Medicare Benefit Policy Manual

Chapter 15 – Covered Medical and Other Health Services

Table of Contents

(Rev. 13, 5-28-04)

(Rev. 23, 10-08-04)

10 - Supplementary Medical Insurance (SMI) Provisions

(Rev. 1, 10-01-03)

HO-245, B3-2000

The supplementary medical insurance plan covers expenses incurred for the following medical and other health services under Part B of Medicare:

- Physician's services, including surgery, consultation, office and institutional calls, and services and supplies furnished incident to a physician's professional service;
- Outpatient hospital services furnished incident to physicians services;
- Outpatient diagnostic services furnished by a hospital;
- Outpatient physical therapy, outpatient occupational therapy, outpatient speech-language pathology services;
- Diagnostic x-ray tests, laboratory tests, and other diagnostic tests;
- X-ray, radium, and radioactive isotope therapy;
- Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;
- Rental or purchase of durable medical equipment for use in the patient's home;
- Ambulance service;
- Prosthetic devices, other than dental, which replace all or part of an internal body organ;
- Leg, arm, back and neck braces and artificial legs, arms, and eyes including adjustments, repairs, and replacements required because of breakage, wear, loss, or change in the patient's physical condition;
- Certain medical supplies used in connection with home dialysis delivery systems;
- Rural health clinic (RHC) services;
- Federally Qualified Health Center (FQHC) services;
- Ambulatory surgical center (ASC) services;
- Screening mammography services;
- Screening pap smears and pelvic exams;
- Screening glaucoma services;
- Influenza, pneumococcal pneumonia, and hepatitis B vaccines;
- Colorectal screening;
- Bone mass measurements;
- Diabetes self-management services;
- Prostate screening; and
- Home health visits after all covered Part A visits have been used.

See §250 for provisions regarding supplementary medical insurance coverage of certain of these services when furnished to hospital and SNF inpatients.

Payment may not be made under Part B for services furnished an individual if the individual is entitled to have payment made for those services under Part A. An individual is considered entitled to have payment made under Part A if the expenses incurred were used to satisfy a Part A deductible or coinsurance amount, or if payment would be made under Part A except for the lack of a request for payment or lack of a physician certification.

Some medical services may be considered for coverage under more than one of the above-enumerated categories. For example, electrocardiograms (EKGs) can be covered as physician's services, services incident to a physician's service, or as other diagnostic tests. It is sufficient to determine that the requirements for coverage under one category are met to permit payment.

Membership dues, subscription fees, charges for service policies, insurance premiums, and other payments analogous to premiums which entitle enrollees to services or to repairs or replacement of devices or equipment or parts thereof without charge or at a reduced charge, are not considered expenses incurred for covered items or services furnished under such contracts or undertakings. Examples of such arrangements are memberships in ambulance companies, insurance for replacement of prosthetic lenses, and service contracts for durable medical equipment.

20 - When Part B Expenses Are Incurred

(Rev. 1, 10-01-03)

B3-2005

Part B expenses for items and services other than expenses for surgery and childbirth (see §20.1, below), are considered to have been incurred on the date the beneficiary received the item or service, regardless of when it was paid for or ordered. Therefore, when an individual orders an item prior to his or her entitlement to supplemental medical insurance (SMI) but receives the item after the effective date of SMI enrollment, the expense is considered incurred after entitlement began. However, if an item **not** custom-made for the beneficiary was ordered but not furnished, no reimbursement can be made. (See §20.3 for rules concerning custom-made items ordered but not furnished and the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," for additional rules concerning the date of incurred expenses for durable medical equipment.)

20.1 - Physician Expense for Surgery, Childbirth, and Treatment for Infertility

(Rev. 1, 10-01-03)

B3-2005.l

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.

20.2 - Physician Expense for Allergy Treatment

(Rev. 1, 10-01-03)

B3-2005.2, B3-4145

Allergists commonly bill separately for the initial diagnostic workup and for the treatment (See §60.2). Where it is necessary to provide treatment over an extended period, the allergist may submit a single bill for all of the treatments, or may bill periodically. In either case the Form CMS-1500 claim shows the Healthcare Common Procedure Coding System (HCPCS) codes and from and through dates of service, or the Form CMS-1450 outpatient claim shows the HCPCS code and date of service (except for critical access hospital (CAH) claims).

20.3 - Artificial Limbs, Braces, and Other Custom Made Items Ordered But Not Furnished

(Rev. 1, 10-01-03)

B3-2005.3

A. Date of Incurred Expense

If a custom-made item was ordered but not furnished to a beneficiary because the individual died or because the order was canceled by the beneficiary or because the beneficiary's condition changed and the item was no longer reasonable and necessary or appropriate, payment can be made based on the supplier's expenses. (See subsection B for determination of the allowed amount.) In such cases, the expense is considered incurred on the date the beneficiary died or the date the supplier learned of the cancellation or that the item was no longer reasonable and necessary or appropriate for the beneficiary's condition. If the beneficiary died or the beneficiary's condition changed and the item was no longer reasonable and necessary or appropriate, payment can be made on either an assigned or unassigned claim. If the beneficiary, for any other reason, canceled the order, payment can be made to the supplier only.

B. Determination of Allowed Amount

The allowed amount is based on the services furnished and materials used, up to the date the supplier learned of the beneficiary's death or of the cancellation of the order or that the item was no longer reasonable and necessary or appropriate. The Durable Medical Equipment Regional Carrier (DMERC), carrier or intermediary, as appropriate, determines the services performed and the allowable amount appropriate in the particular situation. It takes into account any salvage value of the device to the supplier.

Where a supplier breaches an agreement to make a prosthesis, brace, or other custom-made device for a Medicare beneficiary, e.g., an unexcused failure to provide the article within the time specified in the contract, payment may not be made for any work or material expended on the item. Whether a particular supplier has lived up to its agreement, of course, depends on the facts in the individual case.

30 - Physician Services

(Rev. 1, 10-01-03)

B3-2020, B3-4142

A - General

Physician services are the professional services performed by a physician or physicians for a patient including diagnosis, therapy, surgery, consultation, and care plan oversight. The physician must render the service for the service to be covered. (See Publication 100-1, the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, §70, for definition of physician.) A service may be considered to be a physician's service where the physician either examines the patient in person or is able to visualize some aspect of the patient's condition without the interposition of a third person's judgment. Direct visualization would be possible by means of x-rays, electrocardiogram and electroencephalogram tapes, tissue samples, etc.

For example, the interpretation by a physician of an actual electrocardiogram or electroencephalogram reading that has been transmitted via telephone (i.e., electronically rather than by means of a verbal description) is a covered service.

Professional services of the physician are covered if provided within the United States, and may be performed in a home, office, institution, or at the scene of an accident. A patient's home, for this purpose, is anywhere the patient makes his or her residence, e.g., home for the aged, a nursing home, a relative's home.

B - Telephone Services

Services by means of a telephone call between a physician and a beneficiary, or between a physician and a member of a beneficiary's family, are covered under Medicare, but carriers may not make separate payment for these services under the program. The physician work resulting from telephone calls is considered to be an integral part of the prework and postwork of other physician services, and the fee schedule amount for the latter services already includes payment for the telephone calls. See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §270, for coverage of telehealth services.

C - Consultations

A consultation may be paid when the consulting physician initiates treatment on the same day as the consultation. It is only after a transfer of care has occurred that evaluation and management (E&M) services may not be billed as consultations; they must be billed as subsequent office/outpatient visits

Therefore, if covered, a consultation is reimbursable when it is a professional service furnished a patient by a second physician at the request of the attending physician. Such a consultation includes the history and examination of the patient as well as the written report, which is furnished to the attending physician for inclusion in the patient's permanent medical record. These reports must be prepared and submitted to the provider for retention when they involve patients of institutions responsible for maintaining such records, and submitted to the attending physician's office for other patients.

To reimburse laboratory consultations, the services must:

- Be requested by the patient's attending physician;
- Relate to a test result that lies outside of the clinically significant normal or expected/established range relative to the condition of the patient;
- Result in a written narrative report included in the patient's medical record; and
- Require medical judgment by the consultant physician.

A consultation must involve a medical judgment that ordinarily requires a physician. Where a nonphysician laboratory specialist could furnish the information, the service of the physician is not a consultation payable under Part B.

The following indicators can ordinarily distinguish attending physician's claims:

- Therapeutic services are included on the bill in addition to an examination;

- The patient's history is before the examiner while the claim is reviewed and the billing physician has previously rendered other services to the patient; or
- Information in the file indicates that the patient was not referred.

The attending physician may remove himself from the care of the patient and turn the patient over to the person who performed a consultation service. In this situation, the initial examination would be a consultation if the above requirements were met at that time.

D - Patient-Initiated Second Opinions

Patient-initiated second opinions that relate to the medical need for surgery or for major nonsurgical diagnostic and therapeutic procedures (e.g., invasive diagnostic techniques such as cardiac catheterization and gastroscopy) are covered under Medicare. In the event that the recommendation of the first and second physician differs regarding the need for surgery (or other major procedure), a third opinion is also covered. Second and third opinions are covered even though the surgery or other procedure, if performed, is determined not covered. Payment may be made for the history and examination of the patient, and for other covered diagnostic services required to properly evaluate the patient's need for a procedure and to render a professional opinion. In some cases, the results of tests done by the first physician may be available to the second physician.

E - Concurrent Care

Concurrent care exists where more than one physician renders services more extensive than consultative services during a period of time. The reasonable and necessary services of each physician rendering concurrent care could be covered where each is required to play an active role in the patient's treatment, for example, because of the existence of more than one medical condition requiring diverse specialized medical services.

In order to determine whether concurrent physicians' services are reasonable and necessary, the carrier must decide the following:

1. Whether the patient's condition warrants the services of more than one physician on an attending (rather than consultative) basis, and
2. Whether the individual services provided by each physician are reasonable and necessary.

In resolving the first question, the carrier should consider the specialties of the physicians as well as the patient's diagnosis, as concurrent care is usually (although not always) initiated because of the existence of more than one medical condition requiring diverse specialized medical or surgical services. The specialties of the physicians are an indication of the necessity for concurrent services, but the patient's condition and the inherent reasonableness and necessity of the services, as determined by the carrier's medical staff in accordance with locality norms, must also be considered. For example, although cardiology is a sub-specialty of internal medicine, the treatment of both diabetes and of a serious heart condition might require the concurrent services of two physicians, each practicing in internal medicine but specializing in different sub-specialties.

While it would not be highly unusual for concurrent care performed by physicians in different specialties (e.g., a surgeon and an internist) or by physicians in different sub-

specialties of the same specialty (e.g., an allergist and a cardiologist) to be found medically necessary, the need for such care by physicians in the same specialty or sub-specialty (e.g., two internists or two cardiologists) would occur infrequently since in most cases both physicians would possess the skills and knowledge necessary to treat the patient. However, circumstances could arise which would necessitate such care. For example, a patient may require the services of two physicians in the same specialty or sub-specialty when one physician has further limited his or her practice to some unusual aspect of that specialty, e.g., tropical medicine. Similarly, concurrent services provided by a family physician and an internist may or may not be found to be reasonable and necessary, depending on the circumstances of the specific case. If it is determined that the services of one of the physicians are not warranted by the patient's condition, payment may be made only for the other physician's (or physicians') services.

Once it is determined that the patient requires the active services of more than one physician, the individual services must be examined for medical necessity, just as where a single physician provides the care. For example, even if it is determined that the patient requires the concurrent services of both a cardiologist and a surgeon, payment may not be made for any services rendered by either physician which, for that condition, exceed normal frequency or duration unless there are special circumstances requiring the additional care.

The carrier must also assure that the services of one physician do not duplicate those provided by another, e.g., where the family physician visits during the post-operative period primarily as a courtesy to the patient.

Hospital admission services performed by two physicians for the same beneficiary on the same day could represent reasonable and necessary services, provided, as stated above, that the patient's condition necessitates treatment by both physicians. The level of difficulty of the service provided may vary between the physicians, depending on the severity of the complaint each one is treating and that physician's prior contact with the patient. For example, the admission services performed by a physician who has been treating a patient over a period of time for a chronic condition would not be as involved as the services performed by a physician who has had no prior contact with the patient and who has been called in to diagnose and treat a major acute condition.

Carriers should have sufficient means for identifying concurrent care situations. A correct coverage determination can be made on a concurrent care case only where the claim is sufficiently documented for the carrier to determine the role each physician played in the patient's care (i.e., the condition or conditions for which the physician treated the patient). If, in any case, the role of each physician involved is not clear, the carrier should request clarification.

F - Completion of Claims Forms

Separate charges for the services of a physician in completing a Form CMS-1500, a statement in lieu of a Form CMS-1500, or an itemized bill are not covered. Payment for completion of the Form CMS-1500 claim form is considered included in the fee schedule amount.

G - Care Plan Oversight Services

B3-15513

Care plan oversight is supervision of patients under care of home health agencies or hospices that require complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of laboratory and other studies, communication with other health professionals not employed in the same practice who are involved in the patient's care, integration of new information into the care plan, and/or adjustment of medical therapy.

Such services are covered for home health and hospice patients, but are not covered for patients of skilled nursing facilities (SNFs), nursing home facilities, or hospitals.

These services are covered only if all the following requirements are met:

1. The beneficiary must require complex or multi-disciplinary care modalities requiring ongoing physician involvement in the patient's plan of care;
2. The care plan oversight (CPO) services should be furnished during the period in which the beneficiary was receiving Medicare covered HHA or hospice services;
3. The physician who bills CPO must be the same physician who signed the home health or hospice plan of care;
4. The physician furnished at least 30 minutes of care plan oversight within the calendar month for which payment is claimed. Time spent by a physician's nurse or the time spent consulting with one's nurse is not countable toward the 30-minute threshold. Low-intensity services included as part of other evaluation and management services are not included as part of the 30 minutes required for coverage;
5. The work included in hospital discharge day management (codes 99238-99239) and discharge from observation (code 99217) is not countable toward the 30 minutes per month required for work on the same day as discharge but only for those services separately documented as occurring after the patient is actually physically discharged from the hospital;
6. The physician provided a covered physician service that required a face-to-face encounter with the beneficiary within the six months immediately preceding the first care plan oversight service. Only evaluation and management services are acceptable prerequisite face-to-face encounters for CPO. EKG, lab, and surgical services are not sufficient face-to-face services for CPO;
7. The care plan oversight billed by the physician was not routine post-operative care provided in the global surgical period of a surgical procedure billed by the physician;
8. If the beneficiary is receiving home health agency services, the physician did not have a significant financial or contractual interest in the home health agency. A physician who is an employee of a hospice, including a volunteer medical director, should not bill CPO services. Payment for the services of a physician employed by the hospice is included in the payment to the hospice;

9. The physician who bills the care plan oversight services is the physician who furnished them;
10. Services provided incident to a physician's service do not qualify as CPO and do not count toward the 30-minute requirement;
11. The physician is not billing for the Medicare end stage renal disease (ESRD) capitation payment for the same beneficiary during the same month; and
12. The physician billing for CPO must document in the patient's record the services furnished and the date and length of time associated with those services.

30.1 - Provider-Based Physician Services

(Rev. 1, 10-01-03)

A3-3145, B3-2020.6, B3-8000-8099 (only instructions still applicable are included)

Providers may retain physicians on a full-time or part-time basis in, for example, the fields of pathology, psychiatry, anesthesiology, and radiology, and in many instances (especially in teaching hospitals) in other fields of medical specialization as well. Any one of these physicians may be engaged in a variety of activities including teaching, research, administration, supervision of professional or technical personnel, service on hospital committees, and other hospital-wide activities, as well as direct medical services to individual patients. The provider's arrangement may be with a single physician or with a group of physicians who assume joint responsibility for discharging agreed-upon duties.

It is necessary to distinguish between the medical and surgical services rendered by a physician to an individual patient, which are paid under Part B, and provider services (including a physician's services for the provider) which are paid under Part A. This is necessary because the payments are made from different trust funds, both intermediaries and carriers are involved in handling the claims, and the method of determining the payments for Part A benefits differs from the Part B payment calculation.

Provider-based physicians may include those on a salary, or a percentage arrangement, lessors of departments, etc.(whether or not they bill patients directly). The services to the patient are known as the professional component. The services to the provider are known as the provider component.

A - The Professional Component

The professional component of a provider-based physician's services pertains to that part of the physician's activities that is directly related to the medical care of the individual patient. It represents remuneration for the identifiable medical services by the physician that contribute to the diagnosis of the patient's condition or to his treatment. These services are covered under Part B. Claims for professional services are processed by the carrier and are paid, where applicable, under the fee schedule.

B - The Provider Component

The portion of the physician's activities representing services which are not directly related to an identifiable part of the medical care of the individual patient is the provider component. Payment for provider component services can be made only to a provider,

and is included in the provider's prospective payment system (PPS) rate. Provider services include teaching, research conducted in conjunction with and as part of patient care (to the extent that such costs are not met by special research funds), administration, general supervision of professional or technical personnel, laboratory quality control activities, committee work, performance of autopsies, and attending conferences as part of the physician's provider service activities. Such services are covered under Part A where they relate to inpatient services.

30.2 - Teaching Physician Services

(Rev. 1, 10-01-03)

B3-2020.7, B3-8201, and B3-15016

Part B covers services that attending physicians (other than interns and residents) render in the teaching setting to individual patients. These include such services as reviewing the patient's history and physical exams, personally examining the patient within a reasonable time after admission, confirming or revising diagnoses, determining the course of treatment to be followed, assuring that any supervision needed by interns or residents is furnished, and making frequent review of the patient's progress. The medical record must contain signed or countersigned notes by the physician which show that the physician personally reviewed the patient's diagnoses, visited the patient at more critical times of the illness, and discharged the patient. For other services, such as surgical procedures, notes in the record by interns, residents, or nurses, which indicate that the physician was physically present when the service was rendered, are sufficient.

Note that, in order to pay a teaching physician under Part B, the teaching physician must at least be present during the key portion of a service rendered by a resident or intern. When a resident does a visit without teaching physician presence, the teaching physician must repeat the key portions of the visit and have his own documentation in order to get paid.

30.3 - Interns and Residents

(Rev. 1, 10-01-03)

B3-2020.8, A3-3115

For Medicare purposes, the terms "interns" and "residents" include physicians participating in approved postgraduate training programs and physicians who are not in approved programs but who are authorized to practice only in a hospital setting, e.g., individuals with temporary or restricted licenses, or unlicensed graduates of foreign medical schools. Where a senior resident has a staff or faculty appointment or is designated, for example, a "fellow," it does not change the resident's status for the purposes of Medicare coverage and payment. As a general rule, the intermediary pays for services of interns and residents as provider services.

A - Services Furnished by Interns and Residents Within the Scope of an Approved Training Program

Medical and surgical services furnished by interns and residents within the scope of their training program are covered as provider services. Effective with services furnished on

or after July 1, 1987, provider services includes medical and surgical services furnished in a setting that is not part of the provider, where the hospital has agreed to incur all or substantially all of the costs of training in the nonprovider facility.

Where the provider does not incur all or substantially all of the training costs and the services are performed by a licensed physician, the services are payable under Part B by the carrier.

B - Services Furnished by Interns and Residents Outside the Scope of an Approved Training Program - Moonlighting

Medical and surgical services furnished by interns and residents that are not related to their training program, and are performed outside the facility where they have their training program, are covered as physician services where the requirements in the first two bullets below are met. Medical and surgical services furnished by interns and residents that are not related to their training program, and are performed in an outpatient department or emergency room of the hospital where they have their training program, are covered as physicians' services where all three of the following criteria are met:

- The services are identifiable physician services, the nature of which requires performance by a physician in person and which contribute to the diagnosis or treatment of the patient's condition;
- The intern or resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed; and
- The services performed can be separately identified from those services that are required as part of the training program.

When these criteria are met, the services are considered to have been furnished by the individuals in their capacity as physicians and not in their capacity as interns and residents.

30.4 - Optometrist's Services

(Rev. 1, 10-01-03)

B3-2020.25

Effective April 1, 1987, a doctor of optometry is considered a physician with respect to all services the optometrist is authorized to perform under State law or regulation. To be covered under Medicare, the services must be medically reasonable and necessary for the diagnosis or treatment of illness or injury, and must meet all applicable coverage requirements. See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," for exclusions from coverage that apply to vision care services, and the Medicare Claims Processing Manual, Chapter 12, "Physician/Practitioner Billing," for information dealing with payment for items and services furnished by optometrists.

A - FDA Monitored Studies of Intraocular Lenses

Special coverage rules apply to situations in which an ophthalmologist is involved in a Food and Drug Administration (FDA) monitored study of the safety and efficacy of an investigational Intraocular Lens (IOL). The investigation process for IOLs is unique in that there is a core period and an adjunct period. The core study is a traditional, well-

controlled clinical investigation with full record keeping and reporting requirements. The adjunct study is essentially an extended distribution phase for lenses in which only limited safety data are compiled. Depending on the lens being evaluated, the adjunct study may be an extension of the core study or may be the only type of investigation to which the lens may be subject.

All eye care services related to the investigation of the IOL must be provided by the investigator (i.e., the implanting ophthalmologist) or another practitioner (including a doctor of optometry) who provides services at the direction or under the supervision of the investigator and who has an agreement with the investigator that information on the patient is given to the investigator so that he or she may report on the patient to the IOL manufacturer.

Eye care services furnished by anyone other than the investigator (or a practitioner who assists the investigator, as described in the preceding paragraph) are not covered during the period the IOL is being investigated, unless the services are not related to the investigation.

B - Concurrent Care

Where more than one practitioner furnishes concurrent care, services furnished to a beneficiary by both an ophthalmologist and another physician (including an optometrist) may be recognized for payment if it is determined that each practitioner's services were reasonable and necessary. (See §30.E.)

30.5 - Chiropractor's Services

(Rev. 23, Issued: 10-08-04, Effective: 10-01-04, Implementation: 10-04-04)

B3-2020.26

A chiropractor must be licensed or legally authorized to furnish chiropractic services by the State or jurisdiction in which the services are furnished. In addition, a licensed chiropractor must meet the following uniform minimum standards to be considered a physician for Medicare coverage. Coverage extends only to treatment by means of manual manipulation of the spine to correct a subluxation provided such treatment is legal in the State where performed. All other services furnished or ordered by chiropractors are not covered.

If a chiropractor orders, takes, or interprets an x-ray or other diagnostic procedure to demonstrate a subluxation of the spine, the x-ray can be used for documentation. However, there is no coverage or payment for these services or for any other diagnostic or therapeutic service ordered or furnished by the chiropractor. For detailed information on using x-rays to determine subluxation, see §240.1.2.

In addition, in performing manual manipulation of the spine, some chiropractors use manual devices that are hand-held with the thrust of the force of the device being

controlled manually. While such manual manipulation may be covered, there is no separate payment permitted for use of this device.

A - Uniform Minimum Standards

Prior to July 1, 1974

Chiropractors licensed or authorized to practice prior to July 1, 1974, and those individuals who commenced their studies in a chiropractic college before that date must meet all of the following three minimum standards to render payable services under the program:

- Preliminary education equal to the requirements for graduation from an accredited high school or other secondary school;
- Graduation from a college of chiropractic approved by the State's chiropractic examiners that included the completion of a course of study covering a period of not less than 3 school years of 6 months each year in actual continuous attendance covering adequate course of study in the subjects of anatomy, physiology, symptomatology and diagnosis, hygiene and sanitation, chemistry, histology, pathology, and principles and practice of chiropractic, including clinical instruction in vertebral palpation, nerve tracing, and adjusting; and
- Passage of an examination prescribed by the State's chiropractic examiners covering the subjects listed above.

After June 30, 1974

Individuals commencing their studies in a chiropractic college after June 30, 1974, must meet all of the above three standards and all of the following additional requirements:

- Satisfactory completion of 2 years of pre-chiropractic study at the college level;
- Satisfactory completion of a 4-year course of 8 months each year (instead of a 3-year course of 6 months each year) at a college or school of chiropractic that includes not less than 4,000 hours in the scientific and chiropractic courses specified in the second bullet under "**Prior to July 1, 1974**" above, plus courses in the use and effect of x-ray and chiropractic analysis; and
- The practitioner must be over 21 years of age.

B - Maintenance Therapy

Under the Medicare program, Chiropractic maintenance therapy is not *considered to be medically reasonable or necessary, and is therefore not payable.* Maintenance therapy is defined as a treatment plan that seeks to prevent disease, promote health, and prolong and enhance the quality of life; or therapy that is performed to maintain or prevent deterioration of a chronic condition. *When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. For information on how to indicate on a claim a treatment is or is not maintenance, see §240.1.3.*

30.6 - Indian Health Service (IHS) Physician and Nonphysician Services

(Rev. 1, 10-01-03)

AB-02-150

Section 1880 of Title XVIII of the Social Security Act (the Act) provides an exception for Indian Health Service to the general prohibition of payment to Federal Agencies.

The following facilities, which were unable to bill for practitioner services prior to BIPA, may now be paid:

- Outpatient departments of IHS operated hospitals that meet the definition of provider-based in 42 CFR 413.65; and
- Outpatient clinics (freestanding) operated by the IHS.

The following facilities, which were limited by §1880 of the Act, may be paid for services under BIPA or may be paid under another authority under which it qualifies.

- Outpatient departments of tribally operated hospitals that are operated by a tribe or tribal organization; and
- Other outpatient facilities that are tribally operated regardless of ownership.

