the
full range of outcomes (both positive and negative) that
might be expected from more widespread use?

The clinical study must meet all of the criteria stated in Sec-
tion D of this policy.

The above information should be mailed to:

Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services (CMS)
Re: Artificial Heart
Mailstop C1-09-06
7500 Security Blvd.
Baltimore, MD 21244-1850

Clinical studies that are determined by CMS to meet the
above requirements will be listed on the CMS Web site at:
http://www.cms.gov/Medicare/Coverage/Coverage-with-
Evidence-Development/Artificial-Hearts.html.

C. Nationally Non-Covered Indications

All other indications for the use of artificial hearts not other-
wise listed remain noncovered, except in the context of
Category B investigational device exemption clinical trials
(42 CFR 405) or as a routine cost in clinical trials defined
under section 310.1 of the National Coverage Determinations
(NCD) manual.

D. Other

Clinical study criteria:

• The study must be reviewed and approved by the Food and
Drug Administration (FDA).
• The principal purpose of the research study is to test
whether a particular intervention potentially improves the
participants’ health outcomes.
• The research study is well supported by available scientific
and medical information, or it is intended to clarify or es-
ablish the health outcomes of interventions already in
common clinical use.
• The research study does not unjustifiably duplicate existing
studies.
• The research study design is appropriate to answer the re-
search question being asked in the study.
• The research study is sponsored by an organization or in-
dividual capable of executing the proposed study success-
fully.
• The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is FDA-regulated it also must be in compliance with 21 CFR Parts 50 and 56.
• All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).
• The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED.
• The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
• The clinical research study is registered on the ClinicalTrials.gov Web site by the principal sponsor/investigator as demonstrated by having a Clinicaltrial.gov Identifier.
• The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (ICMJE) (http://www.icmje.org). However a full report of the outcomes must be made public no later than three (3) years after the end of data collection.
• The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
• The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability, or Medicaid eligibility.

Consistent with section 1142 of the Social Security Act (the Act), the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

The principal investigator of an artificial heart clinical study seeking Medicare payment should submit the following documentation to the CMS and should expect to be notified when the CMS review is complete:
• Complete study protocol (must be dated or identified with a version number);
• Protocol summary;
• Statement that the submitted protocol version has been agreed upon by the FDA;
• Statement that the above study standards are met;
• Statement that the study addresses at least one of the above questions related to artificial hearts;
• Complete contact information (phone number, email address, and mailing address); and,
• Clinicaltrials.gov Identifier.

20.9.1 - Ventricular Assist Devices (Various Effective Dates Below)
(Rev. 172, Issued: 08-29-14, Effective: 10-30-13, Implementation: 09-30-14)

A. General
A ventricular assist device (VAD) is surgically attached to one or both intact ventricles and is used to assist or augment the ability of a damaged or weakened native heart to pump blood. Improvement in the performance of the native heart may allow the device to be removed.

B. Nationally Covered Indications

1. Post-cardiotomy (effective for services performed on or after October 18, 1993)

Post-cardiotomy is the period following open-heart surgery. VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the Food and Drug Administration (FDA) for that purpose, and the VADs are used according to the FDA-approved labeling instructions.

2. Bridge-to-Transplant (effective for services performed on or after January 22, 1996)
The VADs used for bridge to transplant are covered only if they have received approval from the FDA for that purpose, and the VADs are used according to FDA-approved labeling instructions. All of the following criteria must be fulfilled in order for Medicare coverage to be provided for a VAD used as a bridge to transplant:

• The patient is approved for heart transplantation by a Medicare-approved heart transplant center and is active on the Organ Procurement and Transplantation Network (OPTN) heart transplant waitlist.
• The implanting site, if different than the Medicare-approved transplant center, must receive written permission from the Medicare-approved transplant center under which the patient is listed prior to implantation of the VAD.

3. Destination Therapy (DT) (effective for services performed on or after October 1, 2003)

Destination therapy (DT) is for patients that require mechanical cardiac support. The VADs used for DT are covered only if they have received approval from the FDA for that purpose.

Patient Selection (effective November 9, 2010):
The VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure) who are not candidates for heart transplantation at the time of VAD implant, and meet the following conditions:

• Have failed to respond to optimal medical management (including beta-blockers and ACE inhibitors if tolerated) for 45 of the last 60 days, or have been balloon pump-dependent for 7 days, or IV inotrope-dependent for 14 days; and,
• Have a left ventricular ejection fraction (LVEF) <25%; and,
• Have demonstrated functional limitation with a peak oxygen consumption of \( \leq 14 \text{ ml/kg/min} \) unless balloon pump- or inotrope-dependent or physically unable to perform the test.

Facility Criteria (effective October 30, 2013):
Facilities currently credentialed by the Joint Commission for placement of VADs as DT may continue as Medicare-approved facilities until October 30, 2014. At the conclusion of this transition period, these facilities must be in compliance with the following criteria as determined by a credentialing organization. As of the effective date, new facilities must meet the following criteria as a condition of coverage of this procedure as DT under section 1862(a)(1)(A) of the Social Security Act (the Act):

Beneficiaries receiving VADs for DT must be managed by an explicitly identified cohesive, multidisciplinary team of medical professionals with the appropriate qualifications, training, and experience. The team embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. Collectively, the team must ensure that patients and caregivers have the knowledge and support necessary to participate in shared decision making and to provide appropriate informed consent. The team members must be based at the facility and must include individuals with experience working with patients before and after placement of a VAD.

The team must include, at a minimum:
• At least one physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, left VADs as BTT or DT over the course of the previous 36 months with activity in the last year.
• At least one cardiologist trained in advanced heart failure with clinical competence in medical and device-based management including VADs, and clinical competence in the management of patients before and after heart transplant.
• A VAD program coordinator.
• A social worker.
• A palliative care specialist.

Facilities must be credentialed by an organization approved by the Centers for Medicare & Medicaid Services.

C. Nationally Non-Covered Indications
All other indications for the use of VADs not otherwise listed remain non-covered, except in the context of Category B investigational device exemption clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the National Coverage Determinations (NCD) Manual.

D. Other
This policy does not address coverage of VADs for right ventricular support, biventricular support, use in beneficiaries under the age of 18, use in beneficiaries with complex congenital heart disease, or use in beneficiaries with acute heart failure without a history of chronic heart failure. Coverage under section 1862(a)(1)(A) of the Act for VADs in these situations will be made by local Medicare Administrative Contractors within their respective jurisdictions.

20.15—Electrocardiographic Services

A—General
1. An electrocardiogram (EKG) is a graphic representation of electrical activity within the heart. Electrodes placed on the body in predetermined locations sense this electrical activity, which is then recorded by various means for review and interpretation. EKG recordings are used to diagnose a wide range of heart disease and other conditions that manifest themselves by abnormal cardiac electrical activity.

EKG services are covered diagnostic tests when there are documented signs and symptoms or other clinical indications for providing the service. Coverage includes the review and interpretation of EKGs only by a physician. There is no coverage for EKG services when rendered as a screening test or as part of a routine examination unless performed as part of the one-time, “Welcome to Medicare” preventive physical examination under section 611 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

2. Ambulatory electrocardiography (AECG) refers to services rendered in an outpatient setting over a specified period of time, generally while a patient is engaged in daily activities, including sleep. AECG devices are intended to provide the physician with documented episodes of arrhythmia, which may not be detected using a standard 12-lead EKG. AECG is most typically used to evaluate symptoms that may correlate with intermittent cardiac arrhythmias and/or myocardial ischemia. Such symptoms include syncope, dizziness, chest pain, palpitations, or shortness of breath. Additionally, AECG is used to evaluate patient response to initiation, revision, or discontinuation of arrhythmic drug therapy.

3. The Centers for Medicare & Medicaid Services (CMS), through the national coverage determination (NCD) process, may create new ambulatory EKG monitoring device categories if published, peer-reviewed clinical studies demonstrate evidence of improved clinical utility, or equal utility with additional advantage to the patient, as indicated by improved patient management and/or improved health outcomes in the Medicare population (such as superior ability to detect serious or life-threatening arrhythmias) as compared to devices or services in the currently described categories below.

Descriptions of Ambulatory EKG Monitoring Technologies
1. Dynamic electrocardiography devices that continuously record a real-time EKG, commonly known as Holter™ monitors, typically record over a 24-hour period. The recording is captured either on a magnetic tape or other digital medium. The data is then computer-analyzed at a later time, and a physician interprets the computer-generated report. A 24-hour recording is generally adequate to detect most transient arrhythmias. Documentation of medical necessity is required for monitoring longer than 24 hours. The recording device itself is not covered as durable medical equipment (DME) separate from the total diagnostic service.

2. An event monitor, or event recorder, is a patient-activated or event-activated EKG device that intermittently records cardiac arrhythmic events as they occur. The EKG is recorded on magnetic tape or other digital medium.
Cardiac event monitor technology varies among different devices. For patient-activated event monitors, the patient initiates recording when symptoms appear or when instructed to do so by a physician (e.g., following exercise). For self-sensing, automatically triggered monitors, an EKG is automatically recorded when the device detects an arrhythmia, without patient intervention. Some devices permit a patient to transmit EKG data transtelephonically (i.e., via telephone) to a receiving center where the data is reviewed. A technician may be available at these centers to review transmitted data 24-hours per day. In some instances, when the EKG is determined to be outside certain pre-set criteria by a technician or other non-physician, a physician is available 24-hours per day to review the transmitted data and to make clinical decisions regarding the patient. These services are known as “24-hour attended monitoring.” In other instances, transmitted EKG data is reviewed at a later time and are, therefore, considered “nonattended.”

Cardiac event monitors without transtelephonic capability must be removed from the patient and taken to a location for review of the stored EKG data. Some devices also permit a “time sampling” mode of operation. The “time sampling” mode is not covered under ambulatory EKG monitoring technology. Some cardiac event monitoring devices with trans-telephonic capabilities require the patient to dial the phone number of a central EKG data reception center and initiate transmission of EKG data. Other devices use Internet-based in-home computers to capture and store EKG data. When such devices detect pre-programmed arrhythmias, data is automatically sent via modem and standard telephone lines to a central receiving center, or independent diagnostic testing facility (IDTF), where the data is reviewed. Internet based in-home computer systems may also provide the receiving center with a daily computer-generated report that summarizes 24 hours of EKG data.

Certain cardiac event monitors capture electrical activity with a single electrode attached to the skin. Other devices may employ multiple electrodes in order to record more complex EKG tracings. Additionally, devices may be individually programmed to detect patient-specific factors, electrode malfunction, or other factors. Cardiac event monitors can be further categorized as either “pre-event” or “post-event” recorders, based on their memory capabilities:

a. Pre-symptom Memory Loop Recorder (MLR)

Upon detecting symptoms, the wearer presses a button, which activates the recorder to save (i.e., memorize) an interval of pre-symptom EKG data along with data during and subsequent to the symptomatic event. Self-sensing recorders (also known as event-activated or automatic trigger) do not require patient input to capture these data. Single or multiple events may be recorded. The device is worn at all times, usually for up to 30 days.

b. Post-symptom Recorder

The patient temporarily places this device against the chest when symptoms occur and activates it by pressing a button. These recorders represent old technology, as they do not include a memory loop. The device transmits EKG data transtelephonically in real-time and is usually used for up to 30 days.

B—Nationally Covered Indications

The following indications are covered nationally unless otherwise indicated:

1. Computer analysis of EKGs when furnished in a setting and under the circumstances required for coverage of other EKG services.
2. EKG services rendered by an IDTF, including physician review and interpretation. Separate physician services are not covered unless he/she is the patient’s attending or consulting physician.
3. Emergency EKGs (i.e., when the patient is or may be experiencing a life-threatening event) performed as a laboratory or diagnostic service by a portable x-ray supplier only when a physician is in attendance at the time the service is performed or immediately thereafter.
4. Home EKG services with documentation of medical necessity.
5. Transtelephonic EKG transmissions (effective March 1, 1980) as a diagnostic service for the indications described below, when performed with equipment meeting the standards described below, subject to the limitations and conditions specified below. Coverage is further limited to the amounts payable with respect to the physician’s service in interpreting the results of such transmissions, including charges for rental of the equipment. The device used by the beneficiary is part of a total diagnostic system and is not considered DME separately. Covered uses are to:

a. Detect, characterize, and document symptomatic transient arrhythmias;
b. Initiate, revise, or discontinue arrhythmic drug therapy; or,
c. Carry out early post-hospital monitoring of patients discharged after myocardial infarction (MI); (only if 24-hour coverage is provided, see C.5. below).

Certain uses other than those specified above may be covered if, in the judgment of the local Medicare Administrative Contractor (MAC), such use is medically necessary.

Additionally, the transmitting devices must meet at least the following criteria:

a. They must be capable of transmitting EKG Leads, I, II, or III; and,
b. The tracing must be sufficiently comparable to a conventional EKG.

24-hour attended coverage used as early post-hospital monitoring of patients discharged after MI is only covered if provision is made for such 24-hour attended coverage in the manner described below:

24-hour attended coverage means there must be, at a monitoring site or central data center; an EKG technician or other non-physician, receiving calls and/or EKG data; tape recording devices do not meet this requirement. Further, such technicians...
Ambulatory blood pressure monitoring (ABPM) involves the use of a noninvasive device which is used to measure blood pressure in 24-hour cycles. These 24-hour measurements are stored in the device and are later interpreted by the physician. ABPM must be performed for at least 24 hours to meet coverage criteria.

The ABPM is only covered for those patients with suspected white coat hypertension. Suspected white coat hypertension is defined as:

1. Office blood pressure $\geq 140/90$ mm Hg on at least three separate clinic/office visits with two separate measurements made at each visit;
2. At least two documented blood pressure measurements taken outside the office which are $< 140/90$ mm Hg; and
3. No evidence of end-organ damage.

The information obtained by ABPM is necessary in order to determine the appropriate management of the patient. ABPM is not covered for any other uses. In the rare circumstance that ABPM needs to be performed more than once in a patient, the qualifying criteria described above must be met for each subsequent ABPM test. For those patients that undergo ABPM and have an ambulatory blood pressure of $< 135/85$ without evidence of end-organ damage, it is likely that their cardiovascular risk is similar to that of normotensives. They should be followed over time. Patients for which ABPM demonstrates a blood pressure of $> 135/85$ may be at increased cardiovascular risk, and a physician may wish to consider antihypertensive therapy.

**20.19—Ambulatory Blood Pressure Monitoring**

(Rev. 1, 10-03-03)

**CIM 50-42**

Ambulatory blood pressure monitoring (ABPM) involves the use of a noninvasive device which is used to measure blood pressure in 24-hour cycles. These 24-hour measurements are stored in the device and are later interpreted by the physician. ABPM must be performed for at least 24 hours to meet coverage criteria.

The following indications are non-covered nationally unless otherwise specified below:

1. The time-sampling mode of operation of ambulatory EKG cardiac event monitoring/recording.
2. Separate physician services other than those rendered by an IDTF unless rendered by the patient’s attending or consulting physician.
3. Home EKG services without documentation of medical necessity.
4. Emergency EKG services by a portable x-ray supplier without a physician in attendance at the time of service or immediately thereafter.
5. 24-hour attended coverage used as early post-hospital monitoring of patients discharged after MI unless provision is made for such 24-hour attended coverage in the manner described in section B.5. above.
6. Any marketed Food and Drug Administration (FDA)-approved ambulatory cardiac monitoring device or service that cannot be categorized according to the framework below.

**D—Other**

Ambulatory cardiac monitoring performed with a marketed, FDA-approved device, is eligible for coverage if it can be categorized according to the framework below. Unless there is a specific NCD for that device or service, determination as to whether a device or service that fits into the framework is reasonable and necessary is according to local MAC discretion.

**Electrocardiographic Services Framework**

- **Patient/Event-Activated Intermittent Recorders**
  - Pre-symptom memory loop (Attended)
    - Insertable
    - Non-insertable
  - Post-symptom (no memory loop) (Non-attended)
- **Non-Activated Continuous Recorders**
  - Dynamic Electrocardiography (e.g., Holter™ Monitor) (Non-attended)

**20.20—External Counterpulsation (ECP) Therapy for Severe Angina**

(Effective March 20, 2006)

(Rev. 50, Issued: 03-31-06; Effective: 03-20-06; Implementation: 04-03-06)

**A. General**

External counterpulsation (ECP), commonly referred to as enhanced external counterpulsation, is a noninvasive outpatient treatment for coronary artery disease refractory to medical and/or surgical therapy. Although ECP devices are cleared by the Food and Drug Administration (FDA) for use in treating a variety of cardiac conditions, including stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock, the use of this device to treat cardiac conditions other than stable angina pectoris is not covered, since only that use has developed sufficient evidence to demonstrate its medical effectiveness. Noncoverage of hydraulic versions of these types of devices remains in force.

**B. Nationally Covered Indications**

Effective for services performed on or after July 1, 1999, coverage is provided for the use of ECP for patients who have been diagnosed with disabling angina (Class III or Class IV, Canadian Cardiovascular Society Classification or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as PTCA or cardiac bypass because:

1. Their condition is inoperable, or at high risk of operative complications or post-operative failure;
2. Their coronary anatomy is not readily amenable to such procedures; or
3. They have co-morbid states that create excessive risk.

A full course of therapy usually consists of 35 one-hour treatments which may be offered once or twice daily, usually five days per week. The patient is placed on a treatment table where their lower trunk and lower extremities are wrapped in a series of three compressive air cuffs which inflate and deflate in synchronization with the patient’s cardiac cycle.
During diastole, the three sets of air cuffs are inflated sequentially (distal to proximal) compressing the vascular beds within the muscles of the calves, lower thighs and upper thighs. This action results in an increase in diastolic pressure, generation of retrograde arterial blood flow and an increase in venous return. The cuffs are deflated simultaneously just prior to systole which produces a rapid drop in vascular impedance, a decrease in ventricular workload and an increase in cardiac output.

The augmented diastolic pressure and retrograde aortic flow appear to improve myocardial perfusion, while systolic unloading appears to reduce cardiac workload and oxygen requirements. The increased venous return coupled with enhanced systolic flow appears to increase cardiac output. As a result of this treatment, most patients experience increased time until onset of ischemia, increased exercise tolerance, and a reduction in the number and severity of anginal episodes. Evidence was presented that this effect lasted well beyond the immediate post-treatment phase, with patients symptom-free for several months to two years.

This procedure must be done under direct supervision of a physician.

C. Nationally Non-Covered Indications

All other cardiac conditions not otherwise specified as nationally covered for the use of ECP remain nationally non-covered.

(This NCD last reviewed March 2006.)

20.21—Chelation Therapy for Treatment of Atherosclerosis

(Rev. 1, 10-03-03)

CIM 35-64

Chelation therapy is the application of chelation techniques for the therapeutic or preventive effects of removing unwanted metal ions from the body. The application of chelation therapy using ethylenediamine-tetra-acetic acid (EDTA) for the treatment and prevention of atherosclerosis is controversial. There is no widely accepted rationale to explain the beneficial effects attributed to this therapy. Its safety is questioned and its clinical effectiveness has never been established by well-designed, controlled clinical trials. It is not widely accepted and practiced by American physicians. EDTA chelation therapy for atherosclerosis is considered experimental. For these reasons, EDTA chelation therapy for the treatment or prevention of atherosclerosis is not covered. Some practitioners refer to this therapy as chemoendarterectomy and may also show a diagnosis other than atherosclerosis, such as arteriosclerosis or calcinosis. Claims employing such variant terms should also be denied under this section.


20.22—Ethylenediamine-Tetra-Acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis

(Rev. 1, 10-03-03)

CIM 45-20

The use of EDTA as a chelating agent to treat atherosclerosis, arteriosclerosis, calcinosis, or similar generalized condition not listed by the FDA as an approved use is not covered. Any such use of EDTA is considered experimental. See §20.21 for an explanation of this conclusion.

20.24—Displacement Cardiography

(Rev. 1, 10-03-03)

CIM 50-50

Displacement cardiography, including cardiokymography and photokymography, is a noninvasive diagnostic test used in evaluating coronary artery disease.

A—Cardiokymography

Cardiokymography is covered for services rendered on or after October 12, 1988.

Cardiokymography is a covered service only when it is used as an adjunct to electrocardiographic stress testing in evaluating coronary artery disease and only when the following clinical indications are present:

- For male patients, atypical angina pectoris or nonischemic chest pain;
- For female patients, angina, either typical or atypical.

B—Photokymography—Not Covered

Photokymography remains excluded from coverage.

20.29—Hyperbaric Oxygen Therapy

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 35-10

For purposes of coverage under Medicare, hyperbaric oxygen (HBO) therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure.

A—Covered Conditions

Program reimbursement for HBO therapy will be limited to that which is administered in a chamber (including the one man unit) and is limited to the following conditions:

1. Acute carbon monoxide intoxication.
2. Decompression illness.
4. Gas gangrene.
5. Acute traumatic peripheral ischemia. HBO therapy is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened.
6. Crush injuries and suturing of severed limbs. As in the previous conditions, HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened.
7. Progressive necrotizing infections (necrotizing fasciitis).
8. Acute peripheral arterial insufficiency.
9. Preparation and preservation of compromised skin grafts (not for primary management of wounds).
10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management.
11. Osteoradionecrosis as an adjunct to conventional treatment.
13. Cyanide poisoning.
14. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment.
15. Diabetic wounds of the lower extremities in patients who meet the following three criteria:
   a. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
   b. Patient has a wound classified as Wagner grade III or higher; and
   c. Patient has failed an adequate course of standard wound therapy.

The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes: assessment of a patient's vascular status and correction of any vascular problems in the affected limb if possible, optimization of nutritional status, optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off-loading, and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

B—Noncovered Conditions

All other indications not specified under §270.4(A) are not covered under the Medicare program. No program payment may be made for any conditions other than those listed in §270.4(A).

No program payment may be made for HBO in the treatment of the following conditions:

1. Cutaneous, decubitus, and stasis ulcers.
2. Chronic peripheral vascular insufficiency.
3. Anaerobic septicemia and infection other than clostridial.
4. Skin burns (thermal).
5. Senility.
7. Cardiogenic shock.
8. Sickle cell anemia.
9. Acute thermal and chemical pulmonary damage, i.e., smoke inhalation with pulmonary insufficiency.
10. Acute or chronic cerebral vascular insufficiency.
11. Hepatic necrosis.
12. Aerobic septicemia.
14. Tetanus.
15. Systemic aerobic infection.
16. Organ transplantation.
17. Organ storage.
18. Pulmonary emphysema.
19. Exceptional blood loss anemia.
20. Multiple Sclerosis.
22. Acute cerebral edema.

C—Topical Application of Oxygen

This method of administering oxygen does not meet the definition of HBO therapy as stated above. Also, its clinical efficacy has not been established. Therefore, no Medicare reimbursement may be made for the topical application of oxygen.

Cross reference: §270.5 of this manual.

30.8—Cellular Therapy

(Rev. 1, 10-03-03)

CIM 35-5

Not Covered

Cellular therapy involves the practice of injecting humans with foreign proteins like the placenta or lungs of unborn lambs. Cellular therapy is without scientific or statistical evidence to document its therapeutic efficacy and, in fact, is considered a potentially dangerous practice. Accordingly, cellular therapy is not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

40.2—Home Blood Glucose Monitors

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 60-11

There are several different types of blood glucose monitors that use reflectance meters to determine blood glucose levels. Medicare coverage of these devices varies, with respect to both the type of device and the medical condition of the patient for whom the device is prescribed.

Reflectance colorimeter devices used for measuring blood glucose levels in clinical settings are not covered as durable medical equipment for use in the home because their need for frequent professional recalibration makes them unsuitable for home use. However, some types of blood glucose monitors which use a reflectance meter specifically designed for home use by diabetic patients may be covered as durable medical equipment, subject to the conditions and limitations described below.

Blood glucose monitors are meter devices that read color changes produced on specially treated reagent strips by glucose concentrations in the patient's blood. The patient, using a disposable sterile lancet, draws a drop of blood, places it on a reagent strip and, following instructions which may vary with the device used, inserts it into the device to obtain a reading. Lancets, reagent strips, and other supplies necessary for the proper functioning of the device are also covered for patients for whom the device is indicated. Home blood glucose monitors enable certain patients to better control their blood glucose levels by frequently checking and appropriately contacting their attending physician for advice and treatment. Studies indicate that the patient's ability to carefully follow proper procedures is critical to obtaining satisfactory results with these devices. In addition, the cost of the devices, with their supplies, limits economical use to patients who must make frequent checks of their blood glucose levels. Accordingly, coverage of home blood glucose monitors is limited to patients meeting the following conditions:

1. The patient has been diagnosed as having diabetes;
2. The patient's physician states that the patient is capable of being trained to use the particular device prescribed.
in an appropriate manner. In some cases, the patient may not be able to perform this function, but a responsible individual can be trained to use the equipment and monitor the patient to assure that the intended effect is achieved. This is permissible if the record is properly documented by the patient’s physician; and

3. The device is designed for home rather than clinical use.

There is also a blood glucose monitoring system designed especially for use by those with visual impairments. The monitors used in such systems are identical in terms of reliability and sensitivity to the standard blood glucose monitors described above. They differ by having such features as voice synthesizers, automatic timers, and specially designed arrangements of supplies and materials to enable the visually impaired to use the equipment without assistance.

These special blood glucose monitoring systems are covered under Medicare if the following conditions are met:

- The patient and device meet the three conditions listed above for coverage of standard home blood glucose monitors; and
- The patient’s physician certifies that he or she has a visual impairment severe enough to require use of this special monitoring system.

The additional features and equipment of these special systems justify a higher reimbursement amount than allowed for standard blood glucose monitors. Separately identify claims for such devices and establish a separate reimbursement amount for them.

50—Ear, Nose and Throat (ENT)

50.1—Speech Generating Devices

A. General
Speech generating devices are considered to fall within the durable medical equipment (DME) benefit category established by §1861(n) of the Social Security Act. They are covered for patients who suffer from a severe speech impairment and have a medical condition that warrants the use of a device based on the following definitions.

Speech generating devices are defined as durable medical equipment that provides an individual who has a severe speech impairment with the ability to meet his or her functional, speaking needs. Speech generating devices are speech aids consisting of devices or software that generate speech and are used solely by the individual who has a severe speech impairment. The speech is generated using one of the following methods:

- digitized audible/verbal speech output, using prerecorded messages;
- synthesized audible/verbal speech output which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques;
- synthesized audible/verbal speech output which permits multiple methods of message formulation and multiple methods of device access; or
- software that allows a computer or other electronic device to generate audible/verbal speech.

Other covered features of the device include the capability to generate email, text, or phone messages to allow the patient to “speak” or communicate remotely, as well as the capability to download updates to the covered features of the device from the manufacturer or supplier of the device.

If a speech generating device is limited to use by a patient with a severe speech impairment and is primarily used for the purpose of generating speech, it is not necessary for the device to be dedicated only to audible/verbal speech output to be considered DME. Computers and tablets are generally not considered DME because they are useful in the absence of an illness or injury.

B. Nationally Covered Indications
N/A

C. Nationally Non-Covered Indications
Internet or phone services or any modification to a patient’s home to allow use of the speech generating device are not covered by Medicare because such services or modifications could be used for non-medical equipment such as standard phones or personal computers. In addition, specific features of a speech generating device that are not used by the individual who has a severe speech impairment to meet his or her functional speaking needs are not covered. This would include any computing hardware or software not necessary to allow for generation of audible/verbal speech, email, text or phone messages, such as hardware or software used to create documents and spreadsheets or play games or music, and any other function a computer can perform that is not directly related to meeting the functional speaking communication needs of the patient, including video communications or conferencing. These features of a speech generating device do not fall within the scope of §1861(n) of the Social Security Act and the cost of these features are the responsibility of the beneficiary. Suppliers of speech generating devices are encouraged to furnish the beneficiary with a voluntary Advance Beneficiary Notice (ABN), or similar notice, which informs that these features are not covered and to alert the beneficiary of the expense of these features.

D. Other
Medicare Administrative Contractors acting within their respective jurisdictions have discretion to cover or not cover speech generating devices based on their individual reasonable and necessary determinations.

(This NCD last reviewed July 2015.)

50.2—Electronic Speech Aids
(Rev. 1, 10-03-03)

CIM 65-5
Electronic speech aids are covered under Part B as prosthetic devices when the patient has had a laryngectomy or his larynx is permanently inoperative. There are two types of speech aids. One operates by placing a vibrating head against the throat; the other amplifies sound waves through a tube
which is inserted into the user's mouth. A patient who has had radical neck surgery and/or extensive radiation to the anterior part of the neck would generally be able to use only the “oral tube” model or one of the more sensitive and more expensive “throat contact” devices.

Cross-reference:
The Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §120.

50.3—Cochlear Implantation (Effective April 4, 2005)

A. General
A cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze and code sound. Cochlear implant devices are available in single channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired.

B. Nationally Covered Indications
1. Effective for services performed on or after April 4, 2005, cochlear implantation may be covered for treatment of bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition. Medicare coverage is provided only for those patients who meet all of the following selection guidelines.
   • Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
   • Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
   • Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;
   • No contraindications to surgery; and
   • The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.

2. Effective for services performed on or after April 4, 2005, cochlear implantation may be covered for individuals meeting the selection guidelines above and with hearing test scores of greater than 40% and less than or equal to 60% only when the provider is participating in, and patients are enrolled in, either an FDA-approved category B investigational device exemption clinical trial as defined at 42 CFR 405.201, a trial under the Centers for Medicare & Medicaid (CMS) Clinical Trial Policy as defined at section 310.1 of the National Coverage Determinations Manual, or a prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards.

C. Nationally Non-Covered Indications
Medicare beneficiaries not meeting all of the coverage criteria for cochlear implantation listed are deemed not eligible for Medicare coverage under section 1862(a)(1)(A) of the Social Security Act.

D. Other
All other indications for cochlear implantation not otherwise indicated as nationally covered or non-covered above remain at local Medicare Administrative Contractor discretion.

70.2.1—Services Provided for the Diagnosis and Treatment of Diabetic Sensory Neuropathy with Loss of Protective Sensation (aka Diabetic Peripheral Neuropathy)
(Rev. 1, 10-03-03)

CIM 50-8.1
Presently, peripheral neuropathy, or diabetic sensory neuropathy, is the most common factor leading to amputation in people with diabetes. In diabetes, sensory neuropathy is an anatomically diffuse process primarily affecting sensory and autonomic fibers; however, distal motor findings may be present in advanced cases. Long nerves are affected first, with symptoms typically beginning insidiously in the toes and then advancing proximally. This leads to loss of protective sensation (LOPS), whereby a person is unable to feel minor trauma from mechanical, thermal, or chemical sources. When foot lesions are present, the reduction in autonomic nerve functions may also inhibit wound healing.

Diabetic sensory neuropathy with LOPS is a localized illness of the feet and falls within the regulation’s exception to the general exclusionary rule (see 42 CFR 411.15(l)(1)(ii)). Foot exams for people with diabetic sensory neuropathy with LOPS are reasonable and necessary to allow for early intervention in serious complications that typically afflict diabetics with the disease.

Effective for services furnished on or after July 1, 2002, Medicare covers, as a physician service, an evaluation (examination and treatment) of the feet no more often than every six months for individuals with a documented diagnosis of diabetic sensory neuropathy and LOPS, as long as the beneficiary has not seen a foot care specialist for some other reason in the interim. LOPS shall be diagnosed through sensory testing with the 5.07 monofilament using established guidelines, such as those developed by the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. Five sites should be tested on the planter surface of each foot, according to the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. The areas must be tested randomly since the loss of protective sensation may be patchy in distribution, and the patient may get clues if the test is done rhythmically. Heavily calloused areas should be avoided. As suggested by the American Podiatric Medicine Association, an absence of sensation at two or more sites out of 5 tested on either foot when tested with the 5.07 Semmes-Weinstein monofilament must be present and documented to diagnose peripheral neuropathy with loss of protective sensation.
The examination includes:

1. A patient history, and
2. A physical examination that must consist of at least the following elements:
   - Visual inspection of forefoot and hindfoot (including toe web spaces);
   - Evaluation of protective sensation;
   - Evaluation of foot structure and biomechanics;
   - Evaluation of vascular status and skin integrity;
   - Evaluation of the need for special footwear; and
3. Patient education.

A. Treatment includes, but is not limited to:
   - Local care of superficial wounds;
   - Debridement of corns and calluses; and
   - Trimming and debridement of nails.

The diagnosis of diabetic sensory neuropathy with LOPS should be established and documented prior to coverage of foot care. Other causes of peripheral neuropathy should be considered and investigated by the primary care physician prior to initiating or referring for foot care for persons with LOPS.

70.3—Physician’s Office within an Institution - Coverage of Services and Supplies Incident to a Physician’s Services


Coverage of Services and Supplies Incident to a Physician’s Services

Where a physician establishes an office within a nursing home or other institution, coverage of services and supplies furnished in the office must be determined in accordance with the “incident to a physician’s professional service” provision (see the Medicare Benefit Policy Manual, Chapter 6, “Hospital Services Covered Under Part B,” §20.4.1 or the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §60.1) as in any physician’s office. A physician’s office within an institution must be confined to a separately identified part of the facility which is used solely as the physician’s office and cannot be construed to extend throughout the entire institution. Thus, services performed outside the “office” area would be subject to the coverage rules applicable to services furnished outside the office setting.

In order to accurately apply the criteria in the Medicare Benefit Policy Manual, Chapters 6, §20.4.1, or Chapter 15, “Covered Medical and Other Health Services,” §60.1, the auxiliary medical personnel must be members of the office staff rather than of the institution’s staff, and the cost of supplies must represent an expense to the physician’s office practice. Finally, services performed by the employees of the physician outside the “office” area must be directly supervised by the physician; his presence in the facility as a whole would not suffice to meet this requirement. (In any setting, of course, supervision of auxiliary personnel in and of itself is not considered a “physician’s professional service” to which the services of the auxiliary personnel could be an incidental part, i.e., in addition to supervision, the physician must perform or have performed a personal professional service to the patient to which the services of the auxiliary personnel could be considered an incidental part.) Denials for failure to meet any of these requirements would be based on §1861(s)(2)(A) of the Social Security Act.

Establishment of an office within an institution would not modify rules otherwise applicable for determining coverage of the physician’s personal professional services within the institution. However, in view of the opportunity afforded to a physician who maintains such an office for rendering services to a sizable number of patients in a short period of time or for performing frequent services for the same patient, claims for physicians’ services rendered under such circumstances would require careful evaluation by the MAC to assure that payment is made only for services that are reasonable and necessary.

Cross-reference:

The Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services.”


70.5—Hospital and Skilled Nursing Facility Admission Diagnostic Procedures


These instructions describe the application of the reasonable and necessary payment exclusion to diagnostic procedures, such as chest x-rays, urinalysis, etc. provided to patients upon admission to a hospital or skilled nursing facility.

The major factors which support a determination that a diagnostic procedure performed as part of the admitting procedure to a hospital or skilled nursing facility is reasonable and necessary, are:

A. The test is specifically ordered by the admitting physician (or a hospital or skilled nursing facility staff physician having responsibility for the patient where there is no admitting physician); i.e., it is not furnished under the standing orders of a physician for his patients;
B. The test is medically necessary for the diagnosis or treatment of the individual patient’s condition; and
C. The test does not unnecessarily duplicate the same test performed on an outpatient basis prior to admission or performed in connection with a recent hospital or skilled nursing facility admission.

Where the Medicare Administrative Contractor has not already done so, consult with the Quality Improvement Organizations (QIOs) to obtain information gathered by the QIOs on
a sample basis as to whether x-rays and diagnostic tests are being specifically ordered as described under subsection (A).

80—Eye
(Rev. 1, 10-03-03)

80.1—Hydrophilic Contact Lens for Corneal Bandage

Some hydrophilic contact lenses are used as moist corneal bandages for the treatment of acute or chronic corneal pathology, such as bulbar keratopathy, dry eyes, corneal ulcers and erosion, keratitis, corneal edema, descemetocle, corneal ectasis, Mooren's ulcer, anterior corneal dystrophy, neurotrophic keraconjunctivitis, and for other therapeutic reasons.

Payment may be made under §1861(s)(2) of the Social Security Act for a hydrophilic contact lens approved by the Food and Drug Administration (FDA) and used as a supply incident to a physician's service. Payment for the lens is included in the payment for the physician's service to which the lens is incident. Medicare Administrative Contractors are authorized to accept an FDA letter of approval or other FDA published material as evidence of FDA approval. (See §80.4 for coverage of a hydrophilic contact lens as a prosthetic device.) See the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” and the Medicare Benefit Policy Manual, Chapter 6, “Hospital Services Covered Under Part B,” §20.4.

80.2—Photodynamic Therapy

Photodynamic therapy is a medical procedure which involves the infusion of a photosensitive (light-activated) drug with a very specific absorption peak. This drug is chemically designed to have a unique affinity for the diseased tissue intended for treatment. Once introduced to the body, the drug accumulates and is retained in diseased tissue to a greater degree than in normal tissue. Infusion is followed by the targeted irradiation of this tissue with a non-thermal laser, calibrated to emit light at a wavelength that corresponds to the drug's absorption peak. The drug then becomes active and locally treats the diseased tissue.

Ocular Photodynamic Therapy (OPT)
The OPT is used in the treatment of ophthalmologic diseases. OPT is only covered when used in conjunction with verteporfin (see §80.3, “Photosensitive Drugs”).

- Classic Subfoveal Choroidal Neovascular (CNV) Lesions - OPT is covered with a diagnosis of neovascular age-related macular degeneration (AMD) with predominately classic subfoveal choroidal neovascular (CNV) lesions (where the area of classic CNV occupies ≥ 50% of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram (FA). Subsequent follow-up visits require either an optical coherence tomography or an FA to access treatment response. There are no requirements regarding visual acuity, lesion size, and number of re-treatments.

- Occult Subfoveal CNV Lesions - OPT is non-covered for patients with a diagnosis of AMD with occult and no classic CNV lesions.

- Other Conditions - Use of OPT with verteporfin for other types of AMD (e.g., patients with minimally classic CNV lesions, atrophic, or dry AMD) is non-covered. OPT with verteporfin for other ocular indications such as pathologic myopia or presumed ocular histoplasmosis syndrome, is eligible for coverage through individual Medicare Administrative Contractor discretion.

80.2.1—Ocular Photodynamic Therapy (OPT) - Effective April 2013

A. General

Ocular Photodynamic Therapy (OPT) is used in the treatment of ophthalmologic diseases; specifically, for age-related macular degeneration (AMD), a common eye disease among the elderly. OPT involves the infusion of an intravenous photosensitizing drug called verteporfin followed by exposure to a laser. OPT is only covered when used in conjunction with verteporfin.

Effective July 1, 2001, OPT with verteporfin was approved for a diagnosis of neovascular AMD with predominately classic subfoveal choroidal neovascularization (CNV) lesions (where the area of classic CNV occupies ≥ 50% of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram (FA).

On October 17, 2001, the Centers for Medicare & Medicaid Services (CMS) announced its “intent to cover” OPT with verteporfin for AMD patients with occult and no classic subfoveal CNV as determined by an FA. The October 17, 2001, decision was never implemented.

On March 28, 2002, after thorough review and reconsideration of the October 17, 2001, intent to cover policy, CMS determined that the current non-coverage policy for OPT for verteporfin for AMD patients with occult and no classic subfoveal CNV as determined by an FA should remain in effect.

Effective August 20, 2002, CMS issued a non-coverage instruction for OPT with verteporfin for AMD patients with occult and no classic subfoveal CNV as determined by an FA.

B. Nationally Covered Indications

Effective April 1, 2004, OPT with verteporfin continues to be approved for a diagnosis of neovascular AMD with predominately classic subfoveal CNV lesions (where the area of classic CNV occupies ≥ 50% of the area of the entire lesion) at the initial visit as determined by an FA. (CNV lesions are comprised ofclassic and/or occult components.) Subsequent follow-up visits require either an optical coherence tomography (OCT) (effective April 3, 2013) or an FA (effective April 1, 2004) to access treatment response. There are no requirements regarding visual acuity, lesion size, and number of re-treatments when treating predominantly classic lesions.

In addition, after thorough review and reconsideration of the August 20, 2002, noncoverage policy, CMS determines that
the evidence is adequate to conclude that OPT with verteporfin is reasonable and necessary for treating:

1. Subfoveal occult with no classic CNV associated with AMD; and
2. Subfoveal minimally classic CNV (where the area of classic CNV occupies <50% of the area of the entire lesion) associated with AMD.

The above 2 indications are considered reasonable and necessary only when:

1. The lesions are small (4 disk areas or less in size) at the time of initial treatment or within the 3 months prior to initial treatment; and
2. The lesions have shown evidence of progression within the 3 months prior to initial treatment. Evidence of progression must be documented by deterioration of visual acuity (at least 5 letters on a standard eye examination chart), lesion growth (an increase in at least 1 disk area), or the appearance of blood associated with the lesion.

C. Nationally Non-Covered Indications

Other uses of OPT with verteporfin to treat AMD not already addressed by CMS will continue to be noncovered. These include, but are not limited to, the following AMD indications:

- Juxtafoveal or extrafoveal CNV lesions (lesions outside the fovea),
- Inability to obtain a fluorescein angiogram,
- Atrophic or “dry” AMD.

D. Other

The OPT with verteporfin for other ocular indications, such as pathologic myopia or presumed ocular histoplasmosis syndrome, continue to be eligible for local coverage determinations through individual contractor discretion.

80.3—Photosensitive Drugs


Photosensitive drugs are the light-sensitive agents used in photodynamic therapy. Once introduced into the body, these drugs selectively identify and adhere to diseased tissue. The drugs remain inactive until they are exposed to a specific wavelength of light, by means of a laser, that corresponds to their absorption peak. The activation of a photosensitive drug results in a photochemical reaction which treats the diseased tissue without affecting surrounding normal tissue.

Verteporfin

Verteporfin, a benzoporphyrin derivative, is an intravenous lipophilic photosensitive drug with an absorption peak of 690 nm. Verteporfin was first approved by the Food and Drug Administration on April 12, 2000, and subsequently approved for inclusion in the United States Pharmacopoeia on July 18, 2000, meeting Medicare’s definition of a drug when used in conjunction with ocular photodynamic therapy (OPT) when furnished intravenously incident to a physician’s service. For patients with age-related macular degeneration (AMD), Verteporfin is only covered with a diagnosis of neovascular AMD with predominately classic subfoveal choroidal neovascular (CNV) lesions (where the area of classic CNV occupies ≥ 50% of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram (FA). Subsequent follow-up visits will require either an optical coherence tomography or an FA to access treatment response. OPT with verteporfin is covered for the above indication and will remain non-covered for all other indications related to AMD (see section 80.2). OPT with Verteporfin for use in non-AMD conditions is eligible for coverage through individual Medicare Administrative Contractor discretion.

80.3.1—Verteporfin - Effective April 3, 2013


A. General

Verteporfin, a benzoporphyrin derivative, is an intravenous lipophilic photosensitive drug with an absorption peak of 690 nm. Verteporfin was first approved by the Food and Drug Administration on April 12, 2000, and subsequently approved for inclusion in the United States Pharmacopoeia on July 18, 2000, meeting Medicare’s definition of a drug as defined under §1861(t)(1) of the Social Security Act. Verteporfin is only covered when used in conjunction with ocular photodynamic therapy (OPT) when furnished intravenously incident to a physician’s service.

B. Nationally Covered Indications

Effective April 1, 2004, OPT with verteporfin is covered for patients with a diagnosis of neovascular age-related macular degeneration (AMD) with:

- Predominately classic subfoveal choroidal neovascularization (CNV) lesions (where the area of classic CNV occupies ≥ 50% of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram (FA). (CNV lesions are comprised of classic and/or occult components.) Subsequent follow-up visits require either an optical coherence tomography (effective April 3, 2013) or an FA (effective April 1, 2004) to access treatment response.

There are no requirements regarding visual acuity, lesion size, and number of retreatments when treating predominately classic lesions.

- Subfoveal occult with no classic CNV associated with AMD.
- Subfoveal minimally classic CNV (where the area of classic CNV occupies < 50% of the area of the entire lesion) associated with AMD.

The above 2 indications are considered reasonable and necessary only when:

1. The lesions are small (4 disk areas or less in size) at the time of initial treatment or within the 3 months prior to initial treatment; and
2. The lesions have shown evidence of progression within the 3 months prior to initial treatment. Evidence of progression must be documented by deterioration of visual acuity (at least 5 letters on a standard eye examination chart), lesion growth (an increase in at least 1 disk area), or the appearance of blood associated with the lesion.

C. Nationally Non-Covered Indications

Other uses of OPT with verteporfin to treat AMD not already addressed by the Centers for Medicare & Medicaid Services will continue to be non-covered. These include, but are not
limited to, the following AMD indications: juxtafoveal or extraretinal CNV lesions (lesions outside the fovea), inability to obtain an FA, or atrophic or “dry” AMD.

D. Other

The OPT with verteporfin for other ocular indications, such as pathologic myopia or presumed ocular histoplasmosis syndrome, continue to be eligible for local coverage determinations through individual Medicare Administrative Contractor discretion.

80.4—Hydrophilic Contact Lenses

CIM 65-1

Hydrophilic contact lenses are eyeglasses within the meaning of the exclusion in §1862(a)(7) of the Social Security Act and are not covered when used in the treatment of non-diseased eyes with spherical ametropia, refractive astigmatism, and/or corneal astigmatism. Payment may be made under the prosthetic device benefit, however, for hydrophilic contact lenses when prescribed for an aphakic patient.

Medicare Administrative Contractors are authorized to accept a Food and Drug Administration (FDA) letter of approval or other FDA published material as evidence of FDA approval. (See §80.1 for coverage of a hydrophilic lens as a corneal bandage.)

Cross-references:

The Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §100 and §120.


100-03 Chapter 1, Part 2

110.2—Certain Drugs Distributed by the National Cancer Institute

Under its Cancer Therapy Evaluation, the Division of Cancer Treatment of the National Cancer Institute (NCI), in cooperation with the Food and Drug Administration, approves and distributes certain drugs for use in treating terminally ill cancer patients. One group of these drugs, designated as Group C drugs, unlike other drugs distributed by the NCI, is not limited to use in clinical trials for the purpose of testing their efficacy. Drugs are classified as Group C drugs only if there is sufficient evidence demonstrating their efficacy within a tumor type and that they can be safely administered.

A physician is eligible to receive Group C drugs from the Division of Cancer Treatment only if the following requirements are met:

• A physician must be registered with the NCI as an investigator by having completed an FD-Form 1573;
• A written request for the drug, indicating the disease to be treated, must be submitted to the NCI;
• The use of the drug must be limited to indications outlined in the NCI’s guidelines; and
• All adverse reactions must be reported to the Investigational Drug Branch of the Division of Cancer Treatment.

In view of these NCI controls on distribution and use of Group C drugs, A/B Medicare Administrative Contractors (MACs) may, in the absence of evidence to the contrary, that a Group C drug and the related hospital stay are covered if all other applicable coverage requirements are satisfied.

If there is reason to question coverage in a particular case, the matter should be resolved with the assistance of the Quality Improvement Organization (QIO), or if there is none, the assistance of the MAC’s medical consultants. Information regarding those drugs which are classified as Group C drugs may be obtained from:

Chief, Investigational Drug Branch
Cancer Therapy Evaluation Program
Executive Plaza North, Suite 7134
National Cancer Institute
Rockville, Maryland 20852-7426

110.3—Anti-Inhibitor Coagulant Complex (AICC)
(Rev. 1, 10-03-03)

CIM 45-24

Anti-inhibitor coagulant complex, AICC, is a drug used to treat hemophilia in patients with factor VIII inhibitor antibodies. AICC has been shown to be safe and effective and has Medicare coverage when furnished to patients with hemophilia A and inhibitor antibodies to factor VIII who have major bleeding episodes and who fail to respond to other, less expensive therapies.

140.2—Breast Reconstruction Following Mastectomy
(Rev. 1, 10-03-03)

CIM 35-47

During recent years, there has been a considerable change in the treatment of diseases of the breast such as fibrocystic disease and cancer. While extirpation of the disease remains of primary importance, the quality of life following initial treatment is increasingly recognized as of great concern. The increased use of breast reconstruction procedures is due to several factors:

• A change in epidemiology of breast cancer, including an apparent increase in incidence;
• Improved surgical skills and techniques;
• The continuing development of better prostheses; and
• Increasing awareness by physicians of the importance of postsurgical psychological adjustment.

Reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy is considered a relatively safe and effective noncosmetic procedure. Accordingly, program payment may be made for breast reconstruction surgery following removal of a breast for any medical reason.
Program payment may not be made for breast reconstruction for cosmetic reasons. (Cosmetic surgery is excluded from coverage under §1862(a)(10) of the Act.)

150.2—Osteogenic Stimulator (Various Effective Dates Below)
(Rev. 41, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

CIM 35-48

Electrical Osteogenic Stimulators

A. General

Electrical stimulation to augment bone repair can be attained either invasively or noninvasively. Invasive devices provide electrical stimulation directly at the fracture site either through percutaneously placed cathodes or by implantation of a coiled cathode wire into the fracture site. The power pack for the latter device is implanted into soft tissue near the fracture site and subcutaneously connected to the cathode, creating a self-contained system with no external components. The power supply for the former device is externally placed and the leads connected to the inserted cathodes. With the noninvasive device, opposing pads, wired to an external power supply, are placed over the cast. An electromagnetic field is created between the pads at the fracture site.

B. Nationally Covered Indications

1. Noninvasive Stimulator

The noninvasive stimulator device is covered only for the following indications:

- Nonunion of long bone fractures;
- Failed fusion, where a minimum of 9 months has elapsed since the last surgery;
- Congenital pseudarthroses
- Effective July 1, 1996, as an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc).
- Effective September 15, 1980, nonunion of long bone fractures is considered to exist only after 6 or more months have elapsed without healing of the fracture.
- Effective April 1, 2000, nonunion of long bone fractures is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

2. Invasive (Implantable) Stimulator

The invasive stimulator device is covered only for the following indications:

- Nonunion of long bone fractures;
- Effective July 1, 1996, as an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc).
- Effective April 27, 2005, upon reconsideration of ultrasound stimulation for nonunion fracture healing, CMS determines that the evidence is adequate to conclude that noninvasive ultrasound stimulation for the treatment of nonunion bone fractures prior to surgical intervention is reasonable and necessary. In demonstrating nonunion fractures, CMS expects:
  - A minimum of 2 sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the 2 sets of radiographs; and,
  - Indications that the patient failed at least one surgical intervention for the treatment of the fracture.

B. Nationally Covered Indications

Effective January 1, 2001, ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of nonunion fractures. In demonstrating nonunion fractures, CMS expects:

- A minimum of 2 sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the 2 sets of radiographs.

C. Nationally Non-Covered Indications

Nonunion fractures of the skull, vertebrae and those that are tumor-related are excluded from coverage.

Ultrasonic osteogenic stimulators may not be used concurrently with other non-invasive osteogenic devices.

Ultrasonic Osteogenic Stimulators

A. General

An ultrasonic osteogenic stimulator is a noninvasive device that emits low intensity, pulsed ultrasound. The device is applied to the surface of the skin at the fracture site and ultrasound waves are emitted via a conductive coupling gel to stimulate fracture healing. The ultrasonic osteogenic stimulators are not to be used concurrently with other non-invasive osteogenic devices.

B. Nationally Covered Indications

Effective January 1, 2001, ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of nonunion fractures. In demonstrating nonunion fractures, CMS expects:

- A minimum of 2 sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the 2 sets of radiographs.

This NCD last reviewed June 2005.)
160.6—Carotid Sinus Nerve Stimulator
Effective December 18, 2014, NCD 160.6 is deleted.

160.7—Electrical Nerve Stimulators
Two general classifications of electrical nerve stimulators are employed to treat chronic intractable pain: peripheral nerve stimulators and central nervous system stimulators.

A. Implanted Peripheral Nerve Stimulators
Payment may be made under the prosthetic device benefit for implanted peripheral nerve stimulators. Use of this stimulator involves implantation of electrodes around a selected peripheral nerve. The stimulating electrode is connected by an insulated lead to a receiver unit which is implanted under the skin at a depth not greater than 1/2 inch.
Stimulation is induced by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of electrodes requires surgery and usually necessitates an operating room.

NOTE: Peripheral nerve stimulators may also be employed to assess a patient’s suitability for continued treatment with an electric nerve stimulator. As explained in §160.7.1, such use of the stimulator is covered as part of the total diagnostic service furnished to the beneficiary rather than as a prosthesis.

B. Central Nervous System Stimulators (Dorsal Column and Depth Brain Stimulators)
The implantation of central nervous system stimulators may be covered as therapies for the relief of chronic intractable pain, subject to the following conditions:

1. Types of Implantations
There are two types of implantations covered by this instruction:
• Dorsal Column (Spinal Cord) Neurostimulation - The surgical implantation of neurostimulator electrodes within the dura mater (endodural) or the percutaneous insertion of electrodes in the epidural space is covered.
• Depth Brain Neurostimulation - The stereotactic implantation of electrodes in the deep brain (e.g., thalamus and periaqueductal gray matter) is covered.

2. Conditions for Coverage
No payment may be made for the implantation of dorsal column or depth brain stimulators or services and supplies related to such implantation, unless all of the conditions listed below have been met:
• The implantation of the stimulator is used only as a last resort (if not a last resort) for patients with chronic intractable pain;
• With respect to item a, other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient;
• Patients have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation);
• All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment

CIM 45-4
Not Covered
Vitamin B12 injections to strengthen tendons, ligaments, etc., of the foot are not covered under Medicare because (1) there is no evidence that vitamin B12 injections are effective for the purpose of strengthening weakened tendons and ligaments, and (2) this is nonsurgical treatment under the subluxation exclusion. Accordingly, vitamin B12 injections are not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

Cross reference:

CIM 35-13
Not Covered
The medical effectiveness of the above therapies has not been verified by scientifically controlled studies. Accordingly, reimbursement for these modalities should be denied on the ground that they are not reasonable and necessary as required by §1862(a)(1) of the Act.

CIM 35-20
Not Covered
While electric nerve stimulation has been employed to control chronic intractable pain for some time, its use in the treatment of motor function disorders, such as multiple sclerosis, is a recent innovation, and the medical effectiveness of such therapy has not been verified by scientifically controlled studies. Therefore, where electric nerve stimulation is employed to treat motor function disorders, no reimbursement may be made for the stimulator or for the services related to its implantation since this treatment cannot be considered reasonable and necessary. See §§30.1 and 160.7.

NOTE: For Medicare coverage of deep brain stimulation for essential tremor and Parkinson's disease, see §160.25.
training, and follow up of the patient (including that required to satisfy item c) must be available; and

• Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

Medicare Administrative Contractors may find it helpful to work with Quality Improvement Organizations to obtain the information needed to apply these conditions to claims.

See the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §120, and the following sections in this manual, §§160.2 and 30.1.

160.7.1—Assessing Patients Suitability for Electrical Nerve Stimulation Therapy

(Rev. 149, Issued: 11-30-12, Effective: 06-08-12, Implementation: 01-07-13)

Electrical nerve stimulation is an accepted modality for assessing a patient’s suitability for ongoing treatment with a transcutaneous or an implanted nerve stimulator.

Accordingly, program payment may be made for the following techniques when used to determine the potential therapeutic usefulness of an electrical nerve stimulator:

A. Transcutaneous Electrical Nerve Stimulation (TENS)

This technique involves attachment of a transcutaneous nerve stimulator to the surface of the skin over the peripheral nerve to be stimulated. It is used by the patient on a trial basis and its effectiveness in modulating pain is monitored by the physician, or physical therapist. Generally, the physician or physical therapist is able to determine whether the patient is likely to derive a significant therapeutic benefit from continuous use of a transcutaneous stimulator within a trial period of one month; in a few cases this determination may take longer to make. Document the medical necessity for such services which are furnished beyond the first month. (See §160.13 for an explanation of coverage of medically necessary supplies for the effective use of TENS.)

If TENS significantly alleviates pain, it may be considered as primary treatment; if it produces no relief or greater discomfort than the original pain electrical nerve stimulation therapy is ruled out. However, where TENS produces incomplete relief, further evaluation with percutaneous electrical nerve stimulation may be considered to determine whether an implanted peripheral nerve stimulator would provide significant relief from pain.

Usually, the physician or physical therapist providing the services will furnish the equipment necessary for assessment. Where the physician or physical therapist advises the patient to rent the TENS from a supplier during the trial period rather than supplying it himself/herself, program payment may be made for rental of the TENS as well as for the services of the physician or physical therapist who is evaluating its use. However, the combined program payment which is made for the physician's or physical therapist's services and the rental of the stimulator from a supplier should not exceed the amount which would be payable for the total service, including the stimulator, furnished by the physician or physical therapist alone.

B. Percutaneous Electrical Nerve Stimulation (PENS)

This diagnostic procedure which involves stimulation of peripheral nerves by a needle electrode inserted through the skin is performed only in a physician's office, clinic, or hospital outpatient department. Therefore, it is covered only when performed by a physician or incident to physician's service. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted.

As in the case of TENS (described in subsection A), generally the physician should be able to determine whether the patient is likely to derive a significant therapeutic benefit from continuing use of an implanted nerve stimulator within a trial period of 1 month. In a few cases, this determination may take longer to make. The medical necessity for such diagnostic services which are furnished beyond the first month must be documented.

NOTE: Electrical nerve stimulators do not prevent pain but only alleviate pain as it occurs. A patient can be taught how to employ the stimulator; and once this is done, can use it safely and effectively without direct physician supervision. Consequently, it is inappropriate for a patient to visit his/her physician, physical therapist, or an outpatient clinic on a continuing basis for treatment of pain with electrical nerve stimulation. Once it is determined that electrical nerve stimulation should be continued as therapy and the patient has been trained to use the stimulator; it is expected that a stimulator will be implanted or the patient will employ the TENS on a continual basis in his/her home. Electrical nerve stimulation treatments furnished by a physician in his/her office, by a physical therapist or outpatient clinic are excluded from coverage by §1862(a)(1) of the Act. (See §160.7 for an explanation of coverage of the therapeutic use of implanted peripheral nerve stimulators under the prosthetic devices benefit.) See §160.7 for an explanation of coverage of the therapeutic use of TENS under the durable medical equipment benefit.

160.12—Neuromuscular Electrical Stimulator (NMES)

(Rev. 55, Issued: 05-05-06, Effective: 10-01-06, Implementation: 10-02-06)

Neuromuscular electrical stimulation (NMES) involves the use of a device which transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. There are two broad categories of NMES. One type of device stimulates the muscle when the patient is in a resting state to treat muscle atrophy. The second type is used to enhance functional activity of neurologically impaired patients.

Treatment of Muscle Atrophy

Coverage of NMES to treat muscle atrophy is limited to the treatment of disuse atrophy where nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves, and other non-neurological reasons for disuse atrophy. Some examples would be casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip replacement surgery (until orthotic training begins). (See §160.13 for an explanation of coverage of medically necessary supplies for the effective use of NMES.)
Use for Walking in Patients with Spinal Cord Injury (SCI)

The type of NMES that is use to enhance the ability to walk of SCI patients is commonly referred to as functional electrical stimulation (FES). These devices are surface units that use electrical impulses to activate paralyzed or weak muscles in precise sequence. Coverage for the use of NMES/FES is limited to SCI patients for walking, who have completed a training program which consists of at least 32 physical therapy sessions with the device over a period of three months. The trial period of physical therapy will enable the physician treating the patient for his or her spinal cord injury to properly evaluate the person's ability to use these devices frequently and for the long term. Physical therapy necessary to perform this training must be directly performed by the physical therapist as part of a one-on-one training program.

The goal of physical therapy must be to train SCI patients on the use of NMES/FES devices to achieve walking, not to reverse or retard muscle atrophy.

Coverage for NMES/FES for walking will be covered in SCI patients with all of the following characteristics:

1. Persons with intact lower motor unite (L1 and below) (both muscle and peripheral nerve);
2. Persons with muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently;
3. Persons that demonstrate brisk muscle contraction to NMES and have sensory perception electrical stimulation sufficient for muscle contraction;
4. Persons that possess high motivation, commitment and cognitive ability to use such devices for walking;
5. Persons that can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes;
6. Persons that can demonstrate hand and finger function to manipulate controls;
7. Persons with at least 6-month post recovery spinal cord injury and restorative surgery;
8. Persons with hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and
9. Persons who have demonstrated a willingness to use the device long-term.

NMES/FES for walking will not be covered in SCI patient with any of the following:

1. Persons with cardiac pacemakers;
2. Severe scoliosis or severe osteoporosis;
3. Skin disease or cancer at area of stimulation;
4. Irreversible contracture; or
5. Autonomic dyslexia.

The only settings where therapists with the sufficient skills to provide these services are employed, are inpatient hospitals; outpatient hospitals; comprehensive outpatient rehabilitation facilities; and outpatient rehabilitation facilities. The physical therapy necessary to perform this training must be part of a one-on-one training program.

Additional therapy after the purchase of the DME would be limited by our general policies in coverge of skilled physical therapy.


160.13—Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES)


Transcutaneous Electrical Nerve Stimulation (TENS) and/or Neuromuscular Electrical Stimulation (NMES) can ordinarily be delivered to patients through the use of conventional electrodes, adhesive tapes and lead wires. There may be times, however, where it might be medically necessary for certain patients receiving TENS or NMES treatment to use, as an alternative to conventional electrodes, adhesive tapes and lead wires, a form-fitting conductive garment (i.e., a garment with conductive fibers which are separated from the patient's skin by layers of fabric).

A form-fitting conductive garment (and medically necessary related supplies) may be covered under the program only when:

1. It has received permission or approval for marketing by the Food and Drug Administration;
2. It has been prescribed by a physician for use in delivering covered TENS or NMES treatment; and
3. One of the medical indications outlined below is met:
   - The patient cannot manage without the conductive garment because there is such a large area or so many sites to be stimulated and the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes and lead wires;
   - The patient cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes and lead wires;
   - The patient has a documented medical condition such as skin problems that preclude the application of conventional electrodes, adhesive tapes and lead wires;
   - The patient requires electrical stimulation beneath a cast either to treat disuse atrophy, where the nerve supply to the muscle is intact, or to treat chronic intractable pain; or
   - The patient has a medical need for rehabilitation strengthening (pursuant to a written plan of rehabilitation) following an injury where the nerve supply to the muscle is intact.

A conductive garment is not covered for use with a TENS device during the trial period specified in §160.3 unless:

4. The patient has a documented skin problem prior to the start of the trial period; and
5. The A/B MAC (B)’s medical consultants are satisfied that use of such an item is medically necessary for the patient.

(See conditions for coverage of the use of TENS in the diagnosis and treatment of chronic intractable pain in §§160.3, 160.13 and 160.27 and the use of NMES in the treatment of disuse atrophy in §150.4.)
160.23—Sensory Nerve Conduction Threshold Tests (sNCTs)
(Effective April 1, 2004)

(Rev. 15, 06-18-04)

A. GENERAL

The sNCT is a psychophysical assessment of both central and peripheral nerve functions. It measures the detection threshold of accurately calibrated sensory stimuli. This procedure is intended to evaluate and quantify function in both large and small caliber fibers for the purpose of detecting neurologic disease. Sensory perception and threshold detection are dependent on the integrity of both the peripheral sensory apparatus and peripheral-central sensory pathways. In theory, an abnormality detected by this procedure may signal dysfunction anywhere in the sensory pathway from the receptors, the sensory tracts, the primary sensory cortex, to the association cortex.

This procedure is different and distinct from assessment of nerve conduction velocity, amplitude and latency. It is also different from short-latency somatosensory evoked potentials.

Effective October 1, 2002, CMS initially concluded that there was insufficient scientific or clinical evidence to consider the sNCT test and the device used in performing this test reasonable and necessary within the meaning of section 1862(a)(1) (A) of the law.

Therefore, sNCT was noncovered.

Effective April 1, 2004, based on a reconsideration of current Medicare policy for sNCT, CMS concludes that the use of any type of sNCT device (e.g., “current output” type device used to perform current perception threshold (CPT), pain perception threshold (PPT), or pain tolerance threshold (PTT) testing or “voltage input” type device used for voltage-nerve conduction threshold (v-NCT) testing) to diagnose sensory neuropathies or radiculopathies in Medicare beneficiaries is not reasonable and necessary.

B. Nationally Covered Indications

Not applicable.

C. Nationally Noncovered Indications

All uses of sNCT to diagnose sensory neuropathies or radiculopathies are noncovered.

(This NCD last reviewed June 2004.)

100-03 Chapter 1, Part 3

170.3—Speech-Language Pathology Services for the Treatment of Dysphagia
(Rev. 55, Issued: 05-05-06, Effective: 10-01-06, Implementation: 10-02-06)

Dysphagia is a swallowing disorder that may be due to various neurological, structural, and cognitive deficits. Dysphagia may be the result of head trauma, cerebrovascular accident, neuromuscular degenerative diseases, head and neck cancer, or encephalopathies. While dysphagia can affect any age group, it most often appears among the elderly. Speech-language pathology services are covered under Medicare for the treatment of dysphagia, regardless of the presence of a communication disability.

Patients who are motivated, moderately alert, and have some degree of deglutition and swallowing functions are appropriate candidates for dysphagia therapy. Elements of the therapy program can include thermal stimulation to heighten the sensitivity of the swallowing reflex, exercises to improve oral-motor control, training in laryngeal adduction and compensatory swallowing techniques, and positioning and dietary modifications. Design all programs to ensure swallowing safety of the patient during oral feedings and maintain adequate nutrition.

Cross-reference:
The Medicare Benefit Policy, Chapter 15, “Covered Medical and Other Health Services,” §§220 and 230.3

180.2—Enteral and Parenteral Nutritional Therapy

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation of ICD-10; Implementation: Upon Implementation of ICD-10)

Covered As Prosthetic Device

There are patients who, because of chronic illness or trauma, cannot be sustained through oral feeding. These people must rely on either enteral or parenteral nutritional therapy, depending upon the particular nature of their medical condition.

Coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision which requires that the patient must have a permanently inoperable internal body organ or function thereof. Therefore, enteral and parenteral nutritional therapy are normally not covered under Part B in situations involving temporary impairments.

Coverage of such therapy, however, does not require a medical judgment that the impairment giving rise to the therapy will persist throughout the patient’s remaining years. If the medical record, including the judgment of the attending physician, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met.

If the coverage requirements for enteral or parenteral nutritional therapy are met under the prosthetic device benefit provision, related supplies, equipment and nutrients are also covered under the conditions in the following paragraphs and the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §120.

Parenteral Nutrition Therapy Daily parenteral nutrition is considered reasonable and necessary for a patient with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient’s general condition.

Since the alimentary tract of such a patient does not function adequately, an indwelling catheter is placed percutaneously in the subclavian vein and then advanced into the superior vena cava where intravenous infusion of nutrients is given for part of the day. The catheter is then plugged by the patient until the next infusion. Following a period of hospitalization, which is required to initiate parenteral nutrition and to train the patient in catheter care, solution preparation,
and infusion technique, the parenteral nutrition can be provided safely and effectively in the patient's home by nonprofessional persons who have undergone special training. However, such persons cannot be paid for their services, nor is payment available for any services furnished by non-physician professionals except as services furnished incident to a physician's service.

For parenteral nutrition therapy to be covered under Part B, the claim must contain a physician's written order or prescription and sufficient medical documentation to permit an independent conclusion that the requirements of the prosthetic device benefit are met and that parenteral nutrition therapy is medically necessary. An example of a condition that typically qualifies for coverage is a massive small bowel resection resulting in severe nutritional deficiency in spite of adequate oral intake. However, coverage of parenteral nutrition therapy for this and any other condition must be approved on an individual, case-by-case basis initially and at periodic intervals of no more than 3 months by the Medicare Administrative Contractor (A/B MAC (B)) medical consultant or specially trained staff, relying on such medical and other documentation as the A/B MAC (B) may require. If the claim involves an infusion pump, sufficient evidence must be provided to support a determination of medical necessity for the pump. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.

Nutrient solutions for parenteral therapy are routinely covered. However, Medicare pays for no more than one month's supply of nutrients at any one time. Payment for the nutrients is based on the reasonable charge for the solution components unless the medical record, including a signed statement from the attending physician, establishes that the beneficiary, due to his/her physical or mental state, is unable to safely or effectively mix the solution and there is no family member or other person who can do so. Payment will be on the basis of the reasonable charge for more expensive premixed solutions only under the latter circumstances.

Enteral Nutrition Therapy

Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to, or non-function of, the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. Enteral therapy may be given by nasogastic, jejunostomy, or gastrostomy tubes and can be provided safely and effectively in the home by nonprofessional persons who have undergone special training. However, such persons cannot be paid for their services, nor is payment available for any services furnished by non-physician professionals except as services furnished incident to a physician's service.

Typical examples of conditions that qualify for coverage are head and neck cancer with reconstructive surgery and central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the beneficiary cannot be maintained with oral feeding. However, claims for Part B coverage of enteral nutrition therapy for these and any other conditions must be approved on an individual, case-by-case basis. Each claim must contain a physician's written order or prescription and sufficient medical documentation (e.g., hospital records, clinical findings from the attending physician) to permit an independent conclusion that the patient's condition meets the requirements of the prosthetic device benefit and that enteral nutrition therapy is medically necessary. Allowed claims are to be reviewed at periodic intervals of no more than 3 months by the A/B MAC (B) medical consultant or specially trained staff, and additional medical documentation considered necessary is to be obtained as part of this review.

Medicare pays for no more than one month's supply of enteral nutrients at any one time.

If the claim involves a pump, it must be supported by sufficient medical documentation to establish that the pump is medically necessary, i.e., gravity feeding is not satisfactory due to aspiration, diarrhea, dumping syndrome. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.

Nutritional Supplementation

Some patients require supplementation of their daily protein and caloric intake. Nutritional supplements are often given as a medicine between meals to boost protein-caloric intake or the mainstay of a daily nutritional plan. Nutritional supplementation is not covered under Medicare Part B.

190.2—Diagnostic Pap Smears

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 50-20, CIM 50-20.1

A diagnostic pap smear and related medically necessary services are covered under Medicare Part B when ordered by a physician under one of the following conditions:

- Previous cancer of the cervix, uterus, or vagina that has been or is presently being treated;
- Previous abnormal pap smear;
- Any abnormal findings of the vagina, cervix, uterus, ovaries, or adnexa;
- Any significant complaint by the patient referable to the female reproductive system; or
- Any signs or symptoms that might in the physician's judgment reasonably be related to a gynecologic disorder.

Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer. (See section 210.2.)

100-03 Chapter 1, Part 4

210.1—Prostate Cancer Screening Tests

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 50-55

Covered

A—General

Section 4103 of the Balanced Budget Act of 1997 provides for coverage of certain prostate cancer screening tests subject to certain coverage, frequency, and payment limitations.
Medicare will cover prostate cancer screening tests/ procedures for the early detection of prostate cancer. Coverage of prostate cancer screening tests includes the following procedures furnished to an individual for the early detection of prostate cancer:

- Screening digital rectal examination; and
- Screening prostate specific antigen blood test.

B—Screening Digital Rectal Examinations

Screening digital rectal examinations are covered at a frequency of once every 12 months for men who have attained age 50 (at least 11 months have passed following the month in which the last Medicare-covered screening digital rectal examination was performed). Screening digital rectal examination means a clinical examination of an individual’s prostate for nodules or other abnormalities of the prostate. This screening must be performed by a doctor of medicine or osteopathy (as defined in §1861(r)(1) of the Act), or by a physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse mid-wife (as defined in §1861(aa) and §1861(gg) of the Act) who is authorized under State law to perform the examination, fully knowledgeable about the beneficiary's medical condition, and would be responsible for using the results of any examination performed in the overall management of the beneficiary's specific medical problem.

C—Screening Prostate Specific Antigen Tests

Screening prostate specific antigen tests are covered at a frequency of once every 12 months for men who have attained age 50 (at least 11 months have passed following the month in which the last Medicare-covered screening prostate specific antigen test was performed). Screening prostate specific antigen tests (PSA) means a test to detect the marker for adenocarcinoma of prostate. PSA is a reliable immunocytochemical marker for primary and metastatic adenocarcinoma of prostate. This screening must be ordered by the beneficiary’s physician or by the beneficiary’s physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife (the term “attending physician” is defined in §1861(r)(1) of the Act to mean a doctor of medicine or osteopathy and the term “physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife” are defined in §1861(aa) and §1861(gg) of the Act) who is fully knowledgeable about the beneficiary’s medical condition, and who would be responsible for using the results of any examination performed in the overall management of the beneficiary’s specific medical problem.

220.6—Positron Emission Tomography (PET) Scans

(Rev. 156, Issued: 08-02-13, Effective: 03-07-13, Implementation; 09-03-13)

Positron Emission Tomography (PET) is a minimally invasive diagnostic imaging procedure used to evaluate metabolism in normal tissue as well as in diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders. A radiopharmaceutical is injected into the patient that gives off sub-atomic particles, known as positrons, as it decays. PET uses a positron camera (tomograph) to measure the decay of the radiopharmaceutical. The rate of decay provides biochemical information on the metabolism of the tissue being studied.

NOTE: This manual section 220.6 lists all Medicare-covered uses of PET scans. Except as set forth below in cancer indications listed as “Coverage with Evidence Development”, a particular use of PET scans is not covered unless this manual specifically provides that such use is covered. Although this section 220.6 lists some non-covered uses of PET scans, it does not constitute an exhaustive list of all non-covered uses.

Effective for dates of service on or after March 7, 2013, local Medicare Administrative Contractors (MACs) may determine coverage within their respective jurisdictions for positron emission tomography (PET) using radiopharmaceuticals for their Food and Drug Administration (FDA) approved labeled indications for oncologic imaging.

We emphasize each of the following points:

1. Changing the ‘restrictive’ language of prior PET decisions will not by itself suffice to expand Medicare coverage to new PET radiopharmaceuticals.
2. The scope of this change extends only to FDA-approved indications for oncologic uses of PET tracers.
3. This change does not include screening uses of PET scanning.

The Centers for Medicare & Medicaid Services (CMS) acknowledges the advances relating to the assessment of diagnostic performance and patient safety, as pioneered by the FDA in its regulatory policies and guidelines for diagnostic PET imaging agents and systems during the past decade. We note for completeness that local coverage cannot be in conflict with NCDs or other national policies. Finally, we note that future CMS NCDs, if any, regarding diagnostic PET imaging would not be precluded by this NCD.

(This NCD last reviewed March 2009.)

220.6.1—PET for Perfusion of the Heart (Various Effective Dates Below)

(Rev. 120; Issued: 05-06-10; Effective Date: 04-03-09; Implementation Date: 10-30-09)

1. Rubidium 82 (Effective March 14, 1995)

Effective for services performed on or after March 14, 1995, PET scans performed at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical Rubidium 82 (Rb 82) are covered, provided the requirements below are met:

- The PET scan, whether at rest alone or rest with stress, is performed in place of, but not in addition to, a single photon emission computed tomography (SPECT); or
- The PET scan, whether at rest alone or rest with stress, is used following a SPECT that was found to be inconclusive. In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient. (For purposes of this requirement, an inconclusive test is a test(s) whose results are equivocal, technically uninterruptible, or discordant with a patient’s other clinical data and must be documented in the beneficiary’s file.)
- For any PET scan for which Medicare payment is claimed for dates of services prior to July 1, 2001, the claimant
must submit additional specified information on the claim form (including proper codes and/or modifiers), to indicate the results of the PET scan. The claimant must also include information on whether the PET scan was performed after an inconclusive non-invasive cardiac test. The information submitted with respect to the previous noninvasive cardiac test must specify the type of test performed prior to the PET scan and whether it was inconclusive or unsatisfactory. These explanations are in the form of special G codes used for billing PET scans using Rb 82. Beginning July 1, 2001, claims should be submitted with the appropriate codes.

2. Ammonia N-13 (Effective October 1, 2003)

   Effective for services performed on or after October 1, 2003, PET scans performed at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical ammonia N-13 are covered, provided the requirements below are met:

   - The PET scan, whether at rest alone, or rest with stress, is performed in place of, but not in addition to, a SPECT; or
   - The PET scan, whether at rest alone or rest with stress, is used following a SPECT that was found to be inconclusive. In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient. (For purposes of this requirement, an inconclusive test is a test whose results are equivocal, technically uninterpretable, or discordant with a patient’s other clinical data and must be documented in the beneficiary’s file.)

   (This NCD last reviewed March 2005.)

220.6.2—FDG PET for Lung Cancer (Replaced with Section 220.6.17)
(Rev. 120; Issued: 05-06-10; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.3—FDG PET for Esophageal Cancer (Replaced with Section 220.6.17)
(Rev. 120; Issued: 05-06-10; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.4—FDG PET for Colorectal Cancer (Replaced with Section 220.6.17)
(Rev. 120; Issued: 05-06-10; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.5—FDG PET for Lymphoma (Replaced with Section 220.6.17)
(Rev. 120; Issued: 05-06-10; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.6—FDG PET for Melanoma (Replaced with Section 220.6.17)
(Rev. 120; Issued: 05-06-10; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.7—FDG PET for Head and Neck Cancers (Replaced with Section 220.6.17)
(Rev. 120; Issued: 05-06-10; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.8—FDG PET for Myocardial Viability (Various Effective Dates Below)
(Rev. 31, Issued: 04-04-05; Effective: 01-28-05; Implementation: 04-18-05)

The identification of patients with partial loss of heart muscle movement or hibernating myocardium is important in selecting candidates with compromised ventricular function to determine appropriateness for revascularization. Diagnostic tests such as FDG PET distinguish between dysfunctional but viable myocardial tissue and scar tissue in order to affect management decisions in patients with ischemic cardiomyopathy and left ventricular dysfunction.

1. FDG PET is covered for the determination of myocardial viability following an inconclusive single photon emission computed tomography (SPECT) test from July 1, 2001, through September 30, 2002. Only full ring PET scanners are covered from July 1, 2001, through December 31, 2001. However, as of January 1, 2002, full and partial ring scanners are covered.

2. Beginning October 1, 2002, Medicare covers FDG PET for the determination of myocardial viability as a primary or initial diagnostic study prior to revascularization, or following an inconclusive SPECT. Studies performed by full and partial ring scanners are covered.

Limitations: In the event a patient receives a SPECT test with inconclusive results, a PET scan may be covered. However, if a patient receives a FDG PET study with inconclusive results, a follow up SPECT test is not covered.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary’s medical record, as is normal business practice.

(See §220.12 for SPECT coverage.)

(This NCD last reviewed September 2002.)

220.6.9—FDG PET for Refractory Seizures (Effective July 1, 2001)
(Rev. 120; Issued: 05-06-10; Effective Date: 04-03-09; Implementation Date: 10-30-09)

Beginning July 1, 2001, Medicare covers FDG PET for presurgical evaluation for the purpose of localization of a focus of refractory seizure activity.

Limitations: Covered only for pre-surgical evaluation.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary’s medical record, as is normal business practice.

(This NCD last reviewed June 2001.)

220.6.10—FDG PET for Breast Cancer (Effective October 1, 2002) (Replaced with Section 220.6.17)
(Rev. 120; Issued: 05-06-10; Effective Date: 04-03-09; Implementation Date: 10-30-09)
220.6.11—FDG PET for Thyroid Cancer (Various Effective Dates Below) (Replaced with Section 220.6.17)
(Rev. 120; Issued: 05-06-10; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.12—FDG PET for Soft Tissue Sarcoma (Various Effective Dates Below) (Replaced with Section 220.6.17)
(Rev. 120; Issued: 05-06-10; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.13—FDG PET for Dementia and Neurodegenerative Diseases (Effective September 15, 2004)

A. General

Medicare covers FDG-Positron Emission Tomography (PET) scans for either the differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer’s disease (AD) under specific requirements; OR, its use in a Centers for Medicare & Medicaid Services (CMS)-approved practical clinical trial focused on the utility of FDG-PET in the diagnosis or treatment of dementing neurodegenerative diseases. Specific requirements for each indication are clarified below:

B. Nationally Covered Indications

1. FDG-PET Requirements for Coverage in the Differential Diagnosis of AD and FTD

An FDG-PET scan is considered reasonable and necessary in patients with a recent diagnosis of dementia and documented cognitive decline of at least 6 months, who meet diagnostic criteria for both AD and FTD. These patients have been evaluated for specific alternate neurodegenerative diseases or other causative factors, but the cause of the clinical symptoms remains uncertain.

The following additional conditions must be met before an FDG-PET scan will be covered:

a. The patient’s onset, clinical presentation, or course of cognitive impairment is such that FTD is suspected as an alternative neurodegenerative cause of the cognitive decline. Specifically, symptoms such as social disinhibition, awkwardness, difficulties with language, or loss of executive function are more prominent early in the course of FTD than the memory loss typical of AD;

b. The patient has had a comprehensive clinical evaluation (as defined by the American Academy of Neurology) encompassing a medical history from the patient and a well-acquainted informant (including assessment of activities of daily living), physical and mental status examination (including formal documentation of cognitive decline occurring over at least 6 months) aided by cognitive scales or neuropsychological testing, laboratory tests, and structural imaging such as magnetic resonance imaging (MRI) or computed tomography (CT);

c. The evaluation of the patient has been conducted by a physician experienced in the diagnosis and assessment of dementia;

d. The evaluation of the patient did not clearly determine a specific neurodegenerative disease or other cause for the clinical symptoms, and information available through FDG-PET is reasonably expected to help clarify the diagnosis between FTD and AD and help guide future treatment;

e. The FDG-PET scan is performed in a facility that has all the accreditation necessary to operate nuclear medicine equipment. The reading of the scan should be done by an expert in nuclear medicine, radiology, neurology, or psychiatry, with experience interpreting such scans in the presence of dementia;

f. A brain single photon emission computed tomography (SPECT) or FDG-PET scan has not been obtained for the same indication. (The indication can be considered to be different in patients who exhibit important changes in scope or severity of cognitive decline, and meet all other qualifying criteria listed above and below (including the judgment that the likely diagnosis remains uncertain). The results of a prior SPECT or FDG-PET scan must have been inconclusive or, in the case of SPECT, difficult to interpret due to immaturity or inadequate technology. In these instances, an FDG-PET scan may be covered after 1 year has passed from the time the first SPECT or FDG-PET scan was performed.)

g. The referring and billing provider(s) have documented the appropriate evaluation of the Medicare beneficiary. Providers should establish the medical necessity of an FDG-PET scan by ensuring that the following information has been collected and is maintained in the beneficiary medical record:

- Date of onset of symptoms;
- Diagnosis of clinical syndrome (normal aging; mild cognitive impairment (MCI); mild, moderate, or severe dementia);
- Mini mental status exam (MMSE) or similar test score;
- Presumptive cause (possible, probable, uncertain AD);
- Any neuropsychological testing performed;
- Results of any structural imaging (MRI or CT) performed;
- Relevant laboratory tests (B12, thyroid hormone); and,
- Number and name of prescribed medications.

The billing provider must furnish a copy of the FDG-PET scan result for use by CMS and its Medicare Administrative Contractors upon request. These verification requirements are consistent with Federal requirements set forth in 42 Code of Federal Regulations, section 410.32 generally for diagnostic x-ray tests, diagnostic laboratory tests, and other tests. In summary, section 410.32 requires the billing physician and the referring physician to maintain information in the medical record of each patient to demonstrate medical necessity [410.32(d) (2)] and submit the information demonstrating medical necessity to CMS and/or its agents upon request [410.32(d)(3)(I)] (OMB number 0938-0685).

2. FDG-PET Requirements for Coverage in the Context of a CMS-approved Practical Clinical Trial Utilizing a Specific Protocol to Demonstrate the Utility of FDG-PET in the Diagnosis, and Treatment of Neurodegenerative Dementing Diseases

An FDG-PET scan is considered reasonable and necessary in patients with MCI or early dementia (in clinical circumstances other than those specified in subparagraph 1) only in the context of an approved clinical trial that contains patient safeguards and protections to ensure proper administration, use and evaluation of the FDG-PET scan.
The clinical trial must compare patients who do and do not receive an FDG-PET scan and have as its goal to monitor, evaluate, and improve clinical outcomes. In addition, it must meet the following basic criteria:

a. Written protocol on file;
b. Institutional Review Board review and approval;
c. Scientific review and approval by two or more qualified investigators who are not part of the research team; and,
d. Certification that investigators have not been disqualified.

C. Nationally Non-Covered Indications

All other uses of FDG-PET for patients with a presumptive diagnosis of dementia-causing neurodegenerative disease (e.g., possible or probable AD, clinically typical FTD, dementia of Lewy bodies, or Creutzfeld-Jacob disease) for which CMS has not specifically indicated coverage continue to be non-covered.

D. Other

Not applicable.

220.6.14—FDG PET for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers (Effective January 28, 2005) (Replaced with Section 220.6.17)
(Rev. 120; Issued: 05-06-10; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.15—FDG PET for All Other Cancer Indications Not Previously Specified (Effective January 28, 2005) (Replaced with Section 220.6.17)
(Rev. 120; Issued: 05-06-10; Effective Date: 04-03-09; Implementation Date: 10-30-09)

220.6.16—FDG PET for Infection and Inflammation (Effective March 19, 2008)
(Rev. 84; Issued: 06-27-08; Effective Date: 03-19-08; Implementation Date: 07-28-08)

A. General

The Centers for Medicare & Medicaid Services (CMS) received a formal, complete request to reconsider the current, de facto non-coverage for FDG PET imaging for the following off-label uses, each in lieu of bone, leukocyte, and/or gallium scintigraphy:

1. Suspected chronic osteomyelitis in patients with: (a) previously documented osteomyelitis with suspected recurrence, or; (b) symptoms of osteomyelitis for more than 6 weeks (including diabetic foot ulcers),
2. Investigation of patients with suspected infection of hip prosthesis, and,
3. Fever of unknown origin in patients with a febrile illness of >3 weeks duration, a temperature of >38.3 degrees Centigrade on at least two occasions, and uncertain diagnosis after a thorough history, physical examination, and one week of proper investigation.

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

The CMS is continuing its national non-coverage of FDG PET for the requested indications. Based upon our review, CMS has determined that the evidence is inadequate to conclude that FDG PET for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin improves health outcomes in the Medicare populations, and therefore has determined that FDG PET for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act.

D. Other

The CMS has also determined that the request for coverage is not appropriate for the Coverage with Evidence Development (CED) paradigm.

(This NCD last reviewed March 2008.)

220.6.17 - Positron Emission Tomography (PET) (FDG) for Oncologic Conditions - (Effective June 11, 2013)

A. General

FDG (2-[F18] fluoro-2-deoxy-D-glucose) Positron Emission Tomography (PET) is a minimally-invasive diagnostic imaging procedure used to evaluate glucose metabolism in normal tissue as well as in diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders. FDG is an injected radionuclide (or radiopharmaceutical) that emits sub-atomic particles, known as positrons, as it decays. FDG PET uses a positron camera (tomograph) to measure the decay of FDG. The rate of FDG decay provides biochemical information on glucose metabolism in the tissue being studied. As malignancies can cause abnormalities of metabolism and blood flow, FDG PET evaluation may indicate the probable presence or absence of a malignancy based upon observed differences in biologic activity compared to adjacent tissues.

The Centers for Medicare and Medicaid Services (CMS) was asked by the National Oncologic PET Registry (NOPR) to reconsider section 220.6 of the National Coverage Determinations (NCD) Manual to end the prospective data collection requirements under Coverage with Evidence Development (CED) across all oncologic indications of FDG PET imaging. The CMS received public input indicating that the current coverage framework of prospective data collection under CED be ended for all oncologic uses of FDG PET imaging.

1. Framework

Effective for claims with dates of service on and after June 11, 2013, CMS is adopting a coverage framework that ends the prospective data collection requirements by NOPR under CED for all oncologic uses of FDG PET imaging. CMS is making this change for all NCDs that address coverage of FDG PET for oncologic uses addressed in this decision. This decision does not change coverage for any use of PET imaging using radiopharmaceuticals NaF-18 (fluorine-18 labeled sodium fluoride), ammonia N-13, or rubidium-82 (Rb-82).
2. Initial Anti-tumor Treatment Strategy

CMS continues to believe that the evidence is adequate to determine that the results of FDG PET imaging are useful in determining the appropriate initial anti-tumor treatment strategy for beneficiaries with suspected cancer and improve health outcomes and thus are reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (the Act).

Therefore, CMS continues to nationally cover one FDG PET study for beneficiaries who have cancers that are biopsy proven or strongly suspected based on other diagnostic testing when the beneficiary’s treating physician determines that the FDG PET study is needed to determine the location and/or extent of the tumor for the following therapeutic purposes related to the initial anti-tumor treatment strategy:

• To determine whether or not the beneficiary is an appropriate candidate for an invasive diagnostic or therapeutic procedure; or
• To determine the optimal anatomic location for an invasive procedure; or
• To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor.

See the table at the end of this section for a synopsis of all nationally covered and non-covered oncologic uses of FDG PET imaging.

B.1. Initial Anti-Tumor Treatment Strategy Nationally Covered Indications

a. CMS continues to nationally cover FDG PET imaging for the initial anti-tumor treatment strategy for male and female breast cancer only when used in staging distant metastasis.

b. CMS continues to nationally cover FDG PET to determine initial anti-tumor treatment strategy for melanoma other than for the evaluation of regional lymph nodes.

c. CMS continues to nationally cover FDG PET imaging for the detection of pre-treatment metastasis (i.e., staging) in newly diagnosed cervical cancers.

C1. Initial Anti-Tumor Treatment Strategy Nationally Non-Covered Indications

a. CMS continues to nationally non-cover initial anti-tumor treatment strategy in Medicare beneficiaries who have adenocarcinoma of the prostate.

b. CMS continues to nationally non-cover FDG PET imaging for diagnosis of breast cancer and initial staging of axillary nodes.

c. CMS continues to nationally non-cover FDG PET imaging for the diagnosis of cervical cancer related to initial anti-tumor treatment strategy.

d. CMS continues to nationally non-cover FDG PET imaging for the diagnosis of cervical cancer related to initial anti-tumor treatment strategy.

3. Subsequent Anti-Tumor Treatment Strategy

B.2. Subsequent Anti-Tumor Treatment Strategy Nationally Covered Indications

Three FDG PET scans are nationally covered when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy. All other indications for initial anti-tumor treatment strategy after completion of initial anti-cancer therapy shall be determined by the local Medicare Administrative Contractors.

4. Synopsis of Coverage of FDG PET for Oncologic Conditions

Effective for claims with dates of service on and after June 11, 2013, the chart below summarizes national FDG PET coverage for oncologic conditions:

<table>
<thead>
<tr>
<th>FDG PET for Cancers Tumor Type</th>
<th>Initial Treatment Strategy (formerly “diagnosis” &amp; “staging”)</th>
<th>Subsequent Treatment Strategy (formerly “restaging” &amp; “monitoring response to treatment”)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Esophagus</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Head and Neck (not thyroid, CNS)</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Non-small cell lung</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Ovary</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Brain</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Cervix</td>
<td>Cover with exceptions *</td>
<td>Cover</td>
</tr>
<tr>
<td>Small cell lung</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Soft tissue sarcoma</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Pancreas</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Testes</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Prostate</td>
<td>Non-cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Thyroid</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Breast (male and female)</td>
<td>Cover with exceptions *</td>
<td>Cover</td>
</tr>
<tr>
<td>Melanoma</td>
<td>Cover with exceptions *</td>
<td>Cover</td>
</tr>
<tr>
<td>All other solid tumors</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Myeloma</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>All other cancers not listed</td>
<td>Cover</td>
<td>Cover</td>
</tr>
</tbody>
</table>

*Cervix: Nationally non-covered for the initial diagnosis of cervical cancer related to initial anti-tumor treatment strategy. All other indications for initial anti-tumor treatment strategy for cervical cancer are nationally covered.

*Breast: Nationally non-covered for initial diagnosis and/or staging of axillary lymph nodes. Nationally covered for initial staging of metastatic disease. All other indications for initial anti-tumor treatment strategy for breast cancer are nationally covered.

*Melanoma: Nationally non-covered for initial staging of regional lymph nodes. All other indications for initial anti-tumor treatment strategy for melanoma are nationally covered.
D. Other

N/A

220.6.19 – Positron Emission Tomography NaF-18 (NaF-18 PET) to Identify Bone Metastasis of Cancer (Effective February 26, 2010)

(Rev. 119, Issued: 03-26-10, Effective: 02-26-10, Implementation: 07-06-10)

A. General

Positron Emission Tomography (PET) is a non-invasive, diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the body. A positron camera (tomograph) is used to produce cross-sectional tomographic images, which are obtained from positron-emitting radioactive tracer substances (radiopharmaceuticals) such as F-18 sodium fluoride. NaF-18 PET has been recognized as an excellent technique for imaging areas of altered osteogenic activity in bone. The clinical value of detecting and assessing the initial extent of metastatic cancer in bone is attested by a number of professional guidelines for oncology. Imaging to detect bone metastases is also recommended when a patient, following completion of initial treatment, is symptomatic with bone pain suspicious for metastases from a known primary tumor.

B. Nationally Covered Indications

Effective February 26, 2010, the Centers for Medicare & Medicaid Services (CMS) will cover NaF-18 PET imaging when the beneficiary’s treating physician determines that the NaF-18 PET study is needed to inform the initial antitumor treatment strategy or to guide subsequent antitumor treatment strategy after the completion of initial treatment, and when the beneficiary is enrolled in, and the NaF-18 PET study is designed to collect additional information at the time of the scan to assist in initial antitumor treatment planning or to guide subsequent antitumor treatment strategy after the completion of initial treatment, and when the beneficiary is enrolled in, and the NaF-18 PET provider is participating in, the following type of prospective clinical study:

A NaF-18 PET clinical study that is designed to collect additional information at the time of the scan to assist in initial antitumor treatment planning or to guide subsequent treatment strategy by the identification, location and quantification of bone metastases in beneficiaries in whom bone metastases are strongly suspected based on clinical symptoms or the results of other diagnostic studies. Qualifying clinical studies must ensure that specific hypotheses are addressed; appropriate data elements are collected; hospitals and providers are qualified to provide the PET scan and interpret the results; participating hospitals and providers accurately report data on all enrolled patients not included in other qualifying trials through adequate auditing mechanisms; and all patient confidentiality, privacy, and other Federal laws must be followed.

The clinical studies for which Medicare will provide coverage must answer one or more of the following questions:

Prospectively, in Medicare beneficiaries whose treating physician determines that the NaF-18 PET study results are needed to inform the initial antitumor treatment strategy or to guide subsequent antitumor treatment strategy after the completion of initial treatment, does the addition of NaF-18 PET imaging lead to:

• A change in patient management to more appropriate palliative care; or
• A change in patient management to more appropriate curative care; or
• Improved quality of life; or
• Improved survival?

The study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants’ health outcomes.

b. The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

c. The research study does not unjustifiably duplicate existing studies.

d. The research study design is appropriate to answer the research question being asked in the study.

e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.

f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it also must be in compliance with 21 CFR Parts 50 and 56.

g. All aspects of the research study are conducted according to the appropriate standards of scientific integrity.

h. The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards.

i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.

j. The clinical research study is registered on the www.ClinicalTrials.gov Web site by the principal sponsor/investigator prior to the enrollment of the first study subject.

k. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than three (3) years after the end of data collection.

l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented...
Consistent with section 1142 of the Social Security Act (the Act), the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that the Centers for Medicare and Medicaid Services (CMS) determines meet the above-listed standards and address the above-listed research questions.

C. Nationally Non-Covered Indications

Effective February 26, 2010, CMS determines that the evidence is not sufficient to determine that the results of NaF-18 PET imaging to identify bone metastases improve health outcomes of beneficiaries with cancer and is not reasonable and necessary under §1862(a)(1)(A) of the Act unless it is to inform initial antitumor treatment strategy or to guide subsequent antitumor treatment strategy after completion of initial treatment, and then only under CED. All other uses and clinical indications of NaF-18 PET are nationally non-covered.

D. Other

The only radiopharmaceutical diagnostic imaging agents covered by Medicare for PET cancer imaging are 2-[F-18] Fluoro-D-Glucose (FDG) and NaF-18 (sodium fluoride-18). All other PET radiopharmaceutical diagnostic imaging agents are non-covered for this indication.

(This NCD was last reviewed in February 2010.)

220.7—Xenon Scan


Effective December 18, 2014, NCD 220.7 is deleted.

230.5—Gravlee Jet Washer

(Rev. 1, 10-03-03)

CIM 50-4

The Gravlee Jet Washer is a sterile, disposable, diagnostic device for detecting endometrial cancer. The use of this device is indicated where the patient exhibits clinical symptoms or signs suggestive of endometrial disease, such as irregular or heavy vaginal bleeding.

Program payment cannot be made for the washer or the related diagnostic services when furnished in connection with the examination of an asymptomatic patient. Payment for routine physical checkups is precluded under the statute. (See §1862(a)(7) of the Act.)

(See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions From Coverage," §90).

230.7—Water Purification and Softening Systems Used in Conjunction With Home Dialysis


A. Water Purification Systems

Water used for home dialysis should be chemically free of heavy trace metals and/or organic contaminants that could be hazardous to the patient. It should also be as free of bacteria as possible but need not be biologically sterile. Since the characteristics of natural water supplies in most areas of the country are such that some type of water purification system is needed, such a system used in conjunction with a home dialysis (either peritoneal or hemodialysis) unit is covered under Medicare.

There are two types of water purification systems that will satisfy these requirements:

- Deionization—The removal of organic substances, mineral salts of magnesium and calcium (causing hardness), compounds of fluoride and chloride from tap water using the process of filtration and ion exchange; or
- Reverse Osmosis (RO)—The process used to remove impurities from tap water utilizing pressure to force water through a porous membrane.

Use of both a deionization unit and RO unit in series, theoretically to provide the advantages of both systems, has been determined medically unnecessary since either system can provide water which is both chemically and bacteriologically pure enough for acceptable use in home dialysis. In addition, spare deionization tanks are not covered since they are essentially a precautionary supply rather than a current requirement for treatment of the patient.

Activated carbon filters used as a component of water purification systems to remove unsafe concentrations of chlorine and chloramines are covered when prescribed by a physician.

B. Water Softening System

Except as indicated below, a water softening system used in conjunction with home dialysis is excluded from coverage under Medicare as not being reasonable and necessary within the meaning of §1862(a)(1) of the Social Security Act. Such a system, in conjunction with a home dialysis unit, does not adequately remove the hazardous heavy metal contaminants (such as arsenic) which may be present in trace amounts.

A water softening system may be covered when used to pretreat water to be purified by a RO unit for home dialysis where:

The manufacturer of the RO unit has set standards for the quality of water entering the RO (e.g., the water to be purified by the RO must be of a certain quality if the unit is to perform as intended);
The patient’s water is demonstrated to be of a lesser quality than required; and

The softener is used only to soften water entering the RO unit, and thus, used only for dialysis. (The softener need not actually be built into the RO unit, but must be an integral part of the dialysis system.)

C. Developing Need When a Water Softening System is Replaced with a Water Purification Unit in an Existing Home Dialysis System

The medical necessity of water purification units must be carefully developed when they replace water softening systems in existing home dialysis systems. A purification system may be ordered under these circumstances for a number of reasons. For example, changes in the medical community’s opinions regarding the quality of water necessary for safe dialysis may lead the physician to decide that the quality of water previously used should be improved, or the water quality itself may have deteriorated. Patients may have dialyzed using only an existing water softener previous to Medicare end-stage renal disease coverage because of inability to pay for a purification system. On the other hand, in some cases, the installation of a purification system is not medically necessary. Thus, when such a case comes to the Medicare Administrative Contractor’s (MAC’s) attention, the MAC asks the physician to furnish the reason for the changes. Supporting documentation, such as the suppliers’ recommendations or water analysis, may be required. All such cases should be reviewed by the MAC’s medical consultants.

Cross reference:

The Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,”§110.

230.8—Non-Implantable Pelvic Flood Electrical Stimulator

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 60-24

Non-implantable pelvic floor electrical stimulators provide neuromuscular electrical stimulation through the pelvic floor with the intent of strengthening and exercising pelvic floor musculature. Stimulation is generally delivered by vaginal or anal probes connected to an external pulse generator.

The methods of pelvic floor electrical stimulation vary in location, stimulus frequency (Hz), stimulus intensity or amplitude (mA), pulse duration (duty cycle), treatments per day, number of treatment days per week, length of time for each treatment session, overall time period for device use and between clinic and home settings. In general, the stimulus frequency and other parameters are chosen based on the patient’s clinical diagnosis.

Pelvic floor electrical stimulation with a non-implantable stimulator is covered for the treatment of stress and/or urge urinary incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training.

A failed trial of PME training is defined as no clinically significant improvement in urinary continence after completing 4 weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.

230.12—Dimethyl Sulfoxide (DMSO)

(Rev. 1, 10-03-03)

CIM 45-23

DMSO is an industrial solvent produced as a chemical by-product of paper production from wood pulp. The Food and Drug Administration has determined that the only purpose for which DMSO is safe and effective for humans is in the treatment of the bladder condition, interstitial cystitis. Therefore, the use of DMSO for all other indications is not considered to be reasonable and necessary. Payment may be made for its use only when reasonable and necessary for a patient in the treatment of interstitial cystitis.

230.16—Bladder Stimulators (Pacemakers)

(Rev. 1, 10-03-03)

CIM 65-11

Not Covered

There are a number of devices available to induce emptying of the urinary bladder by using electrical current which forces the muscles of the bladder to contract. These devices (commonly known as bladder stimulators or pacemakers) are characterized by the implantation of electrodes in the wall of the bladder, the rectal cones, or the spinal cord. While these treatments may effectively empty the bladder, the issue of safety involving the initiation of infection, erosion, placement, and material selection has not been resolved. Further, some facilities previously using electronic emptying have stopped using this method due to the pain experienced by the patient.

The use of spinal cord electrical stimulators, rectal electrical stimulators, and bladder wall stimulators is not considered reasonable and necessary. Therefore, no program payment may be made for these devices or for their implant.

230.17—Urinary Drainage Bags

(Rev. 1, 10-03-03)

CIM 65-17

Urinary collection and retention systems are covered as prosthetic devices that replace bladder function in the case of permanent urinary incontinence. Urinary drainage bags that can be used either as bedside or leg drainage bags may be either multi-use or single use systems. Both the multi-use and the single use bags have a system that prevents urine backflow. However, the single use system is non-drainable. There is insufficient evidence to support the medical necessity of a single use system bag rather than the multi-use bag. Therefore, a single use drainage system is subject to the same coverage parameters as the multi-use drainage bags.

240.2—Home Use of Oxygen


A. General

Medicare coverage of home oxygen and oxygen equipment under the durable medical equipment (DME) benefit (see §1861(s)(6)of the Social Security Act) is considered reasonable
and necessary only for patients with significant hypoxemia who meet the medical documentation, laboratory evidence, and health conditions specified in subsections B, C, and D. This section also includes special coverage criteria for portable oxygen systems. Finally, a statement on the absence of coverage of the professional services of a respiratory therapist under the DME benefit is included in subsection F.

B. Medical Documentation

Initial claims for oxygen services must include a completed Form CMS-484 (Certificate of Medical Necessity: Oxygen) to establish whether coverage criteria are met and to ensure that the oxygen services provided are consistent with the physician's prescription or other medical documentation. The treating physician's prescription or other medical documentation must indicate that other forms of treatment (e.g., medical and physical therapy directed at secretions, bronchospasm and infection) have been tried, have not been sufficiently successful, and oxygen therapy is still required. While there is no substitute for oxygen therapy, each patient must receive optimum therapy before long-term home oxygen therapy is ordered. Use Form CMS-484 for recertifications. (See the Medicare Program Integrity Manual, Chapter 5, for completion of Form CMS-484.)

The medical and prescription information in section B of Form CMS-484 can be completed only by the treating physician, the physician's employee, or another clinician (e.g., nurse, respiratory therapist, etc.) as long as that person is not the DME supplier. Although hospital discharge coordinators and medical social workers may assist in arranging for physician-prescribed home oxygen, they do not have the authority to prescribe the services. Suppliers may not enter this information. While this section may be completed by non-physician clinician or a physician employee, it must be reviewed and the Form CMS-484 signed by the attending physician.

A physician's certification of medical necessity for oxygen equipment must include the results of specific testing before coverage can be determined.

Claims for oxygen must also be supported by medical documentation in the patient's record. Separate documentation is used with electronic billing. This documentation may be in the form of a prescription written by the patient's attending physician who has recently examined the patient (normally within a month of the start of therapy) and must specify:

- A diagnosis of the disease requiring home use of oxygen;
- The oxygen flow rate; and
- An estimate of the frequency, duration of use (e.g., 2 liters per minute, 10 minutes per hour, 12 hours per day), and duration of need (e.g., 6 months or lifetime).

NOTE: A prescription for "Oxygen PRN" or "Oxygen as needed" does not meet this last requirement. Neither provides any basis for determining if the amount of oxygen is reasonable and necessary for the patient.

A member of the A/B MAC (B) medical staff should review all claims with oxygen flow rates of more than four liters per minute before payment can be made.

The attending physician specifies the type of oxygen delivery system to be used (i.e., gas, liquid, or concentrator) by signing the completed Form CMS-484. In addition, the supplier or physician may use the space in section C for written confirmation of additional details of the physician's order. The additional order information contained in section C may include the means of oxygen delivery (mask, nasal, cannula, etc.), the specifics of varying flow rates, and/or the noncontinuous use of oxygen as appropriate. The physician confirms this order information with their signature in section D.

New medical documentation written by the patient's attending physician must be submitted to the A/B MAC (B) in support of revised oxygen requirements when there has been a change in the patient's condition and need for oxygen therapy.

A/B MAC (B) are required to conduct periodic, continuing medical necessity reviews on patients whose conditions warrant these reviews and on patients with indefinite or extended periods of necessity as described in the Medicare Program Integrity Manual, Chapter 5, “Items and Services Having Special DMERC Review Considerations.” When indicated, A/B MAC (B) may also request documentation of the results of a repeat arterial blood gas or oximetry study.

NOTE: Section 4152 of OBRA 1990 requires earlier recertification and retesting of oxygen patients who begin coverage with an arterial blood gas result at or above a partial pressure of 55 or an arterial oxygen saturation percentage at or above 89. (See the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS), §100.2.3, for certification and retesting schedules.)

C. Laboratory Evidence

Initial claims for oxygen therapy must also include the results of a blood gas study that has been ordered and evaluated by the attending physician. This is usually in the form of a measurement of the partial pressure of oxygen (PO2) in arterial blood. A measurement of arterial oxygen saturation obtained by ear or pulse oximetry, however, is also acceptable when ordered and evaluated by the attending and performed under his or her supervision or when performed by a qualified provider or supplier of laboratory services.

When the arterial blood gas and the oximetry studies are both used to document the need for home oxygen therapy and the results are conflicting, the arterial blood gas study is the preferred source of documenting medical need. A DME supplier is not considered a qualified provider or supplier of laboratory services for purposes of these guidelines.

This prohibition does not extend to the results of blood gas test conducted by a hospital certified to do such tests. The conditions under which the laboratory tests are performed must be specified in writing and submitted with the initial claim, i.e., at rest, during exercise, or during sleep.

The preferred sources of laboratory evidence are existing physician and/or hospital records that reflect the patient’s medical condition. Since it is expected that virtually all patients who qualify for home oxygen coverage for the first time under these guidelines have recently been discharged from a hospital where they submitted to arterial blood gas tests, the A/B MACs (B) needs to request that such test results be submitted in support of their initial claims for home oxygen. If more than one arterial blood gas test is performed during the patient’s hospital stay, the test result obtained closest to, but no earlier than two days prior to the
hospital discharge date is required as evidence of the need for home oxygen therapy.