See the Medicare Claims Processing Manual Chapter 19 for a description of billing procedures.

Medicare does not pay IHS facilities for other Part B services. For example, the carrier does not pay IHS facilities for durable medical equipment, prosthetics, orthotics, and supplies, clinical laboratory services, ambulance services or any service paid on a reasonable charge basis.

For Medicare purposes, a tribally owned and operated facility is not considered a facility of the HIS.

40 - Effect of Beneficiary Agreements Not to Use Medicare Coverage

(Rev. 1, 10-01-03)

B3-3044, PM-B-97-17

Normally physicians and practitioners are required to submit claims on behalf of beneficiaries for all items and services they provide for which Medicare payment may be made under Part B. Also, they are not allowed to charge beneficiaries in excess of the limits on charges that apply to the item or service being furnished.

However, a physician or practitioner (as defined in §40.4) may opt out of Medicare . A physician or practitioner who opts out is not required to submit claims on behalf of beneficiaries and also is excluded from limits on charges for Medicare covered services.

Only physicians and practitioners that are listed in §40.4 may opt out.

- The **only** situation in which non-opt-out physicians or practitioners, or other suppliers, are not required to submit claims to Medicare for covered services is where a beneficiary or the beneficiary's legal representative refuses, of his/her own free will, to authorize the submission of a bill to Medicare. However, the limits on what the physician, practitioner, or other supplier may collect from the beneficiary continue to apply to charges for the covered service, notwithstanding the absence of a claim to Medicare.

- If an item or service is one that Medicare may cover in some circumstances but not in others, a non-opt-out physician/practitioner, or other supplier, must still submit a claim to Medicare. However, the physician, practitioner or other supplier may choose to provide the beneficiary, prior to the rendering of the item or service, an Advance Beneficiary Notice (ABN) as described in the Medicare Claims Processing Manual Chapter 30 . (Also see §40.24 for a description of the difference between an ABN and a private contract.) An ABN notifies the beneficiary that Medicare is likely to deny the claim and that if Medicare does deny the claim, the beneficiary will be liable for the full cost of the services. Where a valid ABN is given, subsequent denial of the claim relieves the non-opt-out physician/practitioner, or other supplier, of the limitations on charges that would apply if the services were covered.

  Opt-out physicians and practitioners must not use ABNs, because they use private contracts for any item or service that is, or may be, covered by Medicare (except for emergency or urgent care services (see §40.28)).

Where a physician/practitioner, or other supplier, fails to submit a claim to Medicare on behalf of a beneficiary for a covered Part B service within one year of providing the service, or knowingly and willfully charges a beneficiary more than the applicable charge limits on a repeated basis, he/she/it may be subject to civil monetary penalties under §§1848(g)(1) and/or 1848(g)(3) of the Act. Congress enacted these requirements for the protection of all Part B beneficiaries. Application of these requirements cannot be negotiated between a physician/practitioner or other supplier and the beneficiary except where a physician/practitioner is eligible to opt out of Medicare under §40.4 and the remaining requirements of §§40.1 - 40.38 are met. Agreements with Medicare

beneficiaries that are not authorized as described in these manual sections and that purport to waive the claims filing or charge limitations requirements, or other Medicare requirements, have no legal force and effect. For example, an agreement between a physician/practitioner, or other supplier and a beneficiary to exclude services from Medicare coverage, or to excuse mandatory assignment requirements applicable to certain practitioners, is ineffective.

The contractor will refer such cases to the OIG.

This subsection does not apply to noncovered charges.

40.1 - Private Contracts Between Beneficiaries and Physicians/Practitioners

(Rev. 1, 10-01-03)

B3-3044.1

Section 1802 of the Act, as amended by §4507 of the BBA of 1997, permits a physician/practitioner to opt out of Medicare and enter into private contracts with Medicare beneficiaries if specific requirements of this instruction are met.

40.2 - General Rules of Private Contracts

(Rev. 1, 10-01-03)

B3-3044.2

The following rules apply to physicians/practitioners who opt out of Medicare:

- A physician/practitioner may enter into one or more private contracts with Medicare beneficiaries for the purpose of furnishing items or services that would otherwise be covered by Medicare (provided the conditions in §40.1 are met).
- A physician/practitioner who enters into at least one private contract with a Medicare beneficiary (under the conditions of §40.1) and who submits one or more affidavits in accordance with §40.9, opts out of Medicare for a 2-year period unless the opt-out is terminated early according to §40.35 or unless the physician/practitioner fails to maintain opt-out. (See §40.11.) The physician's or practitioner's opt out may be renewed for subsequent 2-year periods.
- Both the private contracts described in the first paragraph of this section and the physician's or practitioner's opt out described in the second paragraph of this section are null and void if the physician/practitioner fails to properly opt out in accordance with the conditions of these instructions.
- Both the private contracts described in the first paragraph of this section and the physician's or practitioner's opt out described in the second paragraph of this section are null and void for the remainder of the opt-out period if the physician/practitioner fails to remain in compliance with the conditions of these instructions during the opt-out period.

- Services furnished under private contracts meeting the requirements of these instructions are not covered services under Medicare, and no Medicare payment will be made for such services either directly or indirectly.

40.3 - Effective Date of the Opt-Out Provision

(Rev. 1, 10-01-03)

B3-3044.3

A physician/practitioner may enter into a private contract with a beneficiary for services furnished no earlier than January 1, 1998.

40.4 - Definition of Physician/Practitioner

(Rev. 4, 01-02-04)

B3-3044.4

For purposes of this provision, the term "physician" is limited to doctors of medicine; doctors of osteopathy; doctors of dental surgery or of dental medicine; doctors of podiatric medicine; and doctors of optometry who are legally authorized to practice dentistry, podiatry, optometry, medicine, or surgery by the State in which such function or action is performed; no other physicians may opt out. Also, for purposes of this provision, the term "practitioner" means any of the following to the extent that they are legally authorized to practice by the State and otherwise meet Medicare requirements:

- Physician assistant;
- Nurse practitioner;
- Clinical nurse specialist;
- Certified registered nurse anesthetist;
- Certified nurse midwife;
- Clinical psychologist; or
- Clinical social worker.

The opt out law does not define "physician" to include chiropractors; therefore, they may not opt out of Medicare and provide services under private contract. Physical therapists in independent practice and occupational therapists in independent practice cannot opt out

because they are not within the opt out law's definition of either a "physician" or "practitioner".

40.5 - When a Physician or Practitioner Opts Out of Medicare

(Rev. 1, 10-01-03)

B3-3044.5

When a physician/practitioner opts out of Medicare, Medicare covers no services provided by that individual and no Medicare payment can be made to that physician or practitioner directly or on a capitated basis. Additionally, no Medicare payment may be made to a beneficiary for items or services provided directly by a physician or practitioner who has opted out of the program.

> **EXCEPTION:** In an emergency or urgent care situation, a physician/practitioner who opts out may treat a Medicare beneficiary with whom he/she does not have a private contract and bill for such treatment. In such a situation, the physician/practitioner may not charge the beneficiary more than what a nonparticipating physician/practitioner would be permitted to charge and must submit a claim to Medicare on the beneficiary's behalf. Payment will be made for Medicare covered items or services furnished in emergency or urgent situations when the beneficiary has not signed a private contract with that physician/practitioner. (See §40.28.)

Under the statute, the physician/practitioner cannot choose to opt out of Medicare for some Medicare beneficiaries but not others; or for some services but not others. The physician/practitioner who chooses to opt out of Medicare may provide covered care to Medicare beneficiaries only through private agreements.

Medicare will make payment for covered, medically necessary services that are ordered by a physician/practitioner who has opted out of Medicare if the ordering physician/ practitioner has acquired a unique provider identification number (UPIN) from Medicare and provided that the services are not furnished by another physician/practitioner who has also opted out. For example, if an opt-out physician/practitioner admits a beneficiary to a hospital, Medicare will reimburse the hospital for medically necessary care.

40.6 - When Payment May be Made to a Beneficiary for Service of an Opt-Out Physician/Practitioner

(Rev. 1, 10-01-03)

B3-3044.6

Payment may be made to a beneficiary for services of an opt out in two cases:

- If the services are emergency or urgent care services furnished by an opt-out physician/practitioner to a beneficiary with whom he/she has a previously existing private contract. (See §40.28 for further discussion of emergency and urgent care services by opt-out physicians and practitioners.); or
- If the opt-out physician/practitioner failed to privately contract with the beneficiary for services that they provided that were not emergency or urgent care services. The CMS expects this case to come to the carrier's attention only in the course of a request for reconsideration of a denied claim or as a result of a complaint from a beneficiary or the beneficiary's legal representative. If the carrier receives such a complaint, it must consider it to be a request for a reconsideration of the denial of payment for services of the opt-out physician/practitioner. It must follow the procedures outlined in §40.11 for cases in which the physician/ practitioner fails to maintain opt-out. If the physician/practitioner does not respond to the carrier's request for a copy of the private contract within 45 days, the carrier must make payment to the beneficiary based upon the payment for a nonparticipating physician/practitioner for that service. It must notify the beneficiary that the physician/practitioner who has opted out must privately contract with the beneficiary or the beneficiary's legal representative for services the physician/practitioner furnished and that no further payment will be made to the beneficiary for services furnished by the opt-out physician/practitioner after 15 days from the postmark of the notice.

40.7 - Definition of a Private Contract

(Rev. 1, 10-01-03)

B3-3044.7

A "private contract" is a contract between a Medicare beneficiary and a physician or other practitioner who has opted out of Medicare for two years for **all** covered items and services the physician/practitioner furnishes to Medicare beneficiaries. In a private contract, the Medicare beneficiary agrees to give up Medicare payment for services furnished by the physician/practitioner and to pay the physician/practitioner without regard to any limits that would otherwise apply to what the physician/practitioner could charge. Pursuant to the statute, once a physician/practitioner files an affidavit notifying the Medicare carrier that the he/she has opted out of Medicare, the physician/practitioner is out of Medicare for two years from the date the affidavit is signed (unless the opt-out is terminated early according to §40.35, or unless the he/she fails to maintain opt-out (See §40.11)). After those two years are over, a physician/practitioner could elect to return to Medicare or to opt out again. A beneficiary who signs a private contract with a

physician/practitioner is not precluded from receiving services from other physicians and practitioners who have not opted out of Medicare.

Physicians or practitioners who provide services to Medicare beneficiaries enrolled in the new Medical Savings Account (MSA) demonstration created by the BBA of 1997 are not required to enter into a private contract with those beneficiaries and to opt out of Medicare under §1802 of the Act.

40.8 - Requirements of a Private Contract

(Rev. 1, 10-01-03)

B3-3044.8

A private contract under this section must:

- Be in writing and in print sufficiently large to ensure that the beneficiary is able to read the contract;
- Clearly state whether the physician/practitioner is excluded from Medicare under §§1128, 1156 or 1892 of the Act;
- State that the beneficiary or the beneficiary's legal representative accepts full responsibility for payment of the physician's or practitioner's charge for all services furnished by the physician/practitioner;
- State that the beneficiary or the beneficiary's legal representative understands that Medicare limits do not apply to what the physician/practitioner may charge for items or services furnished by the physician/practitioner;
- State that the beneficiary or the beneficiary's legal representative agrees not to submit a claim to Medicare or to ask the physician/practitioner to submit a claim to Medicare;
- State that the beneficiary or the beneficiary's legal representative understands that Medicare payment will not be made for any items or services furnished by the physician/practitioner that would have otherwise been covered by Medicare if there was no private contract and a proper Medicare claim had been submitted;
- State that the beneficiary or the beneficiary's legal representative enters into the contract with the knowledge that the beneficiary has the right to obtain Medicare-covered items and services from physicians and practitioners who have not opted out of Medicare, and that the beneficiary is not compelled to enter into private contracts that apply to other Medicare-covered services furnished by other physicians or practitioners who have not opted out;
- State the expected or known effective date and expected or known expiration date of the opt-out period;
- State that the beneficiary or the beneficiary's legal representative understands that Medigap plans do not, and that other supplemental plans may elect not to, make payments for items and services not paid for by Medicare;
- Be signed by the beneficiary or the beneficiary's legal representative and by the physician/practitioner;

- Not be entered into by the beneficiary or by the beneficiary's legal representative during a time when the beneficiary requires emergency care services or urgent care services. (However, a physician/practitioner may furnish emergency or urgent care services to a Medicare beneficiary in accordance with §40.28;)
- Be provided (a photocopy is permissible) to the beneficiary or to the beneficiary's legal representative before items or services are furnished to the beneficiary under the terms of the contract;
- Be retained (original signatures of both parties required) by the physician/practitioner for the duration of the opt-out period;
- Be made available to CMS upon request; and
- Be entered into for each opt-out period.

In order for a private contract with a beneficiary to be effective, the physician/practitioner must file an affidavit with all Medicare carriers to which the physician/practitioner would submit claims, advising that the physician/practitioner has opted out of Medicare. The affidavit must be filed within 10 days of entering into the first private contract with a Medicare beneficiary. Once the physician/practitioner has opted out, such physician/practitioner must enter into a private contract with each Medicare beneficiary to whom the physician/practitioner furnishes covered services (even where Medicare payment would be on a capitated basis or where Medicare would pay an organization for the physician's or practitioner's services to the Medicare beneficiary), with the exception of a Medicare beneficiary needing emergency or urgent care.

If a physician/practitioner has opted out of Medicare, the physician/practitioner must use a private contract for items and services that are, or may be, covered by Medicare (except for emergency or urgent care services (see §40.28)). An opt-out physician/practitioner is not required to use a private contract for an item or service that is definitely excluded from coverage by Medicare.

A non-opt-out physician/practitioner, or other supplier, is required to submit a claim for any item or service that is, or may be, covered by Medicare. Where an item or service may be covered in some circumstances, but not in others, the physician/practitioner, or other supplier, may provide an Advance Beneficiary Notice to the beneficiary, which informs the beneficiary that Medicare may not pay for the item or service, and that if Medicare does not do so, the beneficiary is liable for the full charge. (See §§40, 40.24)

40.9 - Requirements of the Opt-Out Affidavit

(Rev. 1, 10-01-03)

B3-3044.9

Under 1802(b)(3)(B) of the Act, a valid affidavit must:

- Be in writing and be signed by the physician/practitioner;
- Contain the physician's or practitioner's full name, address, telephone number, national provider identifier (NPI) or billing number (if one has been assigned), uniform provider identification number (UPIN) if one has been assigned, or, if

neither an NPI nor a UPIN has been assigned, the physician's or practitioner's tax identification number (TIN);

- State that, except for emergency or urgent care services (as specified in §40.28), during the opt-out period the physician/practitioner will provide services to Medicare beneficiaries only through private contracts that meet the criteria of §40.8 for services that, but for their provision under a private contract, would have been Medicare-covered services;
- State that the physician/practitioner will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will the physician/practitioner permit any entity acting on the physician's/practitioner's behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary, except as specified in §40.28;
- State that, during the opt-out period, the physician/practitioner understands that the physician/practitioner may receive no direct or indirect Medicare payment for services that the physician/practitioner furnishes to Medicare beneficiaries with whom the physician/practitioner has privately contracted, whether as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under a Medicare+Choice plan;
- State that a physician/practitioner who opts out of Medicare acknowledges that, during the opt-out period, the physician's/practitioner's services are not covered under Medicare and that no Medicare payment may be made to any entity for the physician's/practitioner's services, directly or on a capitated basis;
- State on acknowledgment by the physician/practitioner to the effect that, during the opt-out period, the physician/practitioner agrees to be bound by the terms of both the affidavit and the private contracts that the physician/practitioner has entered into;
- Acknowledge that the physician/practitioner recognizes that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by the physician/practitioner during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom the physician/practitioner has not previously privately contracted) without regard to any payment arrangements the physician/practitioner may make;
- With respect to a physician/practitioner who has signed a Part B participation agreement, acknowledge that such agreement terminates on the effective date of the affidavit;
- Acknowledge that the physician/practitioner understands that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services and that the rules of §40.28 apply if the physician/practitioner furnishes such services;
- Identify the physician/practitioner sufficiently so that the carrier can ensure that no payment is made to the physician/practitioner during the opt-out period. If the

physician/practitioner has already enrolled in Medicare, this would include the physician/practitioner's Medicare uniform provider identification number (UPIN), if one has been assigned. If the physician/practitioner has not enrolled in Medicare, this would include the information necessary to be assigned a UPIN; and

- Be filed with all carriers who have jurisdiction over claims the physician/ practitioner would otherwise file with Medicare and be filed no later than 10 days after the first private contract to which the affidavit applies is entered into.

40.10 - Failure to Properly Opt Out

(Rev. 1, 10-01-03)

B3-3044.10

A. A physician/practitioner fails to properly opt out for any of the following reasons:

- Any private contract between the physician/practitioner and a Medicare beneficiary that was entered into before the affidavit described in §40.9 was filed does not meet the specifications of §40.8; or
- The physician/practitioner fails to submit the affidavit(s) in accordance with §40.9.

B. If a physician/practitioner fails to properly opt out in accordance with the above paragraphs of this section, the following will result:

- The physician's or practitioner's attempt to opt out of Medicare is nullified, and all of the private contracts between the physician/practitioner and Medicare beneficiaries for the two-year period covered by the attempted opt out are deemed null and void;
- The physician/practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries, including the items and services furnished under the nullified contracts. A nonparticipating physician/practitioner is subject to the limiting charge provision. For items or services paid under the physician fee schedule, the limiting charge is 115 percent of the approved amount for nonparticipating physicians or practitioners. A participating physician/practitioner is subject to the limitations on charges of the participation agreement the physician/practitioner signed;
- The physician/practitioner may not reassign any claim except as provided in the Medicare Clams Processing Manual, Chapter 1, "General Billing Requirements," §§30.2.12 and 30.2.13;
- The physician/practitioner may neither bill nor collect an amount from the beneficiary except for applicable deductible and coinsurance amounts; and
- The physician/practitioner may make another attempt to properly opt out at any time.

40.11 - Failure to Maintain Opt-Out

(Rev. 1, 10-01-03)

B3-3044.11

A physician/practitioner fails to maintain opt-out under this section if during the opt-out period one of the following occurs:

- The physician/practitioner has filed an affidavit in accordance with §40.9 and has signed private contracts in accordance with §40.8 but,
- The physician/practitioner knowingly and willfully submits a claim for Medicare payment (except as provided in §40.28); or
- Receives Medicare payment directly or indirectly for Medicare-covered services furnished to a Medicare beneficiary (except as provided in §40.28).
- The physician/practitioner fails to enter into private contracts with Medicare beneficiaries for the purpose of furnishing items and services that would otherwise be covered by Medicare, or enters into private contracts that fail to meet the specifications of §40.8; or
- The physician/practitioner fails to comply with the provisions of §40.28 regarding billing for emergency care services or urgent care services; or
- The physician/practitioner fails to retain a copy of each private contract that the physician/practitioner has entered into for the duration of the opt-out period for which the contracts are applicable or fails to permit CMS to inspect them upon request.

If a physician/practitioner fails to maintain opt-out in accordance with the above paragraphs of this section, and fails to demonstrate within 45 days of a notice from the carrier of a violation of the first paragraph of this section that the physician/practitioner has taken good faith efforts to maintain opt-out (including by refunding amounts in excess of the charge limits to the beneficiaries with whom the physician/practitioner did not sign a private contract), the following will result effective 46 days after the date of the notice, **but only for the remainder of the opt-out period.** (However, if the physician/practitioner did not privately contract and refunds coverage, the physician/practitioner may still maintain the opt-out):

- All of the private contracts between the physician/practitioner and Medicare beneficiaries are deemed null and void.
- The physician's or practitioner's opt-out of Medicare is nullified.
- The physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries.
- The physician or practitioner or beneficiary will not receive Medicare payment on Medicare claims for the remainder of the opt-out period, except as stated above.
- The physician or practitioner is subject to the limiting charge provisions as stated in §40.10.

- The practitioner may not reassign any claim except as provided in the Medicare Claims Processing Manual, Chapter 1, "General Billing Requirements," §30.2.13.
- The practitioner may neither bill nor collect any amount from the beneficiary except for applicable deductible and coinsurance amounts.
- The physician or practitioner may not attempt to once more meet the criteria for properly opting out until the 2-year opt-out period expires.

40.12 - Actions to Take in Cases of Failure to Maintain Opt-Out

(Rev. 1, 10-01-03)

B3-3044.12

If the carrier becomes aware that the physician/practitioner has failed to maintain opt-out as indicated in §40.11, it must send the physician/practitioner a letter advising the physician/practitioner that it has received a claim and believes that the physician/ practitioner may have inadvertently failed to maintain opt-out. It must describe the situation in §40.11 that it believes exists and its basis for its belief. It must ask the physician or practitioner to provide it with an explanation within 45 days of what happened and how the physician or practitioner will resolve it. (See the Medicare Claims Processing Manual, Chapter 1, "General Billing Requirements," §70.6, and the Medicare Program Integrity Manual for action when responses are not received within 45 days).

If the carrier received a claim from the opt-out physician/practitioner, it must ask the physician/practitioner if the received claim was: (a) an emergency or urgent situation, with missing documentation, **or** (b) filed in error. When the reason for the letter is that the physician/practitioner filed a claim that the physician/practitioner did not identify as an emergency or urgent care service, the carrier must request that the physician/practitioner submit the following information with the physician's/practitioner's response:

- Emergency/urgent care documentation if the claim was for a service furnished in an emergency or urgent situation but included no documentation to that effect; and/or
- If the claim was filed in error, the carrier must ask the physician/practitioner to explain whether the filing was an isolated incident or a systematic problem affecting a number of claims.

In the case of any potential failure to maintain opt-out (including but not limited to improper submission of a claim), the carrier must explain in its request to the physician or practitioner that it would like to resolve this matter as soon as possible. It must instruct the physician/practitioner to provide the information it requested within 45 days of the date of its development letter. It must provide the physician or practitioner with the name and telephone number of a contact person in case they have any questions.

If the violation was due to a systems problem, the carrier must ask the physician or practitioner to include with his or her response an explanation of the actions being taken to correct the problem and when the physician or practitioner expects the system error to be fixed. If the violation persists beyond the time period indicated in the physician's or practitioner's response, the carrier must contact the physician or practitioner again to

ascertain why the problem still exists and when the physician or practitioner expects to have it corrected. It must repeat this process until the system problem is corrected.

Also, in the carrier's development request, it must advise the physician or practitioner that if no response is received by the due date, the carrier will assume that there has been no correction of the failure to maintain opt-out and that this could result in a determination that the physician/practitioner is once again subject to Medicare rules.

In the case of wrongly filed claims, the carrier must hold the claim and any others it receives from the physician or practitioner in suspense until it hears from the physician or practitioner or the response date lapses. In this case, if the physician or practitioner responds that the claim was filed in error, the carrier must continue processing the claim, deny the claim, and send the physician or practitioner the appropriate Remittance Advice and send the beneficiary a Medicare Summary Notice (MSN) with the appropriate language explaining that the claim was submitted erroneously and the beneficiary is responsible for the physician's or practitioner's charge. In other words, the limiting charge provision does not apply and the beneficiary is responsible for all charges. This process will apply to all claims until the physician or practitioner is able to get the problem fixed.

If the carrier does not receive a response from the physician or practitioner by the development letter due date or if it is determined that the opt-out physician or practitioner knowingly and willfully failed to maintain opt-out, it must notify the physician or practitioner that the effects of failure to maintain opt-out specified in §40.11 apply. **It must formally notify the physician/practitioner of this determination and of the rules that again apply (e.g., mandatory submission of claims, limiting charge, etc.)**. It must specifically include in this letter each of the effects of failing to opt out that are identified in §40.11.

The act of claims submission by the beneficiary for an item or service provided by a physician or practitioner who has opted out is **not** a violation by the physician or practitioner and does not nullify the contract with the beneficiary. However, if there are what the carrier considers to be a substantial number of claims submissions by beneficiaries for items or services by an opt-out physician or practitioner, it must investigate to ensure that contracts between the physician or practitioner and the beneficiaries exist and that the terms of the contracts meet the Medicare statutory requirements outlined in this instruction. If noncompliance with the opt-out affidavit is determined, it must develop claims submission or limiting charge violation cases, as appropriate, based on its findings.

In cases in which the beneficiary files an appeal of the denial of a beneficiary-filed claim for services from an opt-out physician or practitioner, and alleges that there was no private contract, the carrier must ask the physician/practitioner to provide it with a copy of the private contract, but only if the beneficiary authorizes the carrier to do so. Where the physician or practitioner does not provide a copy of a private contract that was signed by the beneficiary before the service was furnished, the carrier must make payment to the beneficiary and proceed as described above.

40.13 - Physician/Practitioner Who Has Never Enrolled in Medicare

(Rev. 1, 10-01-03)

B3-3044.13

For a physician/practitioner who has never enrolled in the Medicare program and wishes to opt out of Medicare, the carrier must provide the physician/practitioner with a Unique Physician Identification Number (UPIN). It can get the full name, address, license number, and tax identification number from this affidavit. All other data requirements should be developed from other data sources (e.g., the American Medical Association, State Licensing Board, etc.). The carrier must annotate its in-house provider file and update the UPIN Registry that the physician/practitioner has opted out of the program. The physician/practitioner must not receive payment during the opt-out period (except in the case of emergency or urgent care services). If the carrier needs additional data elements and cannot obtain that information from another source, it may contact the physician/practitioner directly. It must notify the physician or practitioner that in order to refer or order services for a Medicare patient, the physician or practitioner must have a UPIN.