For those patients whose initial oxygen prescription did not originate during a hospital stay, blood gas studies should be done while the patient is in the chronic stable state, i.e., not during a period of an acute illness or an exacerbation of their underlying disease.

A/B MACs (B) may accept an attending physician’s statement of recent hospital test results for a particular patient, when appropriate, in lieu of copies of actual hospital records.

A repeat arterial blood gas study is appropriate when evidence indicates that an oxygen recipient has undergone a major change in their condition relevant to home use of oxygen. If the A/B MACs (B) has reason to believe that there has been a major change in the patient’s physical condition, it may ask for documentation of the results of another blood gas or oximetry study.

D. Health Conditions

Coverage is available for patients with significant hypoxemia in the chronic stable state, i.e., not during a period of acute illness or an exacerbation of their underlying disease, if:

1) The attending physician has determined that the patient has a health condition outlined in subsection D.1,
2) The patient meets the blood gas evidence requirements specified in subsection D.3, and
3) The patient has appropriately tried other treatment without complete success. (See subsection B.)

1. Conditions for Which Oxygen Therapy May Be Covered

- A severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm, or
- Hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy. Examples of these symptoms and findings are pulmonary hypertension, recurring congestive heart failure due to chronic cor pulmonale, erythrocytosis, impairment of the cognitive process, nocturnal restlessness, and morning headache.

2. Conditions for Which Oxygen Therapy Is Not Covered

- Angina pectoris in the absence of hypoxemia. This condition is generally not the result of a low oxygen level in the blood, and there are other preferred treatments;
- Breathlessness without cor pulmonale or evidence of hypoxemia. Although intermittent oxygen use is sometimes prescribed to relieve this condition, it is potentially harmful and psychologically addicting;
- Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities. There is no evidence that increased PO2 improves the oxygenation of tissues with impaired circulation; or
- Terminal illnesses that do not affect the lungs.

3. Covered Blood Gas Values

If the patient has a condition specified in subsection D.1, the A/B MACs (B) must review the medical documentation and laboratory evidence that has been submitted for a particular patient (see subsections B and C) and determine if coverage is available under one of the three group categories outlined below.

(a)—Group I—Except as modified in subsection d, coverage is provided for patients with significant hypoxemia evidenced by any of the following:

- An arterial PO2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88%, taken at rest, breathing room air;
- An arterial PO2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88%, taken during sleep for a patient who demonstrates an arterial PO2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89%, while awake; or a greater than normal fall in oxygen level during sleep (a decrease in arterial PO2 more than 10 mm Hg, or decrease in arterial oxygen saturation more than 5%) associated with symptoms or signs reasonably attributable to hypoxemia (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia). In either of these cases, coverage is provided only for use of oxygen during sleep, and then only one type of unit will be covered. Portable oxygen, therefore, would not be covered in this situation.

(b)—Group II—Except as modified in subsection d, coverage is available for patients whose arterial PO2 is 56-59 mm Hg or whose arterial blood oxygen saturation is 89%, if there is evidence of:

- Dependent edema suggesting congestive heart failure;
- Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or “P” pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF); or
- Erythrocythemia with a hematocrit greater than 56%.

(c)—Group III—Except as modified in subsection d, A/B MACs (B) must apply a rebuttable presumption that a home program of oxygen use is not medically necessary for patients with arterial PO2 levels at or above 60 mm Hg, or arterial blood oxygen saturation at or above 90%. In order for claims in this category to be reimbursed, the A/B MACs (B) reviewing physician needs to review any documentation submitted in rebuttal of this presumption and grant specific approval of the claims.

The Centers for Medicare & Medicaid expects few claims to be approved for coverage in this category.

(d)—Variable Factors That May Affect Blood Gas Values—In reviewing the arterial PO2 levels and the arterial oxygen saturation percentages specified in subsections D.3.a, b and c, the A/B MAC (B) medical staff must take into account variations in oxygen measurements that may result from such
factors as the patient’s age, the altitude level, or the patient’s decreased oxygen carrying capacity.

E. Portable Oxygen Systems

A patient meeting the requirements specified below may qualify for coverage of a portable oxygen system either (1) by itself or (2) to use in addition to a stationary oxygen system. Portable oxygen is not covered when it is provided only as a backup to a stationary oxygen system. A portable oxygen system is covered for a particular patient if:

- The claim meets the requirements specified in subsections A-D, as appropriate; and
- The medical documentation indicates that the patient is mobile in the home and would benefit from the use of a portable oxygen system in the home. Portable oxygen systems are not covered for patients who qualify for oxygen solely based on blood gas studies obtained during sleep.

F. Respiratory Therapists

Respiratory therapists’ services are not covered under the provisions for coverage of oxygen services under the Part B DME benefit as outlined above. This benefit provides for coverage of home use of oxygen and oxygen equipment, but does not include a professional component in the delivery of such services.

(See §280.1, and the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,”§110).

240.2.1—Home Use of Oxygen in Approved Clinical Trials
(Effective March 20, 2006)

(Rev. 57, Issued: 05-26-06; Effective: 03-20-06; Implementation: 10-03-06 Carriers/10-02-06 FIs)

A. General

Oxygen is a colorless, odorless gas that comprises 21 percent of the atmospheric gases at sea level. Historically, long term supplemental oxygen has been administered in higher than atmospheric concentrations to patients with chronic hypoxemia, generally resulting from cardiac and/or pulmonary disease. The need for supplemental oxygen is assessed by direct or indirect measurement of the partial pressure of oxygen (conventionally expressed in millimeters of mercury, mmHg) and the oxygen saturation of hemoglobin in arterial blood (expressed as a percent). Chronic oxygen therapy is generally administered via nasal cannulae, face mask, or tracheostomy, from a stationary or portable oxygen tank or an oxygen concentrator.

The medical literature documents health benefits as well as serious adverse events associated with supplemental oxygen use. In this light, it is clear that the decision to initiate, continue, or discontinue the use of supplemental oxygen should be guided by high quality scientific evidence.

B. Nationally Covered Indications

Effective for services performed on or after March 20, 2006 the home use of oxygen is covered for those beneficiaries with arterial oxygen partial pressure measurements from 56 to 65 mmHg or oxygen saturation at or above 89% who are enrolled subjects in clinical trials approved by the Centers for Medicare & Medicaid Services and sponsored by the National Heart, Lung & Blood Institute (NHLBI).

C. Nationally Non-Covered Indications

N/A

D. Other

This policy does not alter Medicare coverage for items and services that may be covered or non-covered according to the existing national coverage determination for the home use of oxygen provided outside the context of approved clinical trials (National Coverage Determination Manual, section 240.2 and 310.1).

(This NCD was last reviewed April 2006)

250.1—Treatment of Psoriasis
(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation of ICD-10; Implementation: Upon Implementation of ICD-10)

Psoriasis is a chronic skin disease, for which several conventional methods of treatment have been recognized as covered. These include topical application of steroids or other drugs; ultraviolet light (actinotherapy); and coal tar alone or in combination with ultraviolet B light (Goeckerman treatment).

A newer treatment for psoriasis uses a psoralen derivative drug in combination with ultraviolet A light, known as PUVA. PUVA therapy is covered for treatment of intractable, disabling psoriasis, but only after the psoriasis has not responded to more conventional treatment. The Medicare Administrative Contractor should document this before paying for PUVA therapy.

In addition, reimbursement for PUVA therapy should be limited to amounts paid for other types of photochemotherapy; ordinarily, payment should not be allowed for more than 30 days of treatment, unless improvement is documented.

260.3—Pancreas Transplants
(Effective April 26, 2006)

(Rev. 56, Issued: 05-19-06, Effective: 04-26-06, Implementation: 07-03-06 Carriers/10-02-06 FIs)

A. General

Pancreas transplantation is performed to induce an insulin-independent, euglycemic state in diabetic patients. The procedure is generally limited to those patients with severe secondary complications of diabetes, including kidney failure. However, pancreas transplantation is sometimes performed on patients with labile diabetes and hypoglycemic unawareness.

B. Nationally Covered Indications

Effective for services performed on or after July 1, 1999, whole organ pancreas transplantation is nationally covered by Medicare when performed simultaneous with or after a kidney transplant. If the pancreas transplant occurs after the kidney transplant, immunosuppressive therapy begins with the date of discharge from the inpatient stay for the pancreas transplant.
The transplant is performed on patients with Type 1 diabetes. A typical islet cell transplant requires over 500,000 islet cells, but varies depending on the recipient’s weight. One of the desired patient outcomes is insulin independence. Elimination of clinically significant hypoglycemia episodes and improved glucose control are other important patient outcomes.

One or more pancreata are obtained from donor(s). The islets must be removed within hours after the recovery of the donor pancreas to ensure viability. The islet cells are transplanted by injection into the portal vein of the recipient either using direct visualization, guided ultrasound or percutaneously. The islet cell transplant may be performed alone, in combination with a kidney transplant, or after a kidney transplant. Islet recipients require immunosuppressant therapy to prevent rejection of the transplanted islet cells. Routine follow-up care is necessary for each trial participant.

B. Nationally Covered Indications

Medicare will pay for the routine costs, as well as transplantation and appropriate related items and services, for Medicare beneficiaries participating in a National Institutes of Health (NIH)-sponsored clinical trial(s). The term ‘routine costs’ means reasonable and necessary routine patient care costs, including immunosuppressive drugs and other follow-up care, as defined in section 310.1 of the NCD Manual.

Specifically, Medicare will cover transplantation of pancreatic islet cells, the insulin producing cells of the pancreas. Coverage will include the costs of acquisition and delivery of the pancreatic islet cells, as well as clinically necessary inpatient and outpatient medical care and immunosuppressants.

C. Nationally Noncovered Indications

Partial pancreatic tissue transplantation or islet cell transplantation performed outside the context of a clinical trial continues to be noncovered.

D. Other

Not applicable.

(This NCD last reviewed July 2004.)

260.6—Dental Examination Prior to Kidney Transplantation

(Rev. 1, 10-03-03)

CIM 50-26

Despite the “dental services exclusion” in §1862(a)(12) of the Act (see the Medicare Benefit Policy Manual, Chapter 16, “General Exclusions From Coverage,” §140), an oral or dental examination performed on an inpatient basis as part of a comprehensive workup prior to renal transplant surgery is a covered service. This is because the purpose of the examination is not for the care of the teeth or structures directly supporting the teeth. Rather, the examination is for the identification, prior to a complex surgical procedure, of existing medical problems where the increased possibility of infection would not only reduce the chances for successful surgery but would also expose the patient to additional risks in undergoing such surgery.

Effective for services performed on or after April 26, 2006, pancreas transplants alone (PA) are reasonable and necessary for Medicare beneficiaries in the following limited circumstances:

1. PA will be limited to those facilities that are Medicare-approved for kidney transplantation. (Approved centers can be found at http://www.cms.hhs.gov/ESRDGeneralInformation/02_Data.asp#TopOfPage.)

2. Patients must have a diagnosis of type 1 diabetes:
   - Patient with diabetes must be beta cell autoantibody positive; or
   - Patient must demonstrate insulinopenia defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method. Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose <225 mg/dL.

3. Patients must have a history of medically-uncontrollable labile (brittle) insulin-dependent diabetes mellitus with documented recurrent, severe, acutely life threatening metabolic complications that require hospitalization. Aforementioned complications include frequent hypoglycemia unawareness or recurring severe ketoacidosis, or recurring severe hypoglycemic attacks;

4. Patients must have been optimally and intensively managed by an endocrinologist for at least 12 months with the most medically-recognized advanced insulin formulations and delivery systems;

5. Patients must have the emotional and mental capacity to understand the significant risks associated with surgery and to effectively manage the lifelong need for immunosuppression; and,

6. Patients must otherwise be a suitable candidate for transplantation.

C. Nationally Non-Covered Indications

The following procedure is not considered reasonable and necessary within the meaning of section 1862(a)(1)(A) of the Social Security Act:

1. Transplantation of partial pancreatic tissue or islet cells (except in the context of a clinical trial (see section 260.3.1 of the National Coverage Determinations Manual).

D. Other

Not applicable.

(Rev. 18, Issued 07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

A. General

As a result of section 733 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (P.L. 108-173), The Secretary of the Department of Health and Human Services, acting through the National Institute of Diabetes and Digestive and Kidney Disorders, shall conduct a clinical investigation of pancreatic islet cell transplantation that includes Medicare beneficiaries.

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Such a dental or oral examination would be covered under Part A of the program if performed by a dentist on the hospital's staff, or under Part B if performed by a physician. (When performing a dental or oral examination, a dentist is not recognized as a physician under §1861(r) of the Act.) (See the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, "Definitions," §70.2, and the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §150.)


Electrical stimulation (ES) and electromagnetic therapy have been used or studied for many different applications, one of which is accelerating wound healing. ES for the treatment of wounds is the application of electrical current through electrodes placed directly on the skin in close proximity to the wound. Electromagnetic therapy uses a pulsed magnetic field to induce current. The Centers for Medicare & Medicaid Services (CMS) was asked to reconsider its national non-coverage determination for electromagnetic therapy. After thorough review, CMS determined that the results from the use of electromagnetic therapy for the treatment of wounds were similar to the results from the use of ES. Therefore, effective July 1, 2004, Medicare will cover electromagnetic therapy for the same settings and conditions for which ES is covered. This means Medicare will allow either one covered ES therapy or one covered electromagnetic therapy for the treatment of wounds.

A. Nationally Covered Indications

The use of ES and electromagnetic therapy for the treatment of wounds are considered adjunctive therapies, and will only be covered for chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers. Chronic ulcers are defined as ulcers that have not healed within 30 days of occurrence. ES or electromagnetic therapy will be covered only after appropriate standard wound therapy has been tried for at least 30 days and there are no measurable signs of improved healing. This 30-day period may begin while the wound is acute.

Standard wound care includes: optimization of nutritional status, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, and necessary treatment to resolve any infection that may be present. Standard wound care based on the specific type of wound includes: frequent repositioning of a patient with pressure ulcers (usually every 2 hours), offloading of pressure and good glucose control for diabetic ulcers, establishment of adequate circulation for arterial ulcers, and the use of a compression system for patients with venous ulcers.

Measurable signs of improved healing include: a decrease in wound size (either surface area or volume), decrease in amount of exudates, and decrease in amount of necrotic tissue. ES or electromagnetic therapy must be discontinued when the wound demonstrates 100% epithelialized wound bed.

The ES and electromagnetic therapy services can only be covered when performed by a physician, physical therapist, or incident to a physician service. Evaluation of the wound is an integral part of wound therapy. When a physician, physical therapist, or a clinician incident to a physician, performs ES or electromagnetic therapy, the practitioner must evaluate the wound and contact the treating physician if the wound worsens. If ES or electromagnetic therapy is being used, wounds must be evaluated at least monthly by the treating physician.

B. Nationally Non-Covered Indications

1. ES and electromagnetic therapy will not be covered as an initial treatment modality.
2. Continued treatment with ES or electromagnetic therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.
3. Unsupervised use of ES or electromagnetic therapy for wound therapy will not be covered, as this use has not been found to be medically reasonable and necessary.

C. Other

All other uses of ES and electromagnetic therapy not otherwise specified for the treatment of wounds remain at local Medicare Administrative Contractor discretion.


The durable medical equipment (DME) list that follows is designed to facilitate the Medicare Administrative Contractor's (MAC's) processing of DME claims. This section is designed as a quick reference tool for determining the coverage status of certain pieces of DME and especially for those items commonly referred to by both brand and generic names. The information contained herein is applicable (where appropriate) to all DME national coverage determinations (NCDs) discussed in the DME portion of this manual. The list is organized into two columns. The first column lists alphabetically various generic categories of equipment on which NCDs have been made by the Centers for Medicare & Medicaid Services (CMS); the second column notes the coverage status.

In the case of equipment categories that have been determined by CMS to be covered under the DME benefit, the list outlines the conditions of coverage that must be met if payment is to be allowed for the rental or purchase of the DME by a particular patient, or cross-refers to another section of the manual where the applicable coverage criteria are described in more detail. With respect to equipment categories that cannot be covered as DME, the list includes a brief explanation of why the equipment is not covered. This DME list will be updated periodically to reflect any additional NDCs that CMS may make with regard to other categories of equipment.

When the MAC receives a claim for an item of equipment which does not appear to fall logically into any of the generic categories listed, the MAC has the authority and responsibility for deciding whether those items are covered under the DME benefit.
These decisions must be made by each MAC based on the advice of its medical consultants, taking into account:

- The Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)."
- Whether the item has been approved for marketing by the Food and Drug Administration (FDA) and is otherwise generally considered to be safe and effective for the purpose intended; and
- Whether the item is reasonable and necessary for the individual patient.

The term DME is defined as equipment which:

- Can withstand repeated use; i.e., could normally be rented, and used by successive patients;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of illness or injury; and
- Is appropriate for use in a patient's home.

### Durable Medical Equipment Reference List

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<td>(See Intermittent Positive Pressure Breathing Machines.)</td>
</tr>
<tr>
<td>Fomentation Devices</td>
<td>(See Heating Pads.)</td>
</tr>
<tr>
<td>Gel Flotation Pads and Mattresses</td>
<td>(See Alternating Pressure Pads and Mattresses.)</td>
</tr>
<tr>
<td>Grab Bars</td>
<td>Deny—self-help device; not primarily medical in nature (§1861(n) of the Act).</td>
</tr>
<tr>
<td>Heat and Massage Foam Cushion Pads</td>
<td>Deny—not primarily medical in nature; personal comfort item (§1861(n) and 1862(a)(6) of the Act).</td>
</tr>
<tr>
<td>Heating and Cooling Plants</td>
<td>Deny—environmental control equipment not primarily medical in nature (§1861(n) of the Act).</td>
</tr>
<tr>
<td>Heating Pads</td>
<td>Covered if MAC's medical staff determines patient's medical condition is one for which the application of heat in the form of a heating pad is therapeutically effective.</td>
</tr>
<tr>
<td>Heat Lamps</td>
<td>Covered if the MAC's medical staff determines patient's medical condition is one for which the application of heat in the form of a heat lamp is therapeutically effective.</td>
</tr>
<tr>
<td>Hospital Beds</td>
<td>(See §280.7 of this manual.)</td>
</tr>
<tr>
<td>Hot Packs</td>
<td>(See Heating Pads.)</td>
</tr>
<tr>
<td>Humidifiers (oxygen)</td>
<td>(See Oxygen Humidifiers.)</td>
</tr>
<tr>
<td>Humidifiers (room or central heating system types)</td>
<td>Deny—environmental control equipment; not medical in nature (§1861(n) of the Act).</td>
</tr>
<tr>
<td>Incontinent Pads</td>
<td>Deny—non-reusable supply; hygienic item (§1861(n) of the Act).</td>
</tr>
<tr>
<td>Infusion Pumps</td>
<td>For external and implantable pumps, see §40.2 of this manual. If pump is used with an enteral or parenteral nutritional therapy system, see §180.2 of this manual for special coverage rules.</td>
</tr>
<tr>
<td>Injectors (hypodermic jet)</td>
<td>Deny—not covered self-administered drug supply; pressure powered devices (§1861(a)(2)(A) of the Act) for injection of insulin.</td>
</tr>
<tr>
<td>Intermittent Positive Pressure Breathing Machines</td>
<td>Covered if patient's ability to breathe is severely impaired.</td>
</tr>
<tr>
<td>Iron Lungs</td>
<td>(See Ventilators.)</td>
</tr>
<tr>
<td>Irrigating Kits</td>
<td>Deny—non-reusable supply; hygienic equipment (§1861(n) of the Act).</td>
</tr>
<tr>
<td>Lamb's Wool Pads</td>
<td>(See Alternating Pressure Pads, Mattresses, and Lamb's Wool Pads).</td>
</tr>
<tr>
<td>Leotards</td>
<td>Deny—(See Pressure Leotards.) (§1861(n) of the Act).</td>
</tr>
<tr>
<td>Lymphedema Pumps</td>
<td>Covered (See Pneumatic Compression Devices, §280.6 of this manual.)</td>
</tr>
<tr>
<td>Massage Devices</td>
<td>Deny—personal comfort items; not primarily medical in nature (§1861(n) and 1862(a)(6) of this manual.)</td>
</tr>
<tr>
<td>Mattresses</td>
<td>Covered only where hospital bed is medically necessary. (Separate Charge for replacement mattress should not be allowed where hospital bed with mattress is rented.) (See §280.7 of this manual.)</td>
</tr>
<tr>
<td>Medical Oxygen Regulators</td>
<td>Covered if patient's ability to breathe is severely impaired. (See §240.2 of this manual.)</td>
</tr>
<tr>
<td>Mobile Geriatric Chairs</td>
<td>Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual). (See Rolling Chairs).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Motorized Wheelchairs</td>
<td>Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual).</td>
</tr>
<tr>
<td>Muscle Stimulators</td>
<td>Covered for certain conditions. (See §250.4 of this manual.)</td>
</tr>
<tr>
<td>Nebulizers</td>
<td>Covered if patient's ability to breathe is severely impaired.</td>
</tr>
<tr>
<td>Oscillating Beds</td>
<td>Deny—institutional equipment—inappropriate for home use.</td>
</tr>
<tr>
<td>Over-bed Tables</td>
<td>Deny—convenience item; not primarily medical in nature (§1861(n) of the Act).</td>
</tr>
<tr>
<td>Oxygen</td>
<td>Covered if oxygen has been prescribed for use in connection with medically necessary DME. (See §240.2 of this manual.)</td>
</tr>
<tr>
<td>Oxygen Humidifiers</td>
<td>Covered if oxygen has been prescribed for use in connection with medically necessary DME for purposes of moisturizing oxygen. (See §240.2 of this manual.)</td>
</tr>
<tr>
<td>Oxygen Regulators (Medical)</td>
<td>(See Medical Oxygen Regulators.)</td>
</tr>
<tr>
<td>Oxygen Tents</td>
<td>(See §240.2 of this manual.)</td>
</tr>
<tr>
<td>Paraffin Bath Units (Portable)</td>
<td>(See Portable Paraffin Bath Units.)</td>
</tr>
<tr>
<td>Paraffin Bath Units (Standard)</td>
<td>Deny—institutional equipment; inappropriate for home use.</td>
</tr>
<tr>
<td>Parallel Bars</td>
<td>Deny—support exercise equipment; primarily for institutional use; in the home setting other devices (e.g., walkers) satisfy the patient's need.</td>
</tr>
<tr>
<td>Patient Lifts</td>
<td>Covered if MAC's medical staff determines patient's condition is such that periodic movement is necessary to effect improvement or to arrest/retard deterioration in condition.</td>
</tr>
<tr>
<td>Percussors</td>
<td>Covered for mobilizing respiratory tract secretions in patients with chronic obstructive lung disease, chronic bronchitis, or emphysema, when patient/operator of powered percussor receives appropriate training by a physician/therapist, and no one competent to administer manual therapy is available.</td>
</tr>
<tr>
<td>Portable Oxygen Systems</td>
<td>1. Regulated Covered (adjustable covered under conditions specified in a flow rate). Refer all claims to medical staff for this determination.</td>
</tr>
<tr>
<td>Portable Paraffin Bath Units</td>
<td>2. Preset Deny (flow rate deny emergency, first-aid, or not adjustable precautionary equipment; essentially not therapeutic in nature.</td>
</tr>
<tr>
<td>Portable Room Heaters</td>
<td>Covered when patient has undergone a successful trial period of paraffin therapy ordered by a physician and patient's condition is expected to be relieved by long term use of this modality.</td>
</tr>
<tr>
<td>Portable Whirlpool Pumps</td>
<td>Deny—environmental control equipment; not primarily medical in nature (§1861(n) of the Act).</td>
</tr>
<tr>
<td>Postural Drainage Boards</td>
<td>Covered if patient has a chronic pulmonary condition.</td>
</tr>
<tr>
<td>Preset Portable Oxygen Units</td>
<td>Deny—emergency, first-aid, or precautionary equipment; essentially not therapeutic in nature.</td>
</tr>
<tr>
<td>Pressure Leotards</td>
<td>Deny—non-reusable supply, not rental-type item (§1861(n) of the Act).</td>
</tr>
<tr>
<td>Pulse Tachometers</td>
<td>Deny—not reasonable or necessary for monitoring pulse of homebound patient with/without a cardiac pacemaker.</td>
</tr>
<tr>
<td>Item</td>
<td>Coverage</td>
</tr>
<tr>
<td>-----------------------------</td>
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</tr>
<tr>
<td>Quad-Canes</td>
<td>Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual).</td>
</tr>
<tr>
<td>Raised Toilet Seats</td>
<td>Deny—convenience item; hygienic equipment; not primarily medical in nature (§1861(n) of the Act).</td>
</tr>
<tr>
<td>Reflectance Colorimeters</td>
<td>(See Blood Glucose Analyzers.)</td>
</tr>
<tr>
<td>Respirators</td>
<td>(See Ventilators.)</td>
</tr>
<tr>
<td>Rolling Chairs</td>
<td>Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual). Coverage is limited to those roll-about chairs having casters of at least 5 inches in diameter and specifically designed to meet the needs of ill, injured, or otherwise impaired individuals. Coverage is denied for the wide range of chairs with smaller casters as are found in general use in homes, offices, and institutions for many purposes not related to the care/treatment of ill/injured persons. This type is not primarily medical in nature. (§1861(n) of the Act.)</td>
</tr>
<tr>
<td>Safety Rollers</td>
<td>Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual).</td>
</tr>
<tr>
<td>Sauna Baths</td>
<td>Deny—not primarily medical in nature; personal comfort items (§1861(n) and (1862(a)(6) of the Act).</td>
</tr>
<tr>
<td>Seat Lifts</td>
<td>Covered under conditions specified in §260.4 of this manual. Refer all to medical staff for this determination.</td>
</tr>
<tr>
<td>Self Contained Pacemaker Monitors</td>
<td>Covered when prescribed by a physician for a patient with a cardiac pacemaker. (See §280.3.1 and 280.2 of this manual.)</td>
</tr>
<tr>
<td>Sitz Baths</td>
<td>Covered if the MAC’s medical staff determines patient has an infection or injury of the perineal area and the item has been prescribed by the patient’s physician as part of planned regimen of treatment in patient’s home.</td>
</tr>
<tr>
<td>Spare Tanks of Oxygen</td>
<td>Deny—convenience or precautionary supply.</td>
</tr>
<tr>
<td>Speech Teaching Machines</td>
<td>Deny—education equipment; not primarily medical in nature (§1861(n) of the Act).</td>
</tr>
<tr>
<td>Stairway Elevators</td>
<td>Deny—(See Elevators.) (§1861(n) of the Act).</td>
</tr>
<tr>
<td>Standing Tables</td>
<td>Deny—convenience item; not primarily medical in nature (§1861(n) of the Act).</td>
</tr>
<tr>
<td>Steam Packs</td>
<td>These packs are covered under same conditions as heating pads. (See Heating Pads.)</td>
</tr>
<tr>
<td>Suction Machines</td>
<td>Covered if the MAC’s medical staff determines that the machine specified in the claim is medically required and appropriate for home use without technical/professional supervision.</td>
</tr>
<tr>
<td>Support Hose</td>
<td>Deny (See Fabric Supports.) (§1861(n) of the Act).</td>
</tr>
<tr>
<td>Surgical Leggings</td>
<td>Deny—not-reusable supply; not rental-type item (§1861(n) of the Act).</td>
</tr>
<tr>
<td>Telephone Alert Systems</td>
<td>Deny—these are emergency communications systems and do not serve a diagnostic/therapeutic purpose.</td>
</tr>
<tr>
<td>Toilet Seats</td>
<td>Deny—not medical equipment (§1861(n) of the Act).</td>
</tr>
<tr>
<td>Traction Equipment</td>
<td>Covered if patient has orthopedic impairment requiring traction equipment that prevents ambulation during period of use. (Consider covering devices usable during ambulation; e.g., cervical traction collar, under brace provision.)</td>
</tr>
<tr>
<td>Trapeze Bars</td>
<td>Covered if patient is bed confined and needs a trapeze bar to sit up because of respiratory condition, to change body position for other medical reasons, or to get in/out of bed.</td>
</tr>
</tbody>
</table>

Cross-references:

Medicare Benefit Policy Manual, Chapters 13, “Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Services,” 15, “Covered Medical and Other Health Services,”


280.2—White Cane for Use by a Blind Person
(Rev. 1, 10-03-03)

**CIM 60-3**

Not Covered

A white cane for use by a blind person is more an identifying and self-help device than an item which makes a meaningful contribution in the treatment of an illness or injury.
280.3—Mobility Assistive Equipment (MAE) (Effective May 5, 2005)

(Rev. 37, Issued: 06-03-05; Effective: 05-05-05; Implementation: 07-05-05)

A. General

The Centers for Medicare & Medicaid Services (CMS) addresses numerous items that it terms "mobility assistive equipment" (MAE) and includes within that category canes, crutches, walkers, manual wheelchairs, power wheelchairs, and scooters. This list, however, is not exhaustive.

Medicare beneficiaries may require mobility assistance for a variety of reasons and for varying durations because the etiology of the disability may be due to a congenital cause, injury, or disease. Thus, some beneficiaries experiencing temporary disability may need mobility assistance on a short-term basis, while in contrast, those living with chronic conditions or enduring disabilities will require mobility assistance on a permanent basis.

Medicare beneficiaries who depend upon mobility assistance are found in varied living situations. Some may live alone and independently while others may live with a caregiver or in a custodial care facility. The beneficiary's environment is relevant to the determination of the appropriate form of mobility assistance that should be employed. For many patients, a device of some sort is compensation for the mobility deficit. Many beneficiaries experience co-morbid conditions that can impact their ability to safely utilize MAE independently or to successfully regain independent function even with mobility assistance.

The functional limitation as experienced by a beneficiary depends on the beneficiary's physical and psychological function, the availability of other support, and the beneficiary's living environment. A few examples include muscular spasticity, cognitive deficits, the availability of a caregiver, and the physical layout, surfaces, and obstacles that exist in the beneficiary's living environment.

B. Nationally Covered Indications

Effective May 5, 2005, CMS finds that the evidence is adequate to determine that MAE is reasonable and necessary for beneficiaries who have a personal mobility deficit sufficient to impair their participation in mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations within the home. Determination of the presence of a mobility deficit will be made by an algorithmic process, Clinical Criteria for MAE Coverage, to provide the appropriate MAE to correct the mobility deficit.

Clinical Criteria for MAE Coverage

The beneficiary, the beneficiary's family or other caregiver, or a clinician, will usually initiate the discussion and consideration of MAE use. Sequential consideration of the questions below provides clinical guidance for the coverage of equipment of appropriate type and complexity to restore the beneficiary's ability to participate in MRADLs such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home. These questions correspond to the numbered decision points on the accompanying flow chart. In individual cases where the beneficiary's condition clearly and unambiguously precludes the reasonable use of a device, it is not necessary to undertake a trial of that device for that beneficiary.

1. Does the beneficiary have a mobility limitation that significantly impairs his/her ability to participate in one or more MRADLs in the home? A mobility limitation is one that:
   a. Prevents the beneficiary from accomplishing the MRADLs entirely, or;
   b. Places the beneficiary at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to participate in MRADLs, or;
   c. Prevents the beneficiary from completing the MRADLs within a reasonable timeframe.

2. Are there other conditions that limit the beneficiary's ability to participate in MRADLs at home?
   a. Some examples are significant impairment of cognition or judgment and/or vision.
   b. For these beneficiaries, the provision of MAE might not enable them to participate in MRADLs if the comorbidity prevents effective use of the wheelchair or reasonable completion of the tasks even with MAE.

3. If these other limitations exist, can they be ameliorated or compensated sufficiently such that the additional provision of MAE will be reasonably expected to significantly improve the beneficiary's ability to perform or obtain assistance to participate in MRADLs in the home?
   a. A caregiver, for example a family member, may be compensatory, if consistently available in the beneficiary's home and willing and able to safely operate and transfer the beneficiary to and from the wheelchair and to transport the beneficiary using the wheelchair. The caregiver's need to use a wheelchair to assist the beneficiary in the MRADLs is to be considered in this determination.
   b. If the amelioration or compensation requires the beneficiary's compliance with treatment, for example medications or therapy, substantive non-compliance, whether willing or involuntary, can be grounds for denial of MAE coverage if it results in the beneficiary continuing to have a significant limitation. It may be determined that partial compliance results in adequate amelioration or compensation for the appropriate use of MAE.

4. Does the beneficiary or caregiver demonstrate the capability and the willingness to consistently operate the MAE safely?
   a. Safety considerations include personal risk to the beneficiary as well as risk to others. The determination of safety may need to occur several times during the process as the consideration focuses on a specific device.
   b. A history of unsafe behavior in other venues may be considered.

5. Can the functional mobility deficit be sufficiently resolved by the prescription of a cane or walker?
   a. The cane or walker should be appropriately fitted to the beneficiary for this evaluation.
   b. Assess the beneficiary's ability to safely use a cane or walker.

6. Does the beneficiary's typical environment support the use of wheelchairs including scooters/power-operated vehicles (POVs)?
   a. Determine whether the beneficiary's environment will support the use of these types of MAE.
   b. Keep in mind such factors as physical layout, surfaces, and obstacles, which may render MAE unusable in the beneficiary's home.
7. Does the beneficiary have sufficient upper extremity function to propel a manual wheelchair in the home to participate in MRADLs during a typical day? The manual wheelchair should be optimally configured (seating options, wheelchair, device weight, and other appropriate accessories) for this determination.
   a. Limitations of strength, endurance, range of motion, coordination, and absence or deformity in one or both upper extremities are relevant.
   b. A beneficiary with sufficient upper extremity function may qualify for a manual wheelchair. The appropriate type of manual wheelchair, i.e., light weight, etc., should be determined based on the beneficiary's physical characteristics and anticipated intensity of use.
   c. The beneficiary's home should provide adequate access, maneuvering space and surfaces for the operation of a manual wheelchair.
   d. Assess the beneficiary's ability to safely use a manual wheelchair.

NOTE: If the beneficiary is unable to self-propel a manual wheelchair, and if there is a caregiver who is available, willing, and able to provide assistance, a manual wheelchair may be appropriate.

8. Does the beneficiary have sufficient strength and postural stability to operate a POV/scooter?
   a. A POV is a 3- or 4-wheeled device with tiller steering and limited seat modification capabilities. The beneficiary must be able to maintain stability and position for adequate operation.
   b. The beneficiary's home should provide adequate access, maneuvering space and surfaces for the operation of a POV.
   c. Assess the beneficiary's ability to safely use a POV/scooter.

9. Are the additional features provided by a power wheelchair needed to allow the beneficiary to participate in one or more MRADLs?
   a. The pertinent features of a power wheelchair compared to a POV are typically control by a joystick or alternative input device, lower seat height for slide transfers, and the ability to accommodate a variety of seating needs.
   b. The type of wheelchair and options provided should be appropriate for the degree of the beneficiary's functional impairments.
   c. The beneficiary's home should provide adequate access, maneuvering space and surfaces for the operation of a power wheelchair.
   d. Assess the beneficiary's ability to safely use a power wheelchair.

NOTE: If the beneficiary is unable to use a power wheelchair, and if there is a caregiver who is available, willing, and able to provide assistance, a manual wheelchair is appropriate. A caregiver's inability to operate a manual wheelchair can be considered in covering a power wheelchair so that the caregiver can assist the beneficiary.

See Clinical Criteria for MAE Coverage flow chart on next page.

C. Nationally Non-Covered Indications

Medicare beneficiaries not meeting the clinical criteria for prescribing MAE as outlined above, and as documented by the beneficiary's physician, would not be eligible for Medicare coverage of the MAE.

D. Other

All other durable medical equipment (DME) not meeting the definition of MAE as described in this instruction will continue to be covered, or noncovered, as is currently described in the NCD Manual, in Section 280, Medical and Surgical Supplies. Also, all other sections not altered here and the corresponding policies regarding MAEs which have not been discussed here remain unchanged.

(This NCD last reviewed May 2005).


280.4—Seat Lift

(Rev. 1, 10-03-03)

CIM 60-8

Reimbursement may be made for the rental or purchase of a medically necessary seat lift when prescribed by a physician for a patient with severe arthritis of the hip or knee and patients with muscular dystrophy or other neuromuscular disease when it has been determined the patient can benefit therapeutically from use of the device. In establishing medical necessity for the seat lift, the evidence must show that the item is included in the physician's course of treatment, that it is likely to effect improvement, or arrest or retard deterioration in the patient's condition, and that the severity of the condition is such that the alternative would be chair or bed confinement.

Coverage of seat lifts is limited to those types which operate smoothly, can be controlled by the patient, and effectively assist a patient in standing up and sitting down without other assistance. Excluded from coverage is the type of lift which operates by a spring release mechanism with a sudden, catapult-like motion and jolts the patient from a seated to a standing position. Limit the payment for units which incorporate a recliner feature along with the seat lift to the amount payable for a seat lift without this feature.

Cross Reference:


280.7—Hospital Beds


A. General Requirements for Coverage of Hospital Beds

A physician's prescription, and such additional documentation as the Medicare Administrative Contractor (MAC) medical staff may consider necessary, including medical records and physicians' reports, must establish the medical necessity for a hospital bed due to one of the following reasons:

• The patient's condition requires positioning of the body; e.g., to alleviate pain, promote good body alignment, prevent contractures, avoid respiratory infections, in ways not feasible in an ordinary bed; or
• The patient’s condition requires special attachments that cannot be fixed and used on an ordinary bed.

**B. Physician’s Prescription**

The physician’s prescription which must accompany the initial claim, and supplementing documentation when required, must establish that a hospital bed is medically necessary. If the stated reason for the need for a hospital bed is the patient’s condition requires positioning, the prescription or other documentation must describe the medical condition, e.g., cardiac disease, chronic obstructive pulmonary disease, quadriplegia or paraplegia, and also the severity and frequency of the symptoms of the condition, that necessitates a hospital bed for positioning.

If the stated reason for requiring a hospital bed is the patient’s condition requires special attachments, the prescrip-
IOM 100-03 CHAPTER 1, PART 4

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would be reasonable for a conventional truss used for the charge for this item is substantially in excess of that which benefit when dealing with a reducible hernia.) Thus, when a ordinary truss would be covered. (Like all trusses, it is only of is not functionally more beneficial than a conventional truss. Make program reimbursement for this device only when an sykes hernia control (a spring-type, U-shaped, strapless truss) Based on professional advice, it has been determined that the

C. Variable Height Feature

In well documented cases, the MAC medical staff may determine that a variable height feature of a hospital bed, approved for coverage under subsection A above, is medically necessary and, therefore, covered, for one of the following conditions:

- Severe arthritis and other injuries to lower extremities; e.g., fractured hip—The condition requires the variable height feature to assist the patient to ambulate by enabling the patient to place his or her feet on the floor while sitting on the edge of the bed;
- Severe cardiac conditions—For those cardiac patients who are able to leave bed, but who must avoid the strain of "jumping" up or down;
- Spinal cord injuries, including quadriplegic and paraplegic patients, multiple limb amputee and stroke patients. For those patients who are able to transfer from bed to a wheelchair; with or without help; or
- Other severely debilitating diseases and conditions, if the variable height feature is required to assist the patient to ambulate.

D. Electric Powered Hospital Bed Adjustments

Electric powered adjustments to lower and raise head and foot may be covered when the MAC medical staff determines that the patient's condition requires frequent change in body position and/or there may be an immediate need for a change in body position (i.e., no delay can be tolerated) and the patient can operate the controls and cause the adjustments. Exceptions may be made to this last requirement in cases of spinal cord injury and brain damaged patients.

E. Side Rails

If the patient's condition requires bed side rails, they can be covered when an integral part of, or an accessory to, a hospital bed.

280.11—Corset Used as Hernia Support
(Rev. 1, 10-03-03)

CIM 70-1
A hernia support (whether in the form of a corset or truss) which meets the definition of a brace is covered under Part B under §1861(s)(9) of the Act. See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Services,"§130.

280.12—Sykes Hernia Control
(Rev. 1, 10-03-03)

CIM 70-2
Based on professional advice, it has been determined that the sykes hernia control (a spring-type, U-shaped, strapless truss) is not functionally more beneficial than a conventional truss. Make program reimbursement for this device only when an ordinary truss would be covered. (Like all trusses, it is only of benefit when dealing with a reducible hernia.) Thus, when a charge for this item is substantially in excess of that which would be reasonable for a conventional truss used for the same condition, base reimbursement on the reasonable charges for the conventional truss. See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Services,"§130.

280.14—Infusion Pumps

A. General

Infusion pumps are medical devices used to deliver solutions containing parenteral drugs under pressure at a regulated flow rate.

B. Nationally Covered Indications

The following indications for treatment using infusion pumps are covered under Medicare:

1. External Infusion Pumps

   a. Iron Poisoning (Effective for Services Performed On or After September 26, 1984)

When used in the administration of deferoxamine for the treatment of acute iron poisoning and iron overload, only external infusion pumps are covered.

   b. Thromboembolic Disease (Effective for Services Performed On or After September 26, 1984)

When used in the administration of heparin for the treatment of thromboembolic disease and/or pulmonary embolism, only external infusion pumps used in an institutional setting are covered.

   c. Chemotherapy for Liver Cancer (Effective for Services Performed On or After January 29, 1985)

The external chemotherapy infusion pump is covered when used in the treatment of primary hepatocellular carcinoma or colorectal cancer where this disease is unresectable; OR, where the patient refuses surgical excision of the tumor.

   d. Morphine for Intractable Cancer Pain (Effective for Services Performed On or After April 22, 1985)

Morphine infusion via an external infusion pump is covered when used in the treatment of intractable pain caused by cancer (in either an inpatient or outpatient setting, including a hospice).

   e. Continuous Subcutaneous Insulin Infusion (CSII) Pumps (Effective for Services Performed On or After December 17, 2004)

Continuous subcutaneous insulin infusion (CSII) and related drugs/supplies are covered as medically reasonable and necessary in the home setting for the treatment of diabetic patients who: (1) either meet the updated fasting C-Peptide testing requirement, or; are beta cell autoantibody positive; and, (2) satisfy the remaining criteria for insulin pump therapy as described below. Patients must meet either Criterion A or B as follows:

Criterion A: The patient has completed a comprehensive diabetes education program, and has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per
day), with frequent self-adjustments of insulin doses for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria while on the multiple daily injection regimen:

- Glycosylated hemoglobin level (HbA1c) > 7.0%
- History of recurring hypoglycemia;
- Wide fluctuations in blood glucose before mealtime;
- Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; or
- History of severe glycemic excursions

**Criterion B:** The patient with diabetes has been on a pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment.

### General CSII Criteria

In addition to meeting Criterion A or B above, the following general requirements must be met:

The patient with diabetes must be insulinopenic per the updated fasting C-peptide testing requirement, or, as an alternative, must be beta cell autoantibody positive.

Updated fasting C-peptide testing requirement:

- Insulinopenia is defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method.
- For patients with renal insufficiency and creatinine clearance (actual or calculated from age, gender, weight, and serum creatinine) ≤50 ml/minute, insulinopenia is defined as a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal of the laboratory's measurement method.
- Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose ≤225 mg/dL.
- Levels only need to be documented once in the medical records.

**NOTE:** Payment may also be made for drugs necessary for the effective use of a covered external infusion pump as long as the drug being used with the pump is itself reasonable and necessary for the patient's treatment.

### 2. Implantable Infusion Pumps

#### a. Chemotherapy for Liver Cancer (Effective for Services Performed On or After September 26, 1984)

The implantable infusion pump is covered when used to administer anti-spasmodic drugs intrathecally (e.g., baclofen) to treat chronic intractable spasticity in patients who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

- As indicated by at least a 6-week trial, the patient cannot be maintained on non-invasive methods of spasm control, such as oral anti-spasmodics, either because these methods fail to control adequately the spasticity or produce intolerable side effects. And prior to pump implantation, the patient must have responded favorably to a trial intrathecal dose of the anti-spasmodic drug.

#### b. Anti-Spasmodic Drugs for Severe Spasticity

An implantable infusion pump is covered when used to administer anti-spasmodic drugs intrathecally (e.g., baclofen) to treat chronic intractable spasticity in patients who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

- As indicated by at least a 6-week trial, the patient cannot be maintained on non-invasive methods of spasm control, such as oral anti-spasmodics, either because these methods fail to control adequately the spasticity or produce intolerable side effects. And prior to pump implantation, the patient must have responded favorably to a trial intrathecal dose of the anti-spasmodic drug.

#### c. Opioid Drugs for Treatment of Chronic Intractable Pain

An implantable infusion pump is covered when used to administer opioid drugs (e.g., morphine) intrathecally or epidurally for treatment of severe chronic intractable pain of malignant or nonmalignant origin in patients who have a life expectancy of at least 3 months, and who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

- The patient's history must indicate that he/she would not respond adequately to noninvasive methods of pain control, such as systemic opioids (including attempts to eliminate physical and behavioral abnormalities which may cause an exaggerated reaction to pain); and a preliminary trial of intraspinal opioid drug administration must be undertaken with a temporary intrathecal/epidural catheter to substantiate adequately acceptable pain relief and degree of side effects (including effects on the activities of daily living) and patient acceptance.

#### d. Coverage of Other Uses of Implanted Infusion Pumps

Determinations may be made on coverage of other uses of implanted infusion pumps if the MAC medical staff verifies that:

- The drug is reasonable and necessary for the treatment of the individual patient;
- It is medically necessary that the drug be administered by an implanted infusion pump; and
- The Food and Drug Administration approved labeling for the pump must specify that the drug being administered...
and the purpose for which it is administered is an indicated use for the pump.

e. Implantation of Infusion Pump Is Contraindicated

The implantation of an infusion pump is contraindicated in the following patients:

With a known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.);
or, Who have an active infection;
or, Whose body size is insufficient to support the weight and bulk of the device;
or, With other implanted programmable devices since crosstalk between devices may inadvertently change the prescription.

NOTE: Payment may also be made for drugs necessary for the effective use of an implantable infusion pump as long as the drug being used with the pump is itself reasonable and necessary for the patient’s treatment.

C. Nationally Non-Covered Indications

The following indications for treatment using infusion pumps are not covered under Medicare:

1. External Infusion Pumps

Vancomycin (Effective for Services Beginning On or After September 1, 1996)

Medicare coverage of vancomycin as a durable medical equipment infusion pump benefit is not covered. There is insufficient evidence to support the necessity of using an external infusion pump, instead of a disposable elastomeric pump or the gravity drip method, to administer vancomycin in a safe and appropriate manner.

2. Implantable Infusion Pump

a. Thromboembolic Disease (Effective for Services Performed On or After September 26, 1984.)

There is insufficient published clinical data to support the safety and effectiveness of the heparin implantable pump. Therefore, the use of an implantable infusion pump for infusion of heparin in the treatment of recurrent thromboembolic disease is not covered.

b. Diabetes

An implanted infusion pump for the infusion of insulin to treat diabetes is not covered. The data does not demonstrate that the pump provides effective administration of insulin.

D. Other

Not applicable.

300.1—Obsolete or Unreliable Diagnostic Tests


A. Diagnostic Tests

Do not routinely pay for the following diagnostic tests because they are obsolete and have been replaced by more advanced procedures. The listed tests may be paid for only if the medical need for the procedure is satisfactorily justified by the physician who performs it. When the services are subject to the Quality Improvement Organization (QIO) review, the QIO is responsible for determining that satisfactory medical justification exists.

When the services are not subject to QIO review, the A/B Medicare Administrative Contractor is responsible for determining that satisfactory medical justification exists. This includes:

- Amylase, blood isoenzymes, electrophoretic
- Chromium, blood
- Guanase, blood
- Zinc sulphate turbidity, blood
- Skin test, cat scratch fever
- Skin test, lymphopathia venereum
- Circulation time, one test
- Cephalin flocculation
- Congo red, blood
- Hormones, adrenocorticotropic quantitative animal tests
- Hormones, adrenocorticotropic quantitative bioassay
- Thymol turbidity, blood
- Skin test, actinomycosis
- Skin test, brucellosis
- Skin test, psittacosis
- Skin test, trichinosis
- Calcium, feces, 24-hour quantitative
- Starch, feces, screening
- Chymotrypsin, duodenal contents
- Gastric analysis, pepsin
- Gastric analysis, tubeless
- Calcium saturation clotting time
- Capillary fragility test (Rumpel-Leede)
- Colloidal gold
- Bendien’s test for cancer and tuberculosis
- Bolen’s test for cancer
- Rehfuss test for gastric acidity, and
- Serum seromucoid assay for cancer and other diseases.

B. Cardiovascular Tests

Do not pay for the following phonocardiography and vectorcardiography diagnostic tests because they have been determined to be outmoded and of little clinical value. They include:

- Phonocardiogram with or without ECG lead; with supervision during recording with interpretation and report (when equipment is supplied by the physician),
- Phonocardiogram; tracing only, without interpretation and report (e.g., when equipment is supplied by the hospital, clinic),
- Phonocardiogram; interpretation and report,
- Phonocardiogram with ECG lead, with indirect carotid artery and/or jugular vein tracing, and/or apex cardiogram; with interpretation and report,
- Phonocardiogram; without interpretation and report,
- Phonocardiogram; interpretation and report only,
- Intracardiac,
- Vectorcardiogram (VCG), with or without ECG; with interpretation and report,
- Vectorcardiogram; tracing only, without interpretation and report, and
- Vectorcardiogram; interpretation and report only.
The patient’s regular physician may submit the claim, and (if assignment is accepted) receive the Part B payment, for covered visit services (including emergency visits and related services) which the regular physician arranges to be provided by a substitute physician on an occasional reciprocal basis, if:

- The regular physician is unavailable to provide the visit services;
- The Medicare patient has arranged or seeks to receive the visit services from the regular physician;
- The substitute physician does not provide the visit services to Medicare patients over a continuous period of longer than 60 days subject to the exception noted below; and
- The regular physician identifies the services as substitute physician services meeting the requirements of this section.

If the only substitution services a physician performs in connection with an operation are post-operative services furnished after the expiration of 60 days of the period, the regular physician is not entitled to bill and receive direct payment for them. The substitute physician must bill for these services in his/her own name. The regular physician may, however, bill and receive payment for the services that the substitute physician provides on his/her behalf in the period July 2 through August 30.

The requirements for the submission of claims under reciprocal billing arrangements are the same for assigned and unassigned claims.

A. Physician Medical Group Claims Under Reciprocal Billing Arrangements

The requirements of this section generally do not apply to the substitution arrangements among physicians in the same medical group where claims are submitted in the name of the group. On claims submitted by the group, the group physician who actually performed the service must be identified in the manner described in §30.2.13 with one exception. When a group member provides services on behalf of another group member who is the designated attending physician for a hospice patient, the Q5 modifier may be used by the designated attending physician to bill for services related to a hospice patient’s terminal illness that were performed by another group member.

For a medical group to submit assigned and unassigned claims, the following requirements must be met:

- The regular physician is unavailable to provide the visit services;
- The Medicare patient has arranged or seeks to receive the visit services from the regular physician;
- The substitute physician does not provide the visit services to Medicare patients over a continuous period of longer than 60 days.

Substitute billing services are billed for each entity as follows:

- The medical group must enter in item 24d of Form CMS-1500 the HCPCS code modifier Q5 after the procedure code.
• The independent physician must enter in item 24 of Form CMS-1500 HCPCS code modifier Q5 after the procedure code.
• The designated attending physician for a hospice patient (receiving services related to a terminal illness) bills the Q5 modifier in item 24 of Form CMS-1500 when another group member covers for the attending physician.
• A record of each service provided by the substitute physician must be kept on file and associated with the substitute physician’s UPIN or NPI when required. This record must be made available to the carrier upon request.
• In addition, the medical group physician for whom the substitution services are furnished must be identified by his/her provider identification number (PIN) or NPI when required in block 24J of the appropriate line item.

Physicians who are members of a group but who bill in their own names are treated as independent physicians for purposes of applying the requirements of this section.

Carriers should inform physicians of the compliance requirements when billing for services of a substitute physician. The physician notification should state that, in entering the Q5 modifier, the regular physician (or the medical group, where applicable) is certifying that the services are covered visit services furnished by the substitute physician identified in a record of the regular physician which is available for inspection, and are services for which the regular physician (or group) is entitled to submit the claim. Carriers should include in the notice that penalty for false certifications may be civil or criminal penalties for fraud. The physician’s right to receive payment or to submit claims or accept any assignments may be revoked. The revocation procedures are set forth in §40.

If a line item includes the code Q5 certification, carriers assume that the claim meets the requirements of this section in the absence of evidence to the contrary. Carriers need not track the 60-day period or validate the billing arrangement on a prepayment basis, absent postpayment findings that indicate that the certifications by a particular physician may not be valid.

When carriers make Part B payment under this section, they determine the payment amount as though the regular physician provided the services. The identification of the substitute physician is primarily for purposes of providing an audit trail to verify that the services were furnished, not for purposes of the payment or the limiting charge. Also, notices of noncoverage are to be given in the name of the regular physician.

30.2.11—Physician Payment Under Locum Tenens Arrangements—Claims Submitted to Carriers

(Rev. 1486, Issued: 04-04-08, Effective: 01-01-08, Implementation: 05-05-08)

A. Background

It is a longstanding and widespread practice for physicians to retain substitute physicians to take over their professional practices when the regular physicians are absent for reasons such as illness, pregnancy, vacation, or continuing medical education, and for the regular physician to bill and receive payment for the substitute physician’s services as though he/she performed them. The substitute physician generally has no practice of his/her own and moves from area to area as needed. The regular physician generally pays the substitute physician a fixed amount per diem, with the substitute physician having the status of an independent contractor rather than of an employee. These substitute physicians are generally called “locum tenens” physicians.

Section 125(b) of the Social Security Act Amendments of 1994 makes this procedure available on a permanent basis. Thus, beginning January 1, 1995, a regular physician may bill for the services of a locum tenens physicians. A regular physician is the physician that is normally scheduled to see a patient. Thus, a regular physician may include physician specialists (such as a cardiologist, oncologist, urologist, etc.).

B. Payment Procedure

A patient’s regular physician may submit the claim, and (if assignment is accepted) receive the Part B payment, for covered visit services (including emergency visits and related services) of a locum tenens physician who is not an employee of the regular physician and whose services for patients of the regular physician are not restricted to the regular physician’s offices, if:

• The regular physician is unavailable to provide the visit services;
• The Medicare beneficiary has arranged or seeks to receive the visit services from the regular physician;
• The regular physician pays the locum tenens for his/her services on a per diem or similar fee-for-time basis;
• The substitute physician does not provide the visit services to Medicare patients over a continuous period of longer than 60 days subject to the exception noted below; and
• The regular physician identifies the services as substitute physician services meeting the requirements of this section by entering HCPCS code modifier Q6 (service furnished by a locum tenens physician) after the procedure code. When Form CMS-1500 is next revised, provision will be made to identify the substitute physician by entering his/her unique physician identification number (UPIN) or NPI when required to the carrier upon request.

EXCEPTION: In accordance with section 116 of the “Medicare, Medicaid, and SCHIP Extension Act of 2007” (MMSE), enacted on December 29, 2007, the exception to the 60-day limit on substitute physician billing for physicians called to active duty in the Armed Forces has been extended for services furnished from January 1, 2008 through June 30, 2008. Thus, under this law, a physician called to active duty may bill for substitute physician services furnished from January 1, 2008 through June 30, 2008 for longer than the 60-day limit.

If the only substitution services a physician performs in connection with an operation are post-operative services furnished during the period covered by the global fee, these services need not be identified on the claim as substitution services.

The requirements for the submission of claims under reciprocal billing arrangements are the same for assigned and unassigned claims.

C. Medical Group Claims Under Locum Tenens Arrangements

For a medical group to submit assigned and unassigned claims for the services a locum tenens physician provides for patients of the regular physician who is a member of the group, the requirements of subsection B must be met.
For purposes of these requirements, per diem or similar fee-for-time compensation which the group pays the locum tenens physician is considered paid by the regular physician. Also, a physician who has left the group and for whom the group has engaged a locum tenens physician as a temporary replacement may bill for the temporary physician for up to 60 days. The group must enter in item 24d of Form CMS-1500 the HCPCS modifier Q6 after the procedure code. Until further notice, the group must keep on file a record of each service provided by the substitute physician, associated with the substitute physician's UPIN or NPI when required, and make this record available to the carrier upon request. In addition, the medical group physician for whom the substitution services are furnished must be identified by his/her provider identification number (PIN) or NPI when required on block 24J of the appropriate line item.

Physicians who are members of a group but who bill in their own names are generally treated as independent physicians for purposes of applying the requirements of subsection A for payment for locum tenens physician services. Compensation paid by the group to the locum tenens physician is considered paid by the regular physician for purposes of those requirements. The term "regular physician" includes a physician who has left the group and for whom the group has hired the locum tenens physician as a replacement.

30.3.5—Effect of Assignment Upon Purchase of Cataract Glasses From Participating Physician or Supplier on Claims Submitted to Carriers

(Rev. 1, 10-01-03)

B3-3045.4

A pair of cataract glasses is comprised of two distinct products: a professional product (the prescribed lenses) and a retail commercial product (the frames). The frames serve not only as a holder of lenses but also as an article of personal apparel. As such, they are usually selected on the basis of personal taste and style. Although Medicare will pay only for standard frames, most patients want deluxe frames. Participating physicians and suppliers cannot profitably furnish such deluxe frames unless they can make an extra (noncovered) charge for the frames even though they accept assignment.

Therefore, a participating physician or supplier (whether an ophthalmologist, optometrist, or optician) who accepts assignment on cataract glasses with deluxe frames may charge the Medicare patient the difference between his/her usual charge to private pay patients for glasses with standard frames and his/her usual charge to such patients for glasses with deluxe frames, in addition to the applicable deductible and coinsurance on glasses with standard frames, if all of the following requirements are met:

A. The participating physician or supplier has standard frames available, offers them for sale to the patient, and issues and ABN to the patient that explains the price and other differences between standard and deluxe frames. Refer to Chapter 30.

B. The participating physician or supplier obtains from the patient (or his/her representative) and keeps on file the following signed and dated statement:

Having been informed that an extra charge is being made by the physician or supplier for deluxe frames, that this extra charge is not covered by Medicare, and that standard frames are available for purchase from the physician or supplier at no extra charge, I have chosen to purchase deluxe frames.

Signature  Date

C. The participating physician or supplier itemizes on his/her claim his/her actual charge for the lenses, his/her actual charge for the standard frames, and his/her actual extra charge for the deluxe frames (charge differential).

Once the assigned claim for deluxe frames has been processed, the carrier will follow the ABN instructions as described in §60.
ambulance service is payable under only Part B. If transportation is by a hospital owned and operated ambulance, the hospital bills separately using the ASC X12 837 institutional claim format or on Form CMS-1450 as appropriate. Similarly, if the hospital arranges for the ambulance transportation with an ambulance operator, including paying the ambulance operator, it bills separately. However, if the hospital does not assume any financial responsibility, the billing is to the A/B MAC (B) by the ambulance operator or beneficiary, as appropriate, if an ambulance is used for the transportation of a hospital inpatient to another facility for diagnostic tests or special treatment the ambulance trip is considered part of the DRG, and not separately billable, if the resident hospital is under PPS.

- **Part B Inpatient Services** - Where Part A benefits are not payable, payment may be made to the hospital under Part B for certain medical and other health services. See Chapter 4 for a description of Part B inpatient services.
- **Anesthetist Services “Incident to” Physician Services** - If a physician's practice was to employ anesthetists and to bill on a reasonable charge basis for these services and that practice was in effect as of the last day of the hospital's most recent 12-month cost reporting period ending before September 30, 1983, the physician may continue that practice through cost reporting periods beginning October 1, 1984. However, if the physician chooses to continue this practice, the hospital may not add costs of the anesthetist's service to its base period costs for purposes of its transition payment rates. If it is the existing or new practice of the physician to employ certified registered nurse anesthetists (CRNAs) and other qualified anesthetists and include charges for their services in the physician bills for anesthesia services for the hospital's cost report periods beginning on or after October 1, 1984, and before October 1, 1987, the physician may continue to do so.

**B. Exceptions/Waivers**

These provisions were waived before cost reporting periods beginning on or after October 1, 1986, under certain circumstances. The basic criteria for waiver was that services furnished by outside suppliers are so extensive that a sudden change in billing practices would threaten the stability of patient care. Specific criteria for waiver and processing procedures are in §2804 of the Provider Reimbursement Manual (CMS Pub. 15-1).

40.3—Outpatient Services Treated as Inpatient Services


A. Outpatient Services Followed by Admission Before Midnight of the Following Day

(Effective For Services Furnished Before October 1, 1991)

When a beneficiary receives outpatient hospital services during the day immediately preceding the hospital admission, the outpatient hospital services are treated as inpatient services if the beneficiary has Part A coverage. Hospitals and A/B MACs (A) apply this provision only when the beneficiary is admitted to the hospital before midnight of the day following receipt of outpatient services. The day on which the patient is formally admitted as an inpatient is counted as the first inpatient day.

When this provision applies, services are included in the applicable PPS payment and not billed separately. When this provision applies to hospitals and units excluded from the hospital PPS, services are shown on the bill and included in the Part A payment. See Chapter 1 for A/B MACs (A) requirements for detecting duplicate claims in such cases.

B. Preadmission Diagnostic Services

(Effective for Services Furnished On or After January 1, 1991)

Diagnostic services (including clinical diagnostic laboratory tests) provided to a beneficiary by the admitting hospital, or by an entity wholly owned or wholly operated by the admitting hospital (or by another entity under arrangements with the admitting hospital), within 3 days prior to and including the date of the beneficiary's admission are deemed to be inpatient services and included in the inpatient payment, unless there is no Part A coverage. For example, if a patient is admitted on a Wednesday, outpatient services provided by the hospital on Sunday, Monday, Tuesday, or Wednesday are included in the inpatient Part A payment.

This provision does not apply to ambulance services and maintenance renal dialysis services (see the Medicare Benefit Policy Manual, Chapters 10 and 11, respectively). Additionally, Part A services furnished by skilled nursing facilities, home health agencies, and hospices are excluded from the payment window provisions.

For services provided before October 31, 1994, this provision applies to both hospitals subject to the hospital inpatient prospective payment system (IPPS) as well as those hospitals and units excluded from IPPS.

For services provided on or after October 31, 1994, for hospitals and units excluded from IPPS, this provision applies only to services furnished within one day prior to and including the date of the beneficiary's admission. The hospitals and units that are excluded from IPPS are: psychiatric hospitals and units; inpatient rehabilitation facilities (IRF) and units; long-term care hospitals (LTCH); children's hospitals; and cancer hospitals.

The 3-day (or 1-day) payment window policy does not apply when the admitting hospital is a critical access hospital (CAH). Therefore outpatient diagnostic services rendered to a beneficiary by a CAH, or by an entity that is wholly owned or operated by a CAH, during the payment window, must not be bundled on the claim for the beneficiary's inpatient admission at the CAH. However, outpatient diagnostic services rendered to a beneficiary at a CAH that is wholly owned or operated by a non-CAH hospital, during the payment window, are subject to the 3-day (or 1-day) payment window policy.

The technical portion of any outpatient diagnostic service rendered to a beneficiary at a hospital-owned or hospital-operated physician clinic or practice during the payment window is subject to the 3-day (or 1-day) payment window policy (see MCPP, chapter 12, sections 90.7 and 90.7.1).

The 3-day (or 1-day) payment window policy does not apply to outpatient diagnostic services included in the rural health clinic (RHC) or Federally qualified health center (FQHC) all-inclusive rate (see MCPP, chapter 19, section 20.1).

Outpatient diagnostic services furnished to a beneficiary more than 3 days (for a non-subsection (d) hospital, more than 1 day) preceding the date of the beneficiary's admission to the hospital, by law, are not part of the payment window.
and must not be bundled on the inpatient bill with other outpatient services that were furnished during the span of the 3-day (or 1-day) payment window, even when all of the outpatient services were furnished during a single, continuous outpatient encounter. Instead, the outpatient diagnostic services that were furnished prior to the span of the payment window may be separately billed to Part B.

An entity is considered to be “wholly owned or operated” by the hospital if the hospital is the sole owner or operator. A hospital need not exercise administrative control over a facility in order to operate it. A hospital is considered the sole operator of the facility if the hospital has exclusive responsibility for implementing facility policies (i.e., conducting or overseeing the facility’s routine operations), regardless of whether it also has the authority to make the policies.

For purposes of the 3-day (or 1-day) payment window policy, a “sponsorship” is treated the same as an “ownership”, and a “non-profit” or “not-for-profit” entity is treated the same as a “for-profit” entity. Thus, outpatient diagnostic services provided by the admitting not-for-profit hospital, or by an entity that is wholly sponsored or operated by the admitting not-for-profit hospital, to a beneficiary during the 3 days (or 1 day) immediately preceding and including the date of the beneficiary’s inpatient admission are deemed to be inpatient services and must be bundled on the claim for the beneficiary’s inpatient stay at the not-for-profit hospital.

For this provision, diagnostic services are defined by the presence on the bill of the following revenue and/or CPT codes:

- 0254: Drugs incident to other diagnostic services
- 0255: Drugs incident to radiology
- 030X: Laboratory
- 031X: Laboratory pathological
- 032X: Radiology diagnostic
- 0341, 0343: Nuclear medicine, diagnostic/Diagnostic Radiopharmaceuticals
- 035X: CT scan
- 0371: Anesthesia incident to Radiology
- 0372: Anesthesia incident to other diagnostic services
- 040X: Other imaging services
- 046X: Pulmonary function
- 0471: Audiology diagnostic
- 0483: Cardiology, Cardiac Catheter Lab/Other Cardiology with CPT codes 93451-93464, 93503, 93505, 93530-93533, 93561-93568, 93571-93572, G0275, and G0278 diagnostic
- 0482: Cardiology, Stress Test
- 0483: Cardiology, Echocardiology
- 053X: Osteopathic services
- 061X: MRT
- 062X: Medical/surgical supplies, incident to radiology or other diagnostic services
- 073X: EKG/ECG
- 074X: EEG
- 0918: Testing- Behavioral Health
- 092X: Other diagnostic services

The CWF rejects services furnished January 1, 1991, or later when outpatient bills for diagnostic services with through dates or last date of service (occurrence span code 72) fall on the day of admission or any of the 3 days immediately prior to admission to an IPPS or IPPS-excluded hospital. This reject applies to the bill in process, regardless of whether the outpatient or inpatient bill is processed first. Hospitals must analyze the two bills and report appropriate corrections. For services on or after October 31, 1994, for hospitals and units excluded from IPPS, CWF will reject outpatient diagnostic bills that occur on the day of or one day before admission. For IPPS hospitals, CWF will continue to reject outpatient diagnostic bills for services that occur on the day of or any of the 3 days prior to admission. Effective for dates of service on or after July 1, 2008, CWF will reject diagnostic services when the line item date of service (LIDOS) falls on the day of admission or any of the 3 days immediately prior to an admission to an IPPS hospital or on the day of admission or one day prior to admission for hospitals excluded from IPPS.

Hospitals in Maryland that are under the jurisdiction of the Health Services Cost Review Commission are subject to the 3-day payment window.

C. Other Preadmission Services (Effective for Services Furnished On or After October 1, 1991 and Before June 25, 2010)

Nondiagnostic outpatient services that are related to a patient’s hospital admission and that are provided by the hospital, or by an entity wholly owned or wholly operated by the admitting hospital (or by another entity under arrangements with the admitting hospital), to the patient during the 3 days immediately preceding and including the date of the patient’s admission are deemed to be inpatient services and are included in the inpatient payment. Effective March 13, 1998, we defined nondiagnostic preadmission services as being related to the admission only when there is an exact match (for all digits) between the ICD-9-CM principal diagnosis code assigned for both the preadmission services and the inpatient stay. Thus, whenever Part A covers an admission, the hospital may bill nondiagnostic preadmission services to Part B as outpatient services only if they are not related to the admission. The A/B MACs (A) shall assume, in the absence of evidence to the contrary, that such bills are not admission related and, therefore, are not deemed to be inpatient (Part A) services. If there are both diagnostic and nondiagnostic preadmission services and the nondiagnostic services are unrelated to the admission, the hospital may separately bill the nondiagnostic preadmission services to Part B. This provision applies only when the patient has Part A coverage. This provision does not apply to ambulance services and maintenance renal dialysis. Additionally, Part A services furnished by skilled nursing facilities, home health agencies, and hospices are excluded from the payment window provisions.

For services provided before October 31, 1994, this provision applies to both hospitals subject to IPPS as well as those hospitals and units excluded from IPPS (see section B above).

For services provided on or after October 31, 1994, for hospitals and units excluded from IPPS, this provision applies only to services furnished within one day prior to and including the date of the beneficiary’s admission.

Hospitals must not include on a claim for an inpatient admission any outpatient nondiagnostic services that are not
payable under Part B. For example, oral medications that are considered self-administered drugs under Part B are not payable under the outpatient prospective payment system (OPPS) and must not be bundled on an inpatient claim for purposes of the 3-day (or 1-day) payment window policy.

The 3-day (or 1-day) payment window policy does not apply when the admitting hospital is a critical access hospital (CAH). Therefore, outpatient nondiagnostic services rendered to a beneficiary by a CAH, or by an entity that is wholly owned or operated by a CAH, during the payment window, must not be bundled on the claim for the beneficiary’s inpatient admission at the CAH. However, admission-related outpatient nondiagnostic services rendered to a beneficiary at a CAH that is wholly owned or operated by a non-CAH hospital, during the payment window, are subject to the 3-day (or 1-day) payment window policy.

The technical portion of any admission-related outpatient nondiagnostic service rendered to a beneficiary at a hospital-owned or hospital-operated physician clinic or practice during the payment window is subject to the 3-day (or 1-day) payment window policy (see MCPM, chapter 12, sections 90.7 and 90.7.1).

The 3-day (or 1-day) payment window policy does not apply to outpatient nondiagnostic services that are included in the rural health clinic (RHC) or Federally qualified health center (FQHC) all-inclusive rate (see MCPM, chapter 19, section 20.1).

Outpatient nondiagnostic services furnished to a beneficiary more than 3 days (for a non-subsection (d) hospital, more than 1 day) preceding the date of the beneficiary’s admission to the hospital, by law, are not part of the payment window and must not be bundled on the inpatient bill with other outpatient services that were furnished during the span of the 3-day (or 1-day) payment window, even when all of the outpatient services were furnished during a single, continuous outpatient encounter. Instead, the outpatient nondiagnostic services that were furnished prior to the span of the payment window may be separately billed to Part B.

An entity is considered to be “wholly owned or operated” by the hospital if the hospital is the sole owner or operator. A hospital need not exercise administrative control over a facility in order to operate it. A hospital is considered the sole operator of the facility if the hospital has exclusive responsibility for implementing facility policies (i.e., conducting or overseeing the facility’s routine operations), regardless of whether it also has the authority to make the policies.

For purposes of the 3-day (or 1-day) payment window policy, a “sponsorship” is treated the same as an “ownership,” and a “non-profit” or “not-for-profit” entity is treated the same as a “for-profit” entity. Thus, admission-related outpatient nondiagnostic services provided by the admitting not-for-profit hospital, or by an entity that is wholly sponsored or operated by the admitting not-for-profit hospital, to a beneficiary during the 3 days (or 1 day) immediately preceding and including the date of the beneficiary’s inpatient admission are deemed to be inpatient services and must be bundled on the claim for the beneficiary’s inpatient stay at the not-for-profit hospital.

Hospitals in Maryland that are under the jurisdiction of the Health Services Cost Review Commission are subject to the 3-day payment window.

Effective for dates of service on or after July 1, 2008 and before June 25, 2010, CWF will reject nondiagnostic services when the following is met:

1) There is an exact match (for all digits) between the ICD-9-CM principal diagnosis code assigned for both the preadmission services and the inpatient stay, and

2) The line item date of service (LIDOS) falls on the day of admission or any of the 3 days immediately prior to an admission to an IPPS hospital (or on the day of admission or one day prior to admission for hospitals excluded from IPPS).

40.3.1—Billing Procedures to Avoid Duplicate Payments
(Rev. 1, 10-01-03)
HO-400H
The hospital must install adequate billing procedures to avoid submission of duplicate claims. This includes duplicate claims for the same service and outpatient bills for nonphysician services considered included in the DRG for a related inpatient admission in the facility or in another hospital.

Where the hospital bills separately for nonphysician services provided to a patient either on the day before admission to a PPS hospital or during a patient’s inpatient stay, the claim will be rejected by the FI as a duplicate and the hospital may be subject to sanction penalties per §1128A of the Act.

100-04 Chapter 4
20—Reporting Hospital Outpatient Services Using Healthcare Common Procedure Coding System (HCPCS)
(Rev. 1, 10-03-03)
A3-3626.4, HO-442.6
20.1—General
(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)
Reporting of HCPCS codes is required of acute care hospitals including those paid under alternate payment systems, e.g., Maryland, long-term care hospitals. HCPCS codes are also required of rehabilitation hospitals, psychiatric hospitals, hospital-based RHCs, hospital-based FQHCs, and CAHs reimbursed under Method II (HCPCS required to be billed for fee reimbursed services). This also includes all-inclusive rate hospitals.

HCPCS includes the American Medical Association’s “Current Procedural Terminology,” 4th Edition, (CPT-4) for physician services and CMS developed codes for certain nonphysician services. All of the CPT-4 is contained within HCPCS, and is identified as Level I CPT codes consist of five numeric characters. The CMS developed codes are known as Level II. Level II codes are five-character codes that begin with an alpha character that is followed by either numeric or alpha characters.
Hospital-based and independent ESRD facilities must use HCPCS to bill for blood and blood products, and to bill for drugs and clinical laboratory services paid outside the composite rate. In addition, the hospital is required to report modifiers as applicable and as described in §20.6.

The CAHs are required to report HCPCS only for Part B services not paid to them on a reasonable cost basis, e.g., screening mammographies and bone mass measurements.

The HCPCS codes are required for all outpatient hospital services unless specifically excepted in manual instructions. This means that codes are required on surgery, radiology, other diagnostic procedures, clinical diagnostic laboratory, durable medical equipment, orthotic-prosthetic devices, take-home surgical dressings, therapies, preventative services, immnosuppressive drugs, other covered drugs, and most other services.

When medical and surgical supplies (other than prosthetic and orthotic devices as described in the Medicare Claims Processing Manual, Chapter 20, §10.1) described by HCPCS codes with status indicators other than “H” or “N” are provided incident to a physician’s service by a hospital outpatient department, the HCPCS codes for these items should not be reported because these items represent supplies. Claims containing charges for medical and surgical supplies used in providing hospital outpatient services are submitted to the Medicare contractor providing OPPS payment for the services in which they are used. The hospital should include charges associated with these medical and surgical supplies on claims so their costs are incorporated in ratesetting, and payment for the supplies is packaged into payment for the associated procedures under the OPPS in accordance with 42 CFR 419.2(b)(4).

For example, if the hospital staff in the emergency department initiate the intravenous administration of a drug through an infusion pump described by HCPCS code E0781 (Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient), complete the drug infusion, and discontinue use of the infusion pump before the patient leaves the hospital outpatient department, HCPCS code E0781 should not be reported because the infusion pump was used as a supply and would be paid through OPPS payment for the drug administration service. The hospital should include the charge associated with the infusion pump on the claim.

In another example, if hospital outpatient staff perform a surgical procedure on a patient in which temporary bladder catheterization is necessary and use a catheter described by HCPCS code A4338 (Indwelling catheter; Foley type, two-way latex with coating (Teflon, silicone, silicone elastomer, or hydrophilic, etc.), each), the hospital should not report A4338 because the catheter was used as a supply and would be paid through OPPS payment for the surgical procedure. The hospital should include the charge associated with the urinary catheter on the claim.

When hospital outpatient staff provide a prosthetic or orthotic device, and the HCPCS code that describes that device includes the fitting, adjustment, or other services necessary for the patient’s use of the item, the hospital should not bill a visit or procedure HCPCS code to report the charges associated with the fitting, adjustment, or other related services. Instead, the HCPCS code for the device already includes the fitting, adjustment or other similar services. For example, if the hospital outpatient staff provides the orthotic device described by HCPCS code L1830 (KO, immobilizer, canvas longitudinal, prefabricated, includes fitting and adjustment), the hospital should only bill HCPCS code L1830 and should not bill a visit or procedure HCPCS code to describe the fitting and adjustment.

Claims with required HCPCS coding missing will be returned to the hospital for correction.

Future updates will be issued in a Recurring Update Notification.

20.1.1 – Elimination of 90-day Grace Period for HCPCS (Level I and Level II)

(Rev. 89, 02-06-04)

The CMS had permitted a 90-day grace period for the use of discontinued codes for dates of service January through March 31 that were submitted to Medicare contractors by April 1 of the current year.

The Health Insurance Portability and Accountability Act (HIPAA) requires that medical code sets must be date of service compliant. Since HCPCS is a medical code set, effective January 1, 2005, CMS will no longer provide a 90-day grace period for discontinued HCPCS. The elimination of the grace period applies to the annual HCPCS update and to any mid-year coding changes. Any codes discontinued mid-year will no longer have a 90-day grace period.

The FIs must eliminate the 90-day grace period from their system effective with the January 1, 2005 HCPCS update. FIs will no longer accept discontinued HCPCS codes for dates of service January 1 through March 31 submitted prior to April 1. Hospitals can purchase the American Medical Association’s CPT-4 coding book that is published each October that contains new, revised, and discontinued CPT-4 codes for the upcoming year. CMS posts on its Web site the annual alphanumeric HCPCS file for the upcoming year at the end of each October. Hospitals are encouraged to access CMS Web site to see the new, revised, and discontinued alpha-numeric codes for the upcoming year. The CMS Web site to view the annual HCPCS update is http://www.cms.hhs.gov/providers/ publishdownload/anhcpcdl.asp

The FIs must continue to return to the provider (RTP) claims containing deleted codes.

20.2—Applicability of OPPS to Specific HCPCS Codes

(Rev. 1536, Issued: 06-19-08; Effective: 07-01-08; Implementation: 07-07-08)

The CPT codes generally are created to describe and report physician services, but are also used by other providers/suppliers to describe and report services that they provide. Therefore, the CPT code descriptors do not necessarily reflect the facility component of a service furnished by the hospital. Some CPT code descriptors include reference to a physician
performing a service. For OPPS purposes, unless indicated otherwise, the usage of the term “physician” does not restrict the reporting of the code or application of related policies to physicians only, but applies to all practitioners, hospitals, providers, or suppliers eligible to bill the relevant CPT codes pursuant to applicable portions of the Social Security Act (SSA) of 1965, the Code of Federal Regulations (CFR), and Medicare rules. In cases where there are separate codes for the technical component, professional component, and/or complete procedure, hospitals should report the code that represents the technical component for their facility services. If there is no separate technical component code for the service, hospitals should report the code that represents the complete procedure. Tables describing the treatment of HCPCS codes for OPPS are published in the Federal Register annually.

**20.3—Line Item Dates of Service**

(Rev. 1, 10-03-03)

Where HCPCS is required a line item date of service is also required. (FL 45 on Form CMS-1450).

The FI will return claims to hospitals where a line item date of service is not entered for each HCPCS code reported or if the line item dates of service reported are outside of the statement-covers period.

**20.4—Reporting of Service Units**

(Rev. 1, 10-03-03)

The definition of service units (FL 46 on the Form CMS-1450) where HCPCS code reporting is required is the number of times the service or procedure being reported was performed. The definition of service units (FL 46 on the Form CMS-1450)

The defnition of service units (FL 46 on the Form CMS-1450) where HCPCS code reporting is required is the number of times the service or procedure being reported was performed. If there is no separate technical component code for the service, hospitals should report the code that represents the technical component for their facility services. If there is no separate technical component code for the service, hospitals should report the code that represents the complete procedure. Tables describing the treatment of HCPCS codes for OPPS are published in the Federal Register annually.

**EXAMPLES:**

HCPCS Code | Service Units
---|---
90849 - Multiple-family group psychotherapy | Units > 1
92265 - Needle oculo electromyography, one or more extracranial muscles, one or both eyes, with interpretation and report | Units > 1
95004 - Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, specify number of tests. | Units = no. of tests performed
95681 - Needle electromyography, two extremities with or without related paraspinal areas | Units > 1

The beginning and ending time of the treatment should be recorded in the patient’s medical record along with the note describing the treatment. (The total length of the treatment to the minute could be recorded instead.) If more than one CPT code is billed during a calendar day, then the total number of units that can be billed is constrained by the total treatment time. For example, if 24 minutes of code 97112 and 23 minutes of code 97110 were furnished, then the total treatment time was 47 minutes; so only 3 units can be billed for the treatment. The correct coding is two units of code 97112 and one unit of code 97110, assigning more units to the service that took more time.

**20.5—Clarification of HCPCS Code to Revenue Code Reporting**

(Rev. 1487, Issued: 04-08-08, Effective: 04-01-08, Implementation: 04-07-08)

Generally, CMS does not instruct hospitals on the assignment of HCPCS codes to revenue codes for services provided under OPPS since hospitals’ assignment of cost vary. Where explicit instructions are not provided, providers should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report.

**20.6—Use of Modifiers**

(Rev. 1487, Issued: 04-08-08, Effective: 04-01-08, Implementation: 04-07-08)

The Integrated Outpatient Code Editor (I/OCE) accepts all valid CPT and HCPCS modifiers on OPPS claims. Definitions for the following modifiers may be found in the CPT and HCPCS guides:

**Level I (CPT) Modifiers**

-25, -27, -50, -52, -58, -59, -73, -74, -76, -77, -78, -79, -91

**Level II (HCPCS) Modifiers**

-CA, -E1, -E2, -E3, -E4, -FA, -FB, -FC, -F1, -F2, -F3, -F4, -F5, -F6, -F7, -F8, -F9, -GA, -GG, -GH, -GY, -GZ, -LC, -LD, -LT, -QL, -QM, -RC, -RT, -TA, -T1, -T2, -T3, -T4, -T5, -T6, -T7, -T8, -T9

As indicated in §20.6.2, modifier -50, while it may be used with diagnostic and radiology procedures as well as with surgical procedures, should be used to report bilateral procedures that are performed at the same operative session as a single line item. Modifiers RT and LT are not used when modifier -50 applies. A bilateral procedure is reported on one line using modifier -50. Modifier -50 applies to any bilateral procedure performed on both sides at the same session.
NOTE: Use of modifiers applies to services/procedures performed on the same calendar day.

Other valid modifiers that are used under other payment methods are still valid and should continue to be reported, e.g., those that are used to report outpatient rehabilitation and ambulance services. Modifiers may be applied to surgical, radiology, and other diagnostic procedures. Providers must use any applicable modifier where appropriate. Providers do not use a modifier if the narrative definition of a code indicates multiple occurrences.

EXAMPLES:
The code definition indicates two to four lesions. The code indicates multiple extremities.

Providers do not use a modifier if the narrative definition of a code indicates that the procedure applies to different body parts.

EXAMPLES:
Code 11600 (Excision malignant lesion, trunks, arms, or legs; lesion diameter 0.5 cm. or less)

Code 11640 (Excision malignant lesion, face, ears, eyelids, nose, lips; lesion diameter 0.5 cm. or less)

Modifiers -GN, -GO, and -GP must be used to identify the therapist performing speech language therapy, occupational therapy, and physical therapy respectively.

Modifier -50 (bilateral) applies to diagnostic, radiological, and surgical procedures.

Modifier -52 applies to radiological procedures.

Modifiers -73, and -74 apply only to certain diagnostic and surgical procedures that require anesthesia.

Following are some general guidelines for using modifiers. They are in the form of questions to be considered. If the answer to any of the following questions is yes, it is appropriate to use the applicable modifier:

1. Will the modifier add more information regarding the anatomic site of the procedure?

EXAMPLE: Cataract surgery on the right or left eye.

2. Will the modifier help to eliminate the appearance of duplicate billing?

EXAMPLES: Use modifier 77 to report the same procedure performed more than once on the same date of service but at different encounters.

Use modifier 25 to report significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service.

Use modifier 58 to report staged or related procedure or service by the same physician during the postoperative period.

Use modifier 78 to report a return to the operating room for a related procedure during the postoperative period.

Use modifier 79 to report an unrelated procedure or service by the same physician during the postoperative period.

3. Would a modifier help to eliminate the appearance of unbundling?

EXAMPLE: CPT codes 90765 (Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour) and 36000 (Introduction of needle or intra catheter, vein): If procedure 36000 was performed for a reason other than as part of the IV infusion, modifier -59 would be appropriate.

20.6.1—Where to Report Modifiers on the Hospital Part B Claim

(Rev. 3019, Issued: 08-07-14, Effective: 01-01-12, ICD-10: Upon Implementation of ICD-10, Implementation: 09-08-14, ICD-10: Upon Implementation of ICD-10)

Modifers are reported on the hardcopy Form CMS-1450 with the HCPCS code. See Chapter 25 of this manual for related instructions. There is space for four modifiers on the hardcopy.

See the ASC X12 837 Institutional Claim Implementation Guide for instructions for reporting HCPCS modifiers when using the ASC X12 837 institutional claim format.
The dash that is often seen preceding a modifier should never be reported.

When it is appropriate to use a modifier, the most specific modifier should be used first. That is, when modifiers E1 through E4, FA through F9, LC, LD, RC, and TA through T9 apply, they should be used before modifiers LT, RT, or -59.

20.6.2—Use of Modifiers -50, -LT, and -RT

(Rev. 1, 10-03-03)

Modifier -50 is used to report bilateral procedures that are performed at the same operative session as a single line item. Do not use modifiers RT and LT when modifier -50 applies. Do not submit two line items to report a bilateral procedure using modifier -50.

Modifier -50 applies to any bilateral procedure performed on both sides at the same operative session.

The bilateral modifier -50 is restricted to operative sessions only.

Modifier -50 may not be used:

• To report surgical procedures identified by their terminology as “bilateral,” or
• To report surgical procedures identified by their terminology as “unilateral or bilateral”.

The unit entry to use when modifier -50 is reported is one.

20.6.3—Modifiers -LT and -RT

(Rev. 1, 10-03-03)

Modifiers -LT or -RT apply to codes, which identify procedures, which can be performed on paired organs, e.g., ears, eyes, nostrils, kidneys, lungs, and ovaries.

Modifiers -LT and -RT should be used whenever a procedure is performed on only one side. Hospitals use the appropriate -RT or -LT modifier to identify which of the paired organs was operated upon.

These modifiers are required whenever they are appropriate.

20.6.4—Use of Modifiers for Discontinued Services

(Rev. 3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

A. General

Modifiers provide a way for hospitals to report and be paid for expenses incurred in preparing a patient for a procedure and scheduling a room for performing the procedure where the service is subsequently discontinued. This instruction is applicable to both outpatient hospital departments and to ambulatory surgical centers.

Modifier -73 is used by the facility to indicate that a procedure requiring anesthesia was terminated due to extenuating circumstances or to circumstances that threatened the well being of the patient after the patient had been prepared for the procedure (including procedural pre-medication when provided), and been taken to the room where the procedure was to be performed, but prior to administration of anesthesia. For purposes of billing for services furnished in the hospital outpatient department, anesthesia is defined to include local, regional block(s), moderate sedation/analgesia (“conscious sedation”), deep sedation/analgesia, or general anesthesia. This modifier code was created so that the costs incurred by the hospital to prepare the patient for the procedure and the resources expended in the procedure room and recovery room (if needed) could be recognized for payment even though the procedure was discontinued.

Modifier -74 is used by the facility to indicate that a procedure requiring anesthesia was terminated after the induction of anesthesia or after the procedure was started (e.g., incision made, intubation started, scope inserted) due to extenuating circumstances or circumstances that threatened the well being of the patient. This modifier may also be used to indicate that a planned surgical or diagnostic procedure was discontinued, partially reduced or cancelled at the physician’s discretion after the administration of anesthesia. For purposes of billing for services furnished in the hospital outpatient department, anesthesia is defined to include local, regional block(s), moderate sedation/analgesia (“conscious sedation”), deep sedation/analgesia, and general anesthesia. This modifier code was created so that the costs incurred by the hospital to initiate the procedure (preparation of the patient, procedure room, recovery room) could be recognized for payment even though the procedure was discontinued prior to completion.

Coinciding with the addition of the modifiers -73 and -74, modifiers -52 and -53 were revised. Modifier -52 is used to indicate partial reduction, cancellation, or discontinuation of services for which anesthesia is not planned. The modifier provides a means for reporting reduced services without disturbing the identification of the basic service. Modifier -53 is used to indicate discontinuation of physician services and is not approved for use for outpatient hospital services.

The elective cancellation of a procedure should not be reported.

Modifiers -73 and -74 are only used to indicate discontinued procedures for which anesthesia is planned or provided.

B. Effect on Payment

Procedures that are discontinued after the patient has been prepared for the procedure and taken to the procedure room but before anesthesia is provided will be paid at 50 percent of the full OPPS payment amount. Modifier -73 is used for these procedures. As of January 1, 2016, for procedures that append modifier -73 and that involve implantable devices that are assigned to a device-intensive APC (defined as those APCs with a device offset greater than 40 percent), we will reduce the APC payment amount for the discontinued device-intensive procedure, by 100 percent of the device offset amount prior to applying the additional payment adjustments that apply when the procedure is discontinued as modified by means of a final rule with comment period and published in the November 13, 2015 “Federal Register” (80 FR 70424).

Procedures that are discontinued, partially reduced or cancelled after the procedure has been initiated and/or the patient has received anesthesia will be paid at the full OPPS payment amount. Modifier -74 is used for these procedures.
Procedures for which anesthesia is not planned that are discontinued, partially reduced or cancelled after the patient is prepared and taken to the room where the procedure is to be performed will be paid at 50 percent of the full OPPS payment amount. Modifier -52 is used for these procedures.

20.6.5—Modifiers for Repeat Procedures
(Rev. 1, 10-03-03)
Two repeat procedure modifiers are applicable for hospital use:

- Modifier -76 is used to indicate that the same physician repeated a procedure or service in a separate operative session on the same day.
- Modifier -77 is used to indicate that another physician repeated a procedure or service in a separate operative session on the same day.

If there is a question regarding who the ordering physician was and whether or not the same physician ordered the second procedure, the code selected is based on whether or not the physician performing the procedure is the same.

The procedure must be the same procedure. It is listed once and then listed again with the appropriate modifier.

20.6.6—Modifiers for Radiology Services
(Rev. 1599, Issued: 09-19-08, Effective: 10-01-08, Implementation: 10-06-08)
Modifiers -52 (Reduced Services), -59, -76, and -77, and the Level II modifiers apply to radiology services.

When a radiology procedure is reduced, the correct reporting is to code to the extent of the procedure performed. If no HCPCS code exists for the service that has been completed, report the intended HCPCS code with modifier -52 appended.

**EXAMPLE:** CPT code 71020 (Radiologic examination, chest, two views, frontal and lateral) is ordered. Only one frontal view is performed. CPT code 71010 (Radiologic examination, chest: single view, frontal) is reported. The service is not reported as CPT code 71020-52.

20.6.7—CA Modifier
(Rev. 1, 10-03-03)

**Definition:**
Procedure payable only in the inpatient setting when performed emergently on an outpatient who expires prior to admission.

20.6.8—HCPCS Level II Modifiers
(Rev. 1, 10-03-03)

Generally, these codes are required to add specificity to the reporting of procedures performed on eyelids, fingers, toes, and arteries.

They may be appended to CPT codes.

If more than one level II modifier applies, the HCPCS code is repeated on another line with the appropriate level II modifier:

**EXAMPLE:** Code 26010 (drainage of finger abscess; simple) done on the left thumb and second finger would be coded:

26010FA
26010F1

The Level II modifiers apply whether Medicare is the primary or secondary payer.

20.6.9—Use of HCPCS Modifier -FB
(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

Effective January 1, 2007, the definition of modifier -FB is “Item Provided Without Cost to Provider, Supplier or Practitioner, or Credit Received for Replacement Device (Examples, but not Limited to: Covered Under Warranty, Replaced Due to Defect, Free Samples).” See the Medicare Claims Processing Manual, Pub 100-04, Chapter 4, §61.3 for instructions regarding charges for items billed with the -FB modifier.

The OPPS hospitals must report modifier -FB on the same line as the procedure code (not the device code) for a service that requires a device for which neither the hospital, nor the beneficiary, is liable to the manufacturer. Hospitals must report modifier -FB on the same line as the procedure code for a service that requires a device when the manufacturer gives credit for a device being replaced with a more costly device.

20.6.10—Use of HCPCS Modifier -FC
(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

Effective January 1, 2008, the definition of modifier -FC is “Partial credit received for replaced device.” See the Medicare Claims Processing Manual, Pub 100-04, Chapter 4, §61.3 for instructions regarding charges for items billed with the -FC modifier.

OPPS hospitals must report the -FC modifier for cases in which the hospital receives a partial credit of 50 percent or more of the cost of a new replacement device under warranty, recall, or field action. The hospital must append the -FC modifier to the procedure code (not the device code) that reports the services provided to replace the device.

20.6.11—Use of HCPCS Modifier—PO

Effective January 1, 2015, the definition of modifier -PO is “Services, procedures, and/or surgeries furnished at off-campus provider-based outpatient departments.” This modifier is to be reported with every HCPCS code for all outpatient hospital items and services furnished in an off-campus provider-based department of a hospital. See 42 CFR 413.65(a)(2) for a definition of “campus”. This modifier should not be reported for remote locations of a hospital.
(defined at 42 CFR 413.65(a)(2)) satellite facilities of a hospital (defined at 42 CFR 412.22(h)), or for services furnished in an emergency department.

Reporting of this modifier is voluntary for CY 2015; reporting of this modifier is required beginning January 1, 2016.

20.7 — Billing of ‘C’ HCPCS Codes by Non-OPPS Providers
(Rev. 976, Issued: 06-09-06, Effective: 10-01-06, Implementation: 10-02-06)

Prior to October 1, 2006, the “C” series of HCPCS codes were used exclusively by hospitals subject to OPPS to identify items that may have qualified for transitional pass through payment under OPPS or items or services for which an appropriate HCPCS code did not exist for the purposes of implementing the OPPS. The C-codes could not be used to bill services payable under other payment systems. CMS realized that these C-codes evolved and also target services that are uniquely hospital services that may be provided by an OPPS provider, other providers, or be paid under other payment systems.

Effective October 1, 2006, the following non-OPPS providers may elect to bill using the C-codes or an appropriate CPT code on Types of Bill (TOBs) 12X, 13X, or 85X:

- Critical Access Hospitals (CAHs);
- Indian Health Service Hospitals (IHS);
- Hospitals located in American Samoa, Guam, Saipan or the Virgin Islands; and
- Maryland waiver hospitals.

The OPPS providers shall continue to receive pass-through payment on items or services that qualify for pass through payment. Non-OPPS providers are not eligible for pass through payments.

The C-codes shall be replaced with permanent codes. Whenever a permanent code is established to replace a temporary code, the temporary code is deleted and crossreferenced to the new permanent code. Upon deletion of a temporary code, providers shall bill using the new permanent code.

Providers are encouraged to access the CMS Web site to view the quarterly HCPCS Code updates. The URL to view the quarterly updates is http://www.cms.hhs.gov/HCPCSReleaseCodeSets/.

The billing of C-codes by Method I and Method II Critical Access Hospitals (CAHs) is limited to the billing for facility (technical) services. The C-codes shall not be billed by Method II CAHs for professional services with revenue codes 96X, 97X, or 98X.

230.1 — Coding and Payment for Drugs and Biologicals, and Radiopharmaceuticals
(Rev. 1445, Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

This section provides hospitals with coding instructions and payment information for drugs paid under OPPS. For additional information on coding and payment for drugs and biologicals under the OPPS, see the Medicare Claims Processing Manual, Chapter 17 “Drugs and Biologicals.”

230.2 — Coding and Payment for Drug Administration
(Rev. 2141, Issued: 01-24-11, Effective: 01-01-11, Implementation: 01-03-11)

A. Overview

Drug administration services furnished under the Hospital Outpatient Prospective Payment System (OPPS) during CY 2005 were reported using CPT codes 90780, 90781, and 96400-96459.

Effective January 1, 2006, some of these CPT codes were replaced with more detailed CPT codes incorporating specific procedural concepts, as defined and described by the CPT manual, such as initial, concurrent, and sequential.

Hospitals are instructed to use the full set of CPT codes, including those codes referencing concepts of initial, concurrent, and sequential, to bill for drug administration services furnished in the hospital outpatient department beginning January 1, 2007. In addition, hospitals are instructed to continue billing the HCPCS codes that most accurately describe the service(s) provided.

Hospitals are reminded to bill a separate Evaluation and Management code (with modifier 25) only if a significant, separately identifiable E/M service is performed in the same encounter with OPPS drug administration services.

B. Billing for Infusions and Injections

Beginning in CY 2007, hospitals were instructed to use the full set of drug administration CPT codes (90760-90779; 96401-96549), (96413-96523 beginning in CY 2008) (96360-96549 beginning in CY 2009) when billing for drug administration services provided in the hospital outpatient department. In addition, hospitals are to continue to bill HCPCS code C8957 (Intravenous infusion for therapy/diagnosis; initiation of prolonged infusion (more than 8 hours), requiring use of portable or implantable pump) when appropriate.

Hospitals are expected to report all drug administration CPT codes in a manner consistent with their descriptors, CPT instructions, and correct coding principles. Hospitals should note the conceptual changes between CY 2006 drug administration codes effective under the OPPS and the CPT codes in effect beginning January 1, 2007, in order to ensure accurate billing under the OPPS. Hospitals should report all HCPCS codes that describe the drug administration services provided, regardless of whether or not those services are separately paid or their payment is packaged.


Drug administration services are to be reported with a line item date of service on the day they are provided. In addition,
only one initial drug administration service is to be reported per vascular access site per encounter, including during an encounter where observation services span more 1 calendar day.

C. Payments For Drug Administration Services

For CY 2007, OPPS drug administration APCs were restructured, resulting in a six-level hierarchy where active HCPCS codes have been assigned according to their clinical coherence and resource use. Contrary to the CY 2006 payment structure that bundled payment for several instances of a type of service (non-chemotherapy, chemotherapy by infusion, non-infusion chemotherapy) into a per-encounter APC payment, structure introduced in CY 2007 provides a separate APC payment for each reported unit of a separately payable HCPCS code.

Hospitals should note that the transition to the full set of CPT drug administration codes provides for conceptual differences when reporting, such as those noted below.

- In CY 2006, hospitals were instructed to bill for the first hour (and any additional hours) by each type of infusion service (non-chemotherapy, chemotherapy by infusion, non-infusion chemotherapy). Beginning in CY 2007, the first hour concept no longer exists. CPT codes in CY 2007 and beyond allow for only one initial service per encounter, for each vascular access site, no matter how many types of infusion services are provided; however, hospitals will receive an APC payment for the initial service and separate APC payment(s) for additional hours of infusion or other drug administration services provided they are separately payable.
- In CY 2006, hospitals providing infusion services of different types (non-chemotherapy, chemotherapy by infusion, non-infusion chemotherapy) received payment for the associated per-encounter infusion APC even if these infusions occurred during the same time period. Beginning in CY 2007, CPT hospitals should report only one initial drug administration service, including infusion services, per encounter for each distinct vascular access site, with other services through the same vascular access site being reported via the sequential, concurrent or additional hour codes. Although new CPT guidance has been issued for reporting initial drug administration services, Medicare contractors shall continue to follow the guidance given in this manual.

(NOTE: This list above provides a brief overview of a limited number of the conceptual changes between CY 2006 OPPS drug administration codes and CY 2007 OPPS drug administration codes - this list is not comprehensive and does not include all items hospitals will need to consider during this transition).

For APC payment rates, refer to the most current quarterly version of Addendum B on the CMS Web site at http://www.cms.hhs.gov/HospitalOutpatientPPS/.

D. Infusions Started Outside the Hospital

Hospitals may receive Medicare beneficiaries for outpatient services who are in the process of receiving an infusion at their time of arrival at the hospital (e.g., a patient who arrives via ambulance with an ongoing intravenous infusion initiated by paramedics during transport). Hospitals are reminded to bill for all services provided using the HCPCS code(s) that most accurately describe the service(s) they provided. This includes hospitals reporting an initial hour of infusion, even if the hospital did not initiate the infusion, and additional HCPCS codes for additional or sequential infusion services if needed.

240—Inpatient Part B Hospital Services

(Rev. 3106, Issued: 11-06-14, Effective: 10-01-13, Implementation: 02-10-15)

Medicare pays for hospital (including CAH) inpatient Part B services in the circumstances provided in Pub. 100-02, Medicare Benefit Policy Manual, Chapter 6, §10 (“Medical and Other Health Services Furnished to Inpatients of Participating Hospitals”). Hospitals must bill Part B inpatient services on a 12x Type of Bill. This Part B inpatient claim is subject to the statutory time limit for filing Part B claims described in chapter 1, §70 of this manual.

Inpatient Part B services include inpatient ancillary services that do not require an outpatient status and are not strictly provided in an outpatient setting. Services that require an outpatient status and are provided only in an outpatient setting are not payable inpatient Part B services, including Clinic Visits, Emergency Department Visits, and Observation Services (this is not a complete listing).

Inpatient routine services in a hospital generally are those services included by the provider in a daily service charge—sometimes referred to as the “Room and Board” charge. They include the regular room, dietary and nursing services, minor medical and surgical supplies, medical social services, psychiatric social services, and the use of certain equipment and facilities for which a separate charge is not customarily made to Medicare Part A. Many nursing services provided by the floor nurse (such as IV infusions and injections, blood administration, and nebulizer treatments, etc.) may or may not have a separate charge established depending upon the classification of an item or service as routine or ancillary among providers of the same class in the same State. Some provider’s customary charging practice has established separate charges for these services following the PRM–1 instructions, however, in order for a provider’s customary charging practice to be recognized it must be consistently followed for all patients and this must not result in an inequitable apportionment of cost to the program. If the PRM–1 instructions have not been followed, a provider cannot bill these services as separate charges. Additionally, it is important that the charges for service rendered and documentation meet the definition of the HCPCS in order to separately bill.
240.1 – Editing Of Hospital Part B Inpatient Services: Reasonable and Necessary Part A Hospital Inpatient Denials
(Rev. 3475, Issued: 03-04-16, Effective: 06-06-16, Implementation: 06-06-16)

When inpatient services are denied as not medically necessary or a provider submitted medical necessity denial utilizing occurrence span code "M1", and the services are furnished by a participating hospital, Medicare pays under Part B for physician services and the non-physician medical and other health services provided in Pub. 100-02, Medicare Benefit Policy Manual, Chapter 6, §10.1, "Reasonable and Necessary Part A Hospital Inpatient Claim Denials." The claims processing system shall set edits to prevent payment on Type of Bill 12x for claims containing the revenue codes listed in the table below.

* In the case of Revenue Code 0964, this is used by hospitals that have a CRNA exception.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three. Group Code: PR CARC: 96 RARC: M28 MSN: 21.21

CWF shall edit to ensure that DSMT services are not billed on a 12x claim.

Hospitals are required to report HCPCS codes that identify the services rendered.

<table>
<thead>
<tr>
<th>Revenue Code</th>
<th>010x</th>
<th>011x</th>
<th>012x</th>
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240.2 – Editing Of Hospital Part B Inpatient Services: Other Circumstances in Which Payment Cannot Be Made under Part A
(Rev. 3475, Issued: 03-04-16, Effective: 06-06-16, Implementation: 06-06-16)

When Medicare pays under Part B for the limited set of non-physician medical and other health services provided in Pub. 100-02, Medicare Benefit Policy Manual, chapter 6, §10.2 (that is, when furnished by a participating hospital to an inpatient of the hospital who is not entitled to benefits under Part A, has exhausted his or her Part A benefits, or receives services not covered under Part A), the contractor shall set revenue code edits to prevent payment on Type of Bill 12x for claims containing the revenue codes listed in the table below.

* In the case of Revenue Code 0964, this is used by hospitals that have a CRNA exception.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: PR
CARC: 96
RARC: M28
MSN: 21.21

Hospitals are required to report HCPCS codes that identify the services rendered.

<table>
<thead>
<tr>
<th>Revenue Code</th>
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250 – Special Rules for Critical Access Hospital Outpatient Billing
(Rev. 1111, Issued: 11-09-06, Effective: 04-01-07, Implementation: 04-02-07)

For cost reporting periods beginning before October 1, 2000, a CAH will be paid for outpatient services under the method in 250.1. The BIPA legislation on payment for professional services at 115 percent of what otherwise be paid under the fee schedule is effective for services furnished on or after July 1, 2001. This provision was implemented with respect to cost reporting periods starting on or after October 1, 2001.

For cost reporting period beginning on or after October 1, 2001, the CAH will be paid under the method in item 1 below unless it elects to be paid under the method in §250.1.

If a CAH elects payment under the elective method (cost-based facility payment plus fee schedule for professional services) for a cost reporting period, that election is effective for the entire cost reporting period to which it applies. If the CAH wishes to make a new election or change a previous election, that election should be made in writing, made on an annual basis and delivered to the appropriate FI, at least 30 days in advance of the beginning of the affected cost reporting period.

All outpatient CAH services, other than pneumococcal pneumonia vaccines, influenza vaccines, administration of the vaccines, screening mammograms, and clinical diagnostic laboratory tests are subject to Part B deductible and coinsurance. Regardless of the payment method applicable for a period, payment for outpatient CAH services is not subject to the following payment principles:

- Lesser of cost or charges,
- Reasonable compensation equivalent (RCE) limits,
- Any type of reduction to operating or capital costs under 42 CFR 413.124 or 413.30(j)(7), or
- Blended payment rates for ASC-type, radiology, and other diagnostic services.

See §250.4 below regarding payment for screening mammography services.

250.1—Standard Method - Cost-Based Facility Services, With Billing of Carrier for Professional Services
(Rev. 2581, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

Effective for cost reporting periods beginning on or after January 1, 2004, payment for outpatient CAH services under this method will be made for the lesser of: 1) 80 percent of 101 percent of the reasonable cost of the CAH in furnishing those services, or 2) 101 percent of the reasonable cost of the CAH in furnishing those services, less applicable Part B deductible and coinsurance amounts.

Payment for professional medical services furnished in a CAH to CAH outpatients is made by the carrier on a fee schedule, charge, or other fee basis, as would apply if the services had been furnished in a hospital outpatient department. For purposes of CAH payment, professional medical services are defined as services provided by a physician or

other practitioner, e.g., a physician assistant that could be billed directly to a carrier under Part B of Medicare or a nurse practitioner that could be billed directly to a carrier under Part B of Medicare.

In general, payment for professional medical services, under the cost-based CAH payment plus professional services billed to the carrier method should be made on the same basis as would apply if the services had been furnished in the outpatient department of a hospital.

Bill type 85X is used for all outpatient services including services approved as ASC services. Non-patient laboratory specimens (those not meeting the criteria for reasonable cost payment in §250.6) will be billed on a 14X type of bill.

(See Section 260.6 – Clinical Diagnostic Laboratory Tests Furnished by CAHs.)

100-04 Chapter 8

60.4.2—Facility Billing Requirements for ESAs
(Rev. 2688, Issued: 04-26-13, Effective: 07-01-13, Implementation: 07-01-13)

Hematocrit and Hemoglobin Levels

Renal dialysis facilities are required to report hematocrit or hemoglobin levels for their Medicare patients receiving erythropoietin products. Hematocrit levels are reported in value code 49 and reflect the most recent reading taken before the start of the billing period. Hemoglobin readings before the start of the billing period are reported in value code 48.