If an opt-out physician/practitioner provides emergency or urgent care service to a beneficiary who has not signed a private contact with the physician or practitioner and the physician/practitioner submits an assigned claim, the physician or practitioner must complete Form CMS-855 and enroll in the Medicare program before receiving reimbursement. Under a similar circumstance, if the physician or practitioner submits an unassigned claim, the carrier must pay the beneficiary directly without requiring a completed Form CMS-855. It may use the information from the affidavit to begin the enrollment process.

40.14 - Nonparticipating Physicians or Practitioners Who Opt Out of Medicare

(Rev. 1, 10-01-03)

B3-3044.14

A nonparticipating physician or practitioner may opt out of Medicare at any time in accordance with the following:

- The 2-year opt-out period begins the date the affidavit meeting the requirements of §40.9 is signed, provided the affidavit is filed within 10 days after the physician or practitioner signs his or her first private contract with a Medicare beneficiary.
- If the physician or practitioner does not timely file any required affidavit, the 2-year opt-out period begins when the last such affidavit is filed. Any private contract entered into before the last required affidavit is filed becomes effective upon the filing of the last required affidavit and the furnishing of any items or services to a Medicare beneficiary under such contract before the last required affidavit is filed is subject to standard Medicare rules.

40.15 - Excluded Physicians and Practitioners

(Rev. 1, 10-01-03)

B3-3044.15

An excluded physician or practitioner may opt out of Medicare by submitting the required documentation in accordance with §40.9. When determining effective dates of the exclusion versus the opt-out, the date of exclusion always takes precedence over the date the physician or practitioner opts out of Medicare. A physician or practitioner who has been excluded must comply with 42 CFR 1001.1901, "Scope and Effect of Exclusion."

If an excluded/opt-out physician or practitioner submits a claim to Medicare, the carrier must not make payment for services furnished, ordered, or prescribed on or after the effective date of the exclusion.

The carrier must not make payment to a beneficiary who submits claims for services rendered by an excluded/opt-out physician or practitioner (except where payment would otherwise be made in accordance with the Medicare Program Integrity Manual). It must deny the claim and send the physician or practitioner the appropriate remittance and send the beneficiary a MSN as explained in §40.39.

40.16 - Relationship Between Opt-Out and Medicare Participation Agreements

(Rev. 1, 10-01-03)

B3-3044.16

Participation agreements will terminate on the opt out effective date. See 40.17 for effective date provisions. Physicians and practitioners may not provide services under private contracts with beneficiaries earlier than the effective date of the affidavit. Nonparticipating physicians and practitioners may opt out at any time.

The carrier must updates carrier system files so that it may timely pay participating physicians and practitioners at the correct payment amounts in effect for that part of the fee schedule year before they opt out and to pay them as nonparticipating for emergency or urgent care as of their opt out effective date.

40.17 - Participating Physicians and Practitioners

(Rev. 1, 10-01-03)

B3-3044.17

Participating physicians and practitioners may opt out if they file an affidavit that meets the criteria and which is received by the carrier at least 30 days before the first day of the next calendar quarter showing an effective date of the first day in that quarter (i.e., January 1, April 1, July 1,October 1). They may not provide services under private contracts with beneficiaries earlier than the effective date of the affidavit.

The 30-day notice is required to allow sufficient time for the carrier to accomplish the appropriate system file updates before the effective date. The carrier must make

participating physician status changes no less frequently than at the beginning of each calendar quarter. Therefore, participating physicians or practitioners must provide the carrier with 30 days notice that they intend to opt out at the beginning of the next calendar quarter.

Participating physicians or practitioners may sign private contracts only after the effective date of affidavits filed in accordance with §40.9. They may not provide services under private contracts with beneficiaries earlier than the effective date of the affidavit. It is necessary to treat nonparticipating physicians or practitioners differently from participating physicians or practitioners in order to assure that participating physicians or practitioners are paid properly for the services they furnish before the effective date of the affidavit.

Participating physicians or practitioners are paid at the full fee schedule for the services they furnish to Medicare beneficiaries. However, the law sets the payment amount for nonparticipating physicians or practitioners at 95 percent of the payment amount for participating physicians or practitioners.

Participating physicians or practitioners who opt out are treated as nonparticipating physicians or practitioners as of the effective date of the opt-out affidavit. When a participating physician/practitioner opts out of Medicare, the carrier must pay the physician/practitioner at the higher participating physician/practitioner rate for services rendered in the period before the effective date of the opt-out; and at the nonparticipating rate for services rendered on and after the opt-out date.

40.18 - Physicians or Practitioners Who Choose to Opt Out of Medicare

(Rev. 1, 10-01-03)

B3-3044.18

If a physician/practitioner chooses to opt out of Medicare, it means that the physician/ practitioner opts out for all covered items and services that he or she furnishes. Physicians and practitioners cannot have private contracts that apply to some covered services they furnish but not to others. For example, if a physician or practitioner provides laboratory tests or durable medical equipment incident to his or her professional services and chooses to opt out of Medicare, then the physician/practitioner has opted out of Medicare for payment of lab services and Durable Medical Equipment, Prosthetics, and Orthotics (DMEPOS) as well as for professional services. If a physician or practitioner who has opted out refers a beneficiary to a non-opt-out physician or practitioner for medically necessary services, such as laboratory, DMEPOS or inpatient hospitalization, Medicare would cover those services.

In addition, because suppliers of DMEPOS, independent diagnostic testing facilities, clinical laboratories, etc., cannot opt out, the physician or practitioner owner of such suppliers cannot opt out as such a supplier. Therefore, the participating physician or practitioner becomes a nonparticipating physician or practitioner for purposes of Medicare payment for emergency and urgent care services on the effective date of the opt-out. (See §40.28).

40.19 - Opt-Out Relationship to Noncovered Services

(Rev. 1, 10-01-03)

B3-3044.19

Because Medicare's rules do not apply to items or services that are categorically not covered by Medicare, a private contract is not needed to furnish such items or services to Medicare beneficiaries, and Medicare's claims filing rules and limits on charges do not apply to such items or services. For example, because Medicare does not cover hearing aids, a physician or practitioner, or other supplier, may furnish a hearing aid to a Medicare beneficiary and would not be required to file a claim with Medicare; further, the physician, practitioner, or other supplier would not be subject to any Medicare limit on the amount they could collect for the hearing aid.

If the item or service is one that is not categorically excluded from coverage by Medicare, but may be noncovered in a given case (for example, it is covered only where certain clinical criteria are met and there is a question as to whether the criteria are met), a non-opt-out physician/practitioner or other supplier is **not** relieved of his or her obligation to file a claim with Medicare. If the physician or practitioner or other supplier has given a proper Advance Beneficiary Notice (ABN), they may collect from the beneficiary the full charge if Medicare does deny the claim.

Where a physician or practitioner has opted out of Medicare, he or she must provide covered services only through private contracts that meet the criteria specified in §40.8 (including items and services that are not categorically excluded from coverage but may be excluded in a given case). An opt-out physician or practitioner is prohibited from submitting claims to Medicare (except for emergency or urgent care services furnished to a beneficiary with whom the physician or practitioner did not have a private contract). (See §40.12.)

40.20 - Maintaining Information on Opt-Out Physicians

(Rev. 1, 10-01-03)

B3-3044.20

The carrier must maintain information on the opt-out physicians or practitioners. At a minimum, it must capture the name and UPIN of the physician or practitioner, the effective date of the opt-out affidavit, and the end date of the opt-out period. The carrier may also include other provider-specific information it may need. If cost effective, it may house this information on its provider file.

40.21 - Informing Medicare Managed Care Plans of the Identity of the Opt-Out Physicians or Practitioners

(Rev. 1, 10-01-03)

B3-3044.21

The carrier must develop data exchange mechanisms for furnishing Medicare managed care plans in its service area with timely information on physicians and practitioners who have opted out of Medicare. For example, it may wish to establish an Internet Web site

"Home Page" which houses all of the information on physicians or practitioners who have opted out. It will need to negotiate appropriate opt out information exchange mechanisms with each managed care plan in its service area.

40.22 - Informing the National Supplier Clearinghouse (NSC) of the Identity of the Opt-Out Physicians or Practitioners

(Rev. 1, 10-01-03)

B3-3044.22

The carrier must notify the NSC directly with timely information on physicians or practitioners who have opted out of Medicare. An Internet Web site "Home Page" is not an acceptable means of notifying the NSC. The NSC's address is as follows:

National Supplier Clearinghouse
P.O. Box 100142
Columbia, SC 29202-3142

40.23 - Organizations That Furnish Physician or Practitioner Services

(Rev. 1, 10-01-03)

B3-3044.23

The opt-out applies to all items or services the physician or practitioner furnishes to Medicare beneficiaries, regardless of the location where such items or services are furnished.

Where a physician or practitioner opts out and is a member of a group practice or otherwise reassigns his or her rights to Medicare payment to an organization, the organization may no longer bill Medicare or be paid by Medicare for services that the physician or practitioner furnishes to Medicare beneficiaries. However, if the physician or practitioner continues to grant the organization the right to bill and be paid for the services the physician or practitioner furnishes to patients, the organization may bill and be paid by the beneficiary for the services that are provided under the private contract. The decision of a physician or practitioner to opt out of Medicare does not affect the ability of the group practice or organization to bill Medicare for the services of physicians and practitioners who have not opted out of Medicare.

Corporations, partnerships, or other organizations that bill and are paid by Medicare for the services of physicians or practitioners who are employees, partners, or have other arrangements that meet the Medicare reassignment-of-payment rules cannot opt out because they are neither physicians nor practitioners. Of course, if every physician and practitioner within a corporation, partnership, or other organization opts out, then such corporation, partnership, or other organization would have, in effect, opted out.

40.24 - The Difference Between Advance Beneficiary Notices (ABN) and Private Contracts

(Rev. 1, 10-01-03)

B3-3044.24

An Advance Beneficiary Notice (ABN) allows a beneficiary to make an informed consumer decision by knowing in advance that the beneficiary may have to pay out-of-pocket. An ABN is not needed where the item or service is categorically excluded from Medicare coverage or outside the scope of the benefit.

An ABN is used when the physician/practitioner believes that Medicare will not make payment, while private contracts are used for services that are covered by Medicare and for which payment might be made if a claim were to be submitted.

See the Medicare Claims Processing Manual, Chapter 30, for a description of the ABN.

40.25 - Private Contracting Rules When Medicare is the Secondary Payer

(Rev. 1, 10-01-03)

B3-3044.25

The opt-out physician/practitioner must have a private contract with a Medicare beneficiary for all Medicare-covered services (see §40.7), notwithstanding that Medicare would be the secondary payer in a given situation. No Medicare primary **or** secondary payments will be made for items and services furnished by a physician/practitioner under the private contract.

40.26 - Registration and Identification of Physicians or Practitioners Who Opt Out

(Rev. 1, 10-01-03)

B3-3044.26

The carrier must use the Unique Provider Identification Number (UPIN) Registry to identify opt-out physicians or practitioners nationwide. The Registry can be accessed at http://www.cms.hhs.gov/providers/enrollment/upin/upintoc.asp.

40.27 - System Identification

(Rev. 1, 10-01-03)

B3-3044.27

The carrier must ensure that its system can automatically identify claims that include services furnished by providers or practitioners who have opted out of Medicare. It must not make payment to any opt-out physician/practitioner for items or services furnished on or after the effective date of the physician's or practitioner's opt out affidavit unless there are emergency or urgent care situations involved. In an emergency or urgent care situation, payment can be made for services furnished to a Medicare beneficiary if the

beneficiary has no contract with the opt-out physician/practitioner. See the following section for related instructions.

40.28 - Emergency and Urgent Care Situations

(Rev. 1, 10-01-03)

B3-3044.28

Payment may be made for services furnished by an opt-out physician or practitioner who has not signed a private contract with a Medicare beneficiary for emergency or urgent care items and services furnished to, or ordered or prescribed for, such beneficiary on or after the date the physician opted out.

Where a physician or a practitioner who has opted out of Medicare treats a beneficiary with whom the physician or practitioner does not have a private contract in an emergency or urgent situation, the physician or practitioner may not charge the beneficiary more than the Medicare limiting charge for the service and must submit the claim to Medicare on behalf of the beneficiary for the emergency or urgent care. Medicare payment may be made to the beneficiary for the Medicare covered services furnished to the beneficiary.

In other words, where the physician or practitioner provides emergency or urgent services to the beneficiary, the physician or practitioner must submit a claim to Medicare, and may collect no more than the Medicare limiting charge in the case of a physician, or the deductible and coinsurance in the case of a practitioner. This implements §1802(b)(2)(A)(iii) of the Act, which specifies that the contract may not be entered into when the beneficiary is in need of emergency or urgent care. Because the services are excluded from coverage under §1862(a)(19) of the Act only if they are furnished under private contract, CMS concludes that they are not excluded in this case where there in no private contract, notwithstanding that they were furnished by an opt-out physician or practitioner. Hence, they are covered services furnished by a nonparticipating physician or practitioner, and the rules in effect absent the opt-out would apply in these cases. Specifically, the physician or practitioner may choose to take assignment (thereby agreeing to collect no more than the Medicare deductible and coinsurance based on the allowed amount from the beneficiary) or not to take assignment (and to collect no more than the Medicare limiting charge), but the practitioner must take assignment under §1842(b)(18) of the Act.

Therefore, in this circumstance the physician or practitioner must submit a completed Medicare claim on behalf of the beneficiary with the appropriate HCPCS code and HCPCS modifier that indicates the services furnished to the Medicare beneficiary were emergency or urgent and the beneficiary does not have a private agreement with the physician or practitioner. If the physician or practitioner did not submit **GJ** national HCPCS modifier, then the carrier must deny the claim so that the beneficiary can appeal.

GJ = Opt-out physician/practitioner EMERGENCY OR URGENT SERVICES

This modifier must be used on claims for services rendered by an opt-out physician/ practitioner for an emergency/urgent service. The use of this modifier indicates that the service was furnished by an opt-out physician/practitioner who has not signed a private contract with a Medicare beneficiary for emergency or urgent care items and services

furnished to, or ordered or prescribed for, such beneficiary on or after the date the physician/practitioner opted out.

The carrier must deny payment for emergency or urgent care items and services to both an opt-out physician or practitioner and the beneficiary if these parties have previously entered into a private contract, i.e., prior to the furnishing of the emergency or urgent care items or services but within the physician's or practitioner's opt out period.

Under the emergency and urgent care situation where an opt-out physician or practitioner renders emergency or urgent service to a Medicare beneficiary (e.g., a fractured leg) who has not entered into a private agreement with the physician or practitioner, as stated above the physician or practitioner is required to submit a claim to Medicare with the appropriate modifier (GJ and 54 as discussed further below) and is subject to all the rules and regulations of Medicare including limiting charge. However, if the opt-out physician or practitioner asks the beneficiary, with whom the physician or practitioner has no private contract, to return for a follow up visit (e.g., return within five to six weeks to remove the cast and examine the leg) the physician or practitioner must ask the beneficiary to sign a private contract. In other words, once a beneficiary no longer needs emergency or urgent care (i.e., nonurgent follow up care), Medicare cannot pay for the follow up care and the physician or practitioner can and must, under the opt-out affidavit agreement, ask the beneficiary to sign a private agreement as a condition of further treatment.

The way this would work in the fractured leg example (see previous paragraph) is that the physician or practitioner would bill Medicare for the setting of the fractured leg with the emergency opt out CMS modifier **(GJ)** and the surgical care only modifier (54) to ensure that CMS does not pay the Evaluation and Management (E&M) that is in the global fee for the procedure. The physician or practitioner would then either have the beneficiary sign the private contract or refer the beneficiary to a Medicare physician or practitioner who would bill Medicare using the post op only modifier to be paid for the post op care in the global period.

If the beneficiary continues to be in a condition that requires emergency or urgent care (i.e., unconscious or unstable after surgery for an aneurysm) follow up care would continue to be paid under emergency or urgent care until such time as the beneficiary no longer needed such care. In the absence on controvertible evidence CMS recommends accepting what the physician or practitioner says via the modifiers and doing post-pay records review of frequent users of the opt-out modifier.

40.29 - Definition of Emergency and Urgent Care Situations

(Rev. 1, 10-01-03)

B3-3044.29

Emergency services are defined as being services furnished to an individual who has an emergency medical condition as defined in 42 CFR 424.101. The CMS has adopted the definition of emergency medical condition in that section of the Code of Federal Regulations (CFR). However, it seemed clear that Congress intended that the term "emergency or urgent care services" not be limited to emergency services since they also included "urgent care services." Urgent Care Services are defined in 42 CFR 405.400 as

services furnished within 12 hours in order to avoid the likely onset of an emergency medical condition. For example, if a beneficiary has an ear infection with significant pain, CMS would view that as requiring treatment to avoid the adverse consequences of continued pain and perforation of the eardrum. The patient's condition would not meet the definition of emergency medical condition because **immediate care** is not needed to avoid placing the health of the individual in serious jeopardy or to avoid serious impairment or dysfunction. However, although it does not meet the definition of emergency care, the beneficiary needs care within a relatively short period of time (which CMS defines as 12 hours) to avoid adverse consequences, and the beneficiary may not be able to find another physician or practitioner to provide treatment within 12 hours.

40.30 - Denial of Payment to Employers of Opt-Out Physicians and Practitioners

(Rev. 1, 10-01-03)

B3-3044.30

If an opt-out physician or practitioner is employed in a hospital setting and submits bills for which payment is prohibited, the Part B carrier usually detects and investigates the situation. However, in some instances an opt-out physician or practitioner may have a salary arrangement with a hospital or clinic or work in a group practice and may not directly submit bills for payment. If the carrier detects this situation, it must recover the payment made for the opt-out physician/practitioner from the hospital/clinic/group practice, after appropriate notification.

40.31 - Denial of Payment to Beneficiaries and Others

(Rev. 1, 10-01-03)

B3-3044.31

If a beneficiary submits a claim that includes items or services furnished by an opt-out physician or practitioner on dates on or after the effective date of opt out by such physician or practitioner, the carrier must deny such items or services. (See §40.6.) However, see §40.11 in cases in which the beneficiary appeals the denial on the basis that no private contract was signed.

40.32 - Payment for Medically Necessary Services Ordered or Prescribed by an Opt-out physician or Practitioner

(Rev. 1, 10-01-03)

B3-3044.32

If claims are submitted for any items or services ordered or prescribed by an opt out physician or practitioner under §1802 of the Act, the carrier may pay for medically necessary services of the furnishing entity, provided the furnishing entity is not also a physician or practitioner that has opted out of the Medicare program.

40.33 - Mandatory Claims Submission

(Rev. 1, 10-01-03)

B3-3044.33

Section 1848(g)(4) of the Act, "Physician/Practitioner Submission of Claims," regarding mandatory claims submission, does not apply once a physician or practitioner signs and submits an affidavit to the Medicare carrier opting out of the Medicare program, for the duration of the physician's or practitioner's opt out period, unless the physician or practitioner knowingly and willfully violates a term of the affidavit.

40.34 - Renewal of Opt-Out

(Rev. 1, 10-01-03)

B3-3044.34

A physician or practitioner may renew an opt out without interruption by filing an affidavit with each carrier to which an affidavit was submitted for the first opt out (as specified in §40.9), and to each carrier to which a claim was submitted under §40.28 during the previous opt out period, provided the affidavits are filed within 30 days after the current opt-out period expires.

40.35 - Early Termination of Opt-Out

(Rev. 1, 10-01-03)

B3-3044.35

If a physician or practitioner changes his or her mind after the carrier has approved the affidavit, the opt-out may be terminated within 90 days of the effective date of the affidavit. To properly terminate an opt out, a physician or practitioner must:

- Not have previously opted out of Medicare;
- Notify all Medicare carriers, with which the physician or practitioner filed an affidavit, of the termination of the opt-out no later than 90 days after the effective date of the opt-out period;
- Refund to each beneficiary with whom the physician or practitioner has privately contracted all payment collected in excess of:
    - The Medicare limiting charge (in the case of physicians or practitioners);or
    - The deductible and coinsurance (in the case of practitioners).
- Notify all beneficiaries with whom the physician or practitioner entered into private contracts of the physician's or practitioner's decision to terminate opt out and of the beneficiaries' rights to have claims filed on their behalf with Medicare for services furnished during the period between the effective date of the opt-out and the effective date of the termination of the opt-out period.

When the physician or practitioner properly terminates opt-out in accordance with the second bullet above, the physician or practitioner will be reinstated in Medicare as if

there had been no opt-out, and the provision of §40.3 must not apply unless the physician or practitioner subsequently properly opts out.

40.36 - Appeals

(Rev. 1, 10-01-03)

B3-3044.36

A determination by CMS that a physician or practitioner has failed to properly opt out, failed to maintain opt-out, failed to timely renew opt-out, failed to privately contract, or failed to properly terminate opt-out is an initial determination for purposes of 42 CFR 405.803.

A determination by CMS that no payment can be made to a beneficiary for the services of a physician who has opted out is an initial determination for purposes of 42 CFR 405.803.

See the Medicare Claims Processing Manual, Chapter 29, "Appeals of Claims Decisions," for additional information on appeals.

40.37 - Application to Medicare+Choice Contracts

(Rev. 1, 10-01-03)

B3-3044.37

The Medicare Managed Care Manual contains instructions for M+C organizations about the impact on managed care.

The manual provides in general that M+C organizations:

- Must acquire and maintain information from Medicare carriers on physicians and practitioners who have opted out of Medicare.
- Must make no payment directly or indirectly for Medicare covered services furnished to a Medicare beneficiary by a physician or practitioner who has opted out of Medicare, except for emergency or urgent care services furnished to a beneficiary who has not previously entered into a private contract with the physician or practitioner, in accordance with §40.28.

The carrier must maintain mutually agreeable means of advising M+C organizations of who has opted out. Disputes with M+C organizations about the provision of opt out information should be referred to the CMS Regional Office staff for resolution.

40.38 - Claims Denial Notices to Opt-Out Physicians and Practitioners

(Rev. 1, 10-01-03)

B3-3044.38

To ensure that the notice denying payment to the opt-out physician or practitioner indicates the proper reason for denial of payment, the carrier must include language in the notice appropriate to particular circumstances as follows:

- When the claim is submitted **inadvertently** by the opt-out physician/practitioner, the carrier must use claim adjustment reason code 28 (coverage not in effect at the

time service was provided) at the claim level with group code PR (patient responsibility) and the remark code MA47:

> Our records show that you have opted out of Medicare, agreeing with the patient not to bill Medicare for services/tests/supplies furnished. As a result, we cannot pay this claim. The patient is responsible for payment."

- The carrier uses the following message when the claim is submitted **knowingly and willfully** by the opt-out physician/practitioner. It must use claim adjustment reason code 28 (coverage not in effect at the time service was provided) at the claim level with group code PR (patient responsibility) and the claim level remark code MA56:

> Our records show that you have opted out of Medicare, agreeing with the patient not to bill Medicare for services/tests/supplies furnished. As a result, we cannot pay this claim. The patient is responsible for payment. Under Federal law you cannot charge more than the limiting charge amount.

40.39 - Claims Denial Notices to Beneficiaries

(Rev. 1, 10-01-03)

B3-3044.39

To ensure that the notice to the beneficiary indicates the proper reason for denial of payment, the carrier must include language in the notice appropriate to particular circumstances as follows:

- It must use the following MSN message when the claim is submitted **inadvertently** by the opt-out physician/practitioner:

> MSN # 21.20 - "The provider decided to drop out of Medicare. No payment can be made for this service. You are responsible for this charge."

- It must use the following message when the claim is submitted **knowingly and willfully** by the opt-out physician/practitioner:

> MSN # 21.19 - "The provider decided to drop out of Medicare. No payment can be made for this service. You are responsible for this charge. Under Federal law your doctor cannot charge you more than the limiting charge amount."

- It must use the following message when the claim is submitted by the beneficiary for a service furnished by an opt-out physician/practitioner:

> MSN # 21.20 - "The provider decided to drop out of Medicare. No payment can be made for this service. You are responsible for this charge."

40.40 - Reporting

(Rev. 1, 10-01-03)

B3-3044.40

The carrier must compile cumulative data for CMS on the number of physicians and practitioners who sign up to privately contract with Medicare beneficiaries. It must prepare a quarterly "Private Contracting" report and submit it to central office and a copy to its Regional Office. It must send quarterly reports to:

Centers for Medicare & Medicaid Services
Center for Health Plans and Providers
Provider Purchasing and Administration Group
Division of Practitioner Claims Processing
7500 Security Boulevard
Baltimore MD, 21244-1850

Reports may be faxed to (410) 786-0330, Attn: CMM, PPAG, DPCP, in lieu of mailing a hard copy report. The carrier must prepare a separate report for each contract jurisdiction.

NOTE: For reporting purposes, CMS is interested only in valid/approved affidavits. The carrier must not count affidavits it receives that are invalid/not approved and must be returned to the physician/practitioner for clarification, incompleteness, etc.