To report a hematocrit or hematocrit reading for a new patient on or after January 1, 2006, the provider should report the reading that prompted the treatment of epoetin alfa. The provider may use results documented on form CMS 2728 or the patient’s medical records from a transferring facility.

Effective January 1, 2012, ESRD facilities are required to report hematocrit or hemoglobin levels on all ESRD claims. Reporting the value 99.99 is not permitted when billing for an ESA.

The revenue codes for reporting Epoetin Alfa are 0634 and 0635. All other ESAs are reported using revenue code 0636. The HCPCS code for the ESA must be included:

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>HCPCS Description</th>
<th>Dates of Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>04055</td>
<td>Injection, Epoetin Alfa, 1,000 units (for ESRD on Dialysis)</td>
<td>1/1/2004 through 12/31/2005</td>
</tr>
<tr>
<td>J0886</td>
<td>Injection, Epoetin Alfa, 1,000 units (for ESRD on Dialysis)</td>
<td>1/1/2006 through 12/31/2006</td>
</tr>
<tr>
<td>04081</td>
<td>Injection, Epoetin alfa, 100 units (for ESRD on Dialysis)</td>
<td>1/1/2007 to present</td>
</tr>
<tr>
<td>04054</td>
<td>Injection, Darbepoetin Alfa, 1mcg (for ESRD on Dialysis)</td>
<td>1/1/2004 through 12/31/2005</td>
</tr>
<tr>
<td>J0882</td>
<td>Injection, Darbepoetin Alfa, 1mcg (for ESRD on Dialysis)</td>
<td>1/1/2006 to present</td>
</tr>
<tr>
<td>J0899</td>
<td>Injection, Peginesatide, 0.1 mg (for ESRD on Dialysis)</td>
<td>1/1/2013 to present</td>
</tr>
</tbody>
</table>
Each administration of an ESA is reported on a separate line item with the units reported used as a multiplier by the dosage description in the HCPCS to arrive at the dosage per administration.

**Route of Administration Modifiers**

Patients with end stage renal disease (ESRD) receiving administrations of erythropoiesis stimulating agents (ESA) for the treatment of anemia may receive intravenous administration or subcutaneous administrations of the ESA. Effective for claims with dates of services on or after January 1, 2012, all facilities billing for injections of ESA for ESRD beneficiaries must include the modifier JA on the claim to indicate an intravenous administration or modifier JB to indicate a subcutaneous administration. ESRD claims containing ESA administrations that are submitted without the route of administration modifiers will be returned to the provider for correction. Renal dialysis facilities claim including charges for administrations of the ESA by both methods must report separate lines to identify the number of administration provided using each method.

Effective July 1, 2013, providers must identify when a drug is administered via the dialysate by appending the modifier JE (administered via dialysate).

**ESA Monitoring Policy Modifiers**

Append modifiers ED, EE and GS as applicable, see instructions in section 60.4.1.

**Maximum Allowable Administrations**

The maximum number of administrations of EPO for a billing cycle is 31 times in 30/31 days.

The maximum number of administrations of Aranesp for a billing cycle is 5 times in 30/31 days.

The maximum number of administrations of Peginesatide is 1 time in 30/31 days.

**EXAMPLES:**

- **A. Diagnoses**—The diagnoses must be submitted according to ICD coding guidelines and correlated to the procedure. This information is in Item 21, of the Form CMS-1500.

- **B. Hematocrit (HCT)/Hemoglobin (Hgb)**—There are special HCPCS codes for reporting the injection of EPO for claims with dates of service prior to January 1, 2004. These allow the simultaneous reporting of the patient’s latest HCT or Hgb reading before administration of EPO.

- **C. Units Administered**—The standard unit of EPO is 1,000. The number of 1,000 units administered per line item is included on the claim. The physician’s office enters 1 in the units field for each multiple of 1,000 units. For example, if 12,000 units are administered, 12 is entered. This information is shown in Item 24G (Days/Units) on Form CMS-1500.

- **EXAMPLES:**

The physician and/or staff are instructed to enter a separate line item for injections of EPO at different HCT/Hgb levels. The Q code for each line items is entered in Item 24D.

1. Code Q9920—Injection of EPO, per 1,000 units, at patient HCT of 20 or less/Hgb of 6.8 or less.
2. Codes Q9921 through Q9939—Injection of EPO, per 1,000 units, at patient HCT of 21 to 39/Hgb of 6.9 to 13.1. For HCT levels of 21 or more, up to a HCT of 39/Hgb of 6.9 to 13.1, a Q code that includes the actual HCT levels is used. To convert actual Hgb to corresponding HCT values for Q code reporting, multiply the Hgb value by 3 and round to the nearest whole number. Use the whole number to determine the appropriate Q code.

- **EXAMPLES:** If the patient’s HCT is 25/Hgb is 8.2-8.4, Q9925 must be entered on the claim. If the patient’s HCT is 39/Hgb is 12.9-13.1, Q9939 is entered.

3. Code Q9940—Injection of EPO, per 1,000 units at patient HCT of 40 or above.

A single line item may include multiple doses of EPO administered while the patient’s HCT level remained the same. Codes Q9920-Q9940 will no longer be recognized by the system if submitted after March 31, 2004. If claims for dates of service prior to January 1, 2004 are submitted after March 31, 2004, then code Q4055 must be used.

**EXAMPLES:** A patient’s HCT reading on August 6 was 22/Hgb was 7.3. The patient received 5,000 units of EPO on August 7, August 9, and August 11, for a total of 15,000 units. The first line of Item 24 of Form CMS-1500 shows:

<table>
<thead>
<tr>
<th>Dates of Service</th>
<th>Procedure Code</th>
<th>Days or Units</th>
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</thead>
<tbody>
<tr>
<td>8/7-8/11</td>
<td>Q9922</td>
<td>15</td>
</tr>
</tbody>
</table>

On September 13, the patient’s HCT reading increased to 27/Hgb increased to 9. The patient received 5,100 units of EPO on September 13, September 15, and September 17, for a total of 15,300 units. Since less than 15,500 units were given, the figure is rounded down to 15,000. This line on the claim form shows:

<table>
<thead>
<tr>
<th>Dates of Service</th>
<th>Procedure Code</th>
<th>Days or Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/13-9/17</td>
<td>Q9927</td>
<td>15</td>
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</tbody>
</table>

On October 16, the HCT level increased to 33/Hgb increased to 11. The patient received doses of 4,850 units on October 16, October 18, and October 20 for a total of 14,550 units.
Since more than 14,500 units were administered, the figure is rounded up to 15,000. Form CMS-1500 shows:

<table>
<thead>
<tr>
<th>Dates of Service</th>
<th>Procedure Code</th>
<th>Days or Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/16–10/20</td>
<td>Q9933</td>
<td>15</td>
</tr>
</tbody>
</table>

**NOTE:** Creatinine and weight identified below are required on EPO claims as applicable.

**D.** Date of the Patient’s most recent HCT or Hgb.

**E.** Most recent HCT or Hgb level—(prior to initiation of EPO therapy).

**F.** Date of most recent HCT or Hgb level—(prior to initiation of EPO therapy).

**G.** Patient’s most recent serum creatinine—(within the last month, prior to initiation of EPO therapy).

**H.** Date of most recent serum creatinine—(prior to initiation of EPO therapy).

**I.** Patient’s weight in kilograms

**J.** Patient’s starting dose per kilogram—(The usual starting dose is 50-100 units per kilogram.)

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**60.4.2.2—Completion of Subsequent Form CMS-1500 Claims for Epoetin Alfa (EPO)**

(Rev 118, 03-05-04)

Subsequent claims are completed as initial claims in §60.4.2, except the following fields:

**A. Diagnoses.**

**B. Hematocrit or Hemoglobin**—For dates of service prior to January 1, 2004, this is indicated by the appropriate Q code. For dates of service January 1, 2004, and after, suppliers must indicate the beneficiary's hematocrit on the claim. (See 60.4.2.) Claims include an EJ modifier to the Q code. This allows the contractor to identify subsequent claims, which do not require as much information as initial claims and prevent unnecessary development.

**Number of Units Administered**—Subsequent claims may be submitted electronically.

**90.1—DMERC Denials for Beneficiary Submitted Claims Under Method II**

(Rev. 1, 10-01-03)

A3-3170.6, A3-3644.3, A3-3644.3.A - E, HO-238.2.C, HO-238.3, HO-238.3.A, B3-2231.3.A AND B, B3-2231, B3-4270.1, PRM-1-2709.2.A

Under Method II, beneficiaries may not submit any claims and cannot receive payment for any benefits for home dialysis equipment and supplies. DMERCs must deny unassigned and beneficiary submitted claims with the following MSN messages.

**MSN # 16.6:** "If you have already paid it, you are entitled to a refund from this provider."

Spanish: “Si usted ya lo ha pagado, tiene derecho a un reembolso de su proveedor.”

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**100-04 Chapter 12**

**30.4—Cardiovascular System (Codes 92950-93799)**

(Rev. 979, Issued: 06-09-06, Effective: 07-10-06, Implementation: 07-10-06)

**A. Echocardiography Contrast Agents**

Effective October 1, 2000, physicians may separately bill for contrast agents used in echocardiography. Physicians should use HCPCS Code A9700 (Supply of Injectable Contrast Material for Use in Echocardiography, per study). The type of service code is 9. This code will be carrier-priced.

**B. Electronic Analyses of Implantable Cardioverter-Defibrillators and Pacemakers**

The CPT codes 93731, 93734, 93741 and 93743 are used to report electronic analyses of single or dual chamber pacemakers and single or dual chamber implantable cardioverter-defibrillators. In the office, a physician uses a device called a programmer to obtain information about the status and performance of the device and to evaluate the patient’s cardiac rhythm and response to the implanted device.

Advances in information technology now enable physicians to evaluate patients with implanted cardiac devices without requiring the patient to be present in the physician's office. Using a manufacturer's specific monitor/transmitter, a patient can send complete device data and specific cardiac data to a distant receiving station or secure Internet server. The electronic analysis of cardiac device data that is remotely obtained provides immediate and long-term data on the device and clinical data on the patient’s cardiac functioning equivalent to that obtained during an in-office evaluation. Physicians should report the electronic analysis of an implanted cardiac device using remotely obtained data as described above with CPT code 93731, 93734, 93741 or 93743, depending on the type of cardiac device implanted in the patient.

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**30.6—Evaluation and Management Service Codes - General (Codes 99201 - 99499)**

(Rev. 178, 05-14-04)

B3-15501-15501.1

**30.6.1—Selection of Level of Evaluation and Management Service**

(Rev. 3315, Issued: 08-06-15, Effective: 01-01-16, Implementation: 01-04-16)

**A. Use of CPT Codes**

Advises physicians to use CPT codes (level 1 of HCPCS) to code physician services, including evaluation and management services. Medicare will pay for E/M services for specific non-physician practitioners (i.e., nurse practitioner (NP),...
clinical nurse specialist (CNS) and certified nurse midwife (CNM) whose Medicare benefit permits them to bill these services. A physician assistant (PA) may also provide a physician service, however, the physician collaboration and general supervision rules as well as all billing rules apply to all the above non-physician practitioners. The service provided must be medically necessary and the service must be within the scope of practice for a nonphysician practitioner in the State in which he/she practices. Do not pay for CPT evaluation and management codes billed by physical therapists in independent practice or by occupational therapists in independent practice.

Medical necessity of a service is the overarching criterion for payment in addition to the individual requirements of a CPT code. It would not be medically necessary or appropriate to bill a higher level of evaluation and management service when a lower level of service is warranted. The volume of documentation should not be the primary influence upon which a specific level of service is billed. Documentation should support the level of service reported. The service should be documented during, or as soon as practicable after it is provided in order to maintain an accurate medical record.

B. Selection of Level of Evaluation and Management Service

Instruct physicians to select the code for the service based upon the content of the service. The duration of the visit is an ancillary factor and does not control the level of the service to be billed unless more than 50 percent of the face-to-face time (for non-inpatient services) or more than 50 percent of the floor time (for inpatient services) is spent providing counseling or coordination of care as described in subsection C.

Any physician or non-physician practitioner (NPP) authorized to bill Medicare services will be paid by the Medicare Administrative Contractor at the appropriate physician fee schedule amount based on the rendering UPIN/PIN. “Incident to” Medicare Part B payment policy is applicable for office visits when the requirements for “incident to” are met (refer to sections 60.1, 60.2, and 60.3, chapter 15 in IOM 100-02).

SPLIT/SHARED E/M SERVICE

Office/Clinic Setting

In the office/clinic setting when the physician performs the E/M service the service must be reported using the physician’s UPIN/PIN. When an E/M service is a shared/split encounter between a physician and a non-physician practitioner (NP, PA, CNS or CNM), the service is considered to have been performed “incident to” if the requirements for “incident to” are met and the patient is an established patient. If “incident to” requirements are not met for the shared/split E/M service, the service must be billed under the NPP’s UPIN/PIN, and payment will be made at the appropriate physician fee schedule payment.

Hospital Inpatient/Outpatient (On Campus or Off Campus)/Emergency Department Setting

When a hospital inpatient/hospital outpatient (on campus-outpatient hospital or off campus-outpatient hospital) or emergency department E/M is shared between a physician and an NPP from the same group practice and the physician provides any face-to-face portion of the E/M encounter with the patient, the service may be billed under either the physician’s or the NPP’s UPIN/PIN number. However, if there was no face-to-face encounter between the patient and the physician (e.g., even if the physician participated in the service by only reviewing the patient’s medical record) then the service may only be billed under the NPP’s UPIN/PIN. Payment will be made at the appropriate physician fee schedule rate based on the UPIN/PIN entered on the claim.

EXAMPLES OF SHARED VISITS

1. If the NPP sees a hospital inpatient in the morning and the physician follows with a later face-to-face visit with the patient on the same day, the physician or the NPP may report the service.

2. In an office setting the NPP performs a portion of an E/M encounter and the physician completes the E/M service. If the “incident to” requirements are met, the physician reports the service. If the “incident to” requirements are not met, the service must be reported using the NPP’s UPIN/PIN.

In the rare circumstance when a physician (or NPP) provides a service that does not reflect a CPT code description, the service must be reported as an unlisted service with CPT code 99499. A description of the service provided must accompany the claim. The MAC has the discretion to value the service when the service does not meet the full terms of a CPT code description (e.g., only a history is performed). The MAC also determines the payment based on the applicable percentage of the physician fee schedule depending on whether the claim is paid at the physician rate or the non-physician practitioner rate. CPT modifier -52 (reduced services) must not be used with an evaluation and management service. Medicare does not recognize modifier -52 for this purpose.

C. Selection of Level of Evaluation and Management Service Based On Duration Of Coordination Of Care and/or Counseling

Advise physicians that when counseling and/or coordination of care dominates (more than 50 percent) the face-to-face physician/patient encounter or the floor time (in the case of inpatient services), time is the key or controlling factor in selecting the level of service. In general, to bill an E/M code, the physician must complete at least 2 out of 3 criteria applicable to the type/level of service provided. However, the physician may document time spent with the patient in conjunction with the medical decision-making involved and a description of the coordination of care or counseling provided. Documentation must be in sufficient detail to support the claim.

EXAMPLE: A cancer patient has had all preliminary studies completed and a medical decision to implement chemotherapy. At an office visit the physician discusses the treatment options and subsequent lifestyle effects of treatment the patient may encounter or is experiencing. The physician need not complete a history and physical examination in order to select the level of service. The time spent in counseling/coordination of care and medical decision-making will determine the level of service billed.

The code selection is based on the total time of the face-to-face encounter or floor time, not just the counseling time. The medical record must be documented in sufficient detail to justify the selection of the specific code if time is the basis for selection of the code.

In the office and other outpatient setting, counseling and/or coordination of care must be provided in the presence of the patient if the time spent providing those services is used to
complete multi-system examination.面-to-face time refers to the time with the physician only. Counseling by other staff is not considered to be part of the face-to-face physician/patient encounter time. Therefore, the time spent by the other staff is not considered in selecting the appropriate level of service. The code used depends upon the physician service provided.

In an inpatient setting, the counseling and/or coordination of care must be provided at the bedside or on the patient’s hospital floor or unit that is associated with an individual patient. Time spent counseling the patient or coordinating the patient’s care after the patient has left the office or the physician has left the patient’s floor or begun to care for another patient on the floor is not considered when selecting the level of service to be reported.

The comprehensive history must include a review of all the systems and a complete past (medical and surgical) family history, in established patients, it is acceptable for a physician to review the entire history for a service that involves predominantly coordination of care or counseling.

D. Use of Highest Levels of Evaluation and Management Codes

A/B MACs (B) must advise physicians that to bill the highest levels of visit codes, the services furnished must meet the definition of the code (e.g., to bill a Level 5 new patient visit, the history must meet CPT’s definition of a comprehensive history).

The comprehensive history must include a review of all the systems and a complete past (medical and surgical) family and social history obtained at that visit. In the case of an established patient, it is acceptable for a physician to review the existing record and update it to reflect only changes in the patient’s medical, family, and social history from the last encounter, but the physician must review the entire history for it to be considered a comprehensive history.

The comprehensive examination may be a complete single system exam such as cardiac, respiratory, psychiatric, or a complete multi-system examination.

30.6.1.1 – Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV)

(Rev. 3096, Issued: 10-17-14, Effective: 01-27-14, Implementation: 11-18-14)

A. Definition

1. Initial Preventive Physical Examination (IPPE)

The initial preventive physical examination (IPPE), or “Welcome to Medicare Preventive Visit” is a preventive visit authorized by sections 1861(s)(2)(w) and 1861(w)(w) of the Social Security Act and implementing regulations at 42 CFR 410.16, 411.15(a)(1), and 411.15(k)(11)).

As described in the implementing regulations, the IPPE includes the following:

(1) review of the individual’s medical and social history with attention to modifiable risk factors for disease detection,
(2) review of the individual’s potential (risk factors) for depression or other mood disorders,
(3) review of the individual’s functional ability and level of safety,
(4) an examination to include measurement of the individual’s height, weight, body mass index, blood pressure, a visual acuity screen, and other factors as deemed appropriate, based on the beneficiary’s medical and social history,
(5) end-of-life planning, upon agreement of the individual,
(6) education, counseling, and referral, as deemed appropriate, based on the results of the review and evaluation services described in the previous 5 elements, and,
(7) education, counseling, and referral including a brief written plan (e.g., a checklist or alternative) provided to the individual for obtaining the appropriate screening and other preventive services, which are separately covered under Medicare Part B (that is, pneumococcal, influenza and hepatitis B vaccines and their administration, screening mammography, screening pap smear and screening pelvic examinations, prostate cancer screening tests, colorectal cancer screening tests, diabetes outpatient self-management training services, bone mass measurements, glaucoma screening, medical nutrition therapy for individuals with diabetes or renal disease, cardiovascular screening blood tests, diabetes screening tests, screening ultrasound for abdominal aortic aneurysms, an electrocardiogram, and additional preventive services covered under Medicare Part B through the Medicare national coverage determinations process).

2. Annual Wellness Visit (AWV)

Effective January 1, 2011, Sections 1861(s)(2)(FF) and 1861(1hh) of the Social Security Act and implementing regulations at 42 CFR 410.15, authorize for an AWV providing personalized personal prevention plan services (PPPS). The AWV is preventive visit available to eligible beneficiaries, and identified by HCPCS codes G0438 (Annual wellness visit, including PPPS, first visit) and G0439 (Annual wellness visit, including PPPS, subsequent visit). Information, including definitions of relevant terms and coverage requirements for the AWV are included in Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 280.5.

The first AWV providing PPPS (HCPCS G0438) is a ‘one time’ allowed Medicare benefit and includes the following elements furnished to an eligible beneficiary by a health professional:

Review (and administration if needed) of a health risk assessment,

• Establishment of the individual’s medical/family history,
• Establishment of a list of current providers and suppliers that are regularly involved in providing medical care to the individual,
• Measurement of the individual’s height, weight, body mass index (or waist circumference, if appropriate), blood pressure (BP), and other routine measurements as deemed appropriate, based on the individual’s medical and family history,
• Detection of any cognitive impairment that the individual may have,
• Review of an individual’s potential risk factors for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the health professional may
select from various available standardized screening tests designed for this purpose and recognized by national professional medical organizations,

- Review of the individual’s functional ability and level of safety, based on direct observation of the individual, or the use of appropriate screening questions or a screening questionnaire, which the health professional may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations,

- Establishment of a written screening schedule for the individual, such as a checklist for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Service Task Force (USPSTF) and Advisory Committee of Immunizations Practices (ACIP), and the individual’s health risk assessment, the individual’s health status, screening history, and age-appropriate preventive services covered by Medicare,

- Establishment of a list of risk factors and conditions of which primary, secondary, or tertiary interventions are recommended or underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through an IPPE, and a list of treatment options and their associated risks and benefits,

- Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition, and,

- Any other element(s) determined appropriate by the Secretary through the national coverage determinations process.

Subsequent AWVs providing PPPS (HCPCS G0439) include the following key elements furnished to an eligible beneficiary by a health professional:

- Review (and administration if needed) of a health risk assessment,

- Update of the individual’s medical/family history,

- Update to the list of the individual’s current medical providers and suppliers that are regularly involved in providing medical care to the individual as that list was developed for the first AWV providing PPPS, or the previous subsequent AWV providing PPPS,

- Measurements of an individual’s weight (or waist circumference), blood pressure, and other routine measurements as deemed appropriate, based on the individual’s medical and family history,

- Detection of any cognitive impairment that the individual may have,

- Update to the individual’s written screening schedule as developed at the first AWV providing PPPS,

- Update to the individual’s list of risk factors and conditions for which primary, secondary, or tertiary interventions are recommended or are underway for the individual, as that list was developed at the first AWV providing PPPS, or the previous subsequent AWV providing PPPS,

- Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs, and,

- Any other element determined appropriate by the Secretary through the national coverage determinations process.

See chapter 18 of this manual for additional information regarding preventive services that are separately covered under Medicare Part B.

B. Who May Perform an IPPE or AWV

The contractor pays the appropriate physician fee schedule amount based on the rendering National Provider Identification (NPI) number.

The IPPE may be performed by:

- a doctor of medicine or osteopathy as defined in Section 1861(r)(1) of the Social Security Act, or
- a qualified nonphysician practitioner (nurse practitioner, physician assistant or clinical nurse specialist).

The AWV may be performed by a health professional, which is defined as:

- a doctor of medicine or osteopathy as defined in Section 1861(r)(1) of the Social Security Act, a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5) of the Social Security Act), or
- a medical professional (including a health educator, registered dietitian, nutrition professional, or other licensed practitioner) or a team of such medical professionals, working under the direct supervision of a physician (doctor of medicine or osteopathy).

C. Eligibility

1. IPPE

Medicare pays for one IPPE per beneficiary per lifetime for beneficiaries within the first 12 months of the effective date of the beneficiary’s first Part B coverage period.

2. AWV

Medicare pays for an AWV for a beneficiary who is no longer within 12 months after the effective date of his/her first Medicare Part B coverage period, and who has not received either an IPPE or an AWV providing PPPS within the past 12 months. Medicare pays for only one first AWV (HCPCS G0438), per beneficiary per lifetime. All subsequent AWVs must be billed using HCPCS G0439.

D. Deductible and Coinsurance

1. IPPE

The Medicare deductible and coinsurance apply for the IPPE provided before January 1, 2009.

The Medicare deductible is waived effective for the IPPE provided on or after January 1, 2009. However, the applicable coinsurance continues to apply for the IPPE provided on or after January 1, 2009.

As a result of the Affordable Care Act (ACA), effective for the IPPE provided on or after January 1, 2011, the Medicare deductible and coinsurance (for HCPCS code G0402 only) are waived.

2. AWV

As a result of the ACA, effective January 1, 2011, the Medicare deductible and coinsurance for the AWV (HCPCS G0438 and G0439) are waived.
E. The EKG Component of the IPPE

The once-in-a-lifetime screening EKG may be performed, as appropriate, with a referral from an IPPE.

F. HCPCS Codes Used to Bill the IPPE or AWV

1. HCPCS Codes Used to Bill the IPPE

For IPPE and EKG services provided prior to January 1, 2009, the physician or qualified NPP shall bill HCPCS code G0344 for the IPPE performed face-to-face, and HCPCS code G0366 for performing a screening EKG that includes both the interpretation and report. If the primary physician or qualified NPP performs only the IPPE he/she shall bill HCPCS code G0344 only. The physician or entity that performs the screening EKG tracing only (without interpretation and report) shall bill HCPCS code G0367. The physician or entity that performs the interpretation and report only (without the EKG tracing) shall bill HCPCS code G0368. Medicare will pay for a screening EKG only as part of the IPPE. HCPCS codes G0344, G0366, G0367 and G0368 will not be billable codes effective on or after January 1, 2009.

Effective for a beneficiary who has the IPPE on or after January 1, 2009, and within his/her 12-month enrollment period of Medicare Part B, the IPPE and screening EKG services are billable with the appropriate HCPCS Code(s).

The physician or qualified NPP shall bill HCPCS code G0402 for the IPPE performed face-to-face with the patient.

The physician or entity shall bill HCPCS code G0403 for performing the complete screening EKG that includes the tracing, interpretation and report.

The physician or entity that performs the screening EKG tracing only (without interpretation and report) shall bill HCPCS code G0404.

The physician or entity that performs the screening EKG interpretation and report only, (without the EKG tracing) shall bill HCPCS code G0405.

2. HCPCS Codes Used to Bill the AWV

For the first AWV provided on or after January 1, 2011, the health professional shall bill HCPCS G0438 (Annual wellness visit, including PPPS, first visit). This is a once per beneficiary per lifetime allowable Medicare Part B benefit.

All subsequent AWVs shall be billed with HCPCS G0439 (Annual Wellness Visit, including PPPS, subsequent visit). In the event that a beneficiary selects a new health professional to complete a subsequent AWV, the new health professional will continue to bill the subsequent AWV with HCPCS G0439.

NOTE: For an IPPE or AWV performed during the global period of surgery refer to chapter 12, §30.6.6 of this chapter for reporting instructions.

G. Documentation for the IPPE or AWV

Practitioners eligible to furnish an IPPE or an AWV are required to use the 1995 and 1997 E/M documentation guidelines to document the medical record with the appropriate clinical information. (http://xmarks.com/site/www.cms.hhs.gov/MLNEdWebGuide/25_EMDOC.asp) All referrals and a written medical plan must be included in this documentation.

H. Reporting a Medically Necessary E/M Service Furnished During the Same Encounter as an IPPE or AWV

When the physician or qualified NPP, or for AWV the health professional, provides a significant, separately identifiable medically necessary E/M service in addition to the IPPE or an AWV, CPT codes 99201 – 99215 may be reported depending on the clinical appropriateness of the circumstances. CPT Modifier -25 shall be appended to the medically necessary E/M service identifying this service as a significant, separately identifiable service from the IPPE or AWV code reported (HCPCS code G0344 or G0402, whichever applies based on the date the IPPE is performed, or HCPCS code G0438 or G0439 whichever AWV code applies).

NOTE: Some of the components of a medically necessary E/M service (e.g., a portion of history or physical exam portion) may have been part of the IPPE or AWV and should not be included when determining the most appropriate level of E/M service to be billed for the medically necessary, separately identifiable, E/M service.

30.6.2—Billing for Medically Necessary Visit on Same Occasion as Preventive Medicine Service

See Chapter 18 for payment for covered preventive services.

When a physician furnishes a Medicare beneficiary a covered visit at the same place and on the same occasion as a noncovered preventive medicine service (CPT codes 99381-99397), consider the covered visit to be provided in lieu of a part of the preventive medicine service of equal value to the visit. A preventive medicine service (CPT codes 99381-99397) is a noncovered service. The physician may charge the beneficiary, as a charge for the noncovered remainder of the service, the amount by which the physician's current established charge for the preventive medicine service exceeds his/her current established charge for the covered visit. Pay for the covered visit based on the lesser of the fee schedule amount or the physician's actual charge for the visit. The physician is not required to give the beneficiary written advance notice of noncoverage of the part of the visit that constitutes a routine preventive visit. However, the physician is responsible for notifying the patient in advance of his/her liability for the charges for services that are not medically necessary to treat the illness or injury.

There could be covered and noncovered procedures performed during this encounter (e.g., screening x-ray, EKG, lab tests.). These are considered individually. Those procedures which are for screening for asymptomatic conditions are considered noncovered and, therefore, no payment is made. Those procedures ordered to diagnose or monitor a symptom, medical condition, or treatment are evaluated for medical necessity and, if covered, are paid.

30.6.3—Payment for Immunosuppressive Therapy Management

Physicians bill for management of immunosuppressive therapy using the office or subsequent hospital visit codes that describe the services furnished. If the physician who is managing the immunotherapy is also the transplant surgeon, he
or she bills these visits with modifier “-24” indicating that the visit during the global period is not related to the original procedure if the physician also performed the transplant surgery and submits documentation that shows that the visit is for immunosuppressive therapy.

30.6.6—Payment for Evaluation and Management Services Furnished Provided During Global Period of Surgery

(Rev. 954, Issued: 05-19-06, Effective: 06-01-06, Implementation: 08-20-06)

A. CPT Modifier “-24” - Unrelated Evaluation and Management Service by Same Physician During Postoperative Period

Carriers pay for an evaluation and management service other than inpatient hospital care before discharge from the hospital following surgery (CPT codes 99221-99238) if it was provided during the postoperative period of a surgical procedure, furnished by the same physician who performed the procedure, billed with CPT modifier “-24,” and accompanied by documentation that supports that the service is not related to the postoperative care of the procedure. They do not pay for inpatient hospital care that is furnished during the hospital stay in which the surgery occurred unless the doctor is also treating another medical condition that is unrelated to the surgery. All care provided during the inpatient stay in which the surgery occurred is compensated through the global surgical payment.

B. CPT Modifier “-25” - Significant Evaluation and Management Service by Same Physician on Date of Global Procedure

Medicare requires that Current Procedural Terminology (CPT) modifier -25 should only be used on claims for evaluation and management (E/M) services, and only when these services are provided by the same physician (or same qualified nonphysician practitioner) to the same patient on the same day as another procedure or other service. Carriers pay for an E/M service provided on the day of a procedure with a global fee period if the physician indicates that the service is for a significant, separately identifiable E/M service that is above and beyond the usual pre- and post-operative work of the procedure. Different diagnoses are not required for reporting the E/M service on the same date as the procedure or other service. Modifier -25 is added to the E/M code on the claim.

Both the medically necessary E/M service and the procedure must be appropriately and sufficiently documented by the physician or qualified nonphysician practitioner in the patient’s medical record to support the claim for these services, even though the documentation is not required to be submitted with the claim.

If the physician bills the service with the CPT modifier “-25,” carriers pay for the service in addition to the global fee without any other requirement for documentation unless one of the following conditions is met:

• When inpatient dialysis services are billed (CPT codes 90935, 90945, 90947, and 93937), the physician must document that the service was unrelated to the dialysis and could not be performed during the dialysis procedure;
• When preoperative critical care codes are being billed on the date of the procedure, the diagnosis must support that the service is unrelated to the performance of the procedure; or
• When a carrier has conducted a specific medical review process and determined, after reviewing the data, that an individual or a group has high use of modifier “-25” compared to other physicians, has done a case-by-case review of the records to verify that the use of modifier was inappropriate, and has educated the individual or group, the carrier may impose prepayment screens or documentation requirements for that provider or group. When a carrier has completed a review and determined that a high usage rate of modifier “-57,” the carrier must complete a case-by-case review of the records. Based upon this review, the carrier will educate providers regarding the appropriate use of modifier “-57.” If high usage rates continue, the carrier may impose prepayment screens or documentation requirements for that provider or group.

Carriers may not permit the use of CPT modifier “-25” to generate payment for multiple evaluation and management services on the same day by the same physician, notwithstanding the CPT definition of the modifier.
C. CPT Modifier “.57” - Decision for Surgery Made Within Global Surgical Period

Carriers pay for an evaluation and management service on the day of or on the day before a procedure with a 90-day global surgical period if the physician uses CPT modifier “.57” to indicate that the service resulted in the decision to perform the procedure. Carriers may not pay for an evaluation and management service billed with the CPT modifier “.57” if it was provided on the day of or the day before a procedure with a 0 or 10-day global surgical period.

30.6.7—Payment for Office or Other Outpatient Evaluation and Management (E/M) Visits (Codes 99201 - 99215)
(Rev. 3315, Issued: 08-06-15, Effective: 01-01-16, Implementation: 01-04-16)

A. Definition of New Patient for Selection of E/M Visit Code

Interpret the phrase “new patient” to mean a patient who has not received any professional services, i.e., E/M service or other face-to-face service (e.g., surgical procedure) from the physician or physician group practice (same physician specialty) within the previous 3 years. For example, if a professional component of a previous procedure is billed in a 3 year time period, e.g., a lab interpretation is billed and no E/M service or other face-to-face service with the patient is performed, then this patient remains a new patient for the initial visit. An interpretation of a diagnostic test, reading an x-ray or EKG etc., in the absence of an E/M service or other face-to-face service with the patient does not affect the designation of a new patient.

B. Office/Outpatient E/M Visits Provided on Same Day for Unrelated Problems

As for all other E/M services except where specifically noted, the Medicare Administrative Contractors (MACs) may not pay two E/M office visits billed by a physician (or physician of the same specialty from the same group practice) for the same beneficiary on the same day unless the physician documents that the visits were for unrelated problems in the office, off campus-outpatient hospital, or on campus-outpatient hospital setting which could not be provided during the same encounter (e.g., office visit for blood pressure medication evaluation, followed five hours later by a visit for evaluation of leg pain following an accident).

C. Office/Outpatient or Emergency Department E/M Visit on Day of Admission to Nursing Facility

MACs may not pay a physician for an emergency department visit or an office visit and a comprehensive nursing facility assessment on the same day. Bundle E/M visits on the same date provided in sites other than the nursing facility into the initial nursing facility care code when performed on the same date as the nursing facility admission by the same physician.

D. Drug Administration Services and E/M Visits Billed on Same Day of Service

MACs must advise physicians that CPT code 99211 cannot be paid if it is billed with a drug administration service such as a chemotherapy or nonchemotherapy drug infusion code (effective January 1, 2004). This drug administration policy was expanded in the Physician Fee Schedule Final Rule, November 15, 2004, to also include a therapeutic or diagnostic injection code (effective January 1, 2005). Therefore, when a medically necessary, significant and separately identifiable E/M service (which meets a higher complexity level than CPT code 99211) is performed, in addition to one of these drug administration services, the appropriate E/M CPT code should be reported with modifier -25. Documentation should support the level of E/M service billed. For an E/M service provided on the same day, a different diagnosis is not required.

30.6.8—Payment for Hospital Observation Services and Observation or Inpatient Care Services (Including Admission and Discharge Services)
(Rev. 2282, Issued: 08-26-11, Effective: 01-01-11, Implementation: 11-28-11)

A. Who May Bill Initial Observation Care

Observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment, that are furnished while a decision is being made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge.

In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours. In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours.

Contractors pay for initial observation care billed by only the physician who ordered hospital outpatient observation services and was responsible for the patient during his/her care. A physician who does not have inpatient admitting privileges but who is authorized to furnish hospital outpatient observation services may bill these codes.

For a physician to bill the initial observation care codes, there must be a medical observation record for the patient which contains dated and timed physician’s orders regarding the observation service the patient is to receive, observation, nursing notes, and progress notes prepared by the physician while the patient received observation services. This record must be in addition to any record prepared as a result of an emergency department or outpatient clinic encounter.

Payment for an initial observation care code is for all the care rendered by the ordering physician on the date the patient’s observation services began. All other physicians who furnish consultations or additional evaluations or services while the patient is receiving hospital outpatient observation services must bill the appropriate outpatient service codes.

For example, if an internist orders observation services and asks another physician to additionally evaluate the patient, only the internist may bill the initial observation care code. The other physician who evaluates the patient must bill the new or established office or other outpatient visit codes as appropriate.
For information regarding hospital billing of observation services, see Chapter 4, §290.

B. Physician Billing for Observation Care Following Initiation of Observation Services

Similar to initial observation codes, payment for a subsequent observation care code is for all the care rendered by the treating physician on the day(s) other than the initial or discharge date. All other physicians who furnish consultations or additional evaluations or services while the patient is receiving hospital outpatient observation services must bill the appropriate outpatient service codes.

When a patient receives observation care for less than 8 hours on the same calendar date, the Initial Observation Care, from CPT code range 99218 – 99220, shall be reported by the physician. The Observation Care Discharge Service, CPT code 99217, shall not be reported for this scenario.

When a patient is admitted for observation care and then discharged on a different calendar date, the physician shall report Initial Observation Care, from CPT code range 99218 – 99220, and CPT observation care discharge CPT code 99217. On the rare occasion when a patient remains in observation care for 3 days, the physician shall report an initial observation care code (99218-99220) for the first day of observation care, a subsequent observation care code (99224-99226) for the second day of observation care, and an observation care discharge CPT code 99217 for the observation care on the discharge date. When observation care continues beyond 3 days, the physician shall report a subsequent observation care code (99224-99226) for each day between the first day of observation care and the discharge date.

When a patient receives observation care for a minimum of 8 hours, but less than 24 hours, and is discharged on the same calendar date, Observation or Inpatient Care Services (Including Admission and Discharge Services) from CPT code range 99234 – 99236, shall be reported. The observation discharge, CPT code 99217, cannot also be reported for this scenario.

C. Documentation Requirements for Billing Observation or Inpatient Care Services (Including Admission and Discharge Services)

The physician shall satisfy the E/M documentation guidelines for furnishing observation care or inpatient hospital care. In addition to meeting the documentation requirements for history, examination, and medical decision making documentation in the medical record shall include:

- Documentation stating the stay for observation care or inpatient hospital care involves 8 hours, but less than 24 hours;
- Documentation identifying the billing physician was present and personally performed the services; and
- Documentation identifying the order for observation services, progress notes, and discharge notes were written by the billing physician.

In the rare circumstance when a patient receives observation services for more than 2 calendar dates, the physician shall bill observation services furnished on day(s) other than the initial or discharge date using subsequent observation care codes. The physician may not use the subsequent hospital care codes since the patient is not an inpatient of the hospital.

D. Admission to Inpatient Status Following Observation Care

If the same physician who ordered hospital outpatient observation services also admits the patient to inpatient status before the end of the date on which the patient began receiving hospital outpatient observation services, pay only an initial hospital visit for the evaluation and management services provided on that date. Medicare payment for the initial hospital visit includes all services provided to the patient on the date of admission by that physician, regardless of the site of service. The physician may not bill an initial observation care code for services on the date that he or she admits the patient to inpatient status. If the patient is admitted to inpatient status from hospital outpatient observation care subsequent to the date of initiation of observation services, the physician must bill an initial hospital visit for the services provided on that date. The physician may not bill the hospital observation discharge management code (code 99217) or an outpatient/office visit for the care provided in observation on the date of admission to inpatient status.

E. Hospital Observation During Global Surgical Period

The global surgical fee includes payment for hospital observation (codes 99217, 99218, 99219, 99220, 99224, 99225, 99226, 99234, 99235, and 99236) services unless the criteria for use of CPT modifiers “-24,” “-25,” or “-57” are met. Contractors must pay for these services in addition to the global surgical fee only if both of the following requirements are met:

- The hospital observation service meets the criteria needed to justify billing it with CPT modifiers “-24,” “-25,” or “-57” (decision for major surgery); and
- The hospital observation service furnished by the surgeon meets all of the criteria for the hospital observation code billed.

Examples of the decision for surgery during a hospital observation period are:

- An emergency department physician orders hospital outpatient observation services for a patient with a head injury. A neurosurgeon is called in to evaluate the need for surgery while the patient is receiving observation services and decides that the patient requires surgery. The surgeon would bill the appropriate level of hospital outpatient observation visit code as appropriate with the “-57” modifier to indicate that the decision for surgery was made during the evaluation. The surgeon must bill the office or other outpatient visit code because the patient receiving hospital outpatient observation services is not an inpatient of the hospital. Only the physician who ordered hospital outpatient observation services may bill for observation care.
- A neurosurgeon orders hospital outpatient observation services for a patient with a head injury. During the observation period, the surgeon makes the decision for surgery. The surgeon would bill the appropriate level of hospital observation code with the “-57” modifier to indicate that the decision for surgery was made while the surgeon was providing hospital observation care.

Examples of hospital observation services during the postoperative period of a surgery are:

- A surgeon orders hospital outpatient observation services for a patient with abdominal pain from a kidney stone on the 80th day following a TURP (performed by that surgeon). The surgeon decides that the patient does not require surgery. The surgeon would bill the observation code
with CPT modifier “-24” and documentation to support that the observation services are unrelated to the surgery.
• A surgeon orders hospital outpatient observation services for a patient with abdominal pain from a kidney stone on the 80th day following a TURP (performed by that surgeon). While the patient is in hospital observation, the surgeon decides that the patient requires kidney surgery. The surgeon would bill the observation code with HCPCS modifier “-57” to indicate that the decision for surgery was made while the patient was receiving hospital outpatient observation services. The subsequent surgical procedure would be reported with modifier “-79.”
• A surgeon orders hospital outpatient observation services for a patient with abdominal pain on the 20th day following a resection of the colon (performed by that surgeon). The surgeon determines that the patient requires no further colon surgery and discharges the patient. The surgeon may not bill for the observation services furnished during the global period because they were related to the previous surgery.

An example of a billable hospital observation service on the same day as a procedure is when a physician repairs a laceration of the scalp in the emergency department for a patient with a head injury and then subsequently orders hospital outpatient observation services for that patient. The physician would bill the observation code with a CPT modifier 25 and the procedure code.

30.6.9—Payment for Inpatient Hospital Visits - General
(Rev. 2282, Issued: 08-26-11, Effective: 01-01-11, Implementation: 11-28-11)
A. Hospital Visit and Critical Care on Same Day
When a hospital inpatient or office/outpatient evaluation and management service (E/M) are furnished on a calendar date at which time the patient does not require critical care and the patient subsequently requires critical care, both the critical Care Services (CPT codes 99291 and 99292) and the previous E/M service may be paid on the same date of service. Hospital emergency department services are not paid for the same date as critical care services when provided by the same physician to the same patient.

During critical care management of a patient those services that do not meet the level of critical care shall be reported using an inpatient hospital care service with CPT Subsequent Hospital Care using a code from CPT code range 99231 – 99233.

Both Initial Hospital Care (CPT codes 99221 – 99223) and Subsequent Hospital Care codes are “per diem” services and may be reported only once per day by the same physician or physicians of the same specialty from the same group practice.

Physicians and qualified nonphysician practitioners (NPPs) are advised to retain documentation for discretionary contractor review should claims be questioned for both hospital care and critical care claims. The retained documentation shall support claims for critical care when the same physician or physicians of the same specialty in a group practice report critical care services for the same patient on the same calendar date as other E/M services.

B. Two Hospital Visits Same Day
Contractors pay a physician for only one hospital visit per day for the same patient, whether the problems seen during the encounters are related or not. The inpatient hospital visit descriptors contain the phrase “per day” which means that the code and the payment established for the code represent all services provided on that date. The physician should select a code that reflects all services provided during the date of the service.

C. Hospital Visits Same Day But by Different Physicians
In a hospital inpatient situation involving one physician covering for another, if physician A sees the patient in the morning and physician B, who is covering for A, sees the same patient in the evening, carriers do not pay physician B for the second visit. The hospital visit descriptors include the phrase “per day” meaning care for the day.

If the physicians are each responsible for a different aspect of the patient’s care, pay both visits if the physicians are in different specialties and the visits are billed with different diagnoses. There are circumstances where concurrent care may be billed by physicians of the same specialty.

D. Visits to Patients in Swing Beds
If the inpatient care is being billed by the hospital as inpatient care, the hospital care codes apply. If the inpatient care is being billed by the hospital as nursing facility care, then the nursing facility codes apply.

30.6.9.1—Payment for Initial Hospital Care Services and Observation or Inpatient Care Services (Including Admission and Discharge Services)
(Rev. 2282, Issued: 08-26-11, Effective: 01-01-11, Implementation: 11-28-11)
A. Initial Hospital Care From Emergency Room
Contractors pay for an initial hospital care service if a physician sees a patient in the emergency room and decides to admit the person to the hospital. They do not pay for both E/M services. Also, they do not pay for an emergency department visit by the same physician on the same date of service. When the patient is admitted to the hospital via another site of service (e.g., hospital emergency department, physician’s office, nursing facility), all services provided by the physician in conjunction with that admission are considered part of the initial hospital care when performed on the same date as the admission.

B. Initial Hospital Care on Day Following Visit
Contractors pay both visits if a patient is seen in the office on one date and admitted to the hospital on the next date, even if fewer than 24 hours has elapsed between the visit and the admission.

C. Initial Hospital Care and Discharge on Same Day
When the patient is admitted to inpatient hospital care for less than 8 hours on the same date, then Initial Hospital Care, from CPT code range 99221 – 99223, shall be reported by the physician. The Hospital Discharge Day Management service, CPT codes 99238 or 99239, shall not be reported for this scenario.

When a patient is admitted to inpatient initial hospital care and then discharged on a different calendar date, the physician shall report an Initial Hospital Care from CPT code range 99221 – 99223 and a Hospital Discharge Day Management service, CPT code 99238 or 99239.
When a patient has been admitted to inpatient hospital care for a minimum of 8 hours but less than 24 hours and discharged on the same calendar date, Observation or Inpatient Hospital Care Services (Including Admission and Discharge Services), from CPT code range 99234 – 99236, shall be reported.

D. Documentation Requirements for Billing Observation or Inpatient Care Services (Including Admission and Discharge Services)

The physician shall satisfy the E/M documentation guidelines for admission to and discharge from inpatient observation or hospital care. In addition to meeting the documentation requirements for history, examination and medical decision making documentation in the medical record shall include:

- Documentation stating the stay for hospital treatment or observation care status involves 8 hours but less than 24 hours;
- Documentation identifying the billing physician was present and personally performed the services; and
- Documentation identifying the admission and discharge notes were written by the billing physician.

E. Physician Services Involving Transfer From One Hospital to Another; Transfer Within Facility to Prospective Payment System (PPS) Exempt Unit of Hospital; Transfer From One Facility to Another Separate Entity Under Same Ownership and/or Part of Same Complex; or Transfer From One Department to Another Within Single Facility

Physicians may bill both the hospital discharge management code and an initial hospital care code when the discharge and admission do not occur on the same day if the transfer is between:

- Different hospitals;
- Different facilities under common ownership which do not have merged records; or
- Between the acute care hospital and a PPS exempt unit within the same hospital when there are no merged records.

In all other transfer circumstances, the physician should bill only the appropriate level of subsequent hospital care for the date of transfer.

F. Initial Hospital Care Service History and Physical That Is Less Than Comprehensive

When a physician performs a visit that meets the definition of a Level 5 office visit several days prior to an admission and on the day of admission performs less than a comprehensive history and physical, he or she should report the office visit that reflects the services furnished and also report the lowest level initial hospital care code (i.e., code 99221) for the initial hospital admission. Contractors pay the office visit as billed and the Level 1 initial hospital care code.

Physicians who provide an initial visit to a patient during inpatient hospital care that meets the minimum key component work and/or medical necessity requirements shall report an initial hospital care code (99221-99223). The principal physician of record shall append modifier “-AI” (Principal Physician of Record) to the claim with the initial hospital care code. This modifier will identify the physician who oversees the patient's care from all other physicians who may be furnishing specialty care.

Physicians may bill initial hospital care service codes (99221-99223), for services that were reported with CPT consultation codes (99241 – 99255) prior to January 1, 2010, when the furnished service and documentation meet the minimum key component work and/or medical necessity requirements.

Physicians must meet all the requirements of the initial hospital care codes, including “a detailed or comprehensive history” and “a detailed or comprehensive examination” to report CPT code 99221, which are greater than the requirements for consultation codes 99251 and 99252.

Subsequent hospital care CPT codes 99231 and 99232, respectively, require “a problem focused interval history” and “an expanded problem focused interval history.” An E/M service that could be described by CPT consultation code 99251 or 99252 could potentially meet the component work and medical necessity requirements to report 99231 or 99232.

Physicians may report a subsequent hospital care CPT code for services that were reported as CPT consultation codes (99241 – 99255) prior to January 1, 2010, where the medical record appropriately demonstrates that the work and medical necessity requirements are met for reporting a subsequent hospital care code (under the level selected), even though the reported code is for the provider's first E/M service to the inpatient during the hospital stay.

Reporting CPT code 99499 (Unlisted evaluation and management service) should be limited to cases where there is no other specific E/M code payable by Medicare that describes that service. Reporting CPT code 99499 requires submission of medical records and contractor manual medical review of the service prior to payment. Contractors shall expect reporting under these circumstances to be unusual.

G. Initial Hospital Care Visits by Two Different M.D.s or D.O.s When They Are Involved in Same Admission

In the inpatient hospital setting all physicians (and qualified nonphysician practitioners where permitted) who perform an initial evaluation may bill the initial hospital care codes (99221 – 99223) or nursing facility care codes (99304 – 99306). Contractors consider only one M.D. or D.O. to be the principal physician of record (sometimes referred to as the admitting physician.) The principal physician of record (sometimes referred to as the admitting physician) is identified in Medicare as the physician who oversees the patient's care from all other physicians who may be furnishing specialty care. Only the principal physician of record shall append modifier “-AI” (Principal Physician of Record) in addition to the E/M code. Follow-up visits in the facility setting shall be billed as subsequent hospital care visits and subsequent nursing facility care visits.

30.6.9.2—Subsequent Hospital Visit and Hospital Discharge Day Management (Codes 99231 - 99239)

(Rev. 1460, Issued: 02-22-08, Effective: 04-01-08, Implementation: 04-07-08)

A. Subsequent Hospital Visits During the Global Surgery Period

(Refer to §§40.40.4 on global surgery)

The Medicare physician fee schedule payment amount for surgical procedures includes all services (e.g., evaluation and
management visits) that are part of the global surgery payment; therefore, contractors shall not pay more than that amount when a bill is fragmented for staged procedures.

B. Hospital Discharge Day Management Service

Hospital Discharge Day Management Services, CPT code 99238 or 99239 is a face-to-face evaluation and management (E/M) service between the attending physician and the patient. The E/M discharge day management visit shall be reported for the date of the actual visit by the physician or qualified nonphysician practitioner even if the patient is discharged from the facility on a different calendar date. Only one hospital discharge day management service is payable per patient per hospital stay.

Only the attending physician of record reports the discharge day management service. Physicians or qualified nonphysician practitioners, other than the attending physician, who have been managing concurrent health care problems not primarily managed by the attending physician, and who are not acting on behalf of the attending physician, shall use Subsequent Hospital Care (CPT code range 99231 – 99233) for a final visit.

Medicare pays for the paperwork of patient discharge day management through the pre- and post-service work of an E/M service.

C. Subsequent Hospital Visit and Discharge Management on Same Day

Pay only the hospital discharge management code on the day of discharge (unless it is also the day of admission), in which case, refer to §30.6.9.1 C for the policy on Observation or Inpatient Care Services (Including Admission and Discharge Services CPT Codes 99234 - 99236). Contractors do not pay both a subsequent hospital visit in addition to hospital discharge day management service on the same day by the same physician. Instruct physicians that they may not bill for both a hospital visit and hospital discharge management for the same date of service.

D. Hospital Discharge Management (CPT Codes 99238 and 99239) and Nursing Facility Admission Code When Patient Is Discharged From Hospital and Admitted to Nursing Facility on Same Day

 Contractors pay the hospital discharge code (codes 99238 or 99239) in addition to a nursing facility admission code when they are billed by the same physician with the same date of service.

If a surgeon is admitting the patient to the nursing facility due to a condition that is not as a result of the surgery during the postoperative period of a service with the global surgical period, he/she bills for the nursing facility admission and care with a modifier “-24” and provides documentation that the service is unrelated to the surgery (e.g., return of an elderly patient to the nursing facility in which he/she has resided for five years following discharge from the hospital for cholecystectomy).

Contractors do not pay for a nursing facility admission by a surgeon in the postoperative period of a procedure with a global surgical period if the patient’s admission to the nursing facility is to receive post operative care related to the surgery (e.g., admission to a nursing facility to receive physical therapy following a hip replacement). Payment for the nursing facility admission and subsequent nursing facility services are included in the global fee and cannot be paid separately.

E. Hospital Discharge Management and Death Pronouncement

Only the physician who personally performs the pronouncement of death shall bill for the face-to-face Hospital Discharge Day Management Service, CPT code 99238 or 99239. The date of the pronouncement shall reflect the calendar date of service on the day it was performed even if the paperwork is delayed to a subsequent date.

30.6.10—Consultation Services

(Rev. 2282, Issued: 08-26-11, Effective: 01-01-11, Implementation: 11-28-11)

A. Consultation Services versus Other Evaluation and Management (E/M) Visits

Effective January 1, 2010, the consultation codes are no longer recognized for Medicare part B payment. Physicians shall code patient evaluation and management visits with E/M codes that represent where the visit occurs and that identify the complexity of the visit performed.

In the inpatient hospital setting and the nursing facility setting, physicians (and qualified nonphysician practitioners where permitted) may bill the most appropriate initial hospital care code (99221-99223), subsequent hospital care code (99231 and 99232), initial nursing facility care code (99304-99306), or subsequent nursing facility care code (99307-99310) that reflects the services the physician or practitioner furnished. Subsequent hospital care codes could potentially meet the component work and medical necessity requirements to be reported for an E/M service that could be described by CPT consultation code 99251 or 99252. Contractors shall not find fault in cases where the medical record appropriately demonstrates that the work and medical necessity requirements are met for reporting a subsequent hospital care code (under the level selected), even though the reported code is for the provider’s first E/M service to the inpatient during the hospital stay. Unlisted evaluation and management service (code 99499) shall only be reported for consultation services when an E/M service that could be described by codes 99251 or 99252 is furnished, and there is no other specific E/M code payable by Medicare that describes that service. Reporting code 99499 requires submission of medical records and contractor manual medical review of the service prior to payment. CMS expects reporting under these circumstances to be unusual. The principal physician of record is identified in Medicare as the physician who oversees the patients care from other physicians who may be furnishing specialty care. The principal physician of record shall append modifier “-AF” (Principal Physician of Record), in addition to the E/M code. Follow-up visits in the facility setting shall be billed as subsequent hospital care visits and subsequent nursing facility care visits.