The carrier must use the following report format:

Name of Report: Private Contracting Data

1. Carrier name;
2. Carrier number;
3. Quarter: (beginning and ending date); and
4. Number of "private contracting" affidavits received during report period:

For detail information: (use the following format)

Specialty	Name/Address	PIN	UPIN	Par Status	Affidavit Receipt Date	Effective Date

NOTE: The "Affidavit Receipt Date" column of the report is optional. Because the affidavit receipt date may not be currently available in all systems, it may not be possible to give CMS a quarterly count of the number of private contracting affidavits received. If the carrier's system has the capability to supply CMS with the affidavit receipt date, the carrier must enter the correct date in the "Affidavit Receipt Date" column. If its system cannot supply CMS with the affidavit receipt date, it must leave the "Affidavit Receipt Date" column blank.

The carrier must sort the report data by physician/practitioner specialty.

The report is due 30 days after the end of each quarter (e.g., a report for the quarter April 1, 2003, through June 30, 2003, is due July 30, 2003).

The CMS will notify the carrier if and when this report is either discontinued or put on the CROWD system.

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 §50.4.4.2); 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 (USD-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

(Rev. 1, 10-01-03)

AB-02-072, AB-02-139, B3-2049.2

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:
3. Absent evidence to the contrary, presume that drugs delivered by subcutaneous injection are self-administered by the patient. However, 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 paraplegia 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 and intermediary must report to CMS, every September 1 and March 1, 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 anticipates that contractors will review injectable drugs on a rolling basis and publish their list of excluded drugs as it is developed. For example, contractors should not wait to publish this list until every drug has been reviewed. Contractors must send their exclusion list to the following e-mail address: drugdata@cms.hhs.gov a template that CMS will provide separately, consisting of the following data elements in order:

1. Carrier Name
2. State
3. Carrier ID#
4. HCPCS
5. Descriptor
6. Effective Date of Exclusion
7. End Date of Exclusion
8. Comments

Any exclusion list not provided in the CMS mandated format will be returned for correction.

To view the presently mandated CMS format for this report, open the file located at:

http://cms.hhs.gov/manuals/pm_trans/AB02_139a.zip

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 uses and dosage, as well as 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. 1, 10-01-03)

B3-2049.4

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. 1, 10-01-03)

A3-3157.A, B3-2049.4, HO-230.4.C

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 anti-rabies 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

A3-3157.A.1, HO-230.4.C.1

Effective for services furnished on or after May 1, 1981, the Medicare Part B program covers 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. This includes revaccination of patients at highest risk of pneumococcal infection. Typically, these vaccines are administered once in a lifetime except for persons at highest risk. Effective July 1, 2000, 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.

An initial vaccine may be administered only to persons at high risk (see below) of pneumococcal disease. Revaccination may be 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 five years have [passed since the previous doe of pneumococcal vaccine.

Persons at high risk for whom an initial vaccine may be administered include all people age 65 and older; immunocompetent adults who are at increased risk of pneumococcal disease or its complications because of chronic illness (e.g., cardiovascular disease, pulmonary disease, diabetes mellitus, alcoholism, cirrhosis, or cerebrospinal fluid leaks); and individuals with compromised immune systems (e.g., splenic dysfunction or anatomic asplenia, Hodgkin's disease, lymphoma, multiple myeloma, chronic renal failure, HIV infection, nephrotic syndrome, sickle cell disease, or organ transplantation).

Persons at highest risk and those most likely to have rapid declines in antibody levels are those for whom revaccination may be appropriate. This group includes persons with functional or anatomic asplenia (e.g., sickle cell disease, splenectomy), HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome, or other conditions associated with

immunosuppression such as organ or bone marrow transplantation, and those receiving immunosuppressive chemotherapy. It is not appropriate for routine revaccination of people age 65 or older that are not at highest risk.

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. If the patient is uncertain about his or her vaccination history in the past five years, the vaccine should be given. However, if the patient is certain he/she was were vaccinated in the last five years, the vaccine should not be given. If the patient is certain that the vaccine was given more than five years ago, revaccination is covered only if the patient is at high risk.

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. This coverage is effective for services furnished on or after September 1, 1984. 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 an Hepatitis B Virus (HBV) carrier;
- Homosexual men; and
- Illicit injectable drug abusers.

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 year in the fall or winter. 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 - Unlabeled Use for Anti-Cancer Drugs

(Rev. 1, 10-01-03)

B3-2049.4.C

Effective January 1, 1994, unlabeled uses of FDA approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen for a medically accepted indication are evaluated under the conditions described in this paragraph. A regimen is a combination of anti-cancer agents which has been clinically recognized for the treatment of a specific type of cancer. An example of a drug regimen is: Cyclophosphamide + vincristine + prednisone (CVP) for non-Hodgkin's lymphoma.

In addition to listing the combination of drugs for a type of cancer, there may be a different regimen or combinations which are used at different times in the history of the cancer (induction, prophylaxis of CNS involvement, post remission, and relapsed or refractory disease). A protocol may specify the combination of drugs, doses, and schedules for administration of the drugs. For purposes of this provision, a cancer treatment regimen includes drugs used to treat toxicities or side effects of the cancer treatment regimen when the drug is administered incident to a chemotherapy treatment.

Contractors must not deny coverage based solely on the absence of FDA approved labeling for the use, if the use is supported by one of the following and the use is **not** listed as "not indicated" in any of the three compendia. (See note at the end of this subsection.)

A - American Hospital Formulary Service Drug Information

Drug monographs are arranged in alphabetical order within therapeutic classifications. Within the text of the monograph, information concerning indications is provided; including both labeled and unlabeled uses. Unlabeled uses are identified with daggers. The text must be analyzed to make a determination whether a particular use is supported.

B - American Medical Association Drug Evaluations

Drug evaluations are organized into sections and chapters that are based on therapeutic classifications. The evaluation of a drug provides information concerning indications, including both labeled and unlabeled uses. Unlabeled uses are not specifically identified as such. The text must be analyzed to make a determination whether a particular use is supported. In making these determinations, also refer to the "AMA Drug Evaluations Subscription," Volume III, section 17 (Oncolytic Drugs), chapter 1 (Principles of Cancer Chemotherapy), tables 1 and 2.

Table 1, Specific Agents Used In Cancer Chemotherapy, lists the anti-neoplastic agents which are currently available for use in various cancers. The indications presented in this table for a particular anti-cancer drug include labeled and unlabeled uses (although they are not identified as such). Any indication appearing in this table is considered to be a medically accepted use.

Table 2, Clinical Responses To Chemotherapy, lists some of the currently preferred regimens for various cancers. The table headings include (1) type of cancer, (2) drugs or regimens currently preferred, (3) alternative or secondary drugs or regimens, and (4) other drugs or regimens with reported activity.

A regimen appearing under the preferred or alternative/secondary headings is considered to be a medically accepted use.

A regimen appearing under the heading "Other Drugs or Regimens With Reported Activity" is considered to be for a medically accepted use provided:

- The preferred and alternative/secondary drugs or regimens are contraindicated;
- A preferred and/or alternative/secondary drug or regimen was used but was not tolerated or was ineffective; or
- There was tumor progression or recurrence after an initial response.

C - United States Pharmacopoeia Drug Information (USPDI)

Monographs are arranged in alphabetic order by generic or family name. Indications for use appear as accepted, unaccepted, or insufficient data. An indication is considered to be a medically accepted use only if the indication is listed as accepted. Unlabeled uses are identified with brackets. A separate indications index lists all indications included in USPDI along with the medically accepted drugs used in treatment or diagnosis.

D - A Use Supported by Clinical Research That Appears in Peer Reviewed Medical Literature

This applies only when an unlabeled use does not appear in any of the compendia or is listed as insufficient data or investigational. If an unlabeled use of a drug meets these criteria, the carrier will contact the compendia to see if a report regarding this use is forthcoming. If a report is forthcoming, the carrier uses this information as a basis for making decisions. The compendium process for making decisions concerning unlabeled uses is very thorough and continuously updated. Peer reviewed medical literature includes 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. This does not include in-house publications of pharmaceutical manufacturing companies or abstracts (including meeting abstracts).

In determining whether there is supportive clinical evidence for a particular use of a drug, carrier medical staff (in consultation with local medical specialty groups) will evaluate the quality of the evidence in published peer reviewed medical literature. When evaluating this literature, they will consider (among other things) the following:

- The prevalence and life history of the disease when evaluating the adequacy of the number of subjects and the response rate. While a 20 percent response rate may be adequate for highly prevalent disease states, a lower rate may be adequate for rare diseases or highly unresponsive conditions.
- The effect on the patient's well-being and other responses to therapy that indicate effectiveness, e.g., a significant increase in survival rate or life expectancy or an objective and significant decrease in the size of the tumor or a reduction in symptoms related to the tumor. Stabilization is not considered a response to therapy.
- The appropriateness of the study design. The carrier 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 nonrandomized 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 carrier will use peer reviewed medical literature appearing in the following publications:

- American Journal of Medicine;
- Annals of Internal Medicine;
- The Journal of the American Medical Association;
- Journal of Clinical Oncology;
- Blood;
- Journal of the National Cancer Institute;
- The New England Journal of Medicine;
- British Journal of Cancer;
- British Journal of Hematology;
- British Medical Journal;
- Cancer;
- Drugs;

- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology);
- Lancet; or
- Leukemia.

The carrier is not required to maintain copies of these publications. If a claim raises a question about the use of a drug for a purpose not included in the FDA approved labeling or the compendia, the carrier will ask the physician to submit copies of relevant supporting literature.

Unlabeled uses may also be considered medically accepted if determined by the carrier to be medically accepted generally as safe and effective for the particular use.

NOTE: If a use is identified as not indicated by CMS or the FDA, or if a use is specifically identified as not indicated in one or more of the three compendia mentioned or if the carrier determines, based on peer reviewed medical literature, that a particular use of a drug is not safe and effective, the off-label usage is not supported and, therefore, the drug is not covered.

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 biovailability.

Section 1862(a)(1)(A) of the Act requires that drugs must be reasonable and necessary in order to by 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 - Self-Administered Drugs and Biologicals

(Rev. 1, 10-01-03)

B3-2049.5

Medicare Part B does not cover drugs that are usually self-administered by the patient unless the statute provides for such coverage. The statute explicitly provides coverage, for blood clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, certain oral anti-cancer drugs and anti-emetics used in certain situations.

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

Prednosolone.

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 new 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 hypotension 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

(Rev. 1, 10-01-03)

HO-230.4.B.4.c

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. 1, 10-01-03)

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 antineoplastic 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 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 two 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.

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 base line 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.6, 01-23-04)

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 (ICD-9 diagnosis codes 279.04, 279.05, 279.06, 279.12, and 279.2) in the home. The corresponding HCPCS codes are J1563 and J1564. 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.

60 - Services and Supplies

(Rev. 1, 10-01-03)

B3-2050

A - Noninstitutional Setting

For purposes of this section a noninstitutional setting means all settings other than a hospital or skilled nursing facility

Medicare pays for services and supplies (including drug and biologicals which are not usually self-administered) that are furnished incident to a physician's or other practitioner's services, are commonly included in the physician's or practitioner's bills, and for which payment is not made under a separate benefit category listed in §1861(s) of the Act. Carriers and intermediaries must not apply incident to requirements to services having their own benefit category. Rather, these services should meet the requirements of their own benefit category. For example, diagnostic tests are covered under §1861(s)(3) of the Act and are subject to their own coverage requirements. Depending on the particular tests, the supervision requirement for diagnostic tests or other services may be more or less stringent than supervision requirements for services and supplies furnished incident to physician's or other practitioner's services. Diagnostic tests need not also meet the incident to requirement in this section. Likewise, pneumococcal, influenza, and hepatitis B vaccines are covered under §1861(s)(10) of the Act and need not also meet incident to requirements. (Physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, clinical psychologists, clinical social workers, physical therapists and occupational therapists all have their own benefit categories and may provide services without direct physician supervision and bill directly for these services. When their services are provided as auxiliary personnel (see under direct physician supervision, they may be covered as incident to services, in which case the incident to requirements would apply.

For purposes of this section, physician means physician or other practitioner (physician, physician assistant, nurse practitioner, clinical nurse specialist, nurse midwife, and clinical psychologist) authorized by the Act to receive payment for services incident to his or her own services.

To be covered incident to the services of a physician or other practitioner, services and supplies must be:

- An integral, although incidental, part of the physician's professional service (see §60.1);
- Commonly rendered without charge or included in the physician's bill (see §60.1A);
- Of a type that are commonly furnished in physician's offices or clinics (see §60.1A);
- Furnished by the physician or by auxiliary personnel under the physician's direct supervision (see §60.1B).

B - Institutional Setting

Hospital services incident to physician's or other practitioner's services rendered to outpatients (including drugs and biologicals which are not usually self-administered by the patient) ,and partial hospitalization services incident to such services may also be covered

The hospital's intermediary makes payment for these services under Part B to a hospital.

60.1 - Incident to Physician's Professional Services

(Rev. 1, 10-01-03)

B3-2050.1

Incident to a physician's professional services means that the services or supplies are furnished as an integral, although incidental, part of the physician's personal professional services in the course of diagnosis or treatment of an injury or illness.

A - Commonly Furnished in Physicians' Offices

Services and supplies commonly furnished in physicians' offices are covered under the incident to provision. Where supplies are clearly of a type a physician is not expected to have on hand in his/her office or where services are of a type not considered medically appropriate to provide in the office setting, they would not be covered under the incident to provision.

Supplies usually furnished by the physician in the course of performing his/her services, e.g., gauze, ointments, bandages, and oxygen, are also covered. Charges for such services and supplies must be included in the physicians' bills. (See §50 regarding coverage of drugs and biologicals under this provision.) To be covered, supplies, including drugs and biologicals, must represent an expense to the physician or legal entity billing fir he services or supplies. For example, where a patient purchases a drug and the physician administers it, the cost of the drug is not covered. However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered if the physician purchased it.

B - Direct Personal Supervision

Coverage of services and supplies incident to the professional services of a physician in private practice is limited to situations in which there is direct physician supervision of auxiliary personnel.

Auxiliary personnel means any individual who is acting under the supervision of a physician, regardless of whether the individual is an employee, leased employee, or independent contractor of the physician, or of the legal entity that employs or contracts with the physician. Likewise, the supervising physician may be an employee, leased employee or independent contractor of the legal entity billing and receiving payment for the services or supplies.

However, the physician personally furnishing the services or supplies or supervising the auxiliary personnel furnishing the services or supplies must have a relationship with the legal entity billing and receiving payment for the services or supplies that satisfies the requirements for valid reassignment. As with the physician's personal professional services, the patient's financial liability for the incident to services or supplies is to the physician or other legal entity billing and receiving payment for the services or supplies. Therefore, the incident to services or supplies must represent an expense incurred by the physician or legal entity billing for the services or supplies.

Thus, where a physician supervises auxiliary personnel to assist him/her in rendering services to patients and includes the charges for their services in his/her own bills, the

services of such personnel are considered incident to the physician's service if there is a physician's service rendered to which the services of such personnel are an incidental part and there is direct supervision by the physician.

This does not mean, however, that to be considered incident to, each occasion of service by auxiliary personnel (or the furnishing of a supply) need also always be the occasion of the actual rendition of a personal professional service by the physician. Such a service or supply could be considered to be incident to when furnished during a course of treatment where the physician performs an initial service and subsequent services of a frequency which reflect his/her active participation in and management of the course of treatment. (However, the direct supervision requirement must still be met with respect to every nonphysician service.)

Direct supervision in the office setting does not mean that the physician must be present in the same room with his or her aide. However, the physician must be present in the office suite and immediately available to provide assistance and direction throughout the time the aide is performing services.

If auxiliary personnel perform services outside the office setting, e.g., in a patient's home or in an institution (other than hospital or SNF), their services are covered incident to a physician's service only if there is direct supervision by the physician. For example, if a nurse accompanied the physician on house calls and administered an injection, the nurse's services are covered. If the same nurse made the calls alone and administered the injection, the services are not covered (even when billed by the physician) since the physician is not providing direct supervision. Services provided by auxiliary personnel in an institution (e.g., nursing, or convalescent home) present a special problem in determining whether direct physician supervision exists. The availability of the physician by telephone and the presence of the physician somewhere in the institution does not constitute direct supervision. (See §70.3 of the Medicare National Coverage Determinations Manual for instructions used if a physician maintains an office in an institution.) For hospital patients and for SNF patients who are in a Medicare covered stay, there is no Medicare Part B coverage of the services of physician-employed auxiliary personnel as services incident to physicians' services under §1861(s)(2)(A) of the Act. Such services can be covered only under the hospital or SNF benefit and payment for such services can be made to only the hospital or SNF by a Medicare intermediary. (See §80 concerning physician supervision of technicians performing diagnostic x-ray procedures in a physician's office.)

60.2 - Services of Nonphysician Personnel Furnished Incident to Physician's Services

(Rev. 1, 10-01-03)

B3-2050.2

In addition to coverage being available for the services of such auxiliary personnel as nurses, technicians, and therapists when furnished incident to the professional services of a physician (as discussed in §60.1), a physician may also have the services of certain nonphysician practitioners covered as services incident to a physician's professional services. These nonphysician practitioners, who are being licensed by the States under

various programs to assist or act in the place of the physician, include, for example, certified nurse midwives, clinical psychologists, clinical social workers, physician assistants, nurse practitioners, and clinical nurse specialists. (See §§150 through 200 for coverage instructions for various allied health/nonphysician practitioners' services.)

Services performed by these nonphysician practitioners incident to a physician's professional services include not only services ordinarily rendered by a physician's office staff person (e.g., medical services such as taking blood pressures and temperatures, giving injections, and changing dressings) but also services ordinarily performed by the physician such as minor surgery, setting casts or simple fractures, reading x-rays, and other activities that involve evaluation or treatment of a patient's condition.

Nonetheless, in order for services of a nonphysician practitioner to be covered as incident to the services of a physician, the services must meet all of the requirements for coverage specified in §§60 through 60.1. For example, the services must be an integral, although incidental, part of the physician's personal professional services, and they must be performed under the physician's direct supervision.

A nonphysician practitioner such as a physician assistant or a nurse practitioner may be licensed under State law to perform a specific medical procedure and may be able (see §§190 or 200, respectively) to perform the procedure without physician supervision and have the service separately covered and paid for by Medicare as a physician assistant's or nurse practitioner's service. However, in order to have that same service covered as incident to the services of a physician, it must be performed under the direct supervision of the physician as an integral part of the physician's personal in-office service. As explained in §60.1, this does not mean that each occasion of an incidental service performed by a nonphysician practitioner must always be the occasion of a service actually rendered by the physician. It does mean that there must have been a direct, personal, professional service furnished by the physician to initiate the course of treatment of which the service being performed by the nonphysician practitioner is an incidental part, and there must be subsequent services by the physician of a frequency that reflects the physician's continuing active participation in and management of the course of treatment. In addition, the physician must be physically present in the same office suite and be immediately available to render assistance if that becomes necessary.

Note also that a physician might render a physician's service that can be covered even though another service furnished by a nonphysician practitioner as incident to the physician's service might not be covered. For example, an office visit during which the physician diagnoses a medical problem and establishes a course of treatment could be covered even if, during the same visit, a nonphysician practitioner performs a noncovered service such as acupuncture.

60.3 - Incident to Physician's Service in Clinic

(Rev. 1, 10-01-03)

B3-2050.3

Services and supplies incident to a physician's service in a physician directed clinic or group association are generally the same as those described above.

A physician directed clinic is one where:

1. A physician (or a number of physicians) is present to perform medical (rather than administrative) services at all times the clinic is open;
2. Each patient is under the care of a clinic physician; and
3. The nonphysician services are under medical supervision.

In highly organized clinics, particularly those that are departmentalized, direct physician supervision may be the responsibility of several physicians as opposed to an individual attending physician. In this situation, medical management of all services provided in the clinic is assured. The physician ordering a particular service need not be the physician who is supervising the service. Therefore, services performed by auxiliary personnel and other aides are covered even though they are performed in another department of the clinic.

Supplies provided by the clinic during the course of treatment are also covered. When the auxiliary personnel perform services outside the clinic premises, the services are covered only if performed under the direct supervision of a clinic physician. If the clinic refers a patient for auxiliary services performed by personnel who are not supervised by clinic physicians, such services are not incident to a physician's service.

60.4 - Services Incident to a Physician's Service to Homebound Patients Under General Physician Supervision

(Rev. 1, 10-01-03)

B3-2051

A - When Covered

In some medically underserved areas there are only a few physicians available to provide services over broad geographic areas or to a large patient population. The lack of medical personnel (and, in many instances, a home health agency servicing the area) significantly reduces the availability of certain medical services to homebound patients. Some physicians and physician-directed clinics, therefore, call upon nurses and other paramedical personnel to provide these services under general (rather than direct) supervision. In some areas, such practice has tended to become the accepted method of delivery of these services.

The Senate Finance Committee Report accompanying the 1972 Amendments to the Act recommended that the direct supervision requirement of the "incident to" provision be modified to provide coverage for services provided in this manner.

Accordingly, to permit coverage of certain of these services, the direct supervision criterion in §60.2 above is **not** applicable to individual or intermittent services outlined in this section when they are performed by personnel meeting any pertinent State requirements (e.g., a nurse, technician, or physician extender) and where the criteria listed below also are met:

1 The patient is homebound; i.e., confined to his or her home (see §60.4.1 for the definition of a "homebound" patient and §110.1 (D) for the definition of patient's "place of residence."

2 The service is an integral part of the physician's service to the patient (the patient must be one the physician is treating), and is performed under general physician supervision by employees of the physician or clinic. General supervision means that the physician need not be physically present at the patient's place of residence when the service is performed; however, the service must be performed under his or her overall supervision and control.

The physician orders the service(s) to be performed, and contact is maintained between the nurse or other employee and the physician, e.g., the employee contacts the physician directly if additional instructions are needed, and the physician must retain professional responsibility for the service. All other "incident to" requirements must be met (see §§60-60.4).

3 The services are included in the physician's/clinic's bill, and the physician or clinic has incurred an expense for them (see §60.2).

4 The services of the paramedical are required for the patient's care; that is, they are reasonable and necessary as defined in the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §20.

5 When the service can be furnished by an HHA in the local area, it **cannot** be covered when furnished by a physician/clinic to a homebound patient under this provision, except as described in §60.4.C.

B - Covered Services

Where the requirements in §60.4.A are met, the direct supervision requirement in §60.2 is not applicable to the following services:

1. Injections;
2. Venipuncture;
3. EKGs;
4. Therapeutic exercises;
5. Insertion and sterile irrigation of a catheter;
6. Changing of catheters and collection of catheterized specimen for urinalysis and culture;
7. Dressing changes, e.g., the most common chronic conditions that may need dressing changes are decubitus care and gangrene;
8. Replacement and/or insertion of nasogastric tubes;
9. Removal of fecal impaction, including enemas;
10. Sputum collection for gram stain and culture, and possible acid-fast and/or fungal stain and culture;

11. Paraffin bath therapy for hands and/or feet in rheumatoid arthritis or osteoarthritis;
12. Teaching and training the patient for:
    a. The care of colostomy and ileostomy;
    b. The care of permanent tracheostomy;
    c. Testing urine and care of the feet (diabetic patients only); and
    d. Blood pressure monitoring.

Teaching and training services (also referred to as educational services) can be covered only where they provide knowledge essential for the chronically ill patient's participation in his or her own treatment and only where they can be reasonably related to such treatment or diagnosis. Educational services that provide more elaborate instruction than is necessary to achieve the required level of patient education are not covered. After essential information has been provided, the patient should be relied upon to obtain additional information on his or her own.

C - Relation to Home Health Benefits

This coverage should not be considered as an alternative to home health benefits where there is a participating home health agency in the area which could provide the needed services on a timely basis. For example, two of the three services initially included under this coverage - injections and venipuncture - are skilled nursing services that could be covered as home health services (EKG is not a covered Home Health Agency (HHA) service) if the patient is eligible for home health benefits and there is a home health agency available. Thus, postpayment review of these claims will include measures to assure that physicians and clinics do not provide a substantial number of services under this coverage when they could otherwise have been performed by a home health agency.

In these circumstances, the physician or clinic is expected to assist the patient in obtaining such skilled services together with the other home health services (such as aide services). However, HHA services are not considered available where the HHA cannot respond on a timely basis or where the physician could not have foreseen that intermittent services would be needed.

Refer to the Medicare Claims Processing Manual, Chapter 10, "Home Health Agency Billing," for a more in depth discussion of home health services.

60.4.1 - Definition of Homebound Patient Under the Medicare Home Health (HH) Benefit

(Rev. 1, 10-01-03)

B3-2051.1

This definition applies to homebound for purposes of the Medicare home health benefit. An individual does not have to be bedridden to be considered as confined to home. However, the condition of these patients should be such that there exists a normal inability to leave home and, consequently, leaving his or her home would require a considerable and taxing effort. If the patient does in fact leave the home, the patient may

nevertheless be considered homebound if the absences from the home are infrequent or for periods of relatively short duration. It is expected that in most instances absences from the home will be for the purpose of receiving medical treatment. However, occasional absences from the home for nonmedical purposes, e.g., an occasional trip to the barber, a walk around the block, a drive attendance at a family reunion, funeral, graduation, or other infrequent or unique event would not necessitate a finding that the individual is not homebound if absences are undertaken on an infrequent basis or are of relatively short duration and do not indicate that the patient has the capacity to obtain the health care provided outside rather than in the home.