In the CAH setting, those CAHs that use method II shall bill the appropriate new or established visit code for those physician and non-physician practitioners who have reassigned their billing rights, depending on the relationship status between the physician and patient.
In the office or other outpatient setting where an evaluation is performed, physicians and qualified nonphysician practitioners shall use the CPT codes (99201 – 99215) depending on the complexity of the visit and whether the patient is a new or established patient to that physician. All physicians and qualified nonphysician practitioners shall follow the E/M documentation guidelines for all E/M services. These rules are applicable for Medicare secondary payer claims as well as for claims in which Medicare is the primary payer.

30.6.11—Emergency Department Visits (Codes 99281 - 99288)
(Rev. 1875, Issued: 12-14-09, Effective: 01-01-10, Implementation: 01-04-10)

A. Use of Emergency Department Codes by Physicians Not Assigned to Emergency Department

Any physician seeing a patient registered in the emergency department may use emergency department visit codes (for services matching the code description). It is not required that the physician be assigned to the emergency department.

B. Use of Emergency Department Codes In Office

Emergency department coding is not appropriate if the site of service is an office or outpatient setting or any sight of service other than an emergency department. The emergency department codes should only be used if the patient is seen in the emergency department and the services described by the HCPCS code definition are provided. The emergency department is defined as an organized hospital-based facility for the provision of unscheduled or episodic services to patients who present for immediate medical attention.

C. Use of Emergency Department Codes to Bill Nonemergency Services

Services in the emergency department may not be emergencies. However the codes (99281 - 99288) are payable if the described services are provided.

However, if the physician asks the patient to meet him or her in the emergency department as an alternative to the physician's office and the patient is not registered as a patient in the emergency department, the physician should bill the appropriate office/outpatient visit codes. Normally a lower level emergency department code would be reported for a non-emergency condition.

D. Emergency Department or Office/Outpatient Visits on Same Day As Nursing Facility Admission

Emergency department visit provided on the same day as a comprehensive nursing facility assessment are not paid. Payment for evaluation and management services on the same date provided in sites other than the nursing facility are included in the payment for initial nursing facility care when performed on the same date as the nursing facility admission.

E. Physician Billing for Emergency Department Services Provided to Patient by Both Patient's Personal Physician and Emergency Department Physician

If a physician advises his/her own patient to go to an emergency department (ED) of a hospital for care and the physician subsequently is asked by the ED physician to come to the hospital to evaluate the patient and to advise the ED physician as to whether the patient should be admitted to the hospital or be sent home, the physicians should bill as follows:

- If the patient is admitted to the hospital by the patient's personal physician, then the patient's regular physician should bill only the appropriate level of the initial hospital care (codes 99221 - 99223) because all evaluation and management services provided by that physician in conjunction with that admission are considered part of the initial hospital care when performed on the same date as the admission. The ED physician who saw the patient in the emergency department should bill the appropriate level of the ED codes.
- If the ED physician, based on the advice of the patient's personal physician who came to the emergency department to see the patient, sends the patient home, then the ED physician should bill the appropriate level of emergency department service. The patient's personal physician should also bill the level of emergency department code that describes the service he or she provided in the emergency department. If the patient's personal physician does not come to the hospital to see the patient, but only advises the emergency department physician by telephone, then the patient's personal physician may not bill.

F. Emergency Department Physician Requests Another Physician to See the Patient in Emergency Department or Office/Outpatient Setting

If the emergency department physician requests that another physician evaluate a given patient, the other physician should bill an emergency department visit code. If the patient is admitted to the hospital by the second physician performing the evaluation, he or she should bill an initial hospital care code and not an emergency department visit code.

30.6.12—Critical Care Visits and Neonatal Intensive Care (Codes 99291 - 99292)
(Rev. 2997, Issued: 07-25-14, Effective: Upon implementation of ICD-10: 01-01- 2012 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon implementation of ICD-10)

CRITICAL CARE SERVICES (CODES 99291-99292)

A. Use of Critical Care Codes

Pay for services reported with CPT codes 99291 and 99292 when all the criteria for critical care and critical care services are met. Critical care is defined as the direct delivery by a physician(s) medical care for a critically ill or critically injured patient. A critical illness or injury acutely impairs one or more vital organ systems such that there is a high probability of imminent or life threatening deterioration in the patient's condition.

Critical care involves high complexity decision making to assess, manipulate, and support vital system functions(s) to treat single or multiple vital organ system failure and/or to prevent further life threatening deterioration of the patient's condition.

Examples of vital organ system failure include, but are not limited to: central nervous system failure, circulatory failure, shock, renal, hepatic, metabolic, and/or respiratory failure. Although critical care typically requires interpretation of multiple physiologic parameters and/or application of advanced technology(s), critical care may be provided in life threatening situations when these elements are not present.
Providing medical care to a critically ill, injured, or post-operative patient qualifies as a critical care service only if both the illness or injury and the treatment being provided meet the above requirements.

Critical care is usually, but not always, given in a critical care area such as a coronary care unit, intensive care unit, respiratory care unit, or the emergency department. However, payment may be made for critical care services provided in any location as long as the care provided meets the definition of critical care.

Consult the American Medical Association (AMA) CPT Manual for the applicable codes and guidance for critical care services provided to neonates, infants and children.

B. Critical Care Services and Medical Necessity

Critical care services must be medically necessary and reasonable. Services provided that do not meet critical care services or services provided for a patient who is not critically ill or injured in accordance with the above definitions and criteria but who happens to be in a critical care, intensive care, or other specialized care unit should be reported using another appropriate E/M code (e.g., subsequent hospital care, CPT codes 99231 - 99233).

As described in Section A, critical care services encompass both treatment of “vital organ failure” and “prevention of further life threatening deterioration of the patient's condition.” Therefore, although critical care may be delivered in a moment of crisis or upon being called to the patient's bedside emergently, this is not a requirement for providing critical care service. The treatment and management of the patient's condition, while not necessarily emergent, shall be required, based on the threat of imminent deterioration (i.e., the patient shall be critically ill or injured at the time of the physician's visit).

Chronic Illness and Critical Care:

Examples of patients whose medical condition may not warrant critical care services:

1. Daily management of a patient on chronic ventilator therapy does not meet the criteria for critical care unless the critical care is separately identifiable from the chronic long term management of the ventilator dependence.

2. Management of dialysis or care related to dialysis for a patient receiving ESRD hemodialysis does not meet the criteria for critical care unless the critical care is separately identifiable from the chronic long term management of the dialysis dependence (refer to Chapter 8, §160.4). When a separately identifiable condition (e.g., management of seizures or pericardial tamponade related to renal failure) is being managed, it may be billed as critical care if critical care requirements are met. Modifier –25 should be appended to the critical care code when applicable in this situation.

Examples of patients whose medical condition may warrant critical care services:

1. An 81 year old male patient is admitted to the intensive care unit following abdominal aortic aneurysm resection. Two days after surgery he requires fluids and pressors to maintain adequate perfusion and arterial pressures. He remains ventilator dependent.

2. A 67 year old female patient is 3 days status post mitral valve repair. She develops petechiae, hypotension and hypoxia requiring respiratory and circulatory support.

3. A 70 year old admitted for right lower lobe pneumococcal pneumonia with a history of COPD becomes hypoxic and hypotensive 2 days after admission.

4. A 68 year old admitted for an acute anterior wall myocardial infarction continues to have symptomatic ventricular tachycardia that is marginally responsive to antiarrhythmic therapy.

Examples of patients who may not satisfy Medicare medical necessity criteria, or do not meet critical care criteria or who do not have a critical care illness or injury and therefore not eligible for critical care payment:

1. Patients admitted to a critical care unit because no other hospital beds were available;

2. Patients admitted to a critical care unit for close nursing observation and/or frequent monitoring of vital signs (e.g., drug toxicity or overdose);

3. Patients admitted to a critical care unit because hospital rules require certain treatments (e.g., insulin infusions) to be administered in the critical care unit.

Providing medical care to a critically ill patient should not be automatically deemed to be a critical care service for the sole reason that the patient is critically ill or injured. While more than one physician may provide critical care services to a patient during the critical care episode of an illness or injury each physician must be managing one or more critical illness(es) or injury(ies) in whole or in part.

EXAMPLE: A dermatologist evaluates and treats a rash on an ICU patient who is maintained on a ventilator and nitroglycerine infusion that are being managed by an intensivist. The dermatologist should not report a service for critical care.

C. Critical Care Services and Full Attention of the Physician

The duration of critical care services to be reported is the time the physician spent evaluating, providing care and managing the critically ill or injured patient's care. That time must be spent at the immediate bedside or elsewhere on the floor or unit so long as the physician is immediately available to the patient.

For example, time spent reviewing laboratory test results or discussing the critically ill patient's care with other medical staff in the unit or at the nursing station on the floor may be reported as critical care, even when it does not occur at the bedside, if this time represents the physician's full attention to the management of the critically ill/injured patient.

For any given period of time spent providing critical care services, the physician must devote his or her full attention to the patient and, therefore, cannot provide services to any other patient during the same period of time.

D. Critical Care Services and Qualified Non-Physician Practitioners (NPP)

Critical care services may be provided by qualified NPPs and reported for payment under the NPP's National Provider Identifier (NPI) when the services meet the definition and requirements of critical care services in Sections A and B. The provision of critical care services must be within the scope of practice and licensure requirements for the State in
which the qualified NPP practices and provides the service(s). Collaboration, physician supervision and billing requirements must also be met. A physician assistant shall meet the general physician supervision requirements.

E. Critical Care Services and Physician Time

Critical care is a time-based service, and for each date and encounter entry, the physician's progress note(s) shall document the total time that critical care services were provided. More than one physician can provide critical care at another time and be paid if the service meets critical care, is medically necessary and is not duplicative care. Concurrent care by more than one physician (generally representing different physician specialties) is payable if these requirements are met (refer to the Medicare Benefit Policy Manual, Pub. 100-02, Chapter 15, §30 for concurrent care policy discussion).

The CPT critical care codes 99291 and 99292 are used to report the total duration of time spent by a physician providing critical care services to a critically ill or critically injured patient, even if the time spent by the physician on that date is not continuous. Non-continuous time for medically necessary critical care services may be aggregated. Reporting CPT code 99291 is a prerequisite to reporting CPT code 99292. Physicians of the same specialty within the same group practice bill and are paid as though they were a single physician ($30.6.5).

1. Off the Unit/Floor

   Time spent in activities (excluding those identified previously in Section C) that occur outside of the unit or off the floor (i.e., telephone calls, whether taken at home, in the office, or elsewhere in the hospital) may not be reported as critical care because the physician is not immediately available to the patient. This time is regarded as pre- and post service work bundled in evaluation and management services.

2. Split/Shared Service

   A split/shared E/M service performed by a physician and a qualified NPP of the same group practice (or employed by the same employer) cannot be reported as a critical care service. Critical care services are reflective of the care and management of a critically ill or critically injured patient by an individual physician or qualified non-physician practitioner for the specified reportable period of time.

   Unlike other E/M services where a split/shared service is allowed the critical care service reported shall reflect the evaluation, treatment and management of a patient by an individual physician or qualified non-physician practitioner and shall not be representative of a combined service between a physician and a qualified NPP.

   When CPT code time requirements for both 99291 and 99292 and critical care criteria are met for a medically necessary visit by a qualified NPP the service shall be billed using the appropriate individual NPI number. Medically necessary visit(s) that do not meet these requirements shall be reported as subsequent hospital care services.

3. Unbundled Procedures

   Time involved performing procedures that are not bundled into critical care (i.e., billed and paid separately) may not be included and counted toward critical care time.

   The physician's progress note(s) in the medical record should document that time involved in the performance of separately billable procedures was not counted toward critical care time.

4. Family Counseling/Discussions

   Critical care CPT codes 99291 and 99292 include pre and post service work. Routine daily updates or reports to family members and or surrogates are considered part of this service. However, time involved with family members or other surrogate decision makers, whether to obtain a history or to discuss treatment options (as described in CPT), may be counted toward critical care time when these specific criteria are met:
   a) The patient is unable or incompetent to participate in giving a history and/or making treatment decisions, and
   b) The discussion is necessary for determining treatment decisions.

   For family discussions, the physician should document:
   a. The patient is unable or incompetent to participate in giving history and/or making treatment decisions
   b. The necessity to have the discussion (e.g., “no other source was available to obtain a history” or “because the patient was deteriorating so rapidly I needed to immediately discuss treatment options with the family”),
   c. Medically necessary treatment decisions for which the discussion was needed, and
   d. A summary in the medical record that supports the medical necessity of the discussion

   All other family discussions, no matter how lengthy, may not be additionally counted towards critical care. Telephone calls to family members and or surrogates decision-makers may be counted towards critical care time, but only if they meet the same criteria as described in the aforementioned paragraph.

5. Inappropriate Use of Time for Payment of Critical Care Services

   Time involved in activities that do not directly contribute to the treatment of the critically ill or injured patient may not be counted towards the critical care time, even when they are performed in the critical care unit at a patient’s bedside (e.g., review of literature, and teaching sessions with physician residents whether conducted on hospital rounds or in other venues).

F. Hours and Days of Critical Care that May Be Billed

   Critical care service is a time-based service provided on an hourly or fraction of an hour basis. Payment should not be restricted to a fixed number of hours, a fixed number of physicians, or a fixed number of days, on a per patient basis, for medically necessary critical care services. Time counted towards critical care services may be continuous or intermittent and aggregated in time increments (e.g., 50 minutes of continuous clock time or (5) 10 minute blocks of time spread over a given calendar date). Only one physician may bill for critical care services during any one single period of time even if more than one physician is providing care to a critically ill patient.

   For Medicare Part B physician services paid under the physician fee schedule, critical care is not a service that is paid on a “shift” basis or a “per day” basis. Documentation may be
requested for any claim to determine medical necessity. Examples of critical care billing that may require further review could include: claims from several physicians submitting multiple units of critical care for a single patient, and submitting claims for more than 12 hours of critical care time by a physician for one or more patients on the same given calendar date. Physicians assigned to a critical care unit (e.g., hospitalist, intensivist, etc.) may not report critical care for patients based on a ‘per shift’ basis.

The CPT code 99291 is used to report the first 30-74 minutes of critical care on a given calendar date of service. It should only be used once per calendar date per patient by the same physician or physician group of the same specialty. CPT code 99292 is used to report additional block(s) of time, of up to 30 minutes each beyond the first 74 minutes of critical care. Critical care of less than 30 minutes total duration on a given calendar date is not reported separately using the critical care codes. This service should be reported using another appropriate E/M code such as subsequent hospital care.

Clinical Example of Correct Billing of Time:

A patient arrives in the emergency department in cardiac arrest. The emergency department physician provides 40 minutes of critical care services. A cardiologist is called to the ED and assumes responsibility for the patient, providing 35 minutes of critical care services. The patient stabilizes and is transferred to the CCU. In this instance, the ED physician provided 40 minutes of critical care services and reports only the critical care code (CPT code 99291) and not also emergency department services. The cardiologist may report the 35 minutes of critical care services (also CPT code 99291) provided in the ED. Additional critical care services by the cardiologist in the CCU may be reported on the same calendar date using 99292 or another appropriate E/M code depending on the clock time involved.

G. Counting of Units of Critical Care Services

The CPT code 99291 (critical care, first hour) is used to report the services of a physician providing full attention to a critically ill or critically injured patient from 30-74 minutes on a given date. Only one unit of CPT code 99291 may be billed by a physician for a patient on a given date. Physicians of the same specialty within the same group practice bill and are paid as though they were a single physician and would not each report CPT 99291 on the same date of service.

The following illustrates the correct reporting of critical care services:

<table>
<thead>
<tr>
<th>TOTAL DURATION OF CRITICAL CARE CODES</th>
<th>CPT Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 30 minutes</td>
<td>99232 or 99233 or other appropriate E/M code</td>
</tr>
<tr>
<td>30 - 74 minutes</td>
<td>99291 x 1</td>
</tr>
<tr>
<td>75 - 104 minutes</td>
<td>99291 x 1 and 99292 x 1</td>
</tr>
<tr>
<td>105 - 134 minutes</td>
<td>99291 x 1 and 99292 x 2</td>
</tr>
<tr>
<td>135 - 164 minutes</td>
<td>99291 x 1 and 99292 x 3</td>
</tr>
<tr>
<td>165 - 194 minutes</td>
<td>99291 x 1 and 99292 x 4</td>
</tr>
<tr>
<td>194 minutes or longer</td>
<td>99291 – 99292 as appropriate (per the above illustrations)</td>
</tr>
</tbody>
</table>

H. Critical Care Services and Other Evaluation and Management Services Provided on Same Day

When critical care services are required upon the patient’s presentation to the hospital emergency department, only critical care codes 99291 - 99292 may be reported. An emergency department visit code may not also be reported.

When critical care services are provided on a date where an inpatient hospital or office/outpatient evaluation and management service was furnished earlier on the same date at which time the patient did not require critical care, both the critical care and the previous evaluation and management service may be paid. Hospital emergency department services are not payable for the same calendar date as critical care services when provided by the same physician to the same patient.

Physicians are advised to submit documentation to support a claim when critical care is additionally reported on the same calendar date as when other evaluation and management services are provided to a patient by the same physician or physicians of the same specialty in a group practice.

I. Critical Care Services Provided by Physicians in Group Practice(s)

Medically necessary critical care services provided on the same calendar date to the same patient by physicians representing different medical specialties that are not duplicative services are payable. The medical specialists may be from the same group practice or from different group practices.

Critically ill or critically injured patients may require the care of more than one physician medical specialty. Concurrent critical care services provided by each physician must be medically necessary and not provided during the same instance of time. Medical record documentation must support the medical necessity of critical care services provided by each physician (or qualified NPP). Each physician must accurately report the service(s) he/she provided to the patient in accordance with any applicable global surgery rules or concurrent care rules. (Refer to Medicare Claims Processing Manual, Pub. 100-04, Chapter 12, §40, and the Medicare Benefit Policy Manual, Pub. 100-02, Chapter 15, §30.)

CPT Code 99291

The initial critical care time, billed as CPT code 99291, must be met by a single physician or qualified NPP. This may be performed in a single period of time or be cumulative by the same physician on the same calendar date. A history or physical exam performed by one group partner for another group partner in order for the second group partner to make a medical decision would not represent critical care services.

CPT Code 99292

Subsequent critical care visits performed on the same calendar date are reported using CPT code 99292. The service may represent aggregate time met by a single physician or physicians in the same group practice with the same medical specialty in order to meet the duration of minutes required for CPT code 99292. The aggregated critical care visits must be medically necessary and each aggregated visit must meet the definition of critical care in order to combine the times.
Physicians in the same group practice who have the same specialty may not each report CPT initial critical care code 99291 for critical care services to the same patient on the same calendar date. Medicare payment policy states that physicians in the same group practice who are in the same specialty must bill and be paid as though each were the single physician. (Refer to the Medicare Claims Processing Manual, Pub. 100-04, Chapter 12, §30.6.)

Physician specialty means the self-designated primary specialty by which the physician bills Medicare and is known to the contractor that adjudicates the claims. Physicians in the same group practice who have different medical specialties may bill and be paid without regard to their membership in the same group. For example, if a cardiologist and an endocrinologist are group partners and the critical care services of each are medically necessary and not duplicative, the critical care services may be reported by each regardless of their group practice relationship.

Two or more physicians in the same group practice who have different specialties and who provide critical care to a critically ill or critically injured patient may not in all cases each report the initial critical care code (CPT 99291) on the same date. When the group physicians are providing care that is unique to his/her individual medical specialty and managing at least one of the patient's critical illness(es) or critical injury(es) then the initial critical care service may be payable to each.

However, if a physician or qualified NPP within a group provides “staff coverage” or “follow-up” for each other after the first hour of critical care services was provided on the same calendar date by the previous group clinician (physician or qualified NPP), the subsequent visits by the “covering” physician or qualified NPP in the group shall be billed using CPT critical care add-on code 99292. The appropriate individual NPI number shall be reported on the claim. The services will be paid at the specific physician fee schedule rate for the individual clinician (physician or qualified NPP) billing the service.

Clinical Examples of Critical Care Services

1. Drs. Smith and Jones, pulmonary specialists, share a group practice. On Tuesday Dr. Smith provides critical care services to Mrs. Benson who is comatose and has been in the intensive care unit for 4 days following a motor vehicle accident. She has multiple organ dysfunction including cerebral hematoma, flail chest and pulmonary contusion. Later on the same calendar date Dr. Jones covers for Dr. Smith and provides critical care services. Medically necessary critical care services provided at the different time periods may be reported by both Drs. Smith and Jones. Dr. Smith would report CPT code 99291 for the initial visit and Dr. Jones, as part of the same group practice would report CPT code 99292 on the same calendar date if the appropriate time requirements are met.

2. Mr. Marks, a 79 year old comes to the emergency room with vague joint pains and lethargy. The ED physician evaluates Mr. Marks and phones his primary care physician to discuss his medical evaluation. His primary care physician visits the ER and admits Mr. Marks to the observation unit for monitoring, and diagnostic and laboratory tests. In observation Mr. Marks has a cardiac arrest. His primary care physician provides 50 minutes of critical care services. Mr. Marks’ is admitted to the intensive care unit. On the same calendar day Mr. Marks’ condition deteriorates and he requires intermittent critical care services. In this scenario the ED physician should report an emergency department visit and the primary care physician should report both an initial hospital visit and critical care services.

J. Critical Care Services and Other Procedures Provided on the Same Day by the Same Physician as Critical Care Codes 99291 – 99292

The following services when performed on the same day a physician bills for critical care are included in the critical care service and should not be reported separately:

- The interpretation of cardiac output measurements (CPT 93561, 93562);
- Chest x-rays, professional component (CPT 71010, 71015, 71020);
- Blood draw for specimen (CPT 36415);
- Blood gases, and information data stored in computers (e.g., ECGs, blood pressures, hematologic data-CPT 99090);
- Gastric intubation (CPT 43752, 91105);
- Pulse oximetry (CPT 94760, 94761, 94762);
- Temporary transcutaneous pacing (CPT 92953);
- Ventilator management (CPT 94002 – 94004, 94660, 94662); and
- Vascular access procedures (CPT 36000, 36410, 36415, 36591, 36600).

No other procedure codes are bundled into the critical care services. Therefore, other medically necessary procedure codes may be billed separately.

K. Global Surgery

Critical care services shall not be paid on the same calendar date the physician also reports a procedure code with a global surgical period unless the critical care is billed with CPT modifier -25 to indicate that the critical care is a significant, separately identifiable evaluation and management service that is above and beyond the usual pre and post operative care associated with the procedure that is performed.

Services such as endotracheal intubation (CPT code 31500) and the insertion and placement of a flow directed catheter e.g., Swan-Ganz (CPT code 93503) are not bundled into the critical care codes. Therefore, separate payment may be made for critical care in addition to these services if the critical care was a significant, separately identifiable service and it was reported with modifier -25. The time spent performing the pre, intra, and post procedure work of these unbundled services, e.g., endotracheal intubation, shall be excluded from the determination of the time spent providing critical care.

This policy applies to any procedure with a 0, 10 or 90 day global period including cardiopulmonary resuscitation (CPT code 92950). CPR has a global period of 0 days and is not bundled into critical care codes. Therefore, critical care may be billed in addition to CPR if critical care was a significant, separately identifiable service and it was reported with modifier -25. The time spent performing CPR shall be excluded from the determination of the time spent providing critical care. In this instance it must be the physician who performs the resuscitation who bills for this service. Members of a code team must not each bill Medicare Part B for this service.

When postoperative critical care services (for procedures with a global surgical period) are provided by a physician other than the surgeon, no modifier is required unless all
surgical postoperative care has been officially transferred from the surgeon to the physician performing the critical care services. In this situation, CPT modifiers “-54” (surgical care only) and “-55” (postoperative management only) must be used by the surgeon and intensivist who are submitting claims. Medical record documentation by the surgeon and the physician who assumes a transfer (e.g., intensivist) is required to support claims for services when CPT modifiers -54 and -55 are used indicating the transfer of care from the surgeon to the intensivist. Critical care services must meet all the conditions previously described in this manual section.

L. Critical Care Services Provided During Preoperative Portion and Postoperative Portion of Global Period of Procedure with 90 Day Global Period in Trauma and Burn Cases

Preoperative

Preoperative critical care and/or postoperative care may be paid in addition to a global fee if the patient is critically ill and requires the full attention of the physician, and the critical care is unrelated to the specific anatomic injury or general surgical procedure performed. Such patients may meet the definition of being critically ill and criteria for conditions where there is a high probability of imminent or life threatening deterioration in the patient’s condition.

- For preoperative care modifier -25 (significant, separately identifiable evaluation and management services by the same physician on the day of the procedure) must be used with the HCPCS code.
- For postoperative care modifier -24 (unrelated evaluation and management service by the same physician during a postoperative period) must be used with the HCPCS code.

In addition, for each preoperative and postoperative care the diagnosis must clearly indicate that the critical care was unrelated to the surgery.

M. Teaching Physician Criteria

In order for the teaching physician to bill for critical care services the teaching physician must meet the requirements for critical care described in the preceding sections. For CPT codes determined on the basis of time, such as critical care, the teaching physician must be present for the entire period of time for which the claim is submitted. For example, payment will be made for 35 minutes of critical care services only if the teaching physician is present for the full 35 minutes. (See IOM, Pub 100-04, Chapter 12, § 100.1.4)

1. Teaching

Time spent teaching may not be counted towards critical care time. Time spent by the resident, in the absence of the teaching physician, cannot be billed by the teaching physician as critical care or other time-based services. Only time spent by the resident and teaching physician together with the patient or the teaching physician alone with the patient can be counted toward critical care time.

2. Documentation

A combination of the teaching physician’s documentation and the resident’s documentation may support critical care services. Provided that all requirements for critical care services are met, the teaching physician documentation may tie into the resident’s documentation. The teaching physician may refer to the resident’s documentation for specific patient history, physical findings and medical assessment. However, the teaching physician medical record documentation must provide substantive information including: (1) the time the teaching physician spent providing critical care, (2) that the patient was critically ill during the time the teaching physician saw the patient, (3) what made the patient critically ill, and (4) the nature of the treatment and management provided by the teaching physician. The medical review criteria are the same for the teaching physician as for all physicians. (See the Medicare Claims Processing, Pub. 100-04, Chapter 12, §100.1.1 for teaching physician documentation guidance.)

Unacceptable Example of Documentation:

“I came and saw (the patient) and agree with (the resident)”.

Acceptable Example of Documentation:

“Patient developed hypotension and hypoxia; I spent 45 minutes while the patient was in this condition, providing fluids, pressor drugs, and oxygen. I reviewed the resident’s documentation and I agree with the resident’s assessment and plan of care.”

N. Ventilator Management

Medicare recognizes the ventilator codes (CPT codes 94002 - 94004, 94660 and 94662) as physician services payable under the physician fee schedule. Medicare Part B under the physician fee schedule does not pay for ventilator management services in addition to an evaluation and management service (e.g., critical care services, CPT codes 99291 - 99292) on the same day for the patient even when the evaluation and management service is billed with CPT modifier -25.

30.6.13—Nursing Facility Services

(Rev. 2282, Issued: 08-26-11, Effective: 01-01-11, Implementation: 11-28-11)

A. Visits to Perform the Initial Comprehensive Assessment and Annual Assessments

The distinction made between the delegation of physician visits and tasks in a skilled nursing facility (SNF) and in a nursing facility (NF) is based on the Medicare Statute. Section 1819 (b) (6) (A) of the Social Security Act (the Act) governs SNFs while section 1919 (b) (6) (A) of the Act governs NFs. For further information refer to Medlearn Matters article number SE0418 at www.cms.hhs.gov/medlearn/matters

The federally mandated visit in a SNF and NF must be performed by the physician except as otherwise permitted (42 CFR 483.40 (c) (4)). The principal physician of record must append the modifier “AI”, Principal Physician of Record, to the initial nursing facility care code. This modifier will identify the physician who oversees the patient’s care from other physicians who may be furnishing specialty care. All other physicians who perform an initial evaluation in the nursing facility may bill the initial nursing facility care code. The initial visit is defined in S&C-04-08-08 (see www.cms.hhs.gov/medlearn/matters) as the initial comprehensive assessment visit during which the physician completes a thorough assessment, develops a plan of care and writes or verifies admitting orders for the nursing facility resident. For Survey and Certification requirements, a visit must occur no later than 30 days after admission.
Further, per the Long Term Care regulations at 42 CFR 483.40 (c)(4) and (e) (2), in a SNF the physician may not delegate a task that the physician must personally perform. Therefore, as stated in S&C-04-08 the physician may not delegate the initial visit in a SNF.

The only exception, as to who performs the initial visit, relates to the NF setting. In the NF setting, a qualified NPP (i.e., a nurse practitioner (NP), physician assistant (PA), or a clinical nurse specialist (CNS)), who is not employed by the facility, may perform the initial visit when the State law permits this.) The evaluation and management (E/M) visit shall be within the State scope of practice and licensure requirements where the E/M visit is performed and the requirements for physician collaboration and physician supervision shall be met.

Under Medicare Part B payment policy, other medically necessary E/M visits may be performed and reported prior to and after the initial visit, if the medical needs of the patient require an E/M visit. A qualified NPP may perform medically necessary E/M visits prior to and after the initial visit if all the requirements for collaboration, general physician supervision, licensure and billing are met.

The CPT Nursing Facility Services codes shall be used with place of service (POS) 31 (SNF) if the patient is in a Part A SNF stay. They shall be used with POS 32 (nursing facility) if the patient does not have Part A SNF benefits or if the patient is in a NF or in a non-covered SNF stay (e.g., there was no preceding 3-day hospital stay). The CPT Nursing Facility code definition also includes POS 54 (Intermediate Care Facility/Mentally Retarded) and POS 56 (Psychiatric Residential Treatment Center). For further guidance on POS codes and associated CPT codes refer to §30.6.14.

Effective January 1, 2006, the Initial Nursing Facility Care codes 99301–99303 are deleted.

Beginning January 1, 2006, the new CPT codes, Initial Nursing Facility Care, per day, (99304 – 99306) shall be used to report the initial visit. Only a physician may report these codes for an initial visit performed in a SNF or NF (with the exception of the qualified NPP in the NF setting who is not employed by the facility and when State law permits, as explained above).

A readmission to a SNF or NF shall have the same payment policy requirements as an initial admission in both the SNF and NF settings.

A physician who is employed by the SNF/NF may perform the E/M visits and bill independently to Medicare Part B for payment. An NPP who is employed by the SNF or NF may perform and bill Medicare Part B directly for those services where it is permitted as discussed above. The employer of the PA shall always report the visits performed by the PA. A physician, NP or CNS has the option to bill Medicare Part B directly or to reassign payment for his/her professional service to the facility.

As with all E/M visits for Medicare Part B payment policy, the E/M documentation guidelines apply.

Medically Necessary Visits

Qualified NPPs may perform medically necessary E/M visits prior to and after the physician’s initial federally mandated visit in both the SNF and NF. Medically necessary E/M visits for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member are payable under the physician fee schedule under Medicare Part B. A physician or NPP may bill the most appropriate initial nursing facility care code (CPT codes 99304-99306) or subsequent nursing facility care code (CPT codes 99307-99310), even if the E/M service is provided prior to the initial federally mandated visit.

SNF Setting—Place of Service Code 31

Following the initial visit by the physician, the physician may delegate alternate federally mandated physician visits to a qualified NPP who meets collaboration and physician supervision requirements and is licensed as such by the State and performing within the scope of practice in that State.

NF Setting—Place of Service Code 32

Per the regulations at 42 CFR 483.40 (f), a qualified NPP, who meets the collaboration and physician supervision requirements, the State scope of practice and licensure requirements, and who is not employed by the NF, may at the option of the State, perform the initial visit in a NF, and may perform any other federally mandated physician visit in a NF in addition to performing other medically necessary E/M visits.

Questions pertaining to writing orders or certification and recertification issues in the SNF and NF settings shall be addressed to the appropriate State Survey and Certification Agency departments for clarification.

B. Visits to Comply With Federal Regulations (42 CFR 483.40 (c) (1)) in the SNF and NF

Payment is made under the physician fee schedule by Medicare Part B for federally mandated visits. Following the initial federally mandated visit by the physician or qualified NPP where permitted, payment shall be made for federally mandated visits that monitor and evaluate residents at least once every 30 days for the first 90 days after admission and at least once every 60 days thereafter.

Effective January 1, 2006, the Subsequent Nursing Facility Care, per day, codes 99311–99313 are deleted.

Beginning January 1, 2006, the new CPT codes, Subsequent Nursing Facility Care, per day, (99307 – 99310) shall be used to report federally mandated physician E/M visits and medically necessary E/M visits.

Carriers shall not pay for more than one E/M visit performed by the physician or qualified NPP for the same patient on the same date of service. The Nursing Facility Services codes represent a “per day” service.

The federally mandated E/M visit may serve also as a medically necessary E/M visit if the situation arises (i.e., the patient has health problems that need attention on the day the scheduled mandated physician E/M visit occurs). The physician/qualified NPP shall bill only one E/M visit.

Beginning January 1, 2006, the new CPT code, Other Nursing Facility Service (99318), may be used to report an annual nursing facility assessment visit on the required schedule of visits on an annual basis. For Medicare Part B payment policy, an annual nursing facility assessment visit code may substitute as meeting one of the federally mandated physician visits if the code requirements for CPT code 99318 are fully met and in lieu of reporting a Subsequent Nursing
Facility Care, per day, service (codes 99307 – 99310). It shall not be performed in addition to the required number of federally mandated physician visits. The new CPT annual assessment code does not represent a new benefit service for Medicare Part B physician services.

Qualified NPPs, whether employed or not by the SNF, may perform alternating federally mandated physician visits, at the option of the physician, after the initial federally mandated visit by the physician in a SNF.

Qualified NPPs in the NF setting, who are not employed by the NF and who are working in collaboration with a physician, may perform federally mandated physician visits, at the option of the State.

Medicare Part B payment policy does not pay for additional E/M visits that may be required by State law for a facility admission or for other additional visits to satisfy facility or other administrative purposes. E/M visits, prior to and after the initial federally mandated physician visit, that are reasonable and medically necessary to meet the medical needs of the individual patient (unrelated to any State requirement or administrative purpose) are payable under Medicare Part B.

C. Visits by Qualified Nonphysician Practitioners

All E/M visits shall be within the State scope of practice and licensure requirements where the visit is performed and all the requirements for physician collaboration and physician supervision shall be met when performed and reported by qualified NPPs. General physician supervision and employer billing requirements shall be met for PA services in addition to the PA meeting the State scope of practice and licensure requirements where the E/M visit is performed.

Medically Necessary Visits

Qualified NPPs may perform medically necessary E/M visits prior to and after the physician’s initial visit in both the SNF and NF. Medically necessary E/M visits for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member are payable under the physician fee schedule under Medicare Part B. A physician or NPP may bill the most appropriate initial nursing facility care code (CPT codes 99304-99306) or subsequent nursing facility care code (CPT codes 99307-99310), even if the E/M service is provided prior to the initial federally mandated visit.

SNF Setting--Place of Service Code 31

Following the initial visit by the physician, the physician may delegate alternate federally mandated physician visits to a qualified NPP who meets collaboration and physician supervision requirements and is licensed as such by the State and performing within the scope of practice in that State.

NF Setting--Place of Service Code 32

Per the regulations at 42 CFR 483.40 (f), a qualified NPP who meets the collaboration and physician supervision requirements, the State scope of practice and licensure requirements, and who is not employed by the NF, may at the option of the State, perform the initial visit in a NF, and may perform any other federally mandated physician visit in a NF in addition to performing other medically necessary E/M visits.

Questions pertaining to writing orders or certification and recertification issues in the SNF and NF settings shall be addressed to the appropriate State Survey and Certification Agency departments for clarification.

D. Medically Complex Care

Payment is made for E/M visits to patients in a SNF who are receiving services for medically complex care upon discharge from an acute care facility when the visits are reasonable and medically necessary and documented in the medical record. Physicians and qualified NPPs shall report initial nursing facility care codes for their first visit with the patient. The principal physician of record must append the modifier “-AI” (Principal Physician of Record), to the initial nursing facility care code when billed to identify the physician who oversees the patient’s care from other physicians who may be furnishing specialty care. Follow-up visits shall be billed subsequent nursing facility care visits.

E. Incident to Services

Where a physician establishes an office in a SNF/NF, the “incident to” services and requirements are confined to this discrete part of the facility designated as his/her office. “Incident to” E/M visits, provided in a facility setting, are not payable under the Physician Fee Schedule for Medicare Part B. Thus, visits performed outside the designated “office” area in the SNF/NF would be subject to the coverage and payment rules applicable to SNF/NF setting and shall not be reported using the CPT codes for office or other outpatient visits or use place of service code 11.

F. Use of the Prolonged Services Codes and Other Time-Related Services

Beginning January 1, 2008, typical/average time units for E/M visits in the SNF/NF settings are reestablished. Medically necessary prolonged services for E/M visits (codes 99356 and 99357) in a SNF or NF may be billed with the Nursing Facility Services in the code ranges (99304 – 99306, 99307 – 99310 and 99318).

Counseling and Coordination of Care Visits

With the reestablishment of typical/average time units, medically necessary E/M visits for counseling and coordination of care, for Nursing Facility Services in the code ranges (99304 – 99306, 99307 – 99310 and 99318) that are time-based services, may be billed with the appropriate prolonged services codes (99356 and 99357).

G. Multiple Visits

The complexity level of an E/M visit and the CPT code billed must be a covered and medically necessary visit for each patient (refer to §§1862 (a)(1)(A) of the Act). Claims for an unreasonable number of daily E/M visits by the same physician to multiple patients at a facility within a 24-hour period may result in medical review to determine medical necessity for the visits. The E/M visit (Nursing Facility Services) represents a “per day” service per patient as defined by the CPT code. The medical record must be personally documented by the physician or qualified NPP who performed the E/M visit and the documentation shall support the specific level of E/M visit to each individual patient.

H. Split/Shared E/M Visit

A split/shared E/M visit cannot be reported in the SNF/NF setting. A split/shared E/M visit is defined by Medicare Part B
payment policy as a medically necessary encounter with a patient where the physician and a qualified NPP each personally perform a substantive portion of an E/M visit face-to-face with the same patient on the same date of service. A substantive portion of an E/M visit involves all or some portion of the history, exam or medical decision making key components of an E/M service. The physician and qualified NPP must be in the same group practice or be employed by the same employer. The split/shared E/M visit applies only to selected E/M visits and settings (i.e., hospital inpatient, hospital outpatient, hospital observation, emergency department, hospital discharge, office and non facility clinic visits, and prolonged visits associated with these E/M visit codes). The split/shared E/M policy does not apply to consultation services, critical care services or procedures.

I. SNF/NF Discharge Day Management Service

Medicare Part B payment policy requires a face-to-face visit with the patient provided by the physician or the qualified NPP to meet the SNF/NF discharge day management service as defined by the CPT code. The E/M discharge day management visit shall be reported for the date of the actual visit by the physician or qualified NPP even if the patient is discharged from the facility on a different calendar date. The CPT codes 99315 – 99316 shall be reported for this visit. The Discharge Day Management Service may be reported using CPT code 99315 or 99316, depending on the code requirement, for a patient who has expired, but only if the physician or qualified NPP personally performed the death pronouncement.

30.6.14—Home Care and Domiciliary Care Visits (Codes 99324-99350)

(Rev. 775, Issued: 12-02-05, Effective: 01-01-06, Implementation: 01-03-06)

Physician Visits to Patients Residing in Various Places of Service

The American Medical Association’s Current Procedural Terminology (CPT) 2006 new patient codes 99324 – 99328 and established patient codes 99329 – 99333 (new codes beginning January 2006), for Domiciliary, Rest Home (e.g., Boarding Home), or Custodial Care Services, are used to report evaluation and management (E/M) services to residents residing in a facility which provides room, board, and other personal assistance services, generally on a long-term basis. These CPT codes are used to report E/M services in facilities that provide a living arrangement described by one of the POS listed above must use the level of service code in the CPT code range 99324 – 99337 to report the service they provide. The CPT codes 99321 – 99333 for Domiciliary, Rest Home (e.g., Boarding Home), or Custodial Care Services are deleted beginning January, 2006.

Beginning in 2006, reasonable and medically necessary, face-to-face, prolonged services, represented by CPT codes 99321 – 99333, may be reported with the appropriate companion E/M codes when a physician or qualified NPP provides a prolonged service involving direct (face-to-face) patient contact that is beyond the usual E/M visit service for a Domiciliary, Rest Home (e.g., Boarding Home) or Custodial Care Service. All the requirements for prolonged services at §30.6.15.1 must be met.

The CPT codes 99341 through 99350, Home Services codes, are used to report E/M services furnished to a patient residing in his or her own private residence (e.g., private home, apartment, town home) and not residing in any type of congregate/shared facility living arrangement including assisted living facilities and group homes. The Home Services codes apply only to the specific 2-digit POS 12 (Home). Home Services codes may not be used for billing E/M services provided in settings other than in the private residence of an individual as described above.

Beginning in 2006, E/M services provided to patients residing in a Skilled Nursing Facility (SNF) or a Nursing Facility (NF) must be reported using the appropriate CPT level of service code within the range identified for Initial Nursing Facility Care (new CPT codes 99304 – 99306) and Subsequent Nursing Facility Care (new CPT codes 99307 – 99310). Use the CPT code, Other Nursing Facility Services (new CPT code 99318), for an annual nursing facility assessment. Use CPT codes 99315 – 99316 for SNF/NF discharge services. The CPT codes 99301 – 99303 and 99311 – 99313 are deleted beginning January, 2006. The Home Services codes should not be used for these places of service.

The CPT SNF/NF code definition includes intermediate care facilities (ICFs) and long term care facilities (LTFCFs). These codes are limited to the specific 2-digit POS 31 (SNF), 32 (Nursing Facility), 54 (Intermediate Care Facility/Mentally Retarded) and 56 (Psychiatric Residential Treatment Center).

The CPT nursing facility codes should be used with POS 31 (SNF) if the patient is in a Part A SNF stay and POS 32 (nursing facility) if the patient does not have Part A SNF benefits. There is no longer a different payment amount for a Part A or Part B benefit period in these POS settings.

30.6.14.1—Home Services (Codes 99341 - 99350)

(Rev. 1, 10-01-03)

B3-15515, B3-15066

A. Requirement for Physician Presence

Home services codes 99341-99350 are paid when they are billed to report evaluation and management services provided in a private residence. A home visit cannot be billed by a physician unless the physician was actually present in the beneficiary’s home.

B. Homebound Status

Under the home health benefit the beneficiary must be confined to the home for services to be covered. For home services provided by a physician using these codes, the beneficiary does not need to be confined to the home. The medical record must document the medical necessity of the home visit made in lieu of an office or outpatient visit.

C. Fee Schedule Payment for Services to Homebound Patients under General Supervision

Payment may be made in some medically underserved areas where there is a lack of medical personnel and home health services for injections, EKGs, and venipunctures that are
performed for homebound patients under general physician supervision by nurses and paramedical employees of physicians or physician-directed clinics. Section 10 provides additional information on the provision of services to homebound Medicare patients.

30.6.15—Prolonged Services and Standby Services (Codes 99354 - 99360)

(Rev. 1, 10-01-03)
B3-15511-15511.3

30.6.15.1—Prolonged Services With Direct Face-to-Face Patient Contact Service (ZZZ codes)

(Rev. 2282, Issued: 08-26-11, Effective: 01-01-11, Implementation: 11-28-11)

A. Definition

Prolonged physician services (CPT code 99354) in the office or other outpatient setting with direct face-to-face patient contact which require 1 hour beyond the usual service are payable when billed on the same day by the same physician or qualified nonphysician practitioner (NPP) as the companion evaluation and management codes. The time for usual service refers to the typical/average time units associated with the companion evaluation and management service as noted in the CPT code. Each additional 30 minutes of direct face-to-face patient contact following the first hour of prolonged services may be reported by CPT code 99355.

Prolonged physician services (code 99356) in the inpatient setting, with direct face-to-face patient contact which require 1 hour beyond the usual service are payable when they are billed on the same day by the same physician or qualified NPP as the companion evaluation and management codes. Each additional 30 minutes of direct face-to-face patient contact following the first hour of prolonged services may be reported by CPT code 99357.

Prolonged service of less than 30 minutes total duration on a given date is not separately reported because the work involved is included in the total work of the evaluation and management codes.

Code 99355 or 99357 may be used to report each additional 30 minutes beyond the first hour of prolonged services, based on the place of service. These codes may be used to report the final 15 - 30 minutes of prolonged service on a given date, if not otherwise billed. Prolonged service of less than 15 minutes beyond the first hour or less than 15 minutes beyond the final 30 minutes is not reported separately.

B. Required Companion Codes

- The companion evaluation and management codes for 99354 are the Office or Other Outpatient visit codes (99201 - 99205, 99212 - 99215), the Domiciliary, Rest Home, or Custodial Care Services codes (99324 – 99328, 99334 – 99337), the Home Services codes (99341 - 99345, 99347 – 99350);
- The companion codes for 99355 are 99354 and one of the evaluation and management codes required for 99354 to be used;
- The companion evaluation and management codes for 99356 are the Initial Hospital Care codes and Subsequent Hospital Care codes (99221 - 99223, 99231 – 99233), Nursing Facility Services codes (99304 -99318) or

- The companion codes for 99357 are 99356 and one of the evaluation and management codes required for 99356 to be used.

Prolonged services codes 99354 – 99357 are not paid unless they are accompanied by the companion codes as indicated.

C. Requirement for Physician Presence

Physicians may count only the duration of direct face-to-face contact between the physician and the patient (whether the service was continuous or not) beyond the typical/average time of the visit code billed to determine whether prolonged services can be billed and to determine the prolonged services codes that are allowable. In the case of prolonged office services, time spent by office staff with the patient, or time the patient remains unaccompanied in the office cannot be billed. In the case of prolonged hospital services, time spent reviewing charts or discussion of a patient with house medical staff and not with direct face-to-face contact with the patient, or waiting for test results, for changes in the patient's condition, for end of a therapy, or for use of facilities cannot be billed as prolonged services.

D. Documentation

Documentation is not required to accompany the bill for prolonged services unless the physician has been selected for medical review. Documentation is required in the medical record about the duration and content of the medically necessary evaluation and management service and prolonged services billed. The medical record must be appropriately and sufficiently documented by the physician or qualified NPP to show that the physician or qualified NPP personally furnished the direct face-to-face time with the patient specified in the CPT code definitions. The start and end times of the visit shall be documented in the medical record along with the date of service.

E. Use of the Codes

Prolonged services codes can be billed only if the total duration of all physician or qualified NPP direct face-to-face service (including the visit) equals or exceeds the threshold time for the evaluation and management service the physician or qualified NPP provided (typical/average time associated with the CPT E/M code plus 30 minutes). If the total duration of direct face-to-face time does not equal or exceed the threshold time for the level of evaluation and management service the physician or qualified NPP provided, the physician or qualified NPP may not bill for prolonged services.

F. Threshold Times for Codes 99354 and 99355 (Office or Other Outpatient Setting)

If the total direct face-to-face time equals or exceeds the threshold time for code 99354, but is less than the threshold time for code 99355, the physician should bill the evaluation and management visit code and code 99354. No more than one unit of 99354 is acceptable. If the total direct face-to-face time equals or exceeds the threshold time for code 99355 by no more than 29 minutes, the physician should bill the visit code 99354 and one unit of code 99355. One additional unit of code 99355 is billed for each additional increment of 30 minutes extended duration. Contractors use the following threshold times to determine if the prolonged services codes 99354 and/or 99355 can be billed with the office or other
outpatient settings including domiciliary, rest home, or custodial care services and home services codes.

| Threshold Time for Prolonged Visit Codes 99354 and/or 99355 Billed with Office/Outpatient and Consultation Codes |
|---|---|---|
| Code | Typical Time for Code | Threshold Time to Bill Code 99354 | Threshold Time to Bill Codes 99354 and 99355 |
| 99201 | 10 | 40 | 85 |
| 99202 | 20 | 50 | 95 |
| 99203 | 30 | 60 | 105 |
| 99204 | 45 | 75 | 120 |
| 99205 | 60 | 90 | 135 |
| 99212 | 10 | 40 | 85 |
| 99213 | 15 | 45 | 90 |
| 99214 | 25 | 55 | 100 |
| 99215 | 40 | 70 | 115 |
| 99221 | 30 | 60 | 105 |
| 99222 | 50 | 80 | 125 |
| 99223 | 70 | 100 | 145 |
| 99231 | 15 | 45 | 90 |
| 99232 | 25 | 55 | 100 |

Add 30 minutes to the threshold time for billing codes 99354 and 99355 to get the threshold time for billing code 99354 and two units of code 99357.

| G. Threshold Times for Codes 99356 and 99357 (Inpatient Setting) |
|---|---|---|---|
| Code | Typical Time for Code | Threshold Time to Bill Code 99356 | Threshold Time to Bill Codes 99356 and 99357 |
| 99221 | 30 | 60 | 105 |
| 99222 | 50 | 80 | 125 |
| 99223 | 70 | 100 | 145 |
| 99231 | 15 | 45 | 90 |

Add 30 minutes to the threshold time for billing codes 99356 and 99357 to get the threshold time for billing code 99356 and two units of 99357.

| H. Prolonged Services Associated With Evaluation and Management Services Based on Counseling and/or Coordination of Care (Time-Based) |
|---|---|---|---|
| When an evaluation and management service is dominated by counseling and/or coordination of care (the counseling and/or coordination of care represents more than 50% of the total time with the patient) in a face-to-face encounter between the physician or qualified NPP and the patient in the office/clinic or the floor time (in the scenario of an inpatient service), then the evaluation and management code is selected based on the total time with the patient. The time approximation must meet or exceed the specific CPT code billed (determined by the typical/average time associated with the code levels). The time approximation must meet or exceed the specific CPT code billed (determined by the typical/average time associated with the evaluation and management code) and should not be “rounded” to the next higher level. |

In those evaluation and management services in which the code level is selected based on time, prolonged services may only be reported with the highest code level in that family of codes as the companion code.

<table>
<thead>
<tr>
<th>I. Examples of Billable Prolonged Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXAMPLE 1</td>
</tr>
<tr>
<td>A physician performed a visit that met the definition of visit code 99213 and the total duration of the direct face-to-face services (including the visit) was 65 minutes. The physician bills code 99213 and 1 unit of code 99354.</td>
</tr>
</tbody>
</table>

| EXAMPLE 2 |
| A physician performed a visit that met the definition of an office visit to an established patient that was predominantly counseling, spending 75 minutes |

| EXAMPLE 3 |
| A physician performed an office visit to an established patient that was predominantly counseling, spending 75 minutes |
the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) sets forth revised conditions for Medicare payment of Power Mobility Devices (PMDs). This section of the MMA states that payment for motorized or power wheelchairs may not be made unless a physician (as defined in §1861(r)(1) of the Act), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in §1861(aa)(5)) has conducted a face-to-face examination of the beneficiary and written a prescription for the PMD.

Payment for the history and physical examination will be made through the appropriate evaluation and management (E&M) code corresponding to the history and physical examination of the patient. Due to the MMA requirement that the physician or treating practitioner create a written prescription and a regulatory requirement that the physician or treating practitioner prepare pertinent parts of the medical record for submission to the durable medical equipment supplier, code G0372 (physician service required to establish and document the need for a power mobility device) has been established to recognize additional physician services and resources required to establish and document the need for the PMD.

The G code indicates that all of the information necessary to document the PMD prescription is included in the medical record, and the prescription and supporting documentation is delivered to the PMD supplier within 30 days after the face-to-face examination. Effective October 25, 2005, G0372 will be used to recognize additional physician services and resources required to establish and document the need for the PMD and will be added to the Medicare physician fee schedule.

### J. Examples of Nonbillable Prolonged Services

**EXAMPLE 1**

A physician performed a visit that met the definition of visit code 99212 and the total duration of the direct face-to-face contact (including the visit) was 35 minutes. The physician cannot bill prolonged services because the total duration of direct face-to-face service did not meet the threshold time for billing prolonged services.

**EXAMPLE 2**

A physician performed a visit that met the definition of code 99213 and, while the patient was in the office receiving treatment for 4 hours, the total duration of the direct face-to-face service of the physician was 40 minutes. The physician cannot bill prolonged services because the total duration of direct face-to-face service did not meet the threshold time for billing prolonged services.

**EXAMPLE 3**

A physician provided a subsequent office visit that was predominantly counseling, spending 60 minutes (face-to-face) with the patient. The physician cannot code 99214, which has a typical time of 25 minutes, and one unit of code 99354. The physician must bill the highest level code in the code family (99215 which has 40 minutes typical/average time units associated with it). The additional time spent beyond this code is 20 minutes and does not meet the threshold time for billing prolonged services.

### 30.6.15.2—Prolonged Services Without Direct Face-to-Face Patient Contact Service (Codes 99358 - 99359)

(Rev. 1490, Issued: 04-11-08, Effective: 07-01-08, Implementation: 07-07-08)

Contractors may not pay prolonged services codes 99358 and 99359, which do not require any direct patient face-to-face contact (e.g., telephone calls). Payment for these services is included in the payment for direct face-to-face services that physicians bill. The physician cannot bill the patient for these services since they are Medicare covered services and payment is included in the payment for other billable services.