The above examples are not all-inclusive and are meant to be illustrative of the kinds of infrequent or unique events a patient may attend. Generally speaking, a beneficiary will be considered to be homebound if the beneficiary has a condition due to an illness or injury which restricts ability to leave the residence except with the aid of supportive devices such as crutches, canes, wheelchairs, and walkers, the use of special transportation, or the assistance of another person or if the beneficiary has a condition which is such that leaving home is medically contraindicated. The following are some examples of homebound patients:

- A beneficiary paralyzed from a stroke who is confined to a wheelchair or who requires the aid of crutches in order to walk;
- A beneficiary who is blind or senile and, therefore, requires the assistance of another person in leaving his or her residence;
- A beneficiary who has lost the use of the upper extremities and, therefore, is unable to open doors, use handrails on stairways, etc., and therefore, requires the assistance of another individual in leaving his or her place of residence;
- A beneficiary who has just returned from a hospital stay involving surgery who may be suffering from resultant weakness and pain and, therefore, his or her actions may be restricted by the physician to certain specified and limited activities such as getting out of bed only for a specified period of time, or walking stairs only once a day;
- A beneficiary with arteriosclerotic heart disease of such severity that the beneficiary must avoid all stress and physical activity;
- A beneficiary with a psychiatric problem if the illness is manifested in part by a refusal to leave the home environment or it is not considered safe for the beneficiary to leave home unattended, even if he/she had no physical limitations, and
- A beneficiary in the late stages of ALS or a neurodegenerative disability.

In determining whether the patient has the general inability to leave the home and leaves the home only infrequently or for periods of short duration, it is necessary (as is the case in determining whether skilled nursing services are intermittent) to look at the patient's condition over a period of time rather than for short periods within the home health stay. For example, a patient may leave the home (under the conditions described above, e.g, with severe and taxing effort, with the assistance of others) more frequently during a

short period when, for example, the presence of visiting relatives provides a unique opportunity for such absences, than is normally the case. So long as the patient's overall condition and experience is such that he or she meets these qualifications, he or she should be considered confined to the home.

The aged person who does not often travel from home because of feebleness and insecurity brought on by advanced age is not considered confined to home for purposes of this reimbursement unless the person's condition is analogous to those above.

If for any reason a question is raised as to whether an individual is confined to home, the carrier will ask the physician to furnish the information necessary to establish if the beneficiary is homebound, as defined above.

70 - Sleep Disorder Clinics

(Rev. 1, 10-01-03)

B3-2055

Sleep disorder clinics are facilities in which certain conditions are diagnosed through the study of sleep. Such clinics are for diagnosis, therapy, and research. Sleep disorder clinics may provide some diagnostic or therapeutic services which are covered under Medicare. These clinics may be affiliated either with a hospital or a freestanding facility. Whether a clinic is hospital-affiliated or freestanding, coverage for diagnostic services under some circumstances is covered under provisions of the law different from those for coverage of therapeutic services.

A - Criteria for Coverage of Diagnostic Tests

All reasonable and necessary diagnostic tests given for the medical conditions listed in subsection B are covered when the following criteria are met:

- The clinic is either affiliated with a hospital or is under the direction and control of physicians. Diagnostic testing routinely performed in sleep disorder clinics may be covered even in the absence of direct supervision by a physician;
- Patients are referred to the sleep disorder clinic by their attending physicians, and the clinic maintains a record of the attending physician's orders; and
- The need for diagnostic testing is confirmed by medical evidence, e.g., physician examinations and laboratory tests.

Diagnostic testing that is duplicative of previous testing done by the attending physician to the extent the results are still pertinent is not covered because it is not reasonable and necessary under §1862(a)(1)(A) of the Act.

B - Medical Conditions for Which Testing is Covered

Diagnostic testing is covered only if the patient has the symptoms or complaints of one of the conditions listed below. Most of the patients who undergo the diagnostic testing are not considered inpatients, although they may come to the facility in the evening for testing and then leave after testing is over. The overnight stay is considered an integral part of these tests.

1. **Narcolepsy** - This term refers to a syndrome that is characterized by abnormal sleep tendencies, e.g., excessive daytime sleepiness or disturbed nocturnal sleep. Related diagnostic testing is covered if the patient has inappropriate sleep episodes or attacks (e.g., while driving, in the middle of a meal, in the middle of a conversation), amnesiac episodes, or continuous disabling drowsiness. The sleep disorder clinic must submit documentation that this condition is severe enough to interfere with the patient's well being and health before Medicare benefits may be provided for diagnostic testing. Ordinarily, a diagnosis of narcolepsy can be confirmed by three sleep naps. If more than three sleep naps are claimed, the carrier will require persuasive medical evidence justifying the medical necessity for the additional test(s). It will use HCPCS procedure codes 95828 and 95805.

2. **Sleep Apnea** - This is a potentially lethal condition where the patient stops breathing during sleep. Three types of sleep apnea have been described (central, obstructive, and mixed). The nature of the apnea episodes can be documented by appropriate diagnostic testing. Ordinarily, a single polysomnogram and electroencephalogram (EEG) can diagnose sleep apnea. If more than one such testing session is claimed, the carrier will require persuasive medical evidence justifying the medical necessity for the additional tests. It will use HCPCS procedure codes 95807, 95810, and 95822.

3. **Impotence** - Diagnostic nocturnal penile tumescence testing may be covered, under limited circumstances, to determine whether erectile impotence in men is organic or psychogenic. Although impotence is not a sleep disorder, the nature of the testing requires that it be performed during sleep. The tests ordinarily are covered only where necessary to confirm the treatment to be given (surgical, medical, or psychotherapeutic). Ordinarily, a diagnosis may be determined by two nights of diagnostic testing. If more than two nights of testing are claimed, the carrier will require persuasive medical evidence justifying the medical necessity for the additional tests. It will have its medical staff review questionable cases to ensure that the tests are reasonable and necessary for the individual. It will use HCPCS procedure code 54250. (See the Medicare National Coverage Determinations Manual, Chapter 1, for policy on coverage of diagnosis and treatment of impotence.)

4. **Parasomnia** - Parasomnias are a group of conditions that represent undesirable or unpleasant occurrences during sleep. Behavior during these times can often lead to damage to the surroundings and injury to the patient or to others. Parasomnia may include conditions such as sleepwalking, sleep terrors, and rapid eye movement (REM) sleep behavior disorders. In many of these cases, the nature of these conditions may be established by careful clinical evaluation. Suspected seizure disorders as possible cause of the parasomnia are appropriately evaluated by standard or prolonged sleep EEG studies. In cases where seizure disorders have been ruled out and in cases that present a history of repeated violent or injurious episodes during sleep, polysomnography may be useful in providing a diagnostic classification or prognosis. The carrier must use HCPCS procedure codes 95807, 95810, and/or 95822.

C - Polysomnography for Chronic Insomnia Is Not Covered.

Evidence at the present time is not convincing that polysomnography in a sleep disorder clinic for chronic insomnia provides definitive diagnostic data or that such information is useful in patient treatment or is associated with improved clinical outcome. The use of polysomnography for diagnosis of patients with chronic insomnia is not covered under Medicare because it is not reasonable and necessary under §1862(a)(1)(A) of the Act.

D - Coverage of Therapeutic Services.

Sleep disorder clinics may at times render therapeutic as well as diagnostic services. Therapeutic services may be covered in a hospital outpatient setting or in a freestanding facility provided they meet the pertinent requirements for the particular type of services and are reasonable and necessary for the patient, and are performed under the direct supervision of a physician.

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

(Rev. 1, 10-01-03)

B3-2070

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 or outpatient. Section 410.32(b) of the Code of Federal Regulations (CFR) requires that diagnostic tests covered under §1861(s)(3) of the Act (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; 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. 1, 10-01-03)

B3-2070.1

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 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

(Rev. 1, 10-01-03)

B3-2070.2

The diagnostic testing services performed by a psychologist (who is not a clinical psychologist as defined in §160.A) practicing independently of an institution, agency, or physician's office are covered as other diagnostic tests if a physician orders such testing. Medicare covers this type of testing as an outpatient service if furnished by any psychologist who is licensed or certified to practice psychology in the State or jurisdiction where the psychologist is 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 clinical psychologists,

whose services are covered under this provision include, but are not limited to, educational psychologists and counseling psychologists.)

To determine whether the diagnostic psychological testing services of a particular independent psychologist are covered under Part B in States that have statutory licensure or certification, the carrier secures from the appropriate State agency a current listing of psychologists holding the required credentials. In States or territories that lack statutory licensing and certification, the carrier checks individual qualifications when provider numbers are issued. Possible reference sources are the national directory of membership of the American Psychological Association, which provides data about the educational background of individuals and indicates which members are board-certified, and records and directories of the State or territorial psychological association. If qualification is dependent on a doctoral degree from a currently accredited program, the carrier verifies the date of accreditation of the school involved, since such accreditation is not retroactive. If the reference sources listed above do not provide enough information (e.g., the psychologist is not a member of the association), the carrier contacts the psychologist personally for the required information. Generally, carriers maintain a continuing list of psychologists whose qualifications have been verified.

NOTE: Diagnostic psychological testing services performed by persons who meet these requirements are covered as other diagnostic tests. When, however, the psychologist is not practicing independently, but is on the staff of an institution, agency, or clinic, that entity bills for the diagnostic services.

Expenses for such testing are not subject to the payment limitation on treatment for mental, psychoneurotic, and personality disorders. Independent psychologists are not required by law to accept assignment when performing psychological tests. However, regardless of whether the psychologist accepts assignment, the psychologist must report on the claim form the name and address of the physician who ordered the test.

The carrier considers psychologists as practicing independently when:

They render services on their own responsibility, free of the administrative and professional control of an employer such as a physician, institution, agency;

- The persons they treat are their own patients; and
- They have the right to bill directly, collect and retain the fee for their services.

A psychologist practicing in an office located in an institution may be considered an independently practicing psychologist when both of the following conditions exist:

The office is confined to a separately-identified part of the facility which is used solely as the psychologist's office and cannot be construed as extending throughout the entire institution; and

The psychologist conducts a private practice, i.e., services are rendered to patients from outside the institution as well as to institutional patients

80.3 - Otologic Evaluations

(Rev. 1, 10-01-03)

B3-2070.3, PM-B-01-34, B-02-004, PM AB-02-080

Diagnostic testing, including hearing and balance assessment services, performed by a qualified audiologist is covered as "other diagnostic tests" under §1861(s)(3) of the Act when a physician orders such testing for the purpose of obtaining information necessary for the physician's diagnostic evaluation or to determine the appropriate medical or surgical treatment of a hearing deficit or related medical problem. Services are excluded by virtue of §1862(a)(7) of the Act when the diagnostic information required to determine the appropriate medial or surgical treatment is already known to the physician, or the diagnostic services are performed only to determine the need for or the appropriate type of hearing aid.

Diagnostic services performed by a qualified audiologist and meeting the above requirements are payable as "other diagnostic tests". The payment for these services is determined by the reason the tests were performed, rather than the diagnosis or the patient's condition. Payment for these services is based on the physician fee schedule amount except for audiology services furnished in a hospital outpatient department which are paid under the Outpatient Prospective Payment System. 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.

If a physician refers a beneficiary to an audiologist for evaluation of signs or symptoms associated with hearing loss or ear injury, the audiologist's diagnostic services should be covered even if the only outcome is the prescription of a hearing aid. If a beneficiary undergoes diagnostic testing performed by an audiologist without a physician referral, the tests are not covered even if the audiologist discovers a pathologic condition.

80.3.1 - Definition of Qualified Audiologist

(Rev. 1, 10-01-03)

B3-2070.3

Section 1861(ll)(3) of the Act, provides that a qualified audiologist is an individual with a master's or doctoral degree in audiology and 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),

      Performed not less than nine 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.

To determine whether a particular audiologist is qualified under the above definition, the carrier will need to check individual qualifications. Possible reference sources for determining an audiologist's professional qualifications are the national directory published annually by the American Speech and Hearing Association (which indicates which individuals are certified) and records and directories, which may be available from the State Speech and Hearing Associations. In addition, carriers in states which have statutory licensure or certification should secure from the appropriate State agency a current listing of audiologists holding the required credentials.

NOTE: There is no provision for direct payment to audiologists for therapeutic services.

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 either 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. 1, 10-01-03)

B3-2070.4.C

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 arms and legs, pelvis, vertebral column, and skull;
- Chest films which do not involve the use of contrast media (except routine screening procedures and tests in connection with routine physical examinations); and
- Abdominal films which do not involve the use of contrast media.

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.

90 - X-Ray, Radium, and Radioactive Isotope Therapy

(Rev. 1, 10-01-03)

B3-2075

These services also include materials and services of technicians.

X-ray, radium, and radioactive isotope therapy furnished in a nonprovider facility require direct personal supervision of a physician. The physician need not be in the same room, but must be in the area and immediately available to provide assistance and direction throughout the time the procedure is being performed. This level of physician involvement does not represent a physician's service and cannot be billed as a Part B service. The physician would have to furnish a reasonable and necessary professional service as defined in §§30 of this chapter, in order for the physician's activity to be covered.

However, effective for radiation therapy services furnished on or after April 1, 1989, radiologists' weekly treatment management services are covered.

A separate charge for the services of a physicist is not recognized unless such services are covered under the "incident to" provision (§60.1 of this chapter) or the services are included as part of a technical component service billed by a freestanding radiation therapy center. The incident to provision may also be extended to include all necessary and appropriate services supplied by a radiation physicist assisting a radiologist when the physicist is in the physician's employ and working under his or her direct supervision.

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, leotards, 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. (See §§60.1, 180, 190, 200, and 210.) 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 purchases 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.

Category Code	Definition
IN	Inexpensive and Other Routinely Purchased Items
FS	Frequently Serviced Items
CR	Capped Rental Items

Category Code	Definition
OX	Oxygen and Oxygen Equipment
OS	Ostomy, Tracheostomy & Urological Items
SD	Surgical Dressings
PO	Prosthetics & Orthotics
SU	Supplies
TE	Transcutaneous Electrical Nerve Stimulators

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

(Rev. 1, 10-01-03)

B3-2100.1, A3-3113.1, HO-235.1, HHA-220.1, B3-2100.2, A3-3113.2, HO-235.2, HHA-220.2

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, lambs 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," §30.1, for coverage of home use of hemodialysis.) NOTE: There is a wide variety in types of respirators and suction machines. The DMERC's 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 nonmedical 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 exercycle), 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; and

    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 advance 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 DMERC 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 DMERC or intermediary 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

B3-2100.3, A3-3113.6, HO-235.6, HHA-220.3

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. 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

(Rev. 1, 10-01-03)

B3-2100.4, A3-3113.3, HO-235.3, HHA-220.4

Under the circumstances specified below, payment may be made for repair, maintenance, and replacement of medically required DME which the beneficiary owns or is purchasing, including equipment which had been in use before the user enrolled in Part B of the program.

A - Repairs

B3-2100.4, A3-3113.3A, HO-235.3A

Repairs to equipment, which a beneficiary is purchasing or already owns are covered when necessary to make the equipment serviceable. A service charge may include the use of **"**loaner" equipment where this is required. 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.)

B - Maintenance

B3-2100.4, A3-3113.3.B, HO-235.3.B

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 the beneficiary. Normally, purchasers of DME are given operating manuals which describe the type of servicing an owner may perform to properly maintain the equipment. 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.

This might include, for example, breaking down sealed components and performing tests which require specialized testing equipment not available to the beneficiary.

For capped rental items which have reached the 15-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.

C - Replacement

B3-2100.4, A3-3113.3.C, HO-235.3.C

Replacement of equipment is covered in cases which the beneficiary owns or is purchasing is covered in cases of loss or irreparable damage or wear and when required because of a change in the patient's condition. Expenses for replacement required because of loss or irreparable damage may be reimbursed without a physician's order when in the judgment of the DMERC the equipment as originally ordered, considering the age of the order, still fills the patient's medical needs. However, claims involving replacement equipment necessitated because of wear or a change in the patient's condition must be supported by a current physician's order.

If a capped rental item of equipment has been in continuous use by the patient, on either a rental or purchase basis, for the equipment's useful lifetime or if the item is lost or irreparably damaged, the patient may elect to obtain a new piece of equipment. The contractor determines the reasonable useful lifetime for capped rental equipment but in no case can it be less than five years. Computation of the useful lifetime is based on when the equipment is delivered to the beneficiary, not the age of the equipment.

Payment may not be made for items covered under a manufacturer's or supplier's warranty. (See the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," and the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," in regard to payment for equipment replaced under a warranty.) Cases suggesting malicious damage, culpable neglect, or wrongful disposition of equipment should be investigated and denied where the DMERC determines that it is unreasonable to make program payment under the circumstances. DMERCs refer such cases to the program integrity specialist in the RO.

D - Delivery

B3-2100.4, A3-3113.3.D, HO-235.3.D

Delivery and service charges are covered, but the related payment is included in the fee schedule for the related item. Separate payment is not made.

However, where special circumstances apply, e.g., beneficiary lives in remote area, or equipment could not be obtained from a local dealer special consideration can be applied at the discretion of the DMERC/intermediary.

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 denied. 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 a determination that there is no possibility that the patient's condition may improve sometime in the future. If the medical record, including the judgment of the attending physician, indicates the condition is of long and indefinite duration, the test of permanence is considered met. (Such a device may also be covered under §60.1 as a supply when furnished incident to a physician's service.)

Examples of prosthetic devices include artificial limbs, parenteral and enteral (PEN) nutrition, cardiac pacemakers, prosthetic lenses (see subsection B), breast prostheses (including a surgical brassiere) for postmastectomy patients, maxillofacial devices, and devices which replace all or part of the ear or nose. A urinary collection and retention system with or without a tube is a prosthetic device replacing bladder function in case of permanent urinary incontinence. The foley catheter is also considered a prosthetic device when ordered for a patient with permanent urinary incontinence. However, chucks, diapers, rubber sheets, etc., are supplies that are not covered under this provision. Although hemodialysis equipment is a prosthetic device, payment for the rental or purchase of such equipment in the home is made only for use under the provisions for payment applicable to durable medical equipment.

An exception is that if payment cannot be made on an inpatient's behalf under Part A, hemodialysis equipment, supplies, and services required by such patient could be covered under Part B as a prosthetic device, which replaces the function of a kidney. See the Medicare Benefit Policy Manual, Chapter 11, "End Stage Renal Disease," for payment for hemodialysis equipment used in the home. See the Medicare Benefit Policy Manual,

Chapter 1, "Inpatient Hospital Services," §10, for additional instructions on hospitalization for renal dialysis.

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 blenderized 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(h)(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 irreparable 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 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 far vision, and prosthetic lenses in frames for near 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 is covered when ordered by a physician. General provisions relating to the repair and replacement of durable medical equipment in §110.2 for the repair and replacement of prosthetic devices are applicable. (See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §40.4, for payment for devices replaced under a warranty.) Replacement of conventional eyeglasses or contact lenses furnished in accordance with §120.B.3 is not covered.

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

130 - Leg, Arm, Back, and Neck Braces, Trusses, and Artificial Legs, Arms, and Eyes

(Rev. 1, 10-01-03)

B3-2133, A3-3110.5, HO-228.5, AB-01-06 dated 1/18/01

These appliances are covered under Part B when furnished incident to physicians' services or on a physician's order. A brace includes rigid and semi-rigid devices which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Back braces include, but are not limited to, special corsets, e.g., sacroiliac, sacrolumbar, dorsolumbar corsets, and belts. A terminal device (e.g., hand or hook) is covered under this provision whether an artificial limb is required by the patient. Stump stockings and harnesses (including replacements) are also covered when these appliances are essential to the effective use of the artificial limb.

Adjustments to an artificial limb or other appliance 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

(Rev. 1, 10-01-03)

B3-2134

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 Artificial 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 100-1, 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 torus palatinus (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.

160 - Clinical Psychologist Services

(Rev. 1, 10-01-03)

B3-2150

A - Clinical Psychologist (CP) Defined

To qualify as a clinical psychologist (CP), a practitioner must meet the following requirements:

- Hold a doctoral degree in psychology;
- Be licensed or certified, on the basis of the doctoral degree in psychology, by the State in which he or she practices, at the independent practice level of psychology to furnish diagnostic, assessment, preventive, and therapeutic services directly to individuals.

B - Qualified Clinical Psychologist Services Defined

Effective July 1, 1990, the diagnostic and therapeutic services of CPs and services and supplies furnished incident to such services are covered as the services furnished by a physician or as incident to physician's services are covered. However, the CP must be legally authorized to perform the services under applicable licensure laws of the State in which they are furnished.

C - Types of Clinical Psychologist Services That May Be Covered

The CPs may provide the following services:

- Diagnostic and therapeutic services that the CP is legally authorized to perform in accordance with State law and/or regulation. Carriers pay all qualified CPs based on the physician fee schedule for the diagnostic and therapeutic services. (Psychological tests by practitioners who do not meet the requirements for a CP may be covered under the provisions for diagnostic tests as described in §80.2.
- Services and supplies furnished incident to a CP's services are covered if the requirements that apply to services incident to a physician's services, as described in §60 are met. These services must be:
    - Mental health services that are commonly furnished in CPs' offices;
    - An integral, although incidental, part of professional services performed by the CP;
    - Performed under the direct personal supervision of the CP; i.e., the CP must be physically present and immediately available; and
    - Furnished without charge or included in the CP's bill.

Any person involved in performing the service must be an employee of the CP (or an employee of the legal entity that employs the supervising CP) under the common law control test of the Act, as set forth in 20 CFR 404.1007 and §RS 2101.020 of the Retirement and Survivors Insurance part of the Social Security Program Operations Manual System.

Carriers are required to familiarize themselves with appropriate State laws and/or regulations governing a CP's scope of practice.

D - Noncovered Services

The services of CPs are not covered if the service is otherwise excluded from Medicare coverage even though a clinical psychologist is authorized by State law to perform them. For example, §1862(a)(1)(A) of the Act excludes from coverage 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, even though the services are authorized by State law, the services of a CP that are determined to be not reasonable and necessary are not covered. Additionally, any therapeutic services that are billed by CPs under CPT psychotherapy codes that include medical evaluation and management services are not covered.

E - Requirement for Consultation

When applying for a Medicare provider number, a CP must submit to the carrier a signed Medicare provider/supplier enrollment form that indicates an agreement to the effect that, contingent upon the patient's consent, the CP will attempt to consult with the patient's attending or primary care physician in accordance with accepted professional ethical norms, taking into consideration patient confidentiality.

If the patient assents to the consultation, the CP must attempt to consult with the patient's physician within a reasonable time after receiving the consent. If the CP's attempts to consult directly with the physician are not successful, the CP must notify the physician within a reasonable time that he or she is furnishing services to the patient. Additionally, the CP must document, in the patient's medical record, the date the patient consented or declined consent to consultations, the date of consultation, or, if attempts to consult did not succeed, that date and manner of notification to the physician.

The only exception to the consultation requirement for CPs is in cases where the patient's primary care or attending physician refers the patient to the CP. Also, neither a CP nor a primary care nor attending physician may bill Medicare or the patient for this required consultation.

F - Outpatient Mental Health Services Limitation

All covered therapeutic services furnished by qualified CPs are subject to the outpatient mental health services limitation in Pub 100-1, Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3, "Deductibles, Coinsurance Amounts, and Payment Limitations," §30, (i.e., only 62 1/2 percent of expenses for these services are considered incurred expenses for Medicare purposes). The limitation does not apply to diagnostic services.

G - Assignment Requirement

Assignment is required.

170 - Clinical Social Worker (CSW) Services

(Rev. 1, 10-01-03)

B3-2152

See the Medicare Claims Processing Manual Chapter 12, Physician/Nonphysician Practitioners, §150, "Clinical Social Worker Services," for payment requirements.

A - Clinical Social Worker Defined

Section 1861(hh) of the Act defines a "clinical social worker" as an individual who:

- Possesses a master's or doctor's degree in social work;
- Has performed at least two years of supervised clinical social work; and
- Is licensed or certified as a clinical social worker by the State in which the services are performed; or
- In the case of an individual in a State that does not provide for licensure or certification, has completed at least 2 years or 3,000 hours of post master's degree

supervised clinical social work practice under the supervision of a master's level social worker in an appropriate setting such as a hospital, SNF, or clinic.

B - Clinical Social Worker Services Defined

Section 1861(hh)(2) of the Act defines "clinical social worker services" as those services that the CSW is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed for the diagnosis and treatment of mental illnesses. Services furnished to an inpatient of a hospital or an inpatient of a SNF that the SNF is required to provide as a requirement for participation are not included. The services that are covered are those that are otherwise covered if furnished by a physician or as incident to a physician's professional service.

C - Covered Services

Coverage is limited to the services a CSW is legally authorized to perform in accordance with State law (or State regulatory mechanism established by State law). The services of a CSW may be covered under Part B if they are:

- The type of services that are otherwise covered if furnished by a physician, or as incident to a physician's service. (See §30 for a description of physicians' services and §70 of Pub 100-1, the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, for the definition of a physician.);
- Performed by a person who meets the definition of a CSW (See subsection A.); and
- Not otherwise excluded from coverage.

Carriers should become familiar with the State law or regulatory mechanism governing a CSW's scope of practice in their service area.

D - Noncovered Services

Services of a CSW are not covered when furnished to inpatients of a hospital or to inpatients of a SNF if the services furnished in the SNF are those that the SNF is required to furnish as a condition of participation in Medicare. In addition, CSW services are not covered if they are otherwise excluded from Medicare coverage even though a CSW is authorized by State law to perform them. For example, the Medicare law excludes from coverage 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."

E - Outpatient Mental Health Services Limitation

All covered therapeutic services furnished by qualified CSWs are subject to the outpatient psychiatric services limitation in Pub 100-1, Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3, "Deductibles, Coinsurance Amounts, and Payment Limitations," §30, (i.e., only 62 1/2 percent of expenses for these services are considered incurred expenses for Medicare purposes). The limitation does not apply to diagnostic services.

F - Assignment Requirement

Assignment is required.

180 - Nurse-Midwife (CNM) Services

(Rev. 1, 10-01-03)

B3-2154

A - General

Effective on or after July 1, 1988, the services provided by a certified nurse-midwife or incident to the certified nurse-midwife's services are covered. Payment is made under assignment only.

See the Medicare Claims Processing Manual, Chapter 12, "Physician and Nonphysician Practitioners," §130, for payment methodology for nurse midwife services.

B - Certified Nurse-Midwife Defined

A certified nurse-midwife is a registered nurse who has successfully completed a program of study and clinical experience in nurse-midwifery, meeting guidelines prescribed by the Secretary, or who has been certified by an organization recognized by the Secretary. The Secretary has recognized certification by the American College of Nurse-Midwives and State qualifying requirements in those States that specify a program of education and clinical experience for nurse-midwives for these purposes. A nurse-midwife must:

- Be currently licensed to practice in the State as a registered professional nurse; and
- Meet one of the following requirements:
    1. Be legally authorized under State law or regulations to practice as a nurse-midwife and have completed a program of study and clinical experience for nurse-midwives, as specified by the State; or
    2. If the State does not specify a program of study and clinical experience that nurse-midwives must complete to practice in that State, the nurse-midwife must:
        a. Be currently certified as a nurse-midwife by the American College of Nurse-Midwives;
        b. Have satisfactorily completed a formal education program (of at least one academic year) that, upon completion, qualifies the nurse to take the certification examination offered by the American College of Nurse-Midwives; or
        c. Have successfully completed a formal education program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and have practiced as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976, to July 16, 1982.

C - Covered Services

1 - General - Effective January 1, 1988, through December 31, 1993, the coverage of nurse-midwife services was restricted to the maternity cycle. The maternity cycle is a period that includes pregnancy, labor, and the immediate postpartum period.

Beginning with services furnished on or after January 1, 1994, coverage is no longer limited to the maternity cycle. Coverage is available for services furnished by a nurse-midwife that he or she is legally authorized to perform in the State in which the services are furnished and that would otherwise be covered if furnished by a physician, including obstetrical and gynecological services.

2 - Incident To - Services and supplies furnished incident to a nurse midwife's service are covered if they would have been covered when furnished incident to the services of a doctor of medicine or osteopathy, as described in §60.

D - Noncovered Services

The services of nurse-midwives are not covered if they are otherwise excluded from Medicare coverage even though a nurse-midwife is authorized by State law to perform them. For example, the Medicare program excludes from coverage 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.

Coverage of service to the newborn continues only to the point that the newborn is or would normally be treated medically as a separate individual. Items and services furnished the newborn from that point are not covered on the basis of the mother's eligibility.

E - Relationship With Physician

Most States have licensure and other requirements applicable to nurse-midwives. For example, some require that the nurse-midwife have an arrangement with a physician for the referral of the patient in the event a problem develops that requires medical attention. Others may require that the nurse-midwife function under the general supervision of a physician. Although these and similar State requirements must be met in order for the nurse-midwife to provide Medicare covered care, they have no effect on the nurse-midwife's right to personally bill for and receive direct Medicare payment. That is, billing does not have to flow through a physician or facility.

See §60.2 for coverage of services performed by nurse-midwives incident to the service of physicians.

F - Place of Service

There is no restriction on place of service. Therefore, nurse-midwife services are covered if provided in the nurse-midwife's office, in the patient's home, or in a hospital or other facility, such as a clinic or birthing center owned or operated by a nurse-midwife.

G. Assignment Requirement

Assignment is required.

190 - Physician Assistant (PA) Services

(Rev. 1, 10-01-03)

B3-2156

Effective for services rendered on or after January 1, 1998, any individual who is participating under the Medicare program as a physician assistant for the first time 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 PA services in the State where the services are performed. PAs who were issued billing provider numbers prior to January 1, 1998 may continue to furnish services under the PA benefit.

See the Medicare Claims Processing Manual, Chapter 12, "Physician and Nonphysician Practitioners," §110, for payment methodology for PA services. Payment is made under assignment only.

A - Qualifications for PAs

To furnish covered PA services, the PA must meet the conditions as follows:

1. Have graduated from a physician assistant educational program that is accredited by the Accreditation Review Commission on Education for the Physician Assistant (its predecessor agencies, the Commission on Accreditation of Allied Health Education Programs (CAAHEP) and the Committee on Allied Health Education and Accreditation (CAHEA); or
2. Have passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants (NCCPA); and
3. Be licensed by the State to practice as a physician assistant.

B - Covered Services

Coverage is limited to the services a PA is legally authorized to perform in accordance with State law (or State regulatory mechanism provided by State law).

1 - General

The services of a PA may be covered under Part B, if all of the following requirements 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 all the PA qualifications,
- They are performed under the general supervision of an MD/DO;
- The PA is legally authorized to perform the services in the state in which they are performed; and
- They are not otherwise precluded from coverage because of one of the statutory exclusions.

2 - Incident To

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

3 - Types of PA Services That May Be Covered

State law or regulation governing a PA's scope of practice in the State in which the services are performed applies. Carriers should consider developing lists of covered services. Also, if authorized under the scope of their State license, PAs may furnish services billed under all levels of CPT evaluation and management codes, and diagnostic tests if furnished under the general supervision of a physician.

Examples of the types of services that PAs may provide 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.

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

4 - Services Otherwise Excluded From Coverage

PA services may not be covered if they are otherwise excluded from coverage even though a PA 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 a PA's scope of practice under State law.

C - Physician Supervision

The PA's physician supervisor (or a physician designated by the supervising physician or employer as provided under State law or regulations) is primarily responsible for the overall direction and management of the PA's professional activities and for assuring that the services provided are medically appropriate for the patient. The physician supervisor (or physician designee) need not be physically present with the PA when a service is being furnished to a patient and may be contacted by telephone, if necessary, unless State law or regulations require otherwise.

D - Employment Relationship

Payment for the services of a PA may be made only to the actual qualified employer of the PA that is eligible to enroll in the Medicare program under existing Medicare provider/supplier categories. If the employer of the PA is a professional corporation or other duly qualified legal entity (such as a limited liability company or a limited liability partnership), properly formed, authorized and licensed under State laws and regulations, that permits PA ownership in such corporation nor entity as a stockholder or member, that corporation or entity as the employer may bill for PA services even if a PA is a stockholder or officer of the entity, as long as the entity is entitled to enroll as a "provider of services" or a supplier of services in the Medicare program. Physician Assistants may

not otherwise organize or incorporate and bill for their services directly to the Medicare program, including as, but not limited to sole proprietorships or general partnerships. Accordingly, a qualified employer is not a group of PAs that incorporate to bill for their services. Leasing agencies and staffing companies do not qualify under the Medicare program as "providers of services" or suppliers of services.

200 - Nurse Practitioner (NP) Services

(Rev. 1, 10-01-03)

B3-2158

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:

- American Academy of Nurse Practitioners;
- American Nurses Credentialing Center;
- National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties;
- National Certification Board of Pediatric Nurse Practitioners and Nurses;
- Oncology Nurses Certification Corporation; and
- Critical Care Certification Corporation.

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.

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 NP's 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

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 a NP's scope of practice under State law.

D - Collaboration

Collaboration is a process in which a 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.

210 - Clinical Nurse Specialist (CNS) Services

(Rev. 1, 10-01-03)

B3-2160

Effective for services rendered after January 1, 1998, any individual who is participating under the Medicare program as a clinical nurse specialist (CNS) 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 CNS services in the State where the services are performed. CNSs who were issued billing provider numbers prior to January 1, 1998, may continue to furnish services under the CNS benefit.

Payment for CNS 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 CNSs

In order to furnish covered CNS services, a CNS must meet the conditions as follows:

1. Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to furnish the services of a clinical nurse specialist in accordance with State law;
2. Have a master's degree in a defined clinical area of nursing from an accredited educational institution; and
3. Be certified as a clinical nurse specialist by the American Nurses Credentialing Center.

B - Covered Services

Coverage is limited to the services a CNS is legally authorized to perform in accordance with State law (or State regulatory mechanism provided by State law).

1 - General

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

- They are the types of services that are considered as physician's services if furnished by an MD/DO;
- They are furnished by a person who meets the CNS qualifications (see subsection A);
- The CNS is legally authorized to furnish the services in the State in which they are performed;
- They are furnished in collaboration with an MD/DO as required by State law (see subsection C); and
- They are not otherwise excluded from coverage because of one of the statutory exclusions. (See subsection C.)

2 – Types of CNS Services that May be Covered

State law or regulations governing a CNS' scope of practice in the State in which the services are furnished applies. Carriers must develop a list of covered services based on the State scope of practice.

Examples of the types of services that a CNS may furnish include services that traditionally have been reserved for 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 his or her State license, a CNS may furnish services billed under all levels of evaluation and management codes and diagnostic tests if furnished in collaboration with a physician.

3 - Incident To

If covered CNS services are furnished, services and supplies furnished incident to the services of the CNS 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 CNS Services

Examples of the types of services that CNS may provide are services that traditionally have been reserved for 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. State law or regulation governing a CNS' scope of practice for his or her service area applies.

2 - Services Otherwise Excluded From Coverage

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

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

D - Collaboration

Collaboration is a process in which a CNS works with one or more physicians (MD/DO) to deliver health care services within the scope of the CNS' professional expertise 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 the CNS documenting his or her scope of practice and indicating the relationships that the CNS has with physicians to deal with issues outside the CNS' scope of practice.

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

E - Direct Billing and Payment

A CNS may bill directly and receive direct payment for their services.

F - Assignment Requirement

Assignment is required for the service to be covered.

220 - Coverage of Outpatient Physical Therapy, Occupational Therapy, and Speech-Language Pathology Services under Medical Insurance

(Rev. 5, 01-09-04)

B3-2200, A3-3147, HO-241.1

Coverage of outpatient physical therapy, occupational therapy, and outpatient speech-language pathology services under Part B includes such services furnished directly by the provider and also services furnished under arrangements made by a provider, a physician, a non-physician practitioner, a therapist or a supplier qualified to provide the service.

This includes individual practitioners and approved clinics, rehabilitation agencies, and public health agencies as well as participating hospitals, SNFs, HHAs, CORFs, and other rehabilitation facilities. To qualify as providers of services, clinics, rehabilitation agencies, and public health agencies must meet certain conditions enumerated in the law and enter into an agreement with the Secretary in which they agree not to charge any beneficiary for covered services for which the program will pay and to refund any erroneous collections made.

Reimbursement for therapy provided to Part A inpatients of hospitals or SNFs is included in the respective PPS rate. Reimbursement for therapy provided by home health agencies under a plan of treatment is included in the home health PPS rate. Some therapy services are included in hospital outpatient PPS and some are paid under the therapy fee schedule (see the Medicare Claims Processing instructions for a description of applicable rules).

Therapy may be billed by a home health agency on bill type 34x if there are no home health services billed under a home health plan of care at the same time, and there is a valid therapy plan of treatment (e.g., the patient is not homebound).

220.1 - Therapy Services Furnished Under Arrangements with Providers and Clinics

(Rev. 9, 04-23-04)

B3-2203; A3-3147.1; HO-241.1; Pub 100-1, Chapter 5, §10.3

A. General

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 as 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 or non-physician practitioner with regard to the progress of the patient and to assure that the required plan of treatment is periodically reviewed by the physician;
- Secure from the physician or non-physician practitioner the required certifications and recertifications; and
- See to it 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 by the physician or non-physician practitioner after any necessary consultation with the physical therapist, occupational therapist, or speech-language pathologist as appropriate, who will provide the therapy services.
- Specify the geographical areas in which the services are to be furnished;
- Provide that personnel and services contracted for 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. 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 regulations and applicable Medicare Manuals. The hospital 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.*
- *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 (IRF) or a long term care (LTC) 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 for 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 a home health agency (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) 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 a 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. 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.

SNF Setting	***Applicable Rules***	
Medicare Part A or B	***Consolidated Billing Rules Apply?***	***Hospital May Bill For Outpatient Services?***
Part A (Medicare Covered / PPS) Resident in Medicare-certified part of a SNF	*Yes*	*No*
Medicare Part B Resident in Medicare-certified part of a SNF	*Yes*	*No*
Medicare Part B *Not a Resident in Medicare-certified part of a SNF*	*No*	*Yes*

- *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 Comprehensive Outpatient Rehabilitation Facilities (CORFs), Rehabilitation Agencies, Outpatient Rehabilitation Facilities and offices of physicians 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.*

220.2 - Physical Therapy and Occupational Therapy Provided by Physicians and Physician Employees

(Rev. 1, 10-01-03)

B3-2218

For purposes of occupational therapy services in this section, carriers should substitute the words “occupational therapy” for each occurrence of the words “physical therapy".

Physician employees, under these guidelines, must meet all incident-to requirements and general Medicare coverage requirements.

The following standards apply also to the practitioner services of physician assistants, nurse practitioners, clinical nurse specialists, and to persons providing services incident to practitioner services.

The following standards apply to physical therapy services provided by a physician or by an incident-to employee of the physician in the physician’s office or the beneficiary’s home. Medicare payment is based on the Medicare physician fee schedule less coinsurance and any deductible amounts due. For purposes of this instruction, physical therapy services are those procedures found in the Physical Medicine and Rehabilitation Section of the American Medical Association’s “Current Procedural Terminology (CPT).”

A. The services provided must be provided by, or under the direct supervision of, a physician (a doctor of medicine or osteopathy) who is legally authorized to practice physical therapy services by the State in which he performs such function or action. The patient must be under care of the physician for a condition that is medically necessary, reasonable and appropriate for physical therapy treatment. The services must be considered under accepted standards of medical practice to be a specific and effective treatment for the patient’s condition.

B. The services must be of a level of complexity that require that they be performed by or under the direct supervision of the physician. Services which do not require the performance or supervision of the physician are not considered reasonable or necessary physical therapy services even if they are performed or supervised by a physician.

C. Services must be furnished under a plan of treatment that has been written and developed by the physician caring for the patient. The plan must be established prior to the initiation of treatment, must be signed by the physician, and must be incorporated into the physician's permanent record for the patient. The services provided must relate directly to the written treatment regimen.

1 - The plan of care contains the following information:

- The patient's significant past history;
- Patient's diagnoses that require physical therapy;
- Related physician orders;
- Therapy goals and potential for achievement;
- Any contraindications;
- Patient's awareness and understanding of diagnoses, prognosis, treatment goals; and
- When appropriate, the summary of treatment provided and results achieved during previous periods of physical therapy services.

2 - The plan of care indicates anticipated goals and specifies for the therapy services type, amount, frequency and duration. The amount, frequency, and duration of the physical therapy services must be reasonable and necessary.

3 - The plan of care and results of treatment are reviewed every 30 days. When services are continued for more than 30 days, the physician must recertify the plan of treatment every 30 days. Any change in treatment plan must be noted in writing in the patient record.

D. The physical therapy services provided to the beneficiary must be restorative or for the purpose of designing and teaching a maintenance program for the patient to conduct at home. There must be an expectation that the patient's condition will improve significantly in a reasonable (and generally predictable) period of time, or the services must be necessary for the establishment of a safe and effective maintenance program required in connection with a specific disease state. If the patient's expected restoration potential would be insignificant in relation to the extent and duration of physical therapy services required to achieve such potential, the physical therapy would not be considered reasonable and necessary. If at any point in the treatment it is determined that improvement in the patient's condition will not be achieved, the services will no longer be considered reasonable and necessary.

E. Services that are palliative in nature are not considered necessary and reasonable and are not covered services. These services maintain function and generally do not involve complex physical therapy procedures nor do they require physician judgment and skill for safety and effectiveness.

Where there is an identified risk to the patient, the professional skill of a physician may be required to manage and periodically evaluate the appropriateness of a therapy

maintenance program. When the knowledge and judgment of the physician is necessary to prevent or minimize deterioration caused by a medical condition, reasonable management and evaluation services could be covered.

EXAMPLE

A Parkinson patient who has not been under restorative physical therapy may require the services of a physician to determine the type of exercises that will be effective in maintaining the patient's present functional level. Such a maintenance program, to be covered under Medicare, must include the initial patient evaluation; a maintenance program and care plan appropriate to the capacity and tolerance of the patient; and treatment objectives of the physician and instruction of the patient or family members in carrying out the program. Maintenance programs are subject to reevaluations and may be considered reasonable and necessary.

220.3 - Conditions for Coverage of Outpatient Physical Therapy, Occupational Therapy, or Speech-Language pathology Services

(Rev. 5, 01-09-04)

B3-2206, A3-3148, HO-242

Refer to §230.4 for independent practitioner rules.

Outpatient physical therapy, occupational therapy, or speech-language pathology services furnished to a beneficiary by a participating provider are payable only when furnished in accordance with the following conditions:

- Physician's or non-physician practitioner's certification and recertification;
- Outpatient must be under the care of a physician or non-physician practitioner;
- Outpatient physical therapy, occupational therapy or speech-language pathology services furnished under a plan; and
- Services must be furnished on an outpatient basis.

Each of these conditions is discussed separately in the subsections that follow. In addition, outpatient physical therapy, occupational and speech-language pathology services must meet all of the conditions set forth in the Medicare Benefit Policy Manual, Chapter 1, "Inpatient Hospital Services," §100 and §220, and its subsections of this chapter.

220.3.1 - Physician's Certification and Recertification

(Rev. 5, 01-09-04)

B3-2206.1, A3-3148.1, HO-242.1, A3-3350, A3-3322

A - Content of Physician's Certification

The contractor must not pay for outpatient physical therapy, occupational therapy or speech-language pathology services unless a physician or non-physician practitioner certifies that:

- The services are or were required by the patient.

- A plan for furnishing such services is or was established and periodically reviewed by the physician, or non-physician practitioner. Either the physician, or non-physician practitioner or the qualified physical therapist providing such services establishes a plan of treatment for outpatient physical therapy services. Either the physician, or non-physician practitioner or the qualified occupational therapist providing such services establishes a plan of treatment for outpatient occupational therapy services. Either the physician, or non-physician practitioner or the speech-language pathologist providing such services establishes a plan of treatment for outpatient speech-language pathology services. However, a physician or non-physician practitioner must periodically review a plan established by a speech-language pathologist, occupational therapist or physical therapist. (See §220.3.3.) See §230 for specific requirements for a plan established for physical, occupational, and speech-language pathology therapy services.
- The outpatient physical therapy, occupational therapy or speech-language pathology services are or were furnished while the patient was under the care of a physician or non-physician practitioner. (See §220.3.2.)

Since the certification is closely associated with the plan of treatment, the same physician or non-physician practitioner who established or reviews the plan of treatment must certify the necessity for services. The plan must be written and developed by the physician or non-physician practitioner caring for the patient. The carrier will obtain certification at the time the plan of treatment is established or as soon thereafter as possible.

Physician means a doctor of medicine, osteopathy (including an osteopathic practitioner), podiatric medicine legally authorized to practice by the State in which they perform the services and optometrist (for low vision only). In addition, physician certifications and recertifications by doctors of podiatric medicine or optometry must be consistent with the scope of the professional services provided by a doctor of podiatric medicine or optometry as authorized by applicable State law.

B - Recertification

When outpatient physical therapy, occupational therapy or speech-language pathology services are continued under the same plan of treatment for a period of time, the physician or non-physician practitioner must recertify at intervals of at least once every 30 days from the date last seen by the referring physician or non-physician practitioner that there is a continuing need for such services and estimate how long services are needed. Obtain the recertification at the time the plan of treatment is reviewed since the same interval (at least once every 30 days) is required for the review of the plan. The form of the recertification and the manner of obtaining timely recertification is up to the individual facility and/or practitioner.

C - Method and Disposition of Certifications

There is no requirement that the certification or recertification be entered on any specific form or handled in any specific way as long as the carrier can determine, where necessary, that the certification and recertification requirements are met. The

certification by the physician or non-physician practitioner is retained by the individual facility and/or practitioner, which also certifies on the billing form that the requisite certifications and recertifications have been made by the physician or non-physician practitioner and are on file when it forwards the request for payment to the carrier.

D - Delayed Certification

The individual facility and/or practitioner must obtain certifications and recertifications as promptly as possible. Payment is not made unless the necessary certifications are secured. In addition to complying with the usual content requirements, delayed certifications and recertifications are to include an explanation for the delay and any other evidence the clinic considers necessary in the case. The format of delayed certifications and recertifications and the method by which they are obtained is left to the individual facility and/or practitioner.

220.3.2 - Outpatient Must be Under Care of Physician

(Rev. 5, 01-09-04)

B3-2206.2, A3-3148.2, HO-242.2

Outpatient physical therapy, occupational therapy, or speech-language pathology services must be furnished to an individual who is under the care of a physician or non-physician practitioner who certifies the patient's outpatient therapy services. If the therapy service continues past the 60th day, there must be evidence in the patient's clinical record, which is a part of the therapy documentation, that a physician or non-physician practitioner has seen him/her within 60 days after the therapy began and every 30 days past the 60th day. If the requirement is not met, the therapy services are not covered (reasonable and necessary). The 60-day period begins with the therapist or pathologist initial encounter with the patient, i.e., the day when the evaluation is performed. In the event that an evaluation is not indicated the first treatment session begins the 60-day period. The therapist's or pathologist's first encounter with the patient should occur in a timely manner from the date of the physician's therapy referral. For continuity of care the physician or non-physician practitioner who certifies the patient's need for outpatient therapy services is the same person who meets the visit requirements. In addition, timing of recertifications and the visit requirements should coincide. However, the physician or non-physician practitioner still makes the necessary certifications. (See §§220.3.1, 220.3.3, and 220.3.4.)

220.3.3 - Outpatient Physical Therapy, Occupational Therapy, or Speech-Language Pathology Services Furnished Under Plan

(Rev. 5, 01-09-04)

B3-2206.3, A3-3148.3, HO-242.3

Outpatient physical therapy, occupational therapy, or speech-language pathology services are furnished under a plan established by:

- A physician or non-physician practitioner after any necessary consultation with the physical therapist, occupational therapist, or speech-language pathologist, as appropriate;

- The physical therapist who will provide the physical therapy services;

- The occupational therapist who will provide the occupational therapy services; or

- The speech-language pathologist that will provide the speech-language pathology services.

The plan must be established (that is, reduced to writing either by the person who established the plan or by the provider or clinic itself when it makes a written record of that person's oral orders) before treatment is begun. The plan is promptly signed by the ordering physician, non-physician practitioner, therapist, or pathologist and incorporated into the facility's permanent record for the patient.

The plan relates the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology to its inpatients without having to set up facilities and procedures for furnishing those services to its outpatients. However, if the provider chooses to furnish a particular service, it is bound by its agreement not to charge any individual or other person for items or services for which the individual is entitled to have payment made under the program. Thus, whenever a hospital or SNF furnishes outpatient physical therapy, occupational therapy, or speech-language pathology services to a Medicare beneficiary (either directly or under arrangements with others) it must bill the program under Part B and may charge the patient only for the applicable deductible and coinsurance.

220.3.4 - Requirement That Services Be Furnished on an Outpatient Basis

(Rev. 1, 10-01-03)

B3-2206.4, A3-3148.4, HO-242.4

Outpatient physical therapy, occupational therapy, and speech-language pathology services are payable when furnished by a provider to its outpatients, i.e., to patients in

their homes, to patients who come to the facility's outpatient department, or to inpatients of other institutions.

Coverage includes physical therapy, occupational therapy, and speech-language pathology services furnished by participating hospitals and SNFs to their inpatients who have exhausted Part A inpatient benefits or who are otherwise not eligible for Part A benefits. Providers of outpatient physical therapy, occupational therapy, and speech-language pathology services that have inpatient facilities, other than participating hospitals and SNFs, may not furnish covered outpatient physical therapy or speech-language pathology services to their own inpatients. However, since the inpatients of one institution may be considered the outpatients of another institution, all providers of outpatient physical therapy and speech-language pathology services may furnish such services to inpatients of another health facility.

A certified distinct part of an institution is considered to be a separate institution from a nonparticipating remainder. Consequently, the certified distinct part may render covered outpatient physical therapy, occupational therapy, or speech-language pathology services to the inpatients of the noncertified remainder or to outpatients. The certified part must bill the intermediary under Part B.

While outpatient physical therapy, occupational therapy, and speech-language pathology are payable when furnished in the home, when added expense is caused by a visit to the home, a question must be raised as to whether the rendition of the service in the home is reasonable and necessary. Where the patient is not confined to home, such added expense cannot be considered as reasonable and necessary for the treatment of an illness or injury since the home visit is substantially more costly than the medically appropriate and realistically feasible alternative pattern of care; e.g., in the facility's outpatient department. Consequently, these additional expenses incurred by providers due to travel to a person who is not homebound will not be covered.