### 30.6.15.3—Physician Standby Service (Code 99360)

(Rev. 1, 10-01-03)

Standby services are not payable to physicians. Physicians may not bill Medicare or beneficiaries for standby services. Payment for standby services is included in the Part A payment to the facility. Such services are a part of hospital costs to provide quality care. If hospitals pay physicians for standby services, such services are part of hospital costs to provide quality care.

### 30.6.15.4—Power Mobility Devices (PMDs) (Code G0372)

(Rev. 748, Issued: 11-04-05; Effective/Implementation Dates: 10-25-05)

Section 302(a)(2)(E)(iv) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) sets forth revised conditions for Medicare payment of Power Mobility Devices (PMDs). This section of the MMA states that payment for motorized or power wheelchairs may not be made unless a physician (as defined in §1861(r)(1) of the Act), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in §1861(aa)(5)) has conducted a face-to-face examination of the beneficiary and written a prescription for the PMD.

Payment for the history and physical examination will be made through the appropriate evaluation and management (E&M) code corresponding to the history and physical examination of the patient. Due to the MMA requirement that the physician or treating practitioner create a written prescription and a regulatory requirement that the physician or treating practitioner prepare pertinent parts of the medical record for submission to the durable medical equipment supplier, code G0372 (physician service required to establish and document the need for a power mobility device) has been established to recognize additional physician services and resources required to establish and document the need for the PMD.

The G code indicates that all of the information necessary to document the PMD prescription is included in the medical record, and the prescription and supporting documentation is delivered to the PMD supplier within 30 days after the face-to-face examination. Effective October 25, 2005, G0372 will be used to recognize additional physician services and resources required to establish and document the need for the PMD and will be added to the Medicare physician fee schedule.
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90.1—Physicians in Federal Hospitals
(Rev. 1, 10-01-03)

B3-2020.5

There are many physicians performing services in hospitals operated by the Federal Government, e.g., military, Veterans Administration, and Public Health Service hospitals. Normally Medicare does not pay for the services provided by a physician in a Federal hospital except when the hospital provides services to the public generally as a community institution. Such a physician working in the scope of his Federal employment may be considered as coming within the statutory definition of physician even though he may not have a license to practice in the State in which he is employed.

90.2—Physician Billing for End-Stage Renal Disease Services
(Rev. 1, 10-01-03)

See the Medicare Benefit Policy Manual, Chapter 11, for a description of ESRD policy.

See chapter 8, for billing requirements for physicians and facilities.

90.2.1—Inpatient Hospital Visits With Dialysis Patients
(Rev. 1, 10-01-03)

B3-15062-15062.1

Global billing practices that involve the submission of charges for each day that a patient is hospitalized are allowed. Therefore, carriers may make payment for inpatient hospital visits that are specified relative to time, place, day, and services directly provided to inpatients. This guideline may, however, differ with respect to dialysis charges for inpatient hospital visits with dialysis inpatients. When an ESRD patient is hospitalized, the hospitalization may or may not be due to a renal-related condition. In either case, the patient must continue to be dialyzed.

Chapter 8 provides policy and payment instructions for physicians’ services furnished to dialysis inpatients. It also provides instructions for billing physicians’ renal-related medical services furnished on dialysis days and for dialysis evaluation and management services performed on the same day.

90.3—Physicians’ Services Performed in Ambulatory Surgical Centers (ASC)
(Rev. 1604, Issued: 09-26-08, Effective: 01-08-08, Implementation: 01-05-09)

See Chapter 14, for a description of services that may be billed by an ASC and services separately billed by physicians.

The ASC payment does not include the professional services of the physician. These are billed separately by the physician. Physicians’ services include the services of anesthesiologists administering or supervising the administration of anesthesia to ASC patients and the patients’ recovery from the anesthesia. The term physicians’ services also includes any routine pre- or postoperative services, such as office visits, consultations, diagnostic tests, removal of stitches, changing of dressings, and other services which the individual physician usually performs.

The physician must enter the place of service code (POS) 24 on the claim to show that the procedure was performed in an ASC.

The carrier pays the “facility” fee from the MPFSDB to the physician. The facility fee is for services done in a facility other than the physician’s office and is less than the nonfacility fee for services performed in the physician’s office.

90.4—Billing and Payment in a Health Professional Shortage Area (HPSA)
(Rev. 1273; Issued: 06-29-07; Effective/Implementation Dates: 10-01-07)

In accordance with §1833(m) of the Act, physicians who provide covered professional services in any rural or urban HPSA are entitled to an incentive payment. Beginning January 1, 1989, physicians providing services in certain classes of rural HPSAs were entitled to a 5-percent incentive payment. Effective January 1, 1991, physicians providing services in either rural or urban HPSAs are eligible for a 10-percent incentive payment.

Eligibility for receiving the 10 percent bonus payment is based on whether the specific location at which the service is furnished is within an area that is designated (under section 332(a)(1)(A) of the Public Health Services Act) as a HPSA. The Health Resources and Services Administration (HRSA), within the Department of Health & Human Services, is responsible for designating shortage areas.

HRSA designates three types of HPSAs: geographic, population, and facility-based. Geographic-based HPSAs are areas with shortages of primary care physicians, dentists or psychiatrists. Population-based HPSAs are designations based on underserved populations within an area. Facility-based HPSAs are designations based on a public or non-profit private facility that is providing services to an underserved area or population and has an insufficient capacity to meet their needs.

Section 1833(m) of the Social Security Act (the Act) provides incentive payments for physicians who furnish services in areas designated as HPSAs under section 332(a)(1)(A) of the Public Health Service (PHS) Act. This section of the PHS Act pertains to geographic-based HPSAs. Consequently, Medicare incentive payments are available only in geographic HPSAs.

Although section 1833(m) of the Act provides the authority to recognize the three types of geographic-based HPSAs (primary medical care, dental and mental health), only physicians, including psychiatrists, furnishing services in a primary medical care HPSA are eligible to receive bonus payments. In addition, effective for claims with dates of service on or after July 1, 2004, psychiatrists furnishing services in mental health HPSAs are eligible to receive bonus payments. CMS does not recognize dental HPSAs for the bonus payment program.

It is not enough for the physician merely to have his/her office or primary service location in a HPSA, nor must the beneficiary reside in a HPSA, although frequently this will be the case. The key to eligibility is where the service is actually provided (place of service). For example, a physician providing a service in his/her office, the patient’s home, or in a hospital qualifies for the incentive payment as long as the
specific location of the service is within an area designated as a HPSA. On the other hand, a physician may have an office in a HPSA but go outside the office (and the designated HPSA area) to provide the service. In this case, the physician would not be eligible for the incentive payment. Carrier responsibilities include:

- Informing the physician community of these provisions;
- Providing a direct link to the CMS Web site to access the HPSA automated ZIP code files;
- Providing a direct link to the HRSA’s HPSA database;
- Modifying the claims processing system to recognize and appropriately handle eligible claims;
- Paying physicians the incentive payments; and
- Performing post-payment reviews of samples of paid claims submitted using the AQ modifier.

90.4.1 – Provider Education
(Rev. 1639, Issued: 11-21-08, Effective: 01-01-09, Implementation: 01-05-09)

ZIP Code files for the automated payment of the HPSA bonus payment will be developed and updated annually. Effective for claims with dates of service on or after January 1, 2009, only services provided in areas that are designated as of December 31 of the prior year are eligible for the HPSA bonus payment. Physicians providing services in areas that were designated as of December 31 of the prior year but not on the automated file may use the AQ modifier. Only services provided in areas that were designated as of December 31 of the prior year but not on the automated file may use the modifier. Services provided in areas that are designated throughout the year will not be eligible for the HPSA bonus payment until the following year, provided they are still designated on December 31. Services provided in areas that are de-designated throughout the year will continue to be eligible for the HPSA bonus through the end of the calendar year.

CMS will post on its Web site ZIP codes that are eligible to automatically receive the bonus payment as well as the information on how to determine when the modifier is needed to receive the bonus payment. Through regularly scheduled bulletins and list servs, carriers must notify all physicians to verify their ZIP code eligibility via the CMS Web site or the HRSA Web site for the area where they provide physician services.

90.4.1.1 – Carrier Web Pages
(Rev. 1273; Issued: 06-29-07; Effective/Implementation Dates: 10-01-07)

Carrier Web pages shall direct the physician community to a direct link to the CMS Web site to access the automated HPSA bonus payment file, and a direct link to the HRSA/HPSA designations database.

90.4.2—HPSA Designations
(Rev. 1639, Issued: 11-21-08, Effective: 01-01-09, Implementation: 01-05-09)

HPSA designations are made by the Health Resources and Services Administration’s Division of Shortage Designation (DSD). An automated file of areas eligible for the HPSA bonus payment will be updated on an annual basis and will be effective for services rendered with dates of service on or after January 1 of each calendar year. Physicians may only use the AQ modifier for services furnished in an area that was designated as of December 31 of the prior year. This information can be downloaded from the HRSA Web site.

Carriers will be informed of the availability of the file and the file name via an email notice. Carriers will automatically pay bonuses for services rendered in ZIP Code areas that fully fall within a designated primary care or mental health full county HPSA; are considered to fully fall in the county based on a determination of dominance made by the United States Postal Service (USPS); or are fully within a partial county HPSA area. Should a ZIP Code fall within both a primary care and mental health HPSA, only one bonus will be paid on the service. Bonuses for mental health HPSAs will only be paid when performed by the provider specialty of 26 – psychiatry.

For services rendered in ZIP Code areas that do not fall within a designated full county HPSA; are not considered to fall within the county based on a determination of dominance made by the USPS; or are partially within a partial county HPSA, physicians must still submit a AQ modifier to receive payment.

To determine whether a modifier is needed, physicians must review the information provided on the CMS Web or the HRSA Web site for HPSA designations to determine if the location where they render services is, indeed, within a HPSA bonus area. Physicians may also base the determinations on letters of designations received from HRSA. They must be prepared to provide these letters as documentation upon the request of the carrier and should verify the eligibility of their area for a bonus with their carrier before submitting services with a HPSA modifier.

For services rendered in ZIP Code areas that cannot automatically receive the bonus, it will be necessary to know the census tract of the area to determine if a bonus should be paid and a modifier submitted. Census data can be retrieved by visiting the U.S. Census Bureau website at www.Census.gov or the Federal Financial Institutions Examination Council (FFIEC) website at www.ffi ec.gov/geocode/default.htm. Instructions on how to use these web sites can be found on the CMS web site at http://new.cms.hhs.gov/HPSAPSAPhysician-Bonuses. Neither CMS nor the Medicare carriers can provide information on the functionality of these Web sites.

90.4.3—Claims Coding Requirements
(Rev. 608, Issued: 07-22-05; Effective: 01-01-06; Implementation: 01-03-06)

For services with dates of service prior to January 1, 2005, physicians must indicate that their services were provided in an incentive-eligible rural or urban HPSA by using one of the following modifiers:

- QB—physician providing a service in a rural HPSA; or
- QU—physician providing a service in an urban HPSA.

Effective for claims with dates of service on or after January 1, 2006, the QB and QU modifiers will no longer be accepted. Claims with prior dates of service must still be submitted with those modifiers. The AQ modifier, Physician providing a service in a Health Professional Shortage Area (HPSA), will replace the QB and QU modifiers and will be effective for claims with dates of service on or after January 1, 2006.
For services with dates of service on or after January 1, 2005, the bonus will automatically be paid without the submission of a modifier for the following:

- When services are provided in a zip code area that fully falls within a full county HPSA.
- When services are provided in a zip code area that partially falls within a full county HPSA and has been determined to be dominant for the county by the USPS; and
- When services are provided within a zip code that fully falls within a partial county HPSA.

The submission of the QB or QU modifier, or the AQ modifier for claims with dates of service on or after January 1, 2006, will be required for the following:

- When services are provided in zip code areas that do not fully fall within a designated full county HPSA bonus area.
- When services are provided in a zip code area that partially falls within a full county HPSA but is not considered to be in that county based on the dominance decision made by the USPS.
- When services are provided in a zip code area that partially falls within a partial county HPSA.
- When services are provided in a zip code area that was not included in the automated file based on the date of the data run used to create the file.

In order to be considered for the bonus payment, the name, address, and zip code of where the service was rendered must be included on all electronic and paper claims submissions.

90.4.4—Payment
(Rev. 2040, Issued: 08-27-10, Effective: 01-01-11 and 04-04-11, Implementation: 01-03-11 for the claim identification of the incentive and 04-04-11 for full implementation)

The incentive payment is 10 percent of the amount actually paid, not the approved amount. Contractors pay the incentive payment for services identified on either assigned or unassigned claims.

They do not include the incentive payment with each claim payment. Contractors should:

- Establish a quarterly schedule for issuing incentive payments. These payments are taxable and must be reported to the IRS; and
- Prepare a special incentive remittance to accompany each payment. Include a line item for each assigned claim represented in the incentive check and a “summary” item showing the number of unassigned claims represented. Claims should be identified as HPSA physician, Scarcity, HSIP and/or PCIP in the summary. The sum of the line items and the “summary” item should equal the amount of the check.

90.4.5—Services Eligible for HPSA and Physician Scarcity Bonus Payments
(Rev. 906, Issued: 04-14-06, Effective: 07-01-06, Implementation: 07-03-06)

A. Information in the Professional Component/Technical Component (PC/TC) Indicator Field of the Medicare Physician Fee Schedule Database

Carriers use the information in the Professional Component/Technical Component (PC/TC) indicator field of the Medicare Physician Fee Schedule Database to identify professional services eligible for HPSA and physician scarcity bonus payments. The following are the rules to apply in determining whether to pay the bonus on services furnished within a geographic HPSA or physician scarcity bonus area.

Should carriers receive notification from physicians that they have chosen to forgo the bonus payments, the carriers shall make no bonus payments to that physician for any service.

<table>
<thead>
<tr>
<th>PC/TC Indicator</th>
<th>Bonus Payment Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Pay bonus</td>
</tr>
<tr>
<td>1</td>
<td>Globally billed. Only the professional component of this service qualifies for the bonus payment. The bonus cannot be paid on the technical component of globally billed services. Action: Effective for claims received prior to October 1, 2005, carriers return the service as unprocessable and notify the physician that the professional component must be re-billed if it is performed within a qualifying bonus area. If the technical component is the only component of the service that was performed in the bonus area, there wouldn’t be a qualifying service. Effective for claims received on or after October 1, 2005, carriers shall accept claims with services with a PC/TC indicator of 1 that are eligible for the HPSA or PSA bonus. They shall pay the bonus only on the professional component of the service.</td>
</tr>
<tr>
<td>1</td>
<td>Professional Component (modifier 26). Carriers pay the bonus.</td>
</tr>
<tr>
<td>1</td>
<td>Technical Component (modifier TC). Carriers do not pay the bonus.</td>
</tr>
<tr>
<td>2</td>
<td>Technical Component only. Carriers pay the bonus.</td>
</tr>
<tr>
<td>3</td>
<td>Technical Component only. Carriers do not pay the bonus.</td>
</tr>
<tr>
<td>4</td>
<td>Global test only. Only the professional component of this service qualifies for the bonus payment. Action: Effective for claims received prior to July 1, 2006, carriers return the service as unprocessable. They instruct the provider to re-bill the service as separate professional and technical component procedure codes. Effective for claims received on or after July 1, 2006, except for 93015, carriers shall accept claims with services with a PC/TC indicator of 4 that are eligible for the HPSA or PSA bonus. They shall pay the bonus only on the associated professional component of the service. Since 93015 has two associated professional components, carriers will not be able to make a determination as to which would be the correct component to use to calculate the bonuses. Therefore, carriers shall continue to treat 93015 as unprocessable.</td>
</tr>
<tr>
<td>5</td>
<td>Incident to codes. Carriers do not pay the bonus.</td>
</tr>
<tr>
<td>6</td>
<td>Laboratory physician interpretation codes. Carriers pay the bonus.</td>
</tr>
<tr>
<td>7</td>
<td>Physical therapy service. Carriers do not pay the bonus.</td>
</tr>
<tr>
<td>8</td>
<td>Physician interpretation codes. Carriers pay the bonus.</td>
</tr>
<tr>
<td>9</td>
<td>Concept of PC/TC does not apply. Carriers do not pay the bonus.</td>
</tr>
</tbody>
</table>
NOTE: Codes that have a status of “X” on the Medicare Physician Fee Schedule Database (MFSDDB) have been assigned PC/TC indicator 9 and are not considered physician services for MFSDDB payment purposes. Therefore, neither the HPSA bonus payment nor the physician scarcity area will be paid for these codes.

B. Anesthesia Codes (CPT Codes 00100 Through 01999) That Do Not Appear on the MFSDDB

Anesthesia codes (CPT codes 00100 through 01999) do not appear on the MFSDDB. However, when a medically necessary anesthesia service is furnished within a HPSA or physician scarcity area by a physician, a HPSA bonus and/or physician scarcity bonus is payable.

To claim a bonus payment for anesthesia, physicians bill codes 00100 through 01999 with modifiers QY, QK, AD, AA, or GC to signify that the anesthesia service was performed by a physician along with the QB or QU modifier or the AQ modifier for claims with dates of service on or after January 1, 2006, when required per §90.4.3 or the AR modifier as required per §90.5.3.

C. Mental Health Services

Physicians’ professional mental health services rendered by the provider specialty of 26—psychiatry, are eligible for a HPSA bonus when rendered in a mental health HPSA. The service must have a PC/TC designation per the chart above. Should a zip code fall within both a primary care and mental health HPSA, only one bonus must be paid on the service.

90.4.6—Remittance Messages

(Rev. 280, Issued 08-13-04, Effective/Implementation: October 1, 2004 for the analysis and design phases for the MCS Maintainer and Contractors, January 1, 2005 for the coding, testing, and implementation phases for the MCS Maintainer and Contractors, January 1, 2005 for all phases for the VIPS Maintainers and Contractors)

B3-3350.6

A/B MACs (B) use the following messages for services on which the HPSA/physician scarcity bonus is claimed.

A. Services Where the HPSA/Physician Scarcity Bonus Can Only Be Paid on a Portion of the Billed Service at the Service/Line Level

Claim adjustment reason code 16, “Claim/service lacks information which is needed for adjudication. Additional information is supplied using remittance advice remarks codes whenever appropriate.”

Line level remark code M73, “The HPSA/Physician Scarcity bonus can only be paid on the professional component of this service. Rebill as separate professional and technical components.”

B. Services That Are Not Eligible for HPSA/Physician Scarcity Payments at the Service/Line Level

Line level remark code M74, “This service does not qualify for a HPSA/Physician Scarcity bonus payment.”

NOTE: This is an informational message only.

90.4.7 – Post-payment Review

(Rev. 2914, Issued: 03-25-14, Effective: 03-31-14, Implementation: 03-31-14)

On a post-payment basis, services submitted with the QB or QU modifier, or the AQ modifier for claims with dates of service on or after January 1, 2006, will be subject to validation.

Effective for claims with the dates of service on or after January 1, 2005, the date of the HPSA designation or withdrawal on the HRSA Web site or the date of designation or withdrawal in notification letters from HRSA are used as the effective date for paying the HPSA bonus.

Effective for claims with dates of service on or after January 1, 2006, A/B MAC Part B contractors shall only include services paid with the AQ modifier for post-payment HPSA review. Services with bonuses that were automatically paid based on the ZIP code for the HPSA post-payment review process shall not be included. Additional post-payment will be conducted at the contractor’s discretion. Effective for claims with dates of service on or after January 1, 2009, for Medicare bonus payment purposes, A/B MAC Part B contractors shall only consider services eligible for bonuses if the area was designated as a HPSA as of December 31 of the prior year.

The post-payment review will be conducted each quarter as follows:

- Array each list of physicians by the total amount of incentive payments received.
- Select the 25 percent of physicians on each list who received the highest payments.
- Review a sample of 5 claims by each physician on each list (ensure the sample is representative of different types of settings, if applicable).
- The findings must be transmitted via CROWD (Form 1565E) to central office no later than the 75th day following the close of the CROWD reporting quarter.

Physicians who appear on a list, were previously reviewed, and subsequently found to be in compliance shall be excluded from the current reporting. The 5 claim sample shall be reviewed to ensure the place of service was actually in a HPSA bonus area. In addition, effective for claims with dates of service on or after July 1, 2004, services selected as part of the 25% sample will be verified that they were provided in a mental health HPSA by the physician specialty of 26, psychiatry.

Once a physician has incorrectly claimed incentive payments, the A/B MAC Part B contractors shall continue to monitor the physician’s claims until they are found to be in compliance.

The designations on the HRSA Web site and HRSA letters can be used to verify that services were provided in a HPSA. Physicians are permitted to submit copies of HRSA designation letters as appropriate documentation to their Medicare Administrative Contractor.

If it is determined that a HPSA bonus was paid in error, the A/B MAC Part B contractor will pursue the amount of any overpayment by directly contacting the physician and his/her billing staff. For Medicare HPSA bonus payment purposes, designations are valid for the entire calendar year regardless of whether the HPSA designation is withdrawn by the HRSA during that year.
90.4.8—Reporting
(Rev. 1, 10-01-03)
B3-3350.8, B3-13320, B3-13320.1, B3-13322.3
Reporting instructions are included in Chapter 6 of the Medicare Financial Management Manual.

90.4.9—HPSA Incentive Payments for Physician Services Rendered in a Critical Access Hospital (CAH)
(Rev. 608, Issued: 07-22-05; Effective: 01-01-06; Implementation: 01-03-06)

If a CAH electing the Optional Method (Method II) is located within a mental health HPSA, the psychiatrists providing (outpatient) professional services in the CAH are eligible for the Mental Health and Primary Care HPSA bonus payments. When billing for this service, the CAH must bill using Revenue code 961 plus the applicable HCPCS. This Mental Health HPSA bonus will be paid to the CAH on a quarterly basis by the FI. If an area is designated as both a mental health HPSA and a primary medical HPSA, only one 10% bonus will be paid for the service.

Refer to §250.2 in the Claims Processing Manual, Chapter 4 for additional information.

90.4.10—Administrative and Judicial Review
(Rev. 280, Issued 08-13-04, Effective/Implementation: October 1, 2004 for the analysis and design phases for the MCS Maintainer and A/B MACs (B), January 1, 2005 for the coding, testing, and implementation phases for the MCS Maintainer and A/B MACs (B), January 1, 2005 for all phases for the VIPS Maintainers and A/B MACs (B))

Per Section 413(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, there shall be no administrative or judicial review respecting:

- The identification of a county or area;
- The assignment of a specialty of any physician;
- The assignment of a physician to a county; or
- The assignment of a postal zip code to a county or other area.

170—Clinical Psychologist Services
(Rev. 1, 10-01-03)
B3-2150
See Medicare Benefit Policy Manual, Chapter 15, for general coverage requirements.

Direct payment may be made under Part B for professional services. However, services furnished incident to the professional services of CPs to hospital patients remain bundled. Therefore, payment must continue to be made to the hospital (by the FI) for such “incident to” services.

170.1—Payment
(Rev. 2656, Issuance: 02-07-13, Effective: 02-19-13, Implementation: 02-19-13)

All covered therapeutic services furnished by qualified CPs are subject to the outpatient mental health services limitation (the limitation). Generally, the limitation does not apply to diagnostic services. Refer to §210 below for a discussion of the outpatient mental health limitation.

Payment for the services of CPs is made on the basis of a fee schedule or the actual charge, whichever is less, and only on the basis of assignment.

CPs are identified by specialty code 68 and provider type 27.

190—Medicare Payment for Telehealth Services
(Rev. 1, 10-01-03)
A3-3497, A3-3660.2, B3-4159, B3-15516

190.1—Background
(Rev. 1635, Issued: 11-14-08, Effective: 01-01-09, Implementation: 01-05-09)

Section 223 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) - Revision of Medicare Reimbursement for Telehealth Services amended §1834 of the Act to provide for an expansion of Medicare payment for telehealth services.

Effective October 1, 2001, coverage and payment for Medicare telehealth includes consultation, office visits, individual psychotherapy, and pharmacologic management delivered via a telecommunications system. Eligible geographic areas include rural health professional shortage areas (HPSA) and counties not classified as a metropolitan statistical area (MSA). Additionally, Federal telemedicine demonstration projects as of December 31, 2000, may serve as the originating site regardless of geographic location.

An interactive telecommunications system is required as a condition of payment; however, BIPA does allow the use of asynchronous “store and forward” technology in delivering these services when the originating site is a Federal telemedicine demonstration program in Alaska or Hawaii. BIPA does not require that a practitioner present the patient for interactive telehealth services.

With regard to payment amount, BIPA specified that payment for the professional service performed by the distant site practitioner (i.e., where the expert physician or practitioner is physically located at time of telemedicine encounter) is equal to what would have been paid without the use of telemedicine. Distant site practitioners include only a physician as described in §1861(r) of the Act and a medical practitioner as described in §1842(b)(18)(C) of the Act. BIPA also expanded payment under Medicare to include a $20 originating site facility fee (location of beneficiary).

Previously, the Balanced Budget Act of 1997 (BBA) limited the scope of Medicare telehealth coverage to consultation services and the implementing regulation prohibited the use of an asynchronous, ‘store and forward’ telecommunications system. BBA 1997 also required the professional fee to be shared between the referring and consulting practitioners, and prohibited Medicare payment for facility fees and line charges associated with the telemedicine encounter.

BIPA required that Medicare Part B (Supplementary Medical Insurance) pay for this expansion of telehealth services beginning with services furnished on October 1, 2001.

Section 149 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended §1834 of the Act to
add certain entities as originating sites for payment of telehealth services. Effective for services furnished on or after January 1, 2009, eligible originating sites include a hospital-based or critical access hospital-based renal dialysis center (including satellites); a skilled nursing facility (as defined in §1819(a) of the Act); and a community mental health center (as defined in §1861(f)(3)(B) of the Act). MIPPA also amended §1888(e)(2)(A)(ii) of the Act to exclude telehealth services furnished under §1834(m)(4)(C)(ii)(VII) from the consolidated billing provisions of the skilled nursing facility prospective payment system (SNF PPS).

NOTE: MIPPA did not add independent renal dialysis facilities as originating sites for payment of telehealth services.

The telehealth provisions authorized by §1834(m) of the Act are implemented in 42 CFR 410.78 and 414.65.

190.2—Eligibility Criteria
(Rev. 2848, Issued 12-30-13; Effective 01-01-14; Implementation 01-06-14)

1. Beneficiaries eligible for telehealth services

Medicare beneficiaries are eligible for telehealth services only if they are presented from an originating site located in either a rural health professional shortage area (HPSA) as defined by §332(a)(1) (A) of the Public Health Services Act or in a county outside of a MSA as defined by §1886(d)(2)(D) of the Act.

Effective January 1, 2014, rural HPSAs include HPSAs located outside of a county outside of an MSA as well as those located in rural census tracts as determined by the Office of Rural Health Policy. Also effective January 1, 2014, geographic eligibility for an originating site is established for each calendar year based upon the status of the area as of December 31st of the prior calendar year.

2. Exception to rural HPSA and non MSA geographic requirements

Entities participating in a Federal telemedicine demonstration project that were approved by or were receiving funding from the Secretary of Health and Human Services as of December 31, 2000, qualify as originating sites regardless of geographic location. Such entities are not required to be in a rural HPSA or non-MSA.

3. Originating site defined

The term originating site means the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. Originating sites authorized by law are listed below:

- The office of a physician or practitioner;
- A hospital (inpatient or outpatient);
- A critical access hospital (CAH);
- A rural health clinic (RHC); and
- A federally qualified health center (FQHC);
- A hospital-based or critical access hospital-based renal dialysis center (including satellites) (effective January 1, 2009);
- A skilled nursing facility (SNF) (effective January 1, 2009); and
- A community mental health center (CMHC) (effective January 1, 2009).

NOTE: Independent renal dialysis facilities are not eligible originating sites.

For asynchronous, store and forward telecommunications technologies, an originating site is only a Federal telemedicine demonstration program conducted in Alaska or Hawaii.

190.3—List of Medicare Telehealth Services
(Rev. 3476, Issued: 03-11-16, Effective: 01-01-15, Effective: 04-11-16)

The use of a telecommunications system may substitute for an in-person encounter for professional consultations, office visits, office psychiatry services, and a limited number of other physician fee schedule (PFS) services. The various services and corresponding current procedure terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) codes are listed on the CMS website at www.cms.gov/Medicare/MedicareGeneral-Information/Telehealth/.

NOTE: Beginning January 1, 2010, CMS eliminated the use of all consultation codes, except for inpatient telehealth consultation G-codes. CMS will no longer recognize office/outpatient or inpatient consultation CPT codes for payment of office/outpatient or inpatient visits. Instead, physicians and practitioners are instructed to bill a new or established office/outpatient patient visit CPT code or appropriate hospital or nursing facility care code, as appropriate to the particular patient, for all office/outpatient or inpatient visits.

190.4—Conditions of Payment
(Rev. 1, 10-01-03)

1. Technology

For Medicare payment to occur, interactive audio and video telecommunications must be used, permitting real-time communication between the distant site physician or practitioner and the Medicare beneficiary. As a condition of payment, the patient must be present and participating in the telehealth visit.

2. Exception to the interactive telecommunications requirement

In the case of Federal telemedicine demonstration programs conducted in Alaska or Hawaii, Medicare payment is permitted for telemedicine when asynchronous “store and forward technology” in single or multimedia formats is used as a substitute for an interactive telecommunications system. The originating site and distant site practitioner must be included within the definition of the demonstration program.

3. “Store and forward” defined

For purposes of this instruction, “store and forward” means the asynchronous transmission of medical information to be reviewed at a later time by physician or practitioner at the distant site. A patient’s medical information may include, but not limited to, video clips, still images, x-rays, MRIs, EKGs and EEGs, laboratory results, audio clips, and text. The physician or practitioner at the distant site reviews the case without the patient being present. Store and forward substitutes for an interactive encounter with the patient present; the patient is not present in real-time.
NOTE: Asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines and text messages without visualization of the patient (electronic mail). Photographs must be specific to the patients’ condition and adequate for rendering or confirming a diagnosis and or treatment plan. Dermatological photographs, e.g., a photograph of a skin lesion, may be considered to meet the requirements of a single media format under this instruction.

4. Telepresenters

A medical professional is not required to present the beneficiary to physician or practitioner at the distant site unless medically necessary. The decision of medical necessity will be made by the physician or practitioner located at the distant site.

190.5—Originating Site Facility Fee Payment Methodology

(Rev. 3476, Issued: 03-11-16, Effective: 01-01-15, Effective: 04-11-16)

1. Originating site defined

The term originating site means the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. For asynchronous, store and forward telecommunications technologies, an originating site is only a Federal telemedicine demonstration program conducted in Alaska or Hawaii.

2. Facility fee for originating site

The originating site facility fee is a separately billable Part B payment. The contractor pays it outside of other payment methodologies. This fee is subject to post payment verification.

For telehealth services furnished from October 1, 2001, through December 31, 2002, the originating site facility fee was the lesser of $20 or the actual charge. For services furnished on or after January 1 of each subsequent year, the originating site facility fee is updated by the Medicare Economic Index. The updated fee is included in the Medicare Physician Fee Schedule (MPFS) Final Rule, which is published by November 1 prior to the start of the calendar year for which it is effective. The updated fee for each calendar year is also issued annually in a Recurring Update Notification instruction for January of each year.

3. Payment amount:

The originating site facility fee is a separately billable Part B payment. The payment amount to the originating site is the lesser of 80 percent of the actual charge or 80 percent of the originating site facility fee, except CAHs. The beneficiary is responsible for any unmet deductible amount and Medicare coinsurance.

The originating site facility fee payment methodology for each type of facility is clarified below.

Hospital outpatient department. When the originating site is a hospital outpatient department, payment for the originating site facility fee must be made as described above and not under the OPPS. Payment is not based on the OPPS payment methodology.

Hospital inpatient. For hospital inpatients, payment for the originating site facility fee must be made outside the diagnostic related group (DRG) payment, since this is a Part B benefit, similar to other services paid separately from the DRG payment, e.g., hemophilia blood clotting factor.

Critical access hospitals. When the originating site is a critical access hospital, make payment separately from the cost-based reimbursement methodology. For CAHs, the payment amount is 80 percent of the originating site facility fee.

Federally qualified health centers (FQHCs) and rural health clinics (RHCs). The originating site facility fee for telehealth services is not an FQHC or RHC service. When an FQHC or RHC serves as the originating site, the originating site facility fee must be paid separately from the center or clinic all-inclusive rate.

Physicians’ and practitioners’ offices. When the originating site is a physician’s or practitioner’s office, the payment amount, in accordance with the law, is the lesser of 80 percent of the actual charge or 80 percent of the originating site facility fee, regardless of geographic location. The A/B MAC (B) shall not apply the geographic practice cost index (GPCI) to the originating site facility fee. This fee is statutorily set and is not subject to the geographic payment adjustments authorized under the MFPS.

Hospital-based or critical access-hospital based renal dialysis center or their satellites. When a hospital-based or critical access hospital-based renal dialysis center (or their satellites) serves as the originating site, the originating site facility fee is covered in addition to any composite rate or MCP amount.

Skilled nursing facility (SNF). The originating site facility fee is outside the SNF prospective payment system bundle and, as such, is not subject to SNF consolidated billing. The originating site facility fee is a separately billable Part B payment.

Community Mental Health Center (CMHC). The originating site facility fee is not a partial hospitalization service. The originating site facility fee does not count towards the number of services used to determine payment for partial hospitalization services. The originating site facility fee is not bundled in the per diem payment for partial hospitalization. The originating site facility fee is a separately billable Part B payment.

To receive the originating site facility fee, the provider submits claims with HCPCS code “Q3014, telehealth originating site facility fee”, short description “telehealth facility fee.” The type of service for the telehealth originating site facility fee is “9, other items and services.” For A/B MAC (B) processed claims, the “office” place of service (code 11) is the only payable setting for code Q3014. There is no participation payment differential for code Q3014. Deductible and coinsurance rules apply to Q3014. By submitting Q3014 HCPCS code, the originating site authenticates they are located in either a rural HPSA or non-MSA county.

This benefit may be billed on bill types 12X, 13X, 22X, 23X, 71X, 72X, 73X, 76X, and 85X. Unless otherwise applicable, report the originating site facility fee under revenue code 078X and include HCPCS code “Q3014, telehealth originating site facility fee.”

Hospitals and critical access hospitals bill their A/B/MAC (A) for the originating site facility fee. Telehealth bills originating in inpatient hospitals must be submitted on a 12X TOB using the date of discharge as the line item date of service.

Independent and provider-based RHCs and FQHCs bill the appropriate A/B/MAC (A) using the RHC or FQHC bill type and billing number. HCPCS code Q3014 is the only non-RHC/FQHC service that is billed using the clinic/center bill type and provider number. All RHCs and FQHCs must use revenue code 078X when billing for the originating site facility fee. For all other non-RHC/FQHC services, provider based RHCs and FQHCs must bill using the base provider’s bill type and billing number.
Independent RHCs and FQHCs must bill the A/B MAC (B) for all other non-RHC/FQHC services. If an RHC/FQHC visit occurs on the same day as a telehealth service, the RHC/FQHC serving as an originating site must bill for HCPCS code Q3014 telehealth originating site facility fee on a separate revenue line from the RHC/FQHC visit using revenue code 078X.

Hospital-based or CAH-based renal dialysis centers (including satellites) bill their local A/B/MAC (A) for the originating site facility fee. Telehealth bills originating in renal dialysis centers must be submitted on a 72X TOB. All hospital-based or CAH-based renal dialysis centers (including satellites) must use revenue code 078X when billing for the originating site facility fee. The renal dialysis center serving as an originating site must bill for HCPCS code Q3014, telehealth originating site facility fee, on a separate revenue line from any other services provided to the beneficiary.

Skilled nursing facilities (SNFs) bill their A/B/MAC (A) for the originating site facility fee. Telehealth bills originating in SNFs must be submitted on TOB 22X or 2X. For SNF inpatients in a covered Part A stay, the originating site facility fee must be submitted on a 22X TOB. All SNFs must use revenue code 078X when billing for the originating site facility fee. The SNF serving as an originating site must bill for HCPCS code Q3014, telehealth originating site facility fee, on a separate revenue line from any other services provided to the beneficiary.

Community mental health centers (CMHCs) bill their A/B/MAC (A) for the originating site facility fee. Telehealth bills originating in CMHCs must be submitted on a 76X TOB. All CMHCs must use revenue code 078X when billing for the originating site facility fee. The CMHC serving as an originating site must bill for HCPCS code Q3014, telehealth originating site facility fee, on a separate revenue line from any other services provided to the beneficiary. Note that Q3014 does not count towards the number of services used to determine per diem payments for partial hospitalization services.

The beneficiary is responsible for any unmet deductible amount and Medicare coinsurance.

3. Medicare Practitioners Who May Receive Payment at the Distant Site (i.e., at a site other than where beneficiary is)

As a condition of Medicare Part B payment for telehealth services, the physician or practitioner at the distant site must be licensed to provide the service under state law. When the physician or practitioner at the distant site is licensed under state law to provide a covered telehealth service (i.e., professional consultation, office and other outpatient visits, individual psychotherapy, and pharmacologic management) then he or she may bill for and receive payment for this service when delivered via a telecommunications system. If the physician or practitioner at the distant site is located in a critical access hospital (CAH) that has elected Method II, and the physician or practitioner has reassigned his/her benefits to the CAH, the CAH bills its regular A/B/MAC (A) for the professional services provided at the distant site via a telecommunications system, in any of the revenue codes 096X, 097X or 098X. All requirements for billing distant site telehealth services apply.

4. Medicare Practitioners Who May Bill for Covered Telehealth Services are Listed Below (subject to State law)

Physician.
Nurse practitioner.
Physician assistant.
Nurse-midwife.
Clinical nurse specialist.
Clinical psychologist.*
Clinical social worker.*
Registered dietitian or nutrition professional.
Certified registered nurse anesthetist

*Clinical psychologists and clinical social workers cannot bill for psychotherapy services that include medical evaluation and management services under Medicare. These practitioners may not bill or receive payment for the following CPT codes: 90805, 90807, and 90809.

190.6—Payment Methodology for Physician/Practitioner at the Distant Site

(Rev. 3476, Issued: 03-11-16, Effective: 01-01-15, Effective: 04-11-16)

1. Distant Site Defined

The term “distant site” means the site where the physician or practitioner, providing the professional service, is located at the time the service is provided via a telecommunications system.

2. Payment Amount (professional fee)

The payment amount for the professional service provided via a telecommunications system by the physician or practitioner at the distant site is equal to the current fee schedule amount for the service provided. Payment for an office visit, consultation, individual psychotherapy or pharmacologic management via a telecommunications system should be made at the same amount as when these services are furnished without the use of a telecommunications system. For Medicare payment to occur, the service must be within a practitioner’s scope of practice under State law. The beneficiary is responsible for any unmet deductible amount and applicable coinsurance.
In all other cases, except for MNT services as discussed in Section 190.7—Contractor Editing of Telehealth Claims, telehealth services provided by the physician or practitioner at the distant site are billed to the A/B/MAC (B).

Physicians and practitioners at the distant site bill their A/B/MAC (B) for covered telehealth services, for example, “99245 GT.” Physicians’ and practitioners’ offices serving as a telehealth originating site bill their A/B/MAC (B) for the originating site facility fee.

190.6.2—Exception for Store and Forward (Noninteractive) Telehealth
(Rev. 1, 10-01-03)

In the case of Federal telemedicine demonstration programs conducted in Alaska or Hawaii, store and forward technologies may be used as a substitute for an interactive telecommunications system. Covered store and forward telehealth services are billed with the “GQ” modifier, “via asynchronous telecommunications system.” By using the “GQ” modifier, the distant site physician/practitioner certifies that the asynchronous medical file was collected and transmitted to them at their distant site from a Federal telemedicine demonstration project conducted in Alaska or Hawaii.

190.7—Contractor Editing of Telehealth Claims
(Rev. 997, Issued: 07-07-06; Effective: 01-01-06; Implementation: 08-07-06)

Medicare telehealth services (as listed in section 190.3) are billed with either the “GT” or “GQ” modifier. The contractor shall approve covered telehealth services if the physician or practitioner is licensed under State law to provide the service. Contractors must familiarize themselves with licensure provisions of States for which they process claims and disallow telehealth services furnished by physicians or practitioners who are not authorized to furnish the applicable telehealth service under State law. For example, if a nurse practitioner is not licensed to provide individual psychotherapy under State law, he or she would not be permitted to receive payment for individual psychotherapy under Medicare. The contractor shall install edits to ensure that only properly licensed physicians and practitioners are paid for covered telehealth services.

If a contractor receives claims for professional telehealth services coded with the “GQ” modifier (representing “via asynchronous telecommunications system”), it shall approve/pay for these services only if the physician or practitioner is affiliated with a Federal telemedicine demonstration conducted in Alaska or Hawaii. The contractor may require the physician or practitioner at the distant site to document his or her participation in a Federal telemedicine demonstration program conducted in Alaska or Hawaii prior to paying for telehealth services provided via asynchronous, store and forward technologies.

If a contractor denies telehealth services because the physician or practitioner may not bill for them, the contractor uses MSN message 21.18: “This item or service was not covered when performed or ordered by this practitioner.” The contractor uses remittance advice message 52 when denying the claim based upon MSN message 21.18.

If a service is billed with one of the telehealth modifiers and the procedure code is not designated as a covered telehealth service, the contractor denies the service using MSN message 9.4: “This item or service was denied because information required to make payment was incorrect.” The remittance advice message depends on what is incorrect, e.g., B18 if procedure code or modifier is incorrect, 125 for submission billing errors, 412 for difference inconsistencies. The contractor uses B18 as the explanation for the denial of the claim.

The only claims from institutional facilities that FI’s shall pay for telehealth services at the distant site, except for MNT services, are for physician or practitioner services when the distant site is located in a CAH that has elected Method II, and the physician or practitioner has reassigned his/her benefits to the CAH. The CAH bills its regular FI for the professional services provided at the distant site via a telecommunications system, in any of the revenue codes 096x, 097x or 098x. All requirements for billing distant site telehealth services apply.

Claims from hospitals or CAHs for MNT services are submitted to the hospital's or CAH’s regular FI. Payment is based on the non-facility amount on the Medicare Physician Fee Schedule for the particular HCPCS codes.

210.1—Application of Limitation
(Rev. 2166, Issued: 02-25-11, Effective: 03-25-11, Implementation: 03-25-11)

A. Status of Patient

The limitation is applicable to expenses incurred in connection with the treatment of an individual who is not an inpatient of a hospital. Thus, the limitation applies to mental health services furnished to a person in a physician’s office, in the patient’s home, in a skilled nursing facility, as an outpatient, and so forth. The term “hospital” in this context means an institution which is primarily engaged in providing to inpatients, by or under the supervision of physician(s):

- Diagnostic and therapeutic services for medical diagnosis, treatment and care of injured, disabled, or sick persons;
- Rehabilitation services for injured, disabled, or sick persons; or
- Psychiatric services for the diagnosis and treatment of mentally ill patients.

B. Disorders Subject to Limitation

The term “mental, psychoneurotic, and personality disorders” is defined as the specific psychiatric diagnoses described in the International Classification of Diseases, 9th Revision (ICD-9), under the code range 290-319.

When the treatment services rendered are both for a psychiatric diagnosis as defined in the ICD-9 and one or more nonpsychiatric conditions, separate the expenses for the psychiatric aspects of treatment from the expenses for the nonpsychiatric aspects of treatment. However, in any case in which the psychiatric treatment component is not readily distinguishable from the nonpsychiatric treatment component, all of the expenses are allocated to whichever component constitutes the primary diagnosis.

1. Diagnosis Clearly Meets Definition - If the primary diagnosis reported for a particular service is the same as or equivalent to a condition described in the ICD-9 under the code range 290-319 that represents mental,
psychoneurotic and personality disorders, the expense for the service must be subject to the limitation except as described in subsection D.

2. Diagnosis Does Not Clearly Meet Definition - When it is not clear whether the primary diagnosis reported on the claim meets the definition of mental, psychoneurotic, and personality disorders, it may be necessary to contact the practitioner to clarify the diagnosis. In deciding whether contact is necessary in a given case, give consideration to such factors as the type of services rendered, the diagnosis, and the individual's previous utilization history.

C. Services Subject to Limitation

Medicare Contractors must apply the limitation to claims for professional services that represent mental health treatment furnished to individuals who are not hospital inpatients by physicians, clinical psychologists, clinical social workers, nurse practitioners, clinical nurse specialists and physician assistants. Items and supplies furnished by physicians or other mental health practitioners in connection with treatment are also subject to the limitation.

Generally, Medicare Contractors must apply the limitation only to treatment services. However, diagnostic psychological and neuropsychological testing services performed to evaluate a patient's progress during treatment are considered part of treatment and are subject to the limitation.

D. Services Not Subject to Limitation

1. Diagnosis of Alzheimer's Disease or Related Disorder - When the primary diagnosis reported for a particular service is Alzheimer's Disease or an Alzheimer's related disorder, Medicare Contractors must look to the nature of the service that has been rendered in determining whether it is subject to the limitation. Alzheimer's disease is coded 331.0 in the "International Classification of Diseases, 9th Revision", which is outside the code range 290-319 that represents mental, psychoneurotic and personality disorders. Additionally, Alzheimer's related disorders are identified by contractors under ICD-9 codes that are within the 290-319 code range (290.XX or others as contractors determine appropriate) or outside the 290-319 code range as determined appropriate by contractors. When the primary treatment rendered to a patient with a diagnosis of Alzheimer's disease or a related disorder is psychotherapy, it is subject to the limitation. However, typically, treatment provided to a patient with a diagnosis of Alzheimer's Disease or a related disorder represents medical management of the patient's condition (such as described under CPT code 90862 or any successor code) and is not subject to the limitation. CPT code 90862 describes pharmacologic management, including prescription, use, and review of medication with no more than minimal medical psychotherapy.

2. Brief Office Visits for Monitoring or Changing Drug Prescriptions - Brief office visits for the sole purpose of monitoring or changing drug prescriptions used in the treatment of mental, psychoneurotic and personality disorders are not subject to the limitation. These visits are reported using HCPCS code M0064 or any successor code (brief office visit for the sole purpose of monitoring or changing drug prescriptions used in the treatment of mental, psychoneurotic, and personality disorders). Claims where the diagnosis reported is a mental, psychoneurotic, or personality disorder (other than a diagnosis specified in subsection A) are subject to the limitation except as described in subsection D.

3. Diagnostic Services - Medicare Contractors do not apply the limitation to psychiatric diagnostic evaluations and diagnostic psychological and neuropsychological tests performed to establish or confirm the patient's diagnosis. Diagnostic services include psychiatric diagnostic evaluations billed under CPT codes 90801 or 90802 (or any successor codes) and, psychologically and neuropsychological tests billed under CPT code range 96101-96118 (or any successor code range).

An initial visit to a practitioner for professional services often combines diagnostic evaluation and the start of therapy. Such a visit is neither solely diagnostic nor solely therapeutic. Therefore, contractors must deem the initial visit to be diagnostic so that the limitation does not apply. Separating diagnostic and therapeutic components of a visit is not administratively feasible, unless the practitioner already has separately identified them on the bill. Determining the entire visit to be therapeutic is not justifiable since some diagnostic work must be done before even a tentative diagnosis can be made and certainly before therapy can be instituted. Moreover, the patient should not be disadvantaged because therapeutic as well as diagnostic services were provided in the initial visit. In the rare cases where a practitioner's diagnostic services take more than one visit, Medicare contractors must not apply the limitation to the additional visits. However, it is expected such cases are few. Therefore, when a practitioner bills for more than one visit for professional diagnostic services, Medicare contractors may find it necessary to request documentation to justify the reason for more than one diagnostic visit.

4. Partial Hospitalization Services - Medicare Contractors do not apply the limitation to partial hospitalization services that are not directly provided by a physician, clinical psychologist, nurse practitioner, clinical nurse specialist or a physician assistant. Partial hospitalization services are billed by hospital outpatient departments and community mental health centers (CMHCs) to Medicare Contractors. However, services furnished by physicians, clinical psychologists, nurse practitioners, clinical nurse specialists, and physician assistants to partial hospitalization patients are billed separately from the partial hospitalization program of services. Accordingly, these professional's mental health services to partial hospitalization patients are paid under the physician fee schedule by Medicare Contractors and may be subject to the limitation. (See chapter 4, section 260.1C).

E. Computation of Limitation

Carriers determine the Medicare allowed payment amount for services subject to the limitation. They:

- Multiply this amount by the limitation percentage amount;
- Subtract any unsatisfied deductible; and,
- Multiply the remainder by 0.8 to obtain the amount of Medicare payment.

The beneficiary is responsible for the difference between the amount paid by Medicare and the full allowed amount.

The following examples illustrate the application of the limitation in various circumstances as it is gradually reduced under section 102 of the Medicare Improvements for Patients and
Example #1: In 2010, a clinical psychologist submits a claim for $200 for outpatient treatment of a patient’s mental disorder. The Medicare-approved amount is $120. Since clinical psychologists must accept assignment, the patient is not liable for the $20 in excess charges. The patient previously satisfied the $135 annual Part B deductible. Medicare pays 80 percent of the remaining incurred expenses. The Medicare payment and patient liability are computed as follows:

1. Actual charges .......................................................... $780.00
2. Medicare-approved amount .................................... $120.00
3. Medicare incurred expenses (0.6875 x line 2) .......... $123.75
4. Unmet deductible ..................................................... $135.00
5. Remainder after subtracting deductible (line 3 minus line 4) ................................................................. $25.00
6. Medicare payment (0.80 x line 5) ............................ $492.00
7. Patient liability (line 2 minus line 6) ....................... $288.00

Example #2: In 2012, a clinical social worker submits a claim for $200 for outpatient treatment of a patient’s mental disorder. The Medicare-approved amount is $120. Since clinical social workers must accept assignment, the patient is liable for the $15 in excess charges. The limitation reduces the amount of incurred expenses to 75 percent of the approved amount. The patient previously satisfied $70 of the $135 annual Part B deductible, leaving $65 unmet. The Medicare payment and patient liability are computed as follows:

1. Actual charges .......................................................... $200.00
2. Medicare-approved amount .................................... $120.00
3. Medicare incurred expenses (0.75 x line 2) .......... $90.00
4. Unmet deductible ..................................................... $135.00
5. Remainder after subtracting deductible (line 3 minus line 4) ................................................................. $25.00
6. Medicare payment (0.80 x line 5) ............................ $492.00
7. Patient liability (line 2 minus line 6) ....................... $108.00

Example #3: In calendar year 2013, a physician who does not accept assignment submits a claim for $780 for services in connection with the treatment of a mental disorder that did not require inpatient hospitalization. The Medicare-approved amount is $750. Because the physician does not accept assignment, the patient is liable for the $30 in excess charges. The patient has not satisfied any of the $135 Part B annual deductible. The Medicare payment and patient liability are computed as follows:

1. Actual charges .......................................................... $780.00
2. Medicare-approved amount .................................... $750.00
3. Medicare incurred expenses (0.8125 x line 2) .......... $609.38
4. Unmet deductible ..................................................... $135.00
5. Remainder after subtracting deductible (line 3 minus line 4) ................................................................. $474.38
6. Medicare payment (0.80 x line 5) ............................ $475.50
7. Patient liability (line 1 minus line 6) ....................... $379.50

Example #4: A patient’s Part B expenses during calendar year 2014 are for a physician’s services in connection with the treatment of a mental disorder that initially required inpatient hospitalization, with subsequent physician services furnished on an outpatient basis. The patient has not satisfied any of the $135 Part B deductible. The physician accepts assignment and submits a claim for $780. The Medicare-approved amount is $750. Since the limitation will be completely phased out as of January 1, 2014, the entire $750 Medicare-approved amount is recognized as the total incurred expenses because such expenses are no longer reduced. Also, there is no longer any distinction between mental health services the patient receives as an inpatient or outpatient. The Medicare payment and patient liability are computed as follows:

1. Actual charges .......................................................... $780.00
2. Medicare-approved amount .................................... $750.00
3. Medicare incurred expenses (1.00 x line 2) .......... $750.00
4. Unmet deductible ..................................................... $150.00
5. Remainder after subtracting deductible (line 3 minus line 4) ................................................................. $450.00
6. Medicare payment (0.80 x line 5) ............................ $420.00
7. Patient liability (line 2 minus line 6) ....................... $330.00

100-04 Chapter 13

20—Payment Conditions for Radiology Services

B3-15022

20.1—Professional Component (PC)

(Rev. 1, 10-01-03)

Carriers must pay for the PC of radiology services furnished by a physician to an individual patient in all settings under the fee schedule for physician services regardless of the specialty of the physician who performs the service. For services furnished to hospital patients, carriers pay only if the services meet the conditions for fee schedule payment and are identifiable, direct, and discrete diagnostic or therapeutic services to an individual patient, such as an interpretation of diagnostic procedures and the PC of therapeutic procedures. The interpretation of a diagnostic procedure includes a written report.

20.2—Technical Component (TC)

(Rev. 1, 10-01-03)

20.2.1—Hospital and Skilled Nursing Facility (SNF) Patients

(Rev. 1782; Issued: 07-30-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

Carriers may not pay for the technical component (TC) of radiology services furnished to hospital patients. Payment for physicians’ radiological services to the hospital, e.g., administrative or supervisory services, and for provider services needed to produce the radiology service, is made by the fiscal intermediary (FI)/AB MAC to the hospital as a provider service.

Fls/AB MACs include the TC of radiology services for hospital inpatients except Critical Access Hospitals (CAHs), in the prospective payment system (PPS) payment to hospitals.

Hospital bundling rules exclude payment to suppliers of the TC of a radiology service for beneficiaries in a hospital
inpatient stay. CWF performs reject edits to incoming claims from suppliers of radiology services.