Under the Medicare law, there is no authority to require a provider to furnish a type of service. Therefore, a hospital or SNF may furnish physical therapy, occupational therapy, or speech-language pathology to its inpatients without having to set up facilities and procedures for furnishing those services to its outpatients. However, if the provider chooses to furnish a particular service, it is bound by its agreement not to charge any individual or other person for items or services for which the individual is entitled to have payment made under the program. Thus, whenever a hospital or SNF furnishes outpatient physical therapy, occupational therapy, or speech-language pathology to a Medicare beneficiary (either directly or under arrangements with others) it must bill the program under Part B and may charge the patient only for the applicable deductible and coinsurance.

230 - Payable Rehabilitation Services

(Rev. 5, 01-09-04)

B3-2210

A - General

To be covered PT, OT or speech-language pathology services, the services must relate directly and specifically to an active written treatment regimen established by the physician or non-physician practitioner after any needed consultation with the qualified PT, OT, or speech-language pathologist and must be reasonable and necessary to the treatment of the individual's illness or injury. The physician, non-physician practitioner or the qualified therapist providing such services may establish a plan of treatment for outpatient PT, OT, or speech-language pathology services.

There is a limit for the amount of therapy expenses that is recognized as payable for some years. See the Medicare Claims Processing Manual, Chapter 5, §10.2, for a complete description of this financial limitation.

B - Reasonable and Necessary

To be considered reasonable and necessary the following conditions must be met:

The services must be considered under accepted standards of medical practice to be a specific and effective treatment for the patient's condition;

The services must be of such a level of complexity and sophistication or the condition of the patient must be such that the services required can be safely and effectively performed only by a qualified PT, OT, or speech language pathologist or under the therapist's supervision. Services which do not require the performance or supervision of a therapist are not considered reasonable or necessary PT, OT or speech-language pathology services, even if they are performed or supervised by a therapist. (When the carrier determines the services furnished were of a type that could have been safely and related to the maintenance of function (see subsection D) do not require the skills of a qualified physical therapist.

230.1 - Services Furnished by a Physical or Occupational Therapist in Private Practice

(Rev. 5, 01-09-04)

B3-2215

Private practice includes a therapist whose practice is an unincorporated solo practice, unincorporated partnership, unincorporated group practice, physician group or groups that are not professional corporations, if allowed by State law. Section 1861(r) of the Act defines a physician as a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicines, a doctor of optometry and a chiropractor who is legally authorized to practice medicines by the State in which he performs such function or action and who is acting within the scope of his license when he performs such functions. Physician group practices may employ PTPPs and/or OTPPs if this employee relationship is permitted by State law. However, therapy provided to Medicare beneficiaries must be done while under the "care of a physician who is a doctor

of medicine, osteopathy, podiatric medicine or optometry (low vision rehabilitation only)" or a non-physician practitioner. These physicians or non-physician practitioners provide referrals, certification and recertifications of plans of care for Medicare beneficiaries. As defined in the statute, chiropractors and doctors of dental surgery or dental medicine are not considered physicians for these services and are not able to refer patients for rehabilitation services nor establish therapy plans of care.

For purposes of this provision a physician group practice is defined as one or more physicians and/or non-physician practitioners that desire to bill Medicare as one entity. For further details contact the Office of Financial Management, Division of Provider and Supplier Enrollment.

Private practice also includes a therapist who is practicing therapy as an employee of one of the above or of a professional corporation or other incorporated therapy practice. Private practice does not include individuals when they are working as employees of a provider. A provider as defined in §400.202 includes a hospital, CAH, SNF, HHA, hospice, CORF, CMHC, or an organization qualified under part 485, subpart H (conditions of participation of clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy, occupational therapy and speech-language pathology services) as a clinic, rehabilitation agency, or public health agency.

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 would have to be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. For example, a therapist in private practice may furnish aquatic therapy in a community center pool. The practice would have to rent or lease the pool for those hours, and the use of the pool during that time would have to be restricted to the therapist's patients, in order to recognize the pool as part of the therapist's own practice office during those hours.

Therapists in private practice must be approved as meeting certain requirements, but do not execute a formal provider agreement with the Secretary. For PTPPs and OTPPs, assignment is mandatory. When the PT or OT is the "supplier" of services, the rules for private therapy practice must be followed. When the physician or non-physician practitioner is the "supplier" of services, then the "incident to" rules must be followed.

The PTPPs or OTPPs in a physician group can be either salaried W-2 employees or contract 1099 employees. The PTPP/OTPP contract 1099 employee must follow current reassignment rules that indicate that these services must be provided on the premises that are rented, owned or leased by the physician group, just as required for physicians in a group practice who are reassigning their benefits to the physician group practice

Therapists in private practice employed by physician groups or non-professional corporations who enroll in Medicare as PTPP or OTPP need not be supervised. The therapist must personally supervise therapy assistants. Personal supervision requires that the therapist be in the room during the performance of the service. (For coverage guidelines, see §230 for physical therapy, and §230.4 for occupational therapy.)

Medicare payment is based on the Medicare physician fee schedule less coinsurance and any deductible amounts due.

There is a limit for the amount of therapy expenses that is recognized as payable for some years. See the Medicare Claims Processing Manual, Chapter 5, §10.2, for a complete description of this financial limitation.

NOTE: The limit on expenses applies only to items and services covered under the therapy benefit. It does not apply to items covered under a separate benefit; e.g., braces that are furnished and billed by an occupational or physical therapist and billed as durable medical equipment.

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.

230.2 - Physical Therapy in Private Practice

(Rev. 1, 10-01-03)

A3-3149, HO-242.5

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 provider.

230.3 - Covered Speech-Language Pathology Services

(Rev. 1, 10-01-03)

B3-2216

A - General

Speech-language pathology services are those services 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 the Medicare National Coverage Determinations Manual) They must relate directly and specifically to a written treatment regimen established by the physician, after any needed consultation with the qualified

speech-language pathologist, or by the speech-language pathologist providing such services.

B - Reasonable and Necessary

Speech-language pathology services must be reasonable and necessary to the treatment of the individual's illness or injury. To be considered reasonable and necessary, the following conditions must be met:

- The services must be considered under accepted standards of practice to be a specific and effective treatment for the patient's condition;
- The services must be of such a level of complexity and sophistication, or the patient's condition must be such that the services required can be safely and effectively performed only by or under the supervision of a qualified speech-language pathologist. (See 42 CFR 405.1202(u)(1) and (2).) (When the carrier determines the services furnished were of a type that could have been safely and effectively performed only by qualified speech-language pathologists or under the supervision of a qualified speech-language pathologist, it presumes that such services were properly supervised. However, this presumption is rebuttable and, if in the course of processing claims the carrier finds that speech-language pathology services are not being furnished under proper supervision, it denies the claim and brings this matter to the attention of the RO.);
- There must be an expectation that the patient's condition will improve significantly in a reasonable (and generally predictable) period of time based on the assessment by the physician of the patient's restoration potential after any needed consultation with the qualified speech-language pathologist, or the services must be necessary to the establishment of a safe and effective maintenance program required in connection with a specific disease state; and
- The amount, frequency, and duration of the services must be reasonable under accepted standards of practice. (The carrier should consult with local speech-language pathologists or the State chapter of the American Speech-Language-Hearing Association in the development of any utilization guidelines.)

Claims for speech-language pathology services which are not reasonable and necessary should be considered denied under authority of §1862(a)(1) and, therefore, are subject to the waiver of liability provisions in §1879 of the Act.

C - Application of Guidelines

The following discussion illustrates the application of the above guidelines to the more common situations in which the reasonableness and necessity of speech services furnished is a significant issue.

1 - Restorative Therapy

If an individual's expected restoration potential would be insignificant in relation to the extent and duration of speech-language pathology services required to achieve such potential, the services would not be considered reasonable and necessary. In addition, there must be an expectation that the patient's condition will improve significantly in a reasonable (and generally predictable) period of time. If at any

point in the treatment of an illness or injury it is determined that the expectations will not materialize, the services will no longer constitute covered speech-language pathology services, as they would no longer be reasonable and necessary for the treatment of the patient's condition and would be excluded from coverage under §1862(a)(1) of the Act.

2 - Maintenance Program

After the initial evaluation of the extent of the disorder or illness, if the restoration potential is judged insignificant or, after a reasonable period of trial, the patient's response to treatment is judged insignificant or at a plateau, an appropriate functional maintenance program may be established. The specialized knowledge and judgment of a qualified speech-language pathologist may be required if the treatment aim of the physician is to be achieved; e.g., a multiple sclerosis patient may require the services of a speech-language pathologist to establish a maintenance program designed to fit the patient's level of function. In such a situation, the initial evaluation of the patient's needs, the designing by the qualified speech-language pathologist of a maintenance program which is appropriate to the capacity and tolerance of the patient and the treatment objectives of the physician, the instruction of the patient or family members in carrying out the program, and such infrequent reevaluations as may be required, would constitute covered speech therapy. After the maintenance program has been established and instructions have been given for carrying out the program, the services of the speech-language pathologist would no longer be covered, as they would no longer be considered reasonable and necessary for the treatment of the patient's condition and would be excluded from coverage under §1862(a)(1) of the Act.

If a patient has been under a restorative speech-language pathology program, the speech-language pathologist should regularly reevaluate the condition and adjust the treatment program. Consequently, during the course of treatment the speech-language pathologist should determine when the patient's restorative potential will be achieved and, by the time the restorative program has been completed, should have designed the maintenance program required and instructed the patient or family members in the carrying out of the program. A separate charge for the establishment of the maintenance program under these circumstances would not be recognized. Moreover, where a maintenance program is not established until after the restorative speech-language pathology program has been completed, it would not be considered reasonable and necessary to the treatment of the patient's condition and would be excluded from coverage under §1862(a)(1) of the Act since the maintenance program should have been established during the active course of treatment.

D - Types of Services

Speech-language pathology services can be grouped into two main categories: services concerned with diagnosis or evaluation and therapeutic services.

1 - Diagnostic and Evaluation Services

Unless excluded by §1862(a)(7) of the Act, these services are covered if they are reasonable and necessary. The speech-language pathologist employs a variety of

formal and informal language assessment tests to ascertain the type, causal factor(s), and severity of the speech and language disorders. Reevaluation would be covered only if the patient exhibited a change in functional speech or motivation, clearing of confusion, or the remission of some other medical condition that previously contraindicated speech-language pathology. However, monthly reevaluations; e.g., a Porch Index of Communicative Ability (PICA) for a patient undergoing a restorative speech-language pathology program, are to be considered a part of the treatment session and could not be covered as a separate evaluation for billing purposes.

2 - Therapeutic Services

The following are examples of common medical disorders and resulting communication deficits which may necessitate active restorative therapy:

- Cerebrovascular disease such as cerebral vascular accidents presenting with dysphagia, aphasia/dysphasia, apraxia, and dysarthria;
- Neurological disease such as Parkinsonism or Multiple Sclerosis may exhibit dysarthria, dysphagia, or inadequate respiratory volume/control;
- Mental retardation with disorders such as aphasia or dysarthria; and
- Laryngeal carcinoma requiring laryngectomy resulting in aphonia may warrant therapy of the laryngectomized patient so the patient can develop new communication skills through esophageal speech and/or use of the electrolarynx.

NOTE: Many patients who do not require speech-language pathology services as defined above do require services involving nondiagnostic, nontherapeutic, routine, repetitive, and reinforced procedures or services for their general good and welfare; e.g., the practicing of word drills. Such services do not constitute speech-language pathology services for Medicare purposes and would not be covered since they do not require performance by or the supervision of a qualified speech-language pathologist.

230.4 - Covered Occupational Therapy

(Rev. 1, 10-01-03)

B3-2217

A - General

Covered occupational therapy services must relate directly and specifically to a written treatment regimen established by the physician, after any needed consultation with the qualified occupational therapist, or by the occupational therapist providing the 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 hip fracture/hip replacement patient 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 orthotic 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 subsection 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 a plan of treatment.

B - Coverage Criteria

Occupational therapy designed to improve function is considered reasonable and necessary for the treatment of the individual's illness or injury only where an expectation exists that the therapy will result in a significant practical improvement in the individual's level of functioning within a reasonable period of time. Where an individual's improvement potential is insignificant in relation to the extent and duration of occupational therapy services required to achieve improvement, such services would

not be considered reasonable and necessary and thus are not covered. If a valid expectation of improvement exists at the time the occupational therapy program is instituted, the services would be covered even though the expectation may not be realized. However, in such situations the services would be covered only up to the time at which it would have been reasonable to conclude that the patient is not going to improve. Once a patient has reached the point where no further significant practical improvement can be expected, the skills of an occupational therapist will not be required in the carrying out of any activity and/or exercise program required to maintain function at the level to which it has been restored. Consequently, while the services of an occupational therapist in designing a maintenance program and making infrequent but periodic evaluation of its effectiveness would be covered, carrying out the program is not considered reasonable and necessary for the treatment of illness or injury and such services are not covered.

Generally speaking, occupational therapy is not required to effect improvement or restoration of function where a patient suffers a temporary loss or reduction of function (e.g., temporary weakness which may follow prolonged bed rest following major abdominal surgery) which could reasonably be expected to improve spontaneously as the patient gradually resumes normal activities. Accordingly, occupational therapy furnished in such situations is not considered reasonable and necessary for the treatment of the individual's illness or injury and the services are not covered.

Occupational therapy may also 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, because patient motivation is an appropriate and inherent 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 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 would be a vocational test for a sales clerk. Training an amputee in the use of a prosthesis for telephoning is necessary for everyday activities as well as for employment purposes. Major changes in life style may be mandatory for

an individual with a substantial disability. The techniques of adjustment cannot be considered exclusively vocational or nonvocational.

Services of support personnel (e.g., occupational therapy assistants) and supplies used in furnishing covered therapy (e.g., looms, ceramic tiles, or leather) are included as part of the covered service. These items and services cannot be billed separately; they are considered included in the HCPCS code describing the therapist's service. The restriction on a separate coverage and billing does not apply to items which meet the definition of brace in §130.

230.5 - Coverage for Neuromuscular Electrical Stimulation (NMES)

(Rev. 1, 10-01-03)

AB-02-156

A - Summary

The NMES involves the use of a device, which transmits an electrical impulse to activate muscle groups by way of electrodes. Coverage of NMES to treat muscle atrophy is limited to the treatment of patients with disuse atrophy where the nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves and other non-neurological reasons for disuse atrophy. The type of NMES that is used to enhance walking in spinal cord injury (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. See also the Medicare National Coverage Determinations Manual.)

B - Coverage

For services performed **on or after April 1, 2003**, Medicare will cover NMES/FES to enhance walking for SCI patients who have completed a training program, which consists of at least 32 physical therapy sessions with the device over a period of three months.

Coverage for NMES/FES for walking will be limited to SCI patients with all of the following characteristics:

- Persons with intact lower motor units (L1 and below) (both muscle and peripheral nerve);
- 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;
- Persons that demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction;
- Persons that possess high motivation, commitment and cognitive ability to use such devices for walking;
- Persons that can transfer independently and can demonstrate standing independently for at least three minutes;
- Persons that can demonstrate hand and finger function to manipulate controls;

- Persons with at least 6-month post recovery spinal cord injury and restorative surgery;
- Persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and
- Persons who have demonstrated a willingness to use the device long-term.

NMES/FES to enhance walking for SCI patients will not be covered for SCI patients with any of the following:

- Presence of cardiac pacemakers or cardiac defibulators;
- Severe scoliosis or severe osteoporosis;
- Irreversible contracture;
- Autonomic dysreflexia; or
- Skin disease or cancer at area of stimulation.

240 - Chiropractic Services - General

(Rev. 1, 10-01-03)

B3-2250, B3-4118

The term "physician" under Part B includes a chiropractor who meets the specified qualifying requirements set forth in §30.5 but only for treatment by means of manual manipulation of the spine to correct a subluxation.

Effective for claims with dates of services on or after January 1, 2000, an x-ray is not required to demonstrate the subluxation.

Implementation of the chiropractic benefit requires an appreciation of the differences between chiropractic theory and experience and traditional medicine due to fundamental differences regarding etiology and theories of the pathogenesis of disease. Judgments about the reasonableness of chiropractic treatment must be based on the application of chiropractic principles. So that Medicare beneficiaries receive equitable adjudication of claims based on such principles and are not deprived of the benefits intended by the law, carriers may use chiropractic consultation in carrier review of Medicare chiropractic claims.

Payment is based on the physician fee schedule and made to the beneficiary or, on assignment, to the chiropractor.

A – Verification of Chiropractor's Qualifications

Carriers must establish a reference file of chiropractors eligible for payment as physicians under the criteria in §30.1. They pay only chiropractors on file. Information needed to establish such files is furnished by the CMS RO.

The RO is notified by the appropriate State agency which chiropractors are licensed and whether each meets the national uniform standards.

240.1 - Coverage of Chiropractic Services

(Rev. 1, 10-01-03)

B3-2251

240.1.1 - Manual Manipulation

(Rev. 1, 10-01-03)

B3-2251.1

Coverage of chiropractic service is specifically limited to treatment by means of manual manipulation, i.e., by use of the hands. Additionally, manual devices (i.e., those that are hand-held with the thrust of the force of the device being controlled manually) may be used by chiropractors in performing manual manipulation of the spine. However, no additional payment is available for use of the device, nor does Medicare recognize an extra charge for the device itself.

No other diagnostic or therapeutic service furnished by a chiropractor or under the chiropractor's order is covered. This means that if a chiropractor orders, takes, or interprets an x-ray, or any other diagnostic test, the x-ray or other diagnostic test, can be used for claims processing purposes, but Medicare coverage and payment are not available for those services. This prohibition does not affect the coverage of x-rays or other diagnostic tests furnished by other practitioners under the program. For example, an x-ray or any diagnostic test taken for the purpose of determining or demonstrating the existence of a subluxation of the spine is a diagnostic x-ray test covered under §1861(s)(3) of the Act if ordered, taken, and interpreted by a physician who is a doctor of medicine or osteopathy.

Manual devices (i.e., those that are hand-held with the thrust of the force of the device being controlled manually) may be used by chiropractors in performing manual manipulation of the spine. However, no additional payment is available for use of the device, nor does Medicare recognize an extra charge for the device itself.

Effective for claims with dates of service on or after January 1, 2000, an x-ray is not required to demonstrate the subluxation. However, an x-ray may be used for this purpose if the chiropractor so chooses.

The word "correction" may be used in lieu of "treatment." Also, a number of different terms composed of the following words may be used to describe manual manipulation as defined above:

- Spine or spinal adjustment by manual means;
- Spine or spinal manipulation;
- Manual adjustment; and
- Vertebral manipulation or adjustment.

In any case in which the term(s) used to describe the service performed suggests that it may not have been treatment by means of manual manipulation, the carrier analyst refers the claim for professional review and interpretation.

240.1.2 - Subluxation May Be Demonstrated by X-Ray or Physician's Exam

(Rev. 1, 10-01-03)

B3-2251.2

Subluxation is defined as a motion segment, in which alignment, movement integrity, and/or physiological function of the spine are altered although contact between joint surfaces remains intact.

A subluxation may be demonstrated by an x-ray or by physical examination, as described below.

1. Demonstrated by X-Ray

An x-ray may be used to document subluxation. The x-ray must have been taken at a time reasonably proximate to the initiation of a course of treatment. Unless more specific x-ray evidence is warranted, an x-ray is considered reasonably proximate if it was taken no more than 12 months prior to or 3 months following the initiation of a course of chiropractic treatment. In certain cases of chronic subluxation (e.g., scoliosis), an older x-ray may be accepted provided the beneficiary's health record indicates the condition has existed longer than 12 months and there is a reasonable basis for concluding that the condition is permanent. A previous CT scan and/or MRI is acceptable evidence if a subluxation of the spine is demonstrated.

2. Demonstrated by Physical Examination

Evaluation of musculoskeletal/nervous system to identify:

- Pain/tenderness evaluated in terms of location, quality, and intensity;
- Asymmetry/misalignment identified on a sectional or segmental level;
- Range of motion abnormality (changes in active, passive, and accessory joint movements resulting in an increase or a decrease of sectional or segmental mobility); and
- Tissue, tone changes in the characteristics of contiguous, or associated soft tissues, including skin, fascia, muscle, and ligament.

To demonstrate a subluxation based on physical examination, two of the four criteria mentioned under "physical examination" are required, one of which must be asymmetry/misalignment or range of motion abnormality.

The history recorded in the patient record should include the following:

- Symptoms causing patient to seek treatment;
- Family history if relevant;
- Past health history (general health, prior illness, injuries, or hospitalizations; medications; surgical history);
- Mechanism of trauma;
- Quality and character of symptoms/problem;

- Onset, duration, intensity, frequency, location and radiation of symptoms;
- Aggravating or relieving factors; and
- Prior interventions, treatments, medications, secondary complaints.

A – Documentation Requirements: Initial Visit

The following documentation requirements apply whether the subluxation is demonstrated by x-ray or by physical examination:

1. History as stated above.
2. Description of the present illness including:
    - Mechanism of trauma;
    - Quality and character of symptoms/problem;
    - Onset, duration, intensity, frequency, location, and radiation of symptoms;
    - Aggravating or relieving factors;
    - Prior interventions, treatments, medications, secondary complaints; and
    - Symptoms causing patient to seek treatment.

These symptoms must bear a direct relationship to the level of subluxation. The symptoms should refer to the spine (spondyle or vertebral), muscle (myo),bone (osseo or osteo), rib (costo or costal) and joint (arthro)and be reported as pain (algia), inflammation (itis), or as signs such as swelling, spasticity, etc. Vertebral pinching of spinal nerves may cause headaches, arm, shoulder, and hand problems as well as leg and foot pains and numbness. Rib and rib/chest pains are also recognized symptoms, but in general other symptoms must relate to the spine as such. The subluxation must be causal, i.e., the symptoms must be related to the level of the subluxation that has been cited. A statement on a claim that there is "pain" is insufficient. The location of pain must be described and whether the particular vertebra listed is capable of producing pain in the area determined.

3. Evaluation of musculoskeletal/nervous system through physical examination.
4. Diagnosis: The primary diagnosis must be subluxation, including the level of subluxation, either so stated or identified by a term descriptive of subluxation. Such terms may refer either to the condition of the spinal joint involved or to the direction of position assumed by the particular bone named.
5. Treatment Plan: The treatment plan should include the following:
    - Recommended level of care (duration and frequency of visits);
    - Specific treatment goals; and
    - Objective measures to evaluate treatment effectiveness.
6. Date of the initial treatment.

B – Documentation Requirements: Subsequent Visits

The following documentation requirements apply whether the subluxation is demonstrated by x-ray or by physical examination:

1. History
    - Review of chief complaint;
    - Changes since last visit;
    - System review if relevant.
2. Physical exam
    - Exam of area of spine involved in diagnosis;
    - Assessment of change in patient condition since last visit;
    - Evaluation of treatment effectiveness.
3. Documentation of treatment given on day of visit.

240.1.3 - Necessity for Treatment

(Rev. 23, Issued: 10-08-04, Effective: 10-01-04, Implementation: 10-04-04)

B3-2251.3

The patient must have a significant health problem in the form of a neuromusculoskeletal condition necessitating treatment, and the manipulative services rendered must have a direct therapeutic relationship to the patient's condition and provide reasonable expectation of recovery or improvement of function. The patient must have a subluxation of the spine as demonstrated by x-ray or physical exam, as described above.

Most spinal joint problems fall into the following categories:

- Acute subluxation-A patient's condition is considered acute when the patient is being treated for a new injury, identified by x-ray or physical exam as specified above. The result of chiropractic manipulation is expected to be an improvement in, *or arrest of progression,* of the patient's condition.

- Chronic subluxation-A patient's condition is considered chronic when it is not expected to *significantly improve or be resolved with further treatment* (as is the case with an acute condition), but where the continued therapy can be expected to result in some functional improvement. Once the clinical status has remained stable for a given condition, *without expectation of additional objective clinical improvements,* further manipulative treatment is considered maintenance therapy and is not covered.

*For Medicare purposes, a chiropractor **must** place an AT modifier on a claim when providing active/corrective treatment to treat acute or chronic subluxation. However the presence of the AT modifier may not in all instances indicate that the service is*

reasonable and necessary. As always, contractors may deny if appropriate after medical review.

A - Maintenance Therapy

Maintenance therapy includes services that seek to prevent disease, promote health and prolong and enhance the quality of life, *or maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. The AT modifier must not be placed on the claim when maintenance therapy has been provided. Claims without the AT modifier will be considered as maintenance therapy and denied. Chiropractors who give or receive from beneficiaries an ABN shall follow the instructions in Pub. 100-04, Medicare Claims Processing Manual, Chapter 23, section 20.9.1.1 and include a GA (or in rare instances a GZ) modifier on the claim.*

B – Contraindications

Dynamic thrust is the therapeutic force or maneuver delivered by the physician during manipulation in the anatomic region of involvement. A relative contraindication is a condition that adds significant risk of injury to the patient from dynamic thrust, but does not rule out the use of dynamic thrust. The doctor should discuss this risk with the patient and record this in the chart. The following are **relative contraindications** to dynamic thrust:

- Articular hyper mobility and circumstances where the stability of the joint is uncertain;
- Severe demineralization of bone;
- Benign bone tumors (spine);
- Bleeding disorders and anticoagulant therapy; and
- Radiculopathy with progressive neurological signs.