Upon receipt of a hospital inpatient claim at the CWF, CWF searches paid claim history and compares the period between the hospital inpatient admission and discharge dates to the line item service dates on a line item TC of a radiology service billed by a supplier. The CWF will generate an unsolicited response when the line item service date falls within the admission and discharge dates of the hospital inpatient claim.

Upon receipt of an unsolicited response, the carrier will adjust the TC of the radiology service and recoup the payment.

For CAHs, payment to the CAH for inpatients is made at 101 percent of reasonable cost.

Radiology and other diagnostic services furnished to hospital outpatients are paid under the Outpatient Prospective Payment System (OPPS) to the hospital. This applies to bill types 12X and 13X that are submitted to the FI/AB MAC. Effective 4/1/06, type of bill 14X is for non-patient laboratory specimens and is no longer applicable for radiology services.

As a result of SNF Consolidated Billing (Section 4432(b) of the Balanced Budget Act (BBA) of 1997), carriers may not pay for the TC of radiology services furnished to Skilled Nursing Facility (SNF) inpatients during a Part A covered stay. The SNF must bill radiology services furnished its inpatients in a Part A covered stay and payment is included in the SNF Prospective Payment System (PPS).

Radiology services furnished to outpatients of SNFs may be billed by the supplier performing the service or by the SNF under arrangements with the supplier. If billed by the SNF, Medicare pays according to the Medicare Physician Fee Schedule. SNFs submit claims to the FI/AB MAC with type of bill 22X or 23X.

20.2.2—Services Not Furnished in Hospitals
(Rev. 1, 10-01-03)

Carriers must pay under the fee schedule for the TC of radiology services furnished to beneficiaries who are not patients of any hospital, and who receive services in a physician’s office, a freestanding imaging or radiation oncology center, or other setting that is not part of a hospital.

20.2.3—Services Furnished in Leased Departments
(Rev. 1, 10-01-03)

In the case of procedures furnished in a leased hospital radiology department to a beneficiary who is neither an inpatient nor an outpatient of any hospital, e.g., the patient is referred by an outside physician and is not registered as a hospital outpatient, both the PC and the TC of the services are payable under the fee schedule by the carrier.

90—Services of Portable X-Ray Suppliers
(Rev. 1, 10-01-03)

B3-2070.4, B3-15022.G, B3-4131, B3-4831

Services furnished by portable x-ray suppliers may have as many as four components. Carriers must follow the following rules.

90.1—Professional Component
(Rev. 1, 10-01-03)

Pay the PC of radiologic services furnished by portable x-ray suppliers on the same basis as other physician fee schedule services.

90.2—Technical Component
(Rev. 1, 10-01-03)

Pay the TC of radiologic services furnished by portable x-ray suppliers under the fee schedule on the same basis as TC services generally.

90.3—Transportation Component (HCPCS Codes R0070 - R0076)
(Rev. 3387, Issued: 10-30-15, Effective: 01-01-16, Implementation: 01-01-16)

This component represents the transportation of the equipment to the patient. Establish local RVUs for the transportation R codes based on Medicare Administrative Contractor (MAC) knowledge of the nature of the service furnished. The MACs shall allow only a single transportation payment for each trip the portable x-ray supplier makes to a particular location. When more than one Medicare patient is x-rayed at the same location, e.g., a nursing home, prorate the single fee schedule transportation payment among all patients (Medicare Parts A and B, and non-Medicare) receiving the portable x-ray services during that trip, regardless of their insurance status. For example, for portable x-ray services furnished at a Skilled Nursing Facility (SNF), the transportation fee should be allocated among all patients receiving portable x-ray services at the same location in a single trip irrespective of whether the patient is in a Part A stay, a Part B patient, or not a Medicare beneficiary at all. If the patient is in a Part A SNF stay, the transportation and set up costs are subject to consolidated billing and not separately billable to Medicare Part B. For a privately insured patient, it would be the responsibility of that patient’s insurer. For a Medicare Part B patient, payment would be made under Part B for the share of the transportation fee attributable to that patient.

R0075 must be billed in conjunction with the CPT radiology codes (7000 series) and only when the x-ray equipment used was actually transported to the location where the x-ray was taken. R0075 would not apply to the x-ray equipment stored in the location where the x-ray was done (e.g., a nursing home) for use as needed.

Below are the definitions for each modifier that must be reported with R0075. Only one of these five modifiers shall be reported with R0075. NOTE: If only one patient is served, R0070 should be reported with no modifier since the descriptor for this code reflects only one patient seen.

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN</td>
<td>Two patients served</td>
</tr>
<tr>
<td>UP</td>
<td>Three patients served</td>
</tr>
<tr>
<td>UQ</td>
<td>Four patients served</td>
</tr>
<tr>
<td>UR</td>
<td>Five patients served</td>
</tr>
<tr>
<td>US</td>
<td>Six or more patients served</td>
</tr>
</tbody>
</table>

Payment for the above modifiers must be consistent with the definition of the modifiers. Therefore, for R0075 reported with modifiers, -UN, -UP, -UQ, and -UR, the total payment
for the service shall be divided by 2, 3, 4, and 5 respectively. For modifier –US, the total payment for the service shall be divided by 6 regardless of the number of patients served. For example, if 8 patients were served, R0075 would be reported with modifier –US and the total payment for this service would be divided by 6.

The units field for R0075 shall always be reported as “1” except in extremely unusual cases. The number in the units field should be completed in accordance with the provisions of 100-04, chapter 23, section 10.2 item 24G which defines the units field as the number of times the patient has received the itemized service during the dates listed in the from/to field. The units field must never be used to report the number of patients served during a single trip. Specifically, the units field must reflect the number of services that the specific beneficiary received, not the number of services received by other beneficiaries.

As a contractor priced service, MACs must initially determine a payment rate for portable x-ray transportation services that is associated with the cost of providing the service. In order to determine an appropriate cost, the MACs should, at a minimum, cost out the vehicle, vehicle modifications, gasoline and the staff time involved in only the transportation for a portable x-ray service. A review of the pricing of this service should be done every five years.

Direct costs related to the vehicle carrying the x-ray machine are fully allocable to determining the payment rate. This includes the cost of the vehicle using a recognized depreciation method, the salary and fringe benefits associated with the staff who drive the vehicle, the communication equipment used between the vehicle and the home office, the salary and fringe benefits of the staff who determine the vehicles route (this could be proportional of office staff), repairs and maintenance of the vehicle(s), insurance for the vehicle(s), operating expenses for the vehicles and any other reasonable costs associated with this service as determined by the MACs. The MACs will have discretion for allocating indirect costs (those costs that cannot be directly attributed to portable x-ray transportation) between the transportation service and the technical component of the x-ray tests.

Suppliers may send MACs unsolicited cost information. The MACs may use this cost data as a comparison to its contractor priced determination. The data supplied should reflect a year’s worth (either calendar or corporate fiscal) of information. Each provider who submits such data is to be informed that the data is subject to verification and will be used to supplement other information that is used to determine Medicare’s payment rate.

The MACs are required to update the rate on an annual basis using independently determined measures of the cost of providing the service. A number of readily available measures (e.g., ambulance inflation factor, the Medicare economic index) that are used by the Medicare program to adjust payment rates for other types of services may be appropriate to use to update the rate for years that the MACs does not recalibrate the payment. Each MACs has the flexibility to identify the index it will use to update the rate. In addition, the MACs can consider locally identified factors that are measured independently of CMS as an adjunct to the annual adjustment.

**NOTE:** No transportation charge is payable unless the portable x-ray equipment used was actually transported to the location where the x-ray was taken. For example, MACs do not allow a transportation charge when the x-ray equipment is stored in a nursing home for use as needed. However, a set-up payment (see §90.4, below) is payable in such situations. Further, for services furnished on or after January 1, 1997, MACs may not make separate payment under HCPCS code R0076 for the transportation of EKG equipment by portable x-ray suppliers or any other entity.

**90.4—Set-Up Component (HCPCS Code Q0092)**

(Rev. 1, 10-01-03)

Carriers must pay a set-up component for each radiologic procedure (other than retakes of the same procedure) during both single patient and multiple patient trips under Level II HCPCS code Q0092. Carriers do not make the set-up payment for EKG services furnished by the portable x-ray supplier.

**90.5—Transportation of Equipment Billed by a SNF to a MAC**


When a SNF bills for portable x-ray equipment transported to a site by van or other vehicle, the SNF should bill for the transportation costs using one of the following HCPCS codes along with the appropriate revenue code:

- R0070 Transportation of Portable x-ray Equipment and Personnel to Home or Nursing Home, Per Trip to Facility or Location, One Patient Seen.
- R0075 Transportation of Portable x-ray Equipment and Personnel to Home of Nursing Home, Per Trip to Facility or Location, More than One Patient Seen, Per Patient.

These HCPCS codes are subject to the fee schedule.

Effective April 1, 2006, SNFs are required to report the appropriate modifiers to identify the number of patients served when billing for R0075. See section 90.3, of this chapter for the list of modifiers used to identify on the claim the number of patients served.

MACs shall ensure that payment for R0075 is consistent with the definition of the modifiers.

**NOTE:** When a SNF resident receives a portable x-ray service during the course of a Medicare-covered stay in the SNF, only the service’s professional component (representing the physician’s interpretation of the test results) is a separately billable physician service under Part B (see §20.1 of this chapter and §20.1.1 of Chapter 6). By contrast, the technical component representing the procedure itself, including any associated transportation and setup costs, would be subject to consolidated billing (the SNF “bundling” requirement for services furnished to the SNF’s Part A residents), and must be included on the SNF’s Part A bill for the resident’s covered stay (Bill Type 21x) rather than being billed separately under Part B (see §20.2.1 of this chapter).
100-04 Chapter 15

40 - Medical Conditions List and Instructions
See http://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html for a medical conditions list and instructions to assist ambulance providers and suppliers to communicate the patient's condition to Medicare contractors, as reported by the dispatch center and as observed by the ambulance crew. Use of the medical conditions list does not guarantee payment of the claim or payment for a certain level of service.

In addition to reporting one of the medical conditions on the claim, one of the transportation indicators below may be included on the claim to indicate why it was necessary for the patient to be transported in a particular way or circumstance. The provider or supplier will place the transportation indicator in the "narrative" field on the claim. Information on the appropriate use of transportation indicators is also available at http://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html.

100-04 Chapter 16

10—Background
(Rev. 1, 10-01-03)
B3-2070, B3-2070.1, B3-4110.3, B3-5114
Diagnostic X-ray, laboratory, and other diagnostic tests, including materials and the services of technicians, are covered under the Medicare program. Some clinical laboratory procedures or tests require Food and Drug Administration (FDA) approval before coverage is provided.

A diagnostic laboratory test is considered a laboratory service for billing purposes, regardless of whether it is performed in:
• A physician's office, by an independent laboratory;
• By a hospital laboratory for its outpatients or nonpatients;
• In a rural health clinic; or
• In an HMO or Health Care Prepayment Plan (HCPP) for a patient who is not a member.

When a hospital laboratory performs laboratory tests for nonhospital patients, the laboratory is functioning as an independent laboratory, and still bills the fiscal intermediary (FI). Also, when physicians and laboratories perform the same test, whether manually or with automated equipment, the services are deemed similar.

Laboratory services furnished by an independent laboratory are covered under SMI if the laboratory is an approved Independent Clinical Laboratory. However, as is the case of all diagnostic services, in order to be covered these services must be related to a patient's illness or injury (or symptom or complaint) and ordered by a physician. A small number of laboratory tests can be covered as a preventive screening service.
"Certification" - A laboratory that has met the standards specified in the CLIA.

"Draw Station" - A place where a specimen is collected but no Medicare-covered clinical laboratory testing is performed on the drawn specimen.

"Medicare-approved laboratory" - A laboratory that meets all of the enrollment standards as a Medicare provider including the certification by a CLIA certifying authority.

10.2—General Explanation of Payment

(Rev. 3510, Issued: 04-29-16, Effective: 10-01-16, Implementation: 10-03-16)

Outpatient laboratory services can be paid in different ways:

- Physician Fee Schedule;
- 101 percent of reasonable cost (critical access hospitals (CAH) only);

NOTE: When the CAH bills a 14X bill type as a non-patient laboratory specimen, the CAH is paid under the laboratory fee schedule.

- Laboratory Fee Schedule;
- Outpatient Prospective Payment System, (OPPS) except for most hospitals in the state of Maryland that are subject to waiver; or
- Reasonable Charge

Annually, CMS distributes a list of codes and indicates the payment method. Carriers, and FIs, and A/B MACs pay as directed by this list. Neither deductible nor coinsurance applies to HCPCS codes paid under the laboratory fee schedule. The majority of outpatient laboratory services are paid under the laboratory fee schedule or the OPPS.

Carriers, FIs, and A/B MACs are responsible for applying the correct fee schedule for payment of clinical laboratory tests. FIs/AB MACs must determine which hospitals meet the criteria for payment at the 62 percent fee schedule. Only sole community hospitals with qualified hospital laboratories are eligible for payment under the 62 percent fee schedule. Generally, payment for diagnostic laboratory tests that are not subject to the clinical laboratory fee schedule is made in accordance with the reasonable charge or physician fee schedule methodologies (or at 101 percent of reasonable costs for CAHs).

For Clinical Diagnostic Laboratory services denied due to frequency edits, the contractor shall use the following remittance advice messages and associated codes when rejecting/ denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: CO or PR

CARC: 151
RARC: N/A
MSN: N/A

60—Specimen Collection Fee and Travel Allowance

(Rev. 1, 10-01-03)
B3-5114.1

60.1—Specimen Collection Fee

(Rev. 1, 10-01-03)
B3-5114.1, A3-3628

In addition to the amounts provided under the fee schedules, the Secretary shall provide for and establish a nominal fee to cover the appropriate costs of collecting the sample on which a clinical laboratory test was performed and for which payment is made with respect to samples collected in the same encounter.

A specimen collection fee is allowed in circumstances such as drawing a blood sample through venipuncture (i.e., inserting into a vein a needle with syringe or vacutainer to draw the specimen) or collecting a urine sample by catheterization. A specimen collection fee is not allowed for blood samples where the cost of collecting the specimen is minimal (such as a throat culture or a routine capillary puncture for clotting or bleeding time). This fee will not be paid to anyone who has not extracted the specimen. Only one collection fee is allowed for each type of specimen for each patient encounter, regardless of the number of specimens drawn. When a series of specimens is required to complete a single test (e.g., glucose tolerance test), the series is treated as a single encounter.

60.1.1—Physician Specimen Drawing

(Rev. 1, 10-01-03)
HO-437, A3-3628, B3-5114.1

Medicare allows a specimen collection fee for physicians only when (1) it is the accepted and prevailing practice among physicians in the locality to make separate charges for drawing or collecting a specimen, and (2) it is the customary practice of the physician performing such services to bill separate charges for drawing or collecting the specimen.

60.1.2—Independent Laboratory Specimen Drawing

(Rev. 3071, Issued: 09-19-14, Effective: 12-22-14, Implementation: 12-22-14)

Medicare allows separate charges made by laboratories for drawing or collecting specimens whether or not the specimens are referred to hospitals or independent laboratories. The laboratory does not bill for routine handling charges where a specimen is referred by one laboratory to another.

Medicare allows payment for a specimen collection fee when it is medically necessary for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient. Payment for the specimen collection fee is made based on the clinical laboratory fee schedule. The technician must personally draw the specimen, e.g., venipuncture or urine sample by catheterization. Medicare does not allow a specimen collection fee to the visiting technician if a patient in a facility is (a) not confined to the facility, or (b) the facility has personnel on duty qualified to perform the specimen collection. Medical necessity for such services exists, for example, where a laboratory technician draws a blood specimen from a homebound or an institutionalized patient. A patient need not be bedridden to be homebound. However, where the specimen is a type that would require only the services of a messenger and would not require the skills of a
laboratory technician, e.g., urine or sputum, a specimen pickup service would not be considered medically necessary. (See Chapters 7 and 15 of the Medicare Benefit Policy Manual for a discussion of “homebound” and a more complete definition of a medically necessary laboratory service to a homebound or an institutional patient.)

In addition to the usual information required on claim forms (including the name of the prescribing physician), all independent laboratory claims for such specimen drawing or EKG services prescribed by a physician should be appropriately annotated, e.g., “patient confined to home,” “patient homebound,” or “patient in nursing home, no qualified person on duty to draw specimen.” Carriers must assure the validity of the annotation through scientific claims samples as well as through regular bill review techniques. (This could be done by use of the information in carrier files, and where necessary, contact with the prescribing physician.)

If a physician requests an independent laboratory to obtain specimens in situations which do not meet, or without regard to whether they meet, the medical necessity criteria in Chapter 15 of the Medicare Benefit Policy Manual, an educational contact with the prescribing physician is warranted and, where necessary, corroborating documentation should be obtained on claims until the carrier is assured that the physician prescribes such services only when the criteria are met.

The specimen collection fee is paid based on the location of the independent laboratory where the test is performed and is billed in conjunction with a covered laboratory test.

60.1.3—Specimen Drawing for Dialysis Patients
(Rev. 3056, Issued: 08-29-14, Effective: 04-01-14, Implementation: 12-01-14)

See the Medicare Benefit Policy Manual, Chapter 11, for a description of laboratory services included in the composite rate. With the implementation of the ESRD PPS, effective for claims with dates of service on or after January 1, 2011, all ESRD-related laboratory services are included in the ESRD PPS base rate.

Clinical laboratory tests can be performed individually or in predetermined groups on automated profile equipment. A specimen collection fee determined by CMS will be allowed only in the following circumstances:

• Drawing a blood sample through venipuncture (i.e., inserting into a vein a needle with a syringe or vacutainer to draw the specimen).
• Collecting a urine sample by catheterization.

Special rules apply when such services are furnished to dialysis patients. The specimen collection fee is not separately payable for y patients dialyzed in the facility or for patients dialyzed at home under reimbursement Method I. A specimen collection fee is also not separately payable when an ESRD facility is collecting a specimen for transplant eligibility or other transplant requirements. Payment for specimen collection is included under the ESRD PPS, regardless of whether the laboratory test itself is included in the ESRD PPS or is separately billable with the AY modifier (see §40.6 of this chapter).

Fees for taking specimens in the hospital setting, but outside of the dialysis unit, for use in performing laboratory tests not included in the ESRD composite rate may be paid separately.

60.1.4—Coding Requirements for Specimen Collection
(Rev. 3056, Issued: 08-29-14, Effective: 04-01-14, Implementation: 12-01-14)

The following HCPCS codes and terminology must be used:

• 36415—Collection of venous blood by venipuncture.
• G0471—Collection of venous blood by venipuncture or urine sample by catheterization from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of a home health agency (HHA).
• P9615—Catheterization for collection of specimen(s).

The allowed amount for specimen collection in each of the above circumstances is included in the laboratory fee schedule distributed annually by CMS.

60.2—Travel Allowance
(Rev. 3433, Issued: 12-31-15, Effective: 01-01-16, Implementation: 02-01-16)

In addition to a specimen collection fee allowed under §60.1, Medicare, under Part B, covers a specimen collection fee and travel allowance for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient under §1833(h)(3) of the Act and payment is made based on the clinical laboratory fee schedule. The travel allowance is intended to cover the estimated travel costs of collecting a specimen and to reflect the technician's salary and travel costs.

The additional allowance can be made only where a specimen collection fee is also payable, i.e., no travel allowance is made where the technician merely performs a messenger service to pick up a specimen drawn by a physician or nursing home personnel. The travel allowance may not be paid to a physician unless the trip to the home, or to the nursing home was solely for the purpose of drawing a specimen. Otherwise travel costs are considered to be associated with the other purposes of the trip.

The travel allowance is not distributed by CMS. Instead, the A/B MAC (B) must calculate the travel allowance for each claim using the following rules for the particular Code. The following HCPCS codes are used for travel allowances:

Per Mile Travel Allowance (P9603)

• The minimum “per mile travel allowance” is $0.99. The per mile travel allowance is to be used in situations where the average trip to patients’ homes is longer than 20 miles round trip, and is to be pro-rated in situations where specimens are drawn or picked up from non-Medicare patients in the same trip—one way, in connection with medically necessary laboratory specimen collection drawn from homebound or nursing home bound patient; pro-rated miles actually traveled (A/B MAC (B) allowance on per mile basis); or
• The per mile allowance was computed using the Federal mileage rate plus an additional 45 cents a mile to cover the technician’s time and travel costs. A/B MAC (B) have the option of establishing a higher per mile rate in excess of
the minimum ($0.99 a mile in CY 2016) if local conditions warrant it. The minimum mileage rate will be reviewed and updated in conjunction with the clinical lab fee schedule as needed. At no time will the laboratory be allowed to bill for more miles than are reasonable or for miles not actually traveled by the laboratory technician.

Example 1: In CY 2016, a laboratory technician travels 60 miles round trip from a lab in a city to a remote rural location, and back to the lab to draw a single Medicare patient's blood. The total reimbursement would be $59.40 (60 miles × $0.99 a mile), plus the specimen collection fee.

Example 2: In CY 2016, a laboratory technician travels 40 miles from the lab to a Medicare patient's home to draw blood, and then travels an additional 10 miles to a non-Medicare patient's home and then travels 30 miles to return to the lab. The total miles traveled would be 80 miles. The claim submitted would be for one half of the miles traveled or $39.60 (40 × $0.99), plus the specimen collection fee.

Flat Rate (P9604)
The CMS will pay a minimum of $9.90 (based on CY 2016) one way flat rate travel allowance. The flat rate travel allowance is to be used in areas where average trips are less than 20 miles round trip. The flat rate travel fee is to be pro-rated for more than one blood drawn at the same address, and for stops at the homes of Medicare and non-Medicare patients. The laboratory does the pro-ration when the claim is submitted based on the number of patients seen on that trip. The specimen collection fee will be paid for each patient encountered.

This rate is based on an assumption that a trip is an average of 15 minutes and up to 10 miles one way. It uses the Federal mileage rate and a laboratory technician's time of $17.66 an hour, including overhead. A/B MAC (B) have the option of establishing a flat rate in excess of the minimum of $9.90, if local conditions warrant it. The minimum national flat rate will be reviewed and updated in conjunction with the clinical laboratory fee schedule, as necessitated by adjustments in the Federal travel allowance and salaries.

The claimant identifies round trip travel by use of the LR modifier

Example 3: A laboratory technician travels from the laboratory to a single Medicare patient's home and returns to the laboratory without making any other stops. The flat rate would be calculated as follows: 2 × $9.90 for a total trip reimbursement of $19.80, plus the specimen collection fee.

Example 4: A laboratory technician travels from the laboratory to the homes of five patients to draw blood, four of the patients are Medicare patients and one is not. An additional flat rate would be charged to cover the 5 stops and the return trip to the lab (6 × $9.90 = $59.40). Each of the claims submitted would be for $11.88 ($59.40/5 = $11.88). Since one of the patients is non-Medicare, four claims would be submitted for $3.96 each, plus the specimen collection fee.

Example 5: A laboratory technician travels from a laboratory to a nursing home and draws blood from 5 patients and returns to the laboratory. Four of the patients are on Medicare and one is not. The $9.90 flat rate is multiplied by two to cover the return trip to the laboratory (2 × $9.90 = $19.80) and then divided by five (1/5 of $19.80 = $3.96). Since one of the patients is non-Medicare, four claims would be submitted for $3.96 each, plus the specimen collection fee.

If an A/B MAC (B) determines that it results in equitable payment, the A/B MAC (B) may extend the former payment allowances for additional travel (such as to a distant rural nursing home) to all circumstances where travel is required. This might be appropriate, for example, if the A/B MAC (B)’s former payment allowance was on a per mile basis. Otherwise, it should establish an appropriate allowance and inform the suppliers in its service area. If an A/B MAC (B) decides to establish a new allowance, one method is to consider developing a travel allowance consisting of:

- The current Federal mileage allowance for operating personal automobiles, plus a personnel allowance per mile to cover personnel costs based upon an estimate of average hourly wages and average driving speed.

A/B MAC (B) must prorate travel allowance amounts claimed by suppliers by the number of patients (including Medicare and non-Medicare patients) from whom specimens were drawn on a given trip.

The A/B MAC (B) may determine that payment in addition to the routine travel allowance determined under this section is appropriate if:

- The patient from whom the specimen must be collected is in a nursing home or is homebound; and
- The clinical laboratory tests are needed on an emergency basis outside the general business hours of the laboratory making the collection.
- Subsequent updated travel allowance amounts will be issued by CMS via Recurring Update Notification (RUN) on an annual basis.

110.4—Carrier Contacts With Independent Clinical Laboratories

(Rev. 1, 10-01-03)

B3-2070.1.F

An important role of the carrier is as a communicant of necessary information to independent clinical laboratories. Failure to inform independent laboratories of Medicare regulations and claims processing procedures may have an adverse effect on prosecution of laboratories suspected of fraudulent activities with respect to tests performed by, or billed on behalf of, independent laboratories. United States Attorneys often must prosecute under a handicap or may refuse to prosecute cases where there is no evidence that a laboratory has been specifically informed of Medicare regulations and claims processing procedures.

To assure that laboratories are aware of Medicare regulations and carrier’s policy, notification must be sent to independent laboratories when any changes are made in coverage policy or claims processing procedures. Additionally, to completely document efforts to fully inform independent laboratories of Medicare policy and the laboratory’s responsibilities, previously issued newsletters should be periodically re-issued to remind laboratories of existing requirements.

Some items which should be discussed are the requirements to have the same charges for Medicare and private patients, to document fully the medical necessity for collection of specimens from a skilled nursing facility or a beneficiary’s home, and, in cases when a laboratory service is referred from one independent laboratory to another independent laboratory, to identify the laboratory actually performing the test.
Additionally, when carrier professional relations representatives make personal contacts with particular laboratories, they should prepare and retain reports of contact indicating dates, persons present, and issues discussed.

100-04 Chapter 17

80.1—Oral Cancer Drugs
(Rev. 1, 10-01-03)

A3 3660.13, SNF 536.1

Effective January 1, 1994, oral self administered versions of covered injectable cancer drugs furnished may be paid if other coverage requirements are met. To be covered the drug must have had the same active ingredient as the injectable drug. Effective January 1, 1999, this coverage was expanded to include FDA approved Prodrugs used as anticancer drugs. A Prodrug may have a different chemical composition than the injectable drug but body metabolizing of the Prodrug results in the same chemical composition in the body.

80.1.1—HCPCS Service Coding for Oral Cancer Drugs
(Rev. 1, 10-01-03)

The following codes may be used for drugs other than Prodrugs, when covered:

<table>
<thead>
<tr>
<th>Generic/Chemical Name</th>
<th>How Supplied</th>
<th>HCPCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Busulfan</td>
<td>2 mg/ORAL</td>
<td>J8510</td>
</tr>
<tr>
<td>Capecitabine</td>
<td>150 mg/ORAL</td>
<td>J8520</td>
</tr>
<tr>
<td>Capecitabine</td>
<td>500 mg/ORAL</td>
<td>J8521</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>2.5 mg/ORAL</td>
<td>J8610</td>
</tr>
<tr>
<td>Cyclophosphamide *</td>
<td>25 mg/ORAL</td>
<td>J8530</td>
</tr>
<tr>
<td>Cyclophosphamide * (Treat 50 mg. as 2 units)</td>
<td>50 mg/ORAL</td>
<td>J8530</td>
</tr>
<tr>
<td>Etoposide</td>
<td>50 mg/ORAL</td>
<td>J8560</td>
</tr>
<tr>
<td>Melphalan</td>
<td>2 mg/ORAL</td>
<td>J8600</td>
</tr>
<tr>
<td>Prescription Drug chemotherapeutic NOC</td>
<td>ORAL</td>
<td>J8999</td>
</tr>
</tbody>
</table>

Each tablet or capsule is equal to one unit, except for 50 mg./ORAL of cyclophosphamide (J8530), which is shown as 2 units. The 25 mg and 50 mg share the same code.

NOTE: HIPAA requires that drug claims submitted to DMERCs be identified by NDC.

80.1.2—HCPCS and NDC Reporting for Prodrugs
(Rev. 136, 04-09-04)

FI claims

For oral anti-cancer Prodrugs HCPCS code J8999 is reported with revenue code 0636.

DMERC claims

The supplier reports the NDC code on the claim. The DMERC converts the NDC code to a “WW” HCPCS code for CWF. As new “WW” codes are established for oral anticancer drugs they will be communicated in a Recurring Update Notification.

80.3.1—Requirements for Billing FI for Immunosuppressive Drugs

Hospitals not subject to OPPS bill on ASC X12 837 institutional format or paper Form CMS-1450 with bill type 12x (hospital inpatient Part B) or 13x (hospital outpatient) as appropriate.

For claims with dates of service prior to April 1, 2000, providers report the following entries:

• Occurrence code 36 and date;
• Revenue code 0250; and
• Narrative description.

NOTE: Information regarding the claim form locators that correspond with these fields is found in Chapter 25.

For claims with dates of service on or after April 1, 2000, hospitals report

• Occurrence code 36 and date;
• Revenue code 0636;
• HCPCS code of the immunosuppressive drug; and
• Number of units (the number of units billed must accurately reflect the definition of one unit of service in each code narrative. E.g.: If fifty 10-mg. Prednisone tablets are dispensed, the hospital bills J7506, 100 units (1 unit of J7506 = 5 mg.).

NOTE: Information regarding the claim form locators that correspond with these fields is found in Chapter 25.

The hospital completes the remaining items in accordance with regular billing instructions.

100-04 Chapter 18

90—Diabetes Screening
(Rev. 457, Issued: 01-28-05, Effective: 04-01-05, Implementation: 04-04-05)

90.1—HCPCS Coding for Diabetes Screening
(Rev. 457, Issued: 01-28-05, Effective: 04-01-05, Implementation: 04-04-05)

The following HCPCS codes are to be billed for diabetes screening:

82947 – Glucose, quantitative, blood (except reagent strip)
82950 – post-glucose dose (includes glucose)
82951 – tolerance test (GTT), three specimens (includes glucose)

90.2—Carrier Billing Requirements
(Rev. 3329, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

Effective for dates of service January 1, 2005 and later, carriers shall recognize the above HCPCS codes for diabetes screening.
A/B MACs (B) shall pay for diabetes screening once every 12 months for a beneficiary that is not pre-diabetic. A/B MACs (B) shall pay for diabetes screening at a frequency of once every 6 months for a beneficiary that meets the definition of pre-diabetes.

A claim that is submitted for diabetes screening by a physician or supplier for a beneficiary that does not meet the definition of pre-diabetes shall be submitted in the following manner:

The line item shall contain 82947, 82950 or 82951 with a diagnosis code of V77.1 or ICD-10-CM diagnosis code Z13.1. In addition, modifier "TS" (follow-up service) – shall be reported on the line item.

90.2.1—Modifier Requirements for Pre-diabetes

(Rev. 3329, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

A claim that is submitted for diabetes screening and the beneficiary meets the definition of pre-diabetes shall be submitted in the following manner:

The line item shall contain 82497, 82950 or 82951 with an ICD-9 diagnosis code of V77.1 reported (if ICD-9-CM is applicable), a diagnosis code of Z13.1 in the header. In addition, modifier “TS” (follow-up service) – shall be reported on the line item.

90.3—Fiscal Intermediary (FI) Billing Requirements

(Rev. 3329, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

Effective for dates of service January 1, 2005 and later, A/B MACs (A) shall recognize the above HCPCS codes for diabetes screening.

A/B MACs (A) shall pay for diabetes screening once every 12 months for a beneficiary that is not pre-diabetic. A/B MACs (A) shall pay for diabetes screening at a frequency of once every 6 months for a beneficiary that meets the definition of pre-diabetes.

A claim that is submitted for diabetes screening by a physician or supplier for a beneficiary that does not meet the definition of pre-diabetes shall be submitted in the following manner:

The line item shall contain 82497, 82950 or 82951 with an ICD-9 diagnosis code of V77.1 or, if ICD-10-CM is applicable, a diagnosis code of Z13.1.

90.3.1—Modifier Requirements for Pre-diabetes

(Rev. 3329, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

A claim that is submitted for diabetes screening and the beneficiary meets the definition of pre-diabetes shall be submitted in the following manner:

The line item shall contain 82497, 82950 or 82951 with an ICD-9 diagnosis code of V77.1 (if ICD-9-CM is applicable) or, if ICD-10-CM is applicable, a diagnosis code of Z13.1. In addition, modifier “TS” (follow-up service) – shall be reported on the line item.

90.4—Diagnosis Code Reporting

(Rev. 3329, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

A claim that is submitted for diabetes screening shall include the diagnosis code V77.1 (if ICD-9-CM is applicable) or (if ICD-10-CM is applicable) diagnosis code Z13.1.

90.5—Medicare Summary Notices

(Rev. 3329, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

When denying claims for diabetes screening based upon a CWF reject for 82947, 82950 or 82951 reported with ICD-9 diagnosis code V77.1 or ICD-10-CM diagnosis code Z13.1, contractors shall use MSN 18.4, “This service is being denied because it has not been 6 months since your last examination of this kind.” (See chapter 30 section 40.3.6.4(c) for additional information on ABN’s.)

90.6—Remittance Advice Remark Codes

(Rev. 457, Issued: 01-28-05, Effective: 04-01-05, Implementation: 04-04-05)

Contractors shall use the appropriate remittance advice notice that appropriately explains the denial of payment.

90.7—Claims Adjustment Reason Codes

(Rev. 457, Issued: 01-28-05, Effective: 04-01-05, Implementation: 04-04-05)

Contractors shall use the appropriate claims adjustment reason code such as 119 “Benefit maximum for this time period or occurrence has been reached.”
30.6.1—Adjustments to Monthly Oxygen Fee
(Rev. 1, 10-01-03)

If the prescribed amount of oxygen is less than 1 liter per minute, the fee schedule amount for stationary oxygen rental is reduced by 50 percent.

The fee schedule amount for stationary oxygen equipment is increased under the following conditions. If both conditions apply, contractors use the higher of either of the following add-ons. Contractors may not pay both add-ons:

a. Volume Adjustment - If the prescribed amount of oxygen for stationary equipment exceeds 4 liters per minute, the fee schedule amount for stationary oxygen rental is increased by 50 percent. If the prescribed liter flow for stationary oxygen is different than for portable or different for rest and exercise, contractors use the prescribed amount for stationary systems and for patients at rest. If the prescribed liter flow is different for day and night use, contractors use the average of the two rates.

b. Portable Add-on - If portable oxygen is prescribed, the fee schedule amount for portable equipment is added to the fee schedule amount for stationary oxygen rental.

30.6.2—Purchased Oxygen Equipment
(Rev. 1, 10-01-03)

 Contractors may not pay for oxygen equipment that is purchased on or after June 1, 1989.

30.6.3—Contents Only Fee
(Rev. 1, 10-01-03)

Where the beneficiary owns stationary liquid or gaseous oxygen equipment, the contractor pays the monthly oxygen contents fee. For owned oxygen concentrators, however, contractors do not pay a contents fee.

Where the beneficiary either owns a concentrator or does not own or rent a stationary gaseous or liquid oxygen system and has either rented or purchased a portable system, contractors pay the portable oxygen contents fee.

30.6.4—DMEPOS Clinical Trials and Demonstrations
(Rev. 2993, Effective: ASC X12 – 01-01-12, ICD-10 – Upon Implementation of ICD-10; Implementation: ASC X12 – 08-25-14, ICD-10 – Upon Implementation of ICD-10)

The definition of the QR modifier is "item or service has been provided in a Medicare specified study." When this modifier is attached to a HCPCS code, it generally means the service is part of a CMS related clinical trial, demonstration or study.

The DMERCs shall recognize the "QR" modifier when associated with an oxygen home therapy clinical trial identified by CMS and sponsored by the National Heart, Lung & Blood Institute. DMERCs shall pay these claims if the patient's arterial oxygen partial measurements are from 56 to 65 mmHg, or whose oxygen saturation is at or above 89%.

30.5.3, or in situations where rental claims have been paid but title to the equipment is transferred to the beneficiary during a period of continuous use of less than 13 months.

30.6.5—Servicing of Equipment
(Rev. 1, 10-01-03)

Do not pay for maintenance and servicing of purchased items that require frequent and substantial servicing, or purchased oxygen equipment. (Maintenance and servicing may be paid for purchased items in these two classes if they were purchased prior to June 1, 1989). Reasonable and necessary charges include only those made for parts and labor that are not otherwise covered under a manufacturer's or supplier's warranty. Contractors pay on a lump-sum, as needed basis based on their individual consideration for each item. Payment may not be made for maintenance and servicing of rented equipment other than maintenance and servicing for PEN pumps (under the conditions of §40.3) or the maintenance and servicing fee established for capped rental items in §40.2, or the maintenance and servicing fee established for certain oxygen equipment in 42 CFR 414.210(e)(2).

Servicing of equipment that a beneficiary is purchasing or already owns is covered when necessary to make the equipment serviceable. The service charge may include the use of "loaner" equipment where this is required. If the expense for servicing exceeds the estimated expense of purchasing or renting another item of equipment for the remaining period of medical need, no payment can be made for the amount of the excess. Contractors investigate and deny cases suggesting malicious damage, culpable neglect or wrongful disposition of equipment as discussed in Pub.100-02, Medicare Benefit Policy Manual, Chapter 15 where they determine that it is unreasonable to make program payment under the circumstances. Such cases are referred to the program integrity specialist in the RO.

100.2—Certificates of Medical Necessity (CMN)
(Rev. 1, 10-01-03)

B3-3312

For certain items or services billed to the DME Regional Carrier (DMERC), the supplier must receive a signed Certificate
of Medical Necessity (CMN) from the treating physician. CMNs are not required for the same items when billed by HHAs to RHHIs. Instead, the items must be included in the physician's signed orders on the home health plan of care. See the Medicare Program Integrity Manual, Chapter 6.

The FI will inform other providers (see §01 for definition of provider) of documentation requirements.

Contractors may ask for supporting documentation beyond a CMN.

Refer to the local DMERC Web site described in §10 for downloadable copies of CMN forms.

See the Medicare Program Integrity Manual, Chapter 5, for specific Medicare policies and instructions on the following topics:

- Requirements for supplier retention of original CMNs
- CMN formats, paper and electronic
- List of currently approved CMNs and items requiring CMNs
- Supplier requirements for submitting CMNs
- Requirements for CMNs to also serve as a physician's order
- Civil monetary penalties for violation of CMN requirements
- Supplier requirements for completing portions of CMNs
- Physician requirements for completing portions of CMNs

### 100.2.1—Completion of Certificate of Medical Necessity Forms

(Rev. 2993, Effective: ASC X12 – 01-01-12, ICD-10 – Upon Implementation of ICD-10; Implementation: ASC X12 – 08-25-14, ICD-10 – Upon Implementation of ICD-10)

1. SECTION A: (This may be completed by supplier.)

   a. Certification Type/Date - If this is an initial certification for this patient, the date (MM/DD/YY) is indicated in the space marked "INITIAL". If this is a revised certification (to be completed when the physician changes the order; based on the patient's changing clinical needs), the initial date is indicated in the space marked "INITIAL", and the revision date is indicated in the space marked "REVISED". If this is a recertification, the initial date is indicated in the space marked "INITIAL", and the recertification date is indicated in the space marked "RECERTIFICATION". Whether a REVISED or RECERTIFIED CMN is submitted, the INITIAL date as well as the REVISED or RECERTIFICATION date is always furnished.

   b. Patient Information - This indicates the patient's name, permanent legal address, telephone number, and her/ her health insurance claim number (HIICN) as it appears on her/his Medicare card and on the claim form.

   c. Supplier Information - This indicates the name of the company (supplier name), address, telephone number, and the Medicare supplier number assigned by the National Supplier Clearinghouse (NSC).

   d. Place of Service - This indicates the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, or end stage renal disease (ESRD) facility is 65. See chapter 23 for place of service codes.

   e. Facility Name - This indicates the name and complete address of the facility, if the place of service is a facility.

   f. HCPCS Codes - This is a list of all HCPCS procedure codes for items ordered that require a CMN. Procedure codes that do not require certification are not listed on the CMN.

   g. Patient Date of Birth (DOB), Height, Weight, and Sex - This indicates patient's DOB (MM/DD/YY), height in inches, weight in pounds, and sex (male or female).

   h. Physician Name and Address - This indicates the treating physician's name and complete mailing address.

   i. UPIN - This indicates the treating physician's unique physician identification number (UPIN).

   j. Physician's Telephone Number - This indicates the telephone number where the treating physician can be contacted (preferably where records would be accessible pertaining to this patient) if additional information is needed.

2. SECTION B: (This may not be completed by the supplier. While this section may be completed by a non-physician clinician, or a physician employee, it must be reviewed by the treating physician. Contractors publish this requirement about section B in their bulletins at least annually.)

   a. Estimated Length of Need - This indicates the estimated length of need (the length of time (in months) the physician expects that the patient will require the item for the duration of his/her life, 99 is entered. For recertification and revision CMNs, the cumulative length of need (the total length of time in months from the initial date of need) is entered.

   b. Diagnosis Codes - Listed in the first space is the ICD-9 code that represents the primary reason for ordering this item. Additional ICD-9 codes that would further describe the medical need for the item (up to 3 codes) are also listed. A given CMN may have more than one item billed, and for each item, the primary reason for ordering may be different. For example, a CMN is submitted for a manual wheelchair (K0001) and elevating leg rests (K0195). The primary reason for K0001 is stroke, and the primary reason for K0195 is edema.

   c. Question Section - This section is used to gather clinical information regarding the patient's condition, the need for the DME, and supplies.

   d. Name of Person Answering Section B Questions - If a clinical professional other than the treating physician (e.g., home health nurse, physical therapist, dietician, or a physician employee) answers the questions in section B, he/she must print his/her name, give his/her professional title, and the name of his/her employer, where indicated. If the treating physician answered the questions, this space may be left blank.

3. SECTION C: (This is completed by the supplier.)

   a. Narrative Description of Equipment and Cost - The supplier indicates (1) a narrative description of the item(s) ordered, as well as all options, accessories, supplies, and drugs; (2) the supplier's charge for each item, option, accessory, supply, and drug; and (3) the Medicare fee schedule allowance for each item, option, accessory, supply, or drug, if applicable.

4. SECTION D: (This is completed by the treating physician.)

   a. Physician Attestation - The treating physician's signature certifies the CMN that he/she is reviewing includes sections A, B, C, and D, the answers in section B are correct, and the self-identifying information in section A is correct.
b. Physician Signature and Date - After completion and/or review by the treating physician of sections A, B, and C, the treating physician must sign and date the CMN in section D, verifying the attestation appearing in this section. The treating physician’s signature also certifies the items ordered are medically necessary for this patient. Signature and date stamps are not acceptable.

Certifications and recertifications may not be altered by “whiting out” or “pasting over” and entering new data. Such claims are denied and suppliers that show a pattern of altering CMNs are identified for educational contact and/or audit.

Also suppliers who have questionable utilization or billing practices or who are under sanction are considered for audit.

100.2.2—Evidence of Medical Necessity for Parenteral and Enteral Nutrition (PEN) Therapy

(Rev. 1, 10-01-03)

B3-3324, B3-4450

The PEN coverage is determined by information provided by the treating physician and the PEN supplier. A completed certification of medical necessity (CMN) must accompany and support initial claims for PEN to establish whether coverage criteria are met and to ensure that the PEN therapy provided is consistent with the attending or ordering physician’s prescription. Contractors ensure that the CMN contains pertinent information from the treating physician. Uniform specific medical data facilitate the review and promote consistency in coverage determinations and timelier claims processing.

The medical and prescription information on a PEN CMN can be most appropriately completed by the treating physician or from information in the patient’s records by an employee of the physician for the physician’s review and signature. Although PEN suppliers sometimes may assist in providing the PEN services, they cannot complete the CMN since they do not have the same access to patient information needed to properly enter medical or prescription information. Contractors use appropriate professional relations issuances, training sessions, and meetings to ensure that all persons and PEN suppliers are aware of this limitation of their role.

When properly completed, the PEN CMN includes the elements of a prescription as well as other data needed to determine whether Medicare coverage is possible. This practice will facilitate prompt delivery of PEN services and timely submittal of the related claim.

100-04 Chapter 32

70—Billing Requirements for Islet Cell Transplantation for Beneficiaries in a National Institutes of Health (NIH) Clinical Trial

(Rev. 986, Issued: 06-16-06, Effective: 05-01-06, Implementation: 07-31-06)

For services performed on or after October 1, 2004, Medicare will cover islet cell transplantation for patients with Type I diabetes who are participating in an NIH sponsored clinical trial. See Pub 100-04 (National Coverage Determinations Manual) section 260.3.1 for complete coverage policy.

The islet cell transplant may be done alone or in combination with a kidney transplant. Islet recipients will also need immunosuppressant therapy to prevent rejection of the transplanted islet cells. Routine follow-up care will be necessary for each trial patient. See Pub 100-04, section 310 for further guidance relative to routine care. All other uses for islet cell services will remain non-covered.

70.1—Healthcare Common Procedure Coding System (HCPCS) Codes for Carriers


G0341: Percutaneous islet cell transplant, includes portal vein catheterization and infusion

Short Descriptor: Percutaneous islet cell trans

Type of Service: 2

G0342: Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion

Short Descriptor: Laparoscopy islet cell trans

Type of Service: 2

G0343: Laparotomy for islet cell transplant, includes portal vein catheterization and infusion

Short Descriptor: Laparotomy islet cell transp

Type of Service: 2

70.2—Applicable Modifier for Islet Cell Transplant Claims for Carriers

(Rev. 986, Issued: 06-16-06, Effective: 05-01-06, Implementation: 07-31-06)

Carriers shall instruct physicians to bill using the above procedure code(s) with modifier QR (Item or service provided in a Medicare-specified study) for all claims for islet cell transplantation and routine follow-up care related to this service.

70.3—Special Billing and Payment Requirements for Carriers


Payment and pricing information will be on the October 2004 update of the Medicare Physician Fee Schedule Database (MPFSDB). Pay for islet cell transplants on the basis of the MPFS. Deductible and coinsurance apply for fee-for-service beneficiaries.

70.4—Special Billing and Payment Requirements for A/B MACs (A)

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon implementation of ICD-10)

If ICD-9-CM is applicable, this procedure (ICD-9-CM procedure code 52.85-allotransplantation of cells of Islets of Langerhans) is covered for the clinical trial in an inpatient
All other normal inpatient billing practices apply. bill 13X or 85X.

If a hospital when the transplant was done in conjunction with follow up care when performed in an outpatient department of a hospital and appropriate related items and services, Medicare will pay for two add-ons for isolation of the islet cells, but never for more than two add-ons for a hospital stay, Medicare will pay for two add-ons for isolation of the islet cells, but never for more than two add-ons for a hospital stay.

Inpatient hospitals shall report charges for organ acquisition in Revenue Code 0810, 0811, 0812, 0813, or 0819. This includes charges for the pre-transplant items and services related to the acquisition and delivery of the pancreatic islet cell transplants. As is Medicare's policy with other organ transplants, Medicare contractors deduct acquisition charges prior to processing through the IPPS Pricer. Pancreata procured for islet cell transplant are not included in the prospective payment system. They are paid on a reasonable cost basis. This is a pass-through cost for which interim payments may be made.

Effective for services on or after May 1, 2006, contractors shall accept the QR modifier for islet cell transplantation followed up care when performed in an outpatient department of a hospital when the transplant was done in conjunction with an NIH-sponsored clinical trial, and when billed on type of bill 13X or 85X.

Effective for services on or after May 1, 2006, contractors shall accept the QR modifier for islet cell transplantation followed up care when performed in an outpatient department of a hospital when the transplant was done in conjunction with an NIH-sponsored clinical trial, and when billed on type of bill 13X or 85X.

All other normal inpatient billing practices apply.

### ICD-10-PCS Code

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<thead>
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<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>3E030U1</td>
<td>Introduction of Nonautologous Pancreatic Islet Cells into Peripheral Vein, Open Approach</td>
</tr>
<tr>
<td>3E033U1</td>
<td>Introduction of Nonautologous Pancreatic Islet Cells into Peripheral Vein, Percutaneous Approach</td>
</tr>
<tr>
<td>3E0J3U1</td>
<td>Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Percutaneous Approach</td>
</tr>
<tr>
<td>3E0J7U1</td>
<td>Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Via Natural or Artificial Opening</td>
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<tr>
<td>3E0J8U1</td>
<td>Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Via Natural or Artificial Opening Endoscopic</td>
</tr>
</tbody>
</table>

The applicable TOB is 11X. A secondary diagnoses (diagnoses positions 2 – 9) of ICD-9-CM code V70.7 (examination of participant or control in clinical research) must be present along with condition code 30 (qualifying clinical trial) if ICD-9 is applicable. If ICD-10-CM is applicable, the ICD-10-CM secondary diagnosis code of Z00.6 (examination of participant or control in clinical research) must be present along with condition code 30 (qualifying clinical trial). V70.7 or Z00.6 and condition code 30 alerts the claims processing system that this is a clinical trial. The procedure is paid under inpatient prospective payment system for hospitals with patients in the trial. Deductible and coinsurance apply for fee-for-service beneficiaries.

Inpatient hospitals participating in this trial are entitled to an add-on payment of $18,848.00 for islet isolation services. This amount is in addition to the final IPPS payment made to the hospital. Should two infusions occur during the same hospital stay, Medicare will pay for two add-ons for isolation of the islet cells, but never for more than two add-ons for a hospital stay.

Inpatient hospitals shall report charges for organ acquisition in Revenue Code 0810, 0811, 0812, 0813, or 0819. This includes charges for the pre-transplant items and services related to the acquisition and delivery of the pancreatic islet cell transplants. As is Medicare's policy with other organ transplants, Medicare contractors deduct acquisition charges prior to processing through the IPPS Pricer. Pancreata procured for islet cell transplant are not included in the prospective payment system. They are paid on a reasonable cost basis. This is a pass-through cost for which interim payments may be made.

Effective for services on or after May 1, 2006, contractors shall accept the QR modifier for islet cell transplantation followed up care when performed in an outpatient department of a hospital when the transplant was done in conjunction with an NIH-sponsored clinical trial, and when billed on type of bill 13X or 85X.

All other normal inpatient billing practices apply.

### 70.5—Special Billing and Payment Requirements Medicare Advantage (MA) Beneficiaries


CMS will make payment directly on a fee-for-service basis for the routine costs of pancreatic islet cell transplants as well as transplantation and appropriate related items and services, for MA beneficiaries participating in an NIH-sponsored clinical trial. MA organizations will not be liable for payment for routine costs of this new clinical trial until MA payments can be appropriately adjusted to take into account the cost of this national coverage decision. Medicare contractors shall make payment on behalf of MA organizations directly to providers of these islet cell transplants in accordance with Medicare payment rules, except that beneficiaries are not responsible for the Part A and Part B deductibles. MA enrollees will be liable for any applicable coinsurance amounts MA organizations have in place for clinical trial benefits.

### 100 – Billing Requirements for Expanded Coverage of Cochlear Implantation

(CMS, Issued: 07-01-05; Effective: 04-04-05; Implementation: 07-25-05)

Effective for dates of services on and after April 4, 2005, the Centers for Medicare & Medicaid Services (CMS) has expanded the coverage for cochlear implantation to cover moderate-to-severe hearing loss in individuals with hearing test scores equal to or less than 40% correct in the best aided listening condition on tape-recorded tests of open-set sentence recognition and who demonstrate limited benefit from amplification. (See Publication 100-03, chapter 1, section 50.3, for specific coverage criteria).

In addition CMS is covering cochlear implantation for individuals with open-set sentence recognition test scores of greater than 40% to less than or equal to 60% correct but only when the provider is participating in, and patients are enrolled in, either:

- A Food and Drug Administration (FDA)-approved category B investigational device exemption (IDE) clinical trial; or
- A trial under the CMS clinical trial policy (see Pub. 100-03, section 310.1); or

A prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for national coverage analyses and meeting specific quality standards.

### 100-08 Chapter 5

#### 5.2.3—Detailed Written Orders

(CMS, Issued: 10-09-15; Effective: 11-10-15, Implementation: 11-10-15)

All DMEPOS items other than those referenced in 42 CFR 410.38(c)(4) and 410.38(g)(2) require detailed written orders prior to billing. Detailed written orders may take the form of
a photocopy, facsimile image, electronically maintained, or original “pen-and-ink” document. (See chapter 3, section 3.2.4.)

The written order must be sufficiently detailed, including all options or additional features that will be separately billed or that will require an upgraded code. The description can be either a narrative description (e.g., lightweight wheelchair base) or a brand name/model number. All orders must clearly specify the start date of the order.

If the written order is for supplies that will be provided on a periodic basis, the written order should include appropriate information on the quantity used, frequency of change, and duration of need. For example, an order for surgical dressings might specify one 4 x 4 hydrocolloid dressing that is changed 1-2 times per week for 1 month or until the ulcer heals.

If the supply is a drug, the order must specify the name of the drug, concentration (if applicable), dosage, frequency of administration, and duration of infusion (if applicable).

Someone other than the physician may complete the detailed description of the item. However, the treating physician/practitioner must review the detailed description and personally sign and date the order to indicate agreement.

The supplier must have a detailed written order prior to submitting a claim. If a supplier does not have a faxed, photocopied, electronic or pen and ink detailed written order signed and dated by the treating physician/practitioner in their records before they submit a claim to Medicare (i.e., if there is no order or only a verbal order), the claim will be denied. If the claim is for an item for which an order is required by statute (e.g., therapeutic shoes for diabetics, oral anticancer drugs, oral antiemetic drugs which are a replacement for intravenous antiemetic drugs), the claim will be denied as not meeting the benefit category and is therefore not appealable by the supplier (see Pub. 100-04, chapter 29, for more information on appeals). For all other items, (except those listed in section 5.2.4), if the supplier does not have an order that has been both signed and dated by the treating physician before billing the Medicare program, the item will be denied as not reasonable and necessary.

Medical necessity information (e.g., applicable diagnosis code, narrative description of the patient’s condition, abilities, and limitations) is NOT in itself considered to be part of the order although it may be put on the same document as the order.