Dynamic thrust is absolutely contraindicated near the site of demonstrated subluxation and proposed manipulation in the following:

- Acute arthropathies characterized by acute inflammation and ligamentous laxity and anatomic subluxation or dislocation; including acute rheumatoid arthritis and ankylosing spondylitis;

- Acute fractures and dislocations or healed fractures and dislocations with signs of instability;
- An unstable os odontoideum;
- Malignancies that involve the vertebral column;
- Infection of bones or joints of the vertebral column;
- Signs and symptoms of myelopathy or cauda equina syndrome;
- For cervical spinal manipulations, vertebrobasilar insufficiency syndrome; and
- A significant major artery aneurysm near the proposed manipulation.

240.1.4 – Location of Subluxation

(Rev. 1, 10-01-03)

B3-2251.4

The precise level of the subluxation must be specified by the chiropractor to substantiate a claim for manipulation of the spine. This designation is made in relation to the part of the spine in which the subluxation is identified:

Area of Spine	Names of Vertebrae	Number of Vertebrae	Short Form or Other Name
Neck	Occiput	7	Occ, CO
	Cervical		C1 thru C7
	Atlas		C1
	Axis		C2
Back	Dorsal or	12	D1 thru D12
	Thoracic		T1 thru T12
	Costovertebral		R1 thru R12
	Costotransverse		R1 thru R12
Low Back	Lumbar	5	L1 thru L5
Pelvis	IIii, r and 1		I, Si
Sacral	Sacrum, Coccyx		S, SC

In addition to the vertebrae and pelvic bones listed, the Ilii (R and L) are included with the sacrum as an area where a condition may occur which would be appropriate for chiropractic manipulative treatment.

There are two ways in which the level of the subluxation may be specified.

- The exact bones may be listed, for example: C5, C6, etc.
- The area may suffice if it implies only certain bones such as: Occipito-atlantal (occiput and C1 (atlas)), lumbo-sacral (L5 and Sacrum), sacro-iliac (sacrum and ilium).

Following are some common examples of acceptable descriptive terms for the nature of the abnormalities:

- Off-centered
- Misalignment
- Malpositioning
- Spacing - abnormal, altered, decreased, increased
- Incomplete dislocation
- Rotation
- Listhesis - antero, postero, retro, lateral, spondylo
- Motion - limited, lost, restricted, flexion, extension, hyper mobility, hypomotility, aberrant

Other terms may be used. If they are understood clearly to refer to bone or joint space or position (or motion) changes of vertebral elements, they are acceptable.

240.1.5 - Treatment Parameters

(Rev. 23, Issued: 10-08-04, Effective: 10-01-04, Implementation: 10-04-04)

B3-2251.5

The chiropractor should be afforded the opportunity to effect improvement or arrest or retard deterioration in such condition within a reasonable and generally predictable period of time. Acute subluxation (e.g., strains or sprains) problems may require as many as three months of treatment but some require very little treatment. In the first several days, treatment may be quite frequent but decreasing in frequency with time or as improvement is obtained.

Chronic spinal joint condition implies, of course, the condition has existed for a longer period of time and that, in all probability, the involved joints have already “set” and fibrotic tissue has developed. This condition may require a longer treatment time, but not with higher frequency.

Some chiropractors have been identified as using an “intensive care” concept of treatment. Under this approach multiple daily visits (as many as four or five in a single day) are given in the office or clinic and so-called room or ward fees are charged since

the patient is confined to bed usually for the day. The room or ward fees are not covered and reimbursement under Medicare will be limited to not more than one treatment per day.

250 - Medical and Other Health Services Furnished to Inpatients of Hospitals and Skilled Nursing Facilities

(Rev. 1, 10-01-03)

B3-2255

There are several services which, when provided to a hospital or SNF inpatient, are covered under Part B, even though the patient has Part A coverage for the hospital or SNF stay. Those services are:

- Physicians' services (including the services of residents and interns in unapproved teaching programs);
- Physician assistant services, furnished after December 31,1990;
- Certified nurse-midwife services, as described in §180, furnished after December 31, 1990; and
- Qualified clinical psychologist services, as defined in §160, furnished after December 31, 1990;
- Screening mammography services;
- Screening pap smears and pelvic exams;
- Screening glaucoma services;
- Influenza, pneumococcal pneumonia, and hepatitis B vaccines and their administrations;
- Colorectal screening;
- Bone mass measurements;
- Diabetes self-management; and
- Prostate screening;

Because of the bundling requirement described in paragraph B, pneumococcal and hepatitis B vaccine services must be provided directly or arranged for by the hospital in order to be covered when furnished to a hospital inpatient. The other services listed are not subject to bundling but, because they are excluded from the statutory definition of inpatient hospital services, may be covered only under Part B.

Payment may be made under Part B for the medical and other health services enumerated in paragraph C, but only where no payment can be made for such services under Part A. For example, payment may be made under Part B for the services in question where the beneficiary is an inpatient of a hospital or skilled nursing facility (SNF) and has exhausted his or her allowed days of inpatient coverage under Part A (or has elected not to use his or her lifetime reserve days). In the case of an inpatient of a SNF, Part B payment may be made if the patient is receiving Part A benefits for most of his or her

care but the participating SNF does not furnish the services to its inpatients either directly or under arrangements (i.e., does not bill for services furnished to its inpatients by other suppliers).

A - Conditions for Part A Payment

In hospitals (including hospitals under the prospective payment system (PPS)) and SNFs, Part B payment may be made for the services listed in paragraph C if the services are reasonable and necessary and if:

- No Part A payment is made at all for the hospital or SNF stay because of patient exhaustion of benefit days before admission;
- The admission was disapproved as not reasonable and necessary and limitation of liability payment was not made;
- The patient was not otherwise eligible for or entitled to coverage under Part A (see the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions From Coverage," §180); or
- In the case of a hospital paid under the PPS, no Part A day outlier payment is made (for discharges before October 1997) for one or more outlier days due to patient exhaustion of benefit days after admission but before the case's arrival at outlier status or because outlier days are otherwise not covered and waiver of liability payment is not made. (Outlier days are days for which extra payment is made under PPS for long stay cases.)

Part B payment may be made for the medical and other health services listed in paragraph C when they are reasonable and necessary and furnished at any time during the stay if no Part A payment is made. However, if only day outlier payment is denied under Part A, Part B payment may be made for only the services furnished on the denied outlier days.

In non-PPS hospitals and in SNFs, Part B payment may be made for the indicated covered services delivered on any day for which Part A payment is denied (i.e., because of patient exhaustion of benefit days, the patient or services received were not at the hospital level or SNF level of care, or the patient was not otherwise eligible for or entitled to payment under Part A).

B - Bundling of Services to Hospital Inpatients

In the case of a hospital inpatient, the services described in paragraph C are covered only if they are furnished by the hospital directly, or by another entity under arrangements made by the hospital. Only the hospital is allowed to bill for the services, and the bills must be submitted to the intermediary rather than to the carrier.

Certain services are exempt from the bundling requirement and may be billed directly to the carrier even when furnished to a hospital inpatient. (See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions From Coverage," §170.)

C - Covered Part B Services When Part A Coverage is Not Available

The medical and other services covered under Part B when furnished to patients of hospitals and SNFs include the following:

- Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests;
- X-ray, radium, and radioactive isotope therapy including materials and services of technicians;
- Surgical dressings, splints, casts, and other devices used for reduction of fractures and dislocations;
- Prosthetic devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue), or all or part of the function of a permanently inoperative or malfunctioning internal body organ, including replacement or repairs of such devices;
- Leg, arm, back, and neck braces, trusses, and artificial legs, arms, and eyes, including adjustments, repairs, and replacements required because of breakage, wear, loss, or a change in the patient's physical condition;
- Outpatient physical therapy, outpatient occupational therapy, and outpatient speech-language pathology services; and
- Ambulance services.

260 - Ambulatory Surgical Center Services

(Rev. 1, 10-01-03)

B3-2265

Facility services furnished by ambulatory surgical centers (ASCs) in connection with certain surgical procedures are covered under Part B. To receive coverage of and payment for its services under this provision, a facility must be certified as meeting the requirements for an ASC and enter into a written agreement with CMS. Medicare periodically updates the list of covered procedures and related payment amounts through release of regulations and Program Memoranda. The ASC must accept Medicare's payment for such procedures as payment in full with respect to those services defined as ASC facility services.

Where services are performed in an ASC, the physician and others who perform covered services may also be paid for his/her professional services; however, the "professional" rate is then adjusted since the ASC incurs the facility costs.

260.1 - Definition of Ambulatory Surgical Center (ASC)

(Rev. 1, 10-01-03)

B3-2265.1

An ASC for purposes of this benefit is a distinct entity that operates exclusively for the purpose of furnishing outpatient surgical services to patients. It enters into an agreement with CMS to do so. An ASC is either independent (i.e., not a part of a provider of services or any other facility), or operated by a hospital (i.e., under the common ownership, licensure, or control of a hospital). If the hospital based surgery center is certified as an ASC it is considered and ASC and is subject to rules for ASCs. If a hospital based surgery center is not certified as an ASC it continues under the program as part of the hospital. In this case the applicable outpatient payment rules apply. This may

be OPPS, for most hospitals, or may be provisions for hospitals excluded from OPPS. See the Medicare Claims Processing Manual, Chapter 4, for billing and payment requirements for hospital outpatient services.

260.2 - Ambulatory Surgical Center Services

(Rev. 1, 10-01-03)

B3-2265.2

The ASC facility services are services furnished in an ASC in connection with a covered surgical procedure that are otherwise covered if furnished on an inpatient or outpatient basis in a hospital in connection with that procedure. Not included in the definition of facility services are medical and other health services, even though furnished within the ASC, which are covered under other portions of the Medicare program, or not furnished in connection with covered surgical procedures. This distinction between covered ASC facility services and services which are not covered ASC facility services is important, since the facility payment rate includes only the covered ASC facility services. Services which are not covered ASC facility services such as physicians' services and prosthetic devices other than intraocular lenses (IOLs), may be covered and billable under other Medicare provisions.

Since there is no uniformity among ASCs as to what items and services they include in their facility fee or charge, the Medicare definition of covered facility services is both inclusive and exclusive. The regulations specify what are and are not facility services. Facility services are items and services furnished in connection with listed covered procedures, which are covered if furnished in a hospital operating suite or hospital outpatient department in connection with such procedures. These do not include physicians' services, or medical and other health services for which payment may be made under other Medicare provisions (e.g., services of an independent laboratory located on the same site as the ASC).

Examples of covered ASC facility services include:

- **Nursing Services, Services of Technical Personnel, and Other Related Services -** These include all services in connection with covered procedures furnished by nurses and technical personnel who are employees of the ASC. In addition to the nursing staff, this category includes orderlies, technical personnel, and others involved in patient care;
- **Use by the Patient of the ASC's Facilities -** This category includes operating and recovery rooms, patient preparation areas, waiting rooms, and other areas used by the patient or offered for use by the patient's relatives in connection with surgical services; and
- **Drugs, Biologicals, Surgical Dressings, Supplies, Splints, Casts, Appliances, and Equipment -** This category includes all supplies and equipment commonly furnished by the ASC in connection with surgical procedures. See below for certain exceptions. Drugs and biologicals are limited to those that cannot be self-administered. (See §60.)

Coverage policy for surgical dressings is similar to that followed under Part B. Under Part B, coverage for surgical dressings is limited to primary dressings; i.e., therapeutic and protective coverings applied directly to lesions on the skin or on openings to the skin required as the result of surgical procedures. (Items such as Ace bandages, elastic stockings and support hose, Spence boots and other foot coverings, leotards, knee supports, surgical leggings, gauntlets, and pressure garments for the arms and hands are generally used as secondary coverings and therefore are not covered as surgical dressings.) Surgical dressings usually are applied first by a physician and are covered as "incident to" a physician's service in a physician's office setting. In the ASC setting, such dressings are included in the facility's services.

However, others may reapply surgical dressings later, including the patient or a member of the patient's family. When the patient on a physician's order obtains surgical dressings from a supplier, e.g., a drugstore, the surgical dressing is covered under Part B. The same policy applies in the case of dressings obtained by the patient on a physician's order following surgery in an ASC; the dressings are covered and paid as a Part B service by the local Part B carrier, included in the definition of facility services.

Similarly, "other supplies, splints, and casts" include only those furnished by the ASC at the time of the surgery. Additional covered supplies and materials furnished later are generally furnished as "incident to" a physician's service, not as an ASC facility service. The term "supplies" includes those required for both the patient and ASC personnel, e.g., gowns, masks, drapes, hoses, and scalpels, whether disposable or reusable.

Diagnostic or Therapeutic Items and Services

These are items and services furnished by ASC staff in connection with covered surgical procedures. With respect to diagnostic tests, many ASCs perform simple tests just before surgery, primarily urinalysis and blood hemoglobin or hematocrit, which are generally included in their facility charges. To the extent that such simple tests are included in the ASC's facility charges, they are considered facility services. However, under the Medicare program, diagnostic tests are not covered in laboratories independent of a physician's office, rural health clinic, or hospital unless the laboratories meet the regulatory requirements for the conditions for coverage of services of independent laboratories. (See 42 CFR 405.1310.) Therefore, diagnostic tests performed by the ASC other than those generally included in the facility's charge are not covered under Part B as such and are not be billed to the carrier as diagnostic tests. If the ASC has its laboratory certified as meeting the regulatory conditions, then the laboratory itself bills the carrier (or the beneficiary) for the tests performed.

The ASC may make arrangements with an independent laboratory or other laboratory, such as a hospital laboratory, to perform diagnostic tests it requires prior to surgery. In general, however, the necessary laboratory tests are done outside the ASC prior to scheduling of surgery, since the test results often determine whether the beneficiary should even have the surgery done on an outpatient basis in the first place.

Administrative, Recordkeeping, and Housekeeping Items and Services

These include the general administrative functions necessary to run the facility e.g., scheduling, cleaning, utilities, and rent.

Blood, Blood Plasma, Platelets, etc., Except Those to Which Blood Deductible Applies

While covered procedures are limited to those not expected to result in extensive loss of blood, in some cases, blood or blood products are required. Usually the blood deductible results in no expenses for blood or blood products being included under this provision. However, where there is a need for blood or blood products beyond the deductible, they are considered ASC facility services and no separate charge is permitted to the beneficiary or the program.

Materials for Anesthesia

These include the anesthetic itself, and any materials, whether disposable or reusable, necessary for its administration.

Intraocular Lenses (IOLs)

Effective for services furnished on or after March 12, 1990, ASC facility services include intraocular lenses approved by the Food and Drug Administration (FDA) for insertion during or subsequent to cataract surgery.

FDA has classified IOLs into the following four categories, any of which are included:

- Anterior chamber angle fixation lenses;
- Iris fixation lenses;
- Irido-capsular fixation lenses; and
- Posterior chamber lenses.

While FDA has approved many IOLs, it still considers some IOLs investigational. The fact that they are covered under Medicare is an exception to the general policy not to cover experimental or investigational items or services. The exception is made because the Congress, recognizing the widespread use of IOLs, directed the FDA to study them without interfering with availability to patients.

The carrier is not concerned with whether a given item or service is an ASC facility service, unless the ASC makes a separate charge for it. In such a case, the carrier determines whether the item or service falls into the categories described in the following section. If it determines the item or service does fall into one of those categories, it makes payment following the applicable rules for such items and services found elsewhere in this chapter. If the item or service does not fall into one of the categories described, the carrier denies the claim.

260.3 - Services Furnished in ASCs Which are Not ASC Facility Services

(Rev. 1, 10-01-03)

B3-2265.3

A single payment is made to an ASC that encompasses all “facility services” furnished by the ASC in connection with a covered procedure. However, a number of items and services covered under Medicare may be furnished in an ASC which are not considered

facility services, and which the ASC payment does not include. These non-ASC services are covered and paid for under the applicable provisions of Part B. In addition, the ASC may be part of a medical complex that includes other entities, such as an independent laboratory, supplier of durable medical equipment, or a physician's office, which are covered as separate entities under Part B. In general, an item or service separately covered under Medicare is not considered an ASC service. Examples of services payable in addition to ASC services are found in §260.4.

260.4 - Coverage of Services in ASCs, Which are Not ASC Services

(Rev. 1, 10-01-03)

B3-2265.4

Physicians' Services

This category includes most covered services performed in ASCs, which are not considered ASC facility services. Physicians' services were covered before coverage of ASC services, and the ASC amendment did not change this. Consequently, physicians who perform covered services in ASCs receive payment under the existing Part B system. 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 post-operative services, such as office visits, consultations, diagnostic tests, removal of stitches, changing of dressings, and other services which are defined in the set "global" fee for a given surgical procedure (CPT code). The carrier applies the same criteria, limits and understandings to physicians' services for procedures done in the ASC that were applied to the procedures done by the same physicians on an inpatient hospital basis.

The Sale, Lease, or Rental of Durable Medical Equipment (DME) to ASC Patients for Use in Their Homes

If the ASC furnished items of DME to patients, it must have a DME supplier number, and it is treated as a DME supplier, as described in §§110. While an ASC is not a "provider of services" under Medicare, the carrier considers it a "supplier of services" for purposes of the second paragraph of §110. All the rules and conditions ordinarily applicable to DME are applicable where ASCs furnish such items.

Prosthetic Devices

Prosthetic devices, other than intraocular lenses (IOLs), whether implanted, inserted, or otherwise applied by covered surgical procedures, are covered, but are not included in the ASC facility payment amount. However, §4063(b) of P.L. 100-203 amended §1833 (i)(2)(A) of the Act to mandate that payment for an intraocular lens (IOL) inserted during or subsequent to cataract surgery in an ASC be included in the facility payment rate. This bundling of the payment for an IOL with the facility fee is effective for services furnished on or after March 12, 1990. More information on coverage of prosthetic devices may be found in §120. Further information on the coverage of IOLs may be found in §260.2.

Ambulance Services

If the ASC furnishes ambulance services, they are covered as ambulance services pursuant to the terms and conditions of the Medicare Benefit Policy Manual, Chapter 10, "Ambulance Services," §§10.

Leg, Arm, Back, and Neck Braces

These items of equipment, like prosthetic devices, are covered under Part B, but are not included in the ASC facility payment amount. Coverage of these items is described in §130.

Artificial Legs, Arms, and Eyes

Like prosthetic devices and braces, this equipment is not considered part of an ASC facility service and so is not included in the ASC facility payment rate. Information regarding the coverage of these items is set out in §130.

Services of Independent Laboratory

As noted in §260.2, only a very limited number and type of diagnostic tests are considered ASC facility services and included in the ASC facility payment rate. In most cases, diagnostic tests performed directly by an ASC are not considered ASC facility services and are not covered under Medicare because §1861(s) of the statute limits coverage of diagnostic tests in facilities other than physicians' offices, rural health clinics, or hospitals to facilities that meet the statutory definition of an independent laboratory. (See §§80.1 for a description of independent laboratories and covered services.) Accordingly, if an ASC wishes to provide laboratory services directly, it has its laboratory certified as an independent laboratory for the services to be covered. Otherwise, the ASC makes arrangements with a covered laboratory or laboratories for laboratory services, as provided in 42 CFR 416.49. If the ASC has a certified independent laboratory, the laboratory itself bills the carrier, pursuant to §§80.

260.5 - List of Covered Ambulatory Surgical Center Procedures

(Rev. 1, 10-01-03)

B3-2266

The law ties coverage of ambulatory surgical center (ASC) services under Part B to specified surgical procedures, which are contained in a list revised and published periodically by CMS. Groupings and related prices are also published periodically. These are published in the Federal Register and on the CMS Web site.

260.5.1 - Nature and Applicability of ASC List

(Rev. 1, 10-01-03)

B3-2266.1

With respect to facility services, the carrier makes payment for a procedure performed in an independent facility on a Medicare beneficiary only if the procedure is on the list. (The payment is the ASC facility services amount, subject to wage index adjustment and applicable deductible and coinsurance.) If a procedure is not on the list, the carrier makes no payment for ASC facility services. This policy applies to all facilities with an

agreement with CMS to be covered as ASCs, both independent facilities and those hospital-affiliated ambulatory surgical centers which choose to be covered as ASCs and enter into the ASC agreement.

The list of covered procedures merely indicates procedures, which are covered and paid for if performed in the ASC setting. It does not require these procedures to be performed in such settings, nor is any out-of-the-ordinary justification or special review required if listed procedures are performed on a hospital inpatient basis. The choice of operating site remains a matter for the professional judgment of the patient's physician. Also, all the general coverage rules regarding the medical necessity of a particular procedure for a particular patient are applicable to ASC services in the same manner as all other covered services.

260.5.2 - Nomenclature and Organization of the List

(Rev. 1, 10-01-03)

B3-2266.2

The listed procedures are all considered "surgical procedures" for coverage purposes under the ASC provision, regardless of the specific use to which the procedure is put. For example, many of the "oscopy" procedures listed - bronchoscopy, laryngoscopy, etc., may be employed for either diagnostic or therapeutic purposes, or both at the same time, such as when the "oscopy" permits both detection and removal of a polyp. Those procedures are considered "surgical procedures" within the context of the ASC provision. Also, surgical procedures are commonly thought of as those involving an incision of some type, whether done with a scalpel or (more recently) a laser, followed by removal or repair of an organ or other tissue. In recent years, the development of fiber optics technology, together with new surgical instruments utilizing that technology, has resulted in surgical procedures that, while invasive and manipulative, do not require incisions. Instead, the procedures are performed without an incision through various body openings. Those procedures, some of which include the "oscopy" procedures mentioned above, are also considered surgical procedures for purposes of the ASC provision, and several are included in the list of covered procedures.

260.5.3 - Rebundling of CPT Codes

(Rev. 1, 10-01-03)

B3-2266.3

Instructions regarding the Correct Coding Initiative apply to coverage of ASC facility services.

270 - Telehealth Services

(Rev. 1, 10-01-03)

AB-01-69 dated 5-1-2001, AB-02-052, AB 02-053, AB-03-070, B3-15516.C

A - Summary

Effective October 1, 2001, coverage and payment for Medicare telehealth includes consultation, office visits, individual psychotherapy and pharmacologic management

delivered via a telecommunications system and provides for adding or deleting services from this list. Effective March 1, 2003, the psychiatric diagnostic interview examination was added to the list of Medicare telehealth services. Eligible geographic areas are expanded beyond rural health professional shortage areas to include counties not in 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, asynchronous "store and forward" technology may be used in delivering these services when the originating site is a Federal telemedicine demonstration program in Alaska or Hawaii. A physician or practitioner is not required to present the patient as a condition of payment for interactive telehealth services.

Payment for the professional service performed by the distant site physician or 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 physicians or practitioners include only physicians as described in §1861(r) of the Act and a medical practitioner as described in §1842(b)(18)(C) of the Act. The originating site facility (location of beneficiary) receives a $20 facility fee updated annually by the Medicare Economic Index.

270.1 - Eligibility Criteria

(Rev. 1, 10-01-03)

Furnished by CMS

Beneficiaries are eligible for telehealth services **only** if they are presented from an originating site located either in a rural HPSA or in a county outside of a MSA.

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.

An originating site is the location of an eligible Medicare beneficiary at the time the service being furnished via telecommunications system occurs. Originating sites authorized by law are listed below.

- The office of a physician or practitioner.
- A hospital.
- A critical access hospital.
- A rural health clinic.
- A federally qualified health center.

270.2 – List of Medicare Telehealth Services

(Rev. 1, 10-01-03)

Furnished by CMS

The use of a telecommunications system may substitute for a face-to-face, "hands on" encounter for consultations, office visits, individual psychotherapy pharmacologic management and psychiatric diagnostic interview examination. These services and corresponding current procedure terminology (CPT) codes are listed below.

- Consultations (CPT codes 99241 - 99275).
- Office or other outpatient visits (CPT codes 99201 - 99215).
- Individual psychotherapy (CPT codes 90804 - 90809).
- Pharmacologic management (CPT code 90862).
- Psychiatric diagnostic interview examination (CPT code 90801) (Effective March 1, 2003).

270.3 – Conditions of Payment

(Rev. 1, 10-01-03)

Furnished by CMS

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.

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.

For the purposes of this instruction, store and forward means the asynchronous transmission of medical information to be reviewed at a later time by a 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 or a treatment plan. Dermatological photographs, e.g., photographs of a skin lesion, may be considered to meet the requirement of a single media format under this instruction.

Telepresenters: A medical professional is not required to present the beneficiary to the 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.

270.4 – Payment – Physician/Practitioner at a Distant Site

(Rev. 1, 10-01-03)

Furnished by CMS

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.

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 telehealth services (see §270.2) 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.

Medicare Practitioners Who May Receive Payment at the Distant Site (i.e., at a Site Other Than Where a 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 (see §270.2) then he or she may bill for and receive payment for this service when delivered via a telecommunications system.

Medicare practitioners who may bill for a covered telehealth service are listed below (subject to State law):

- Physician;
- Nurse practitioner;
- Physician assistant;
- Nurse midwife;
- Clinical nurse specialist;
- Clinical psychologist; and
- Clinical social worker.

* 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.

270.5 - Originating Site Facility Fee Payment Methodology

(Rev. 1, 10-01-03)

Furnished by CMS

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.

For telehealth services (see §270.2) furnished from October 1, 2001, through December 31, 2002, the originating site fee is the lesser of $20 or the actual charge. For services furnished on or after January 1 of each subsequent year, the Medicare Economic Index (MEI) will update the facility fee for the originating site annually.

For telehealth services furnished from October 1, 2001, through December 31, 2002, the payment amount to the originating site is the lesser of 80 percent of the actual charge or the originating site facility fee of $20. 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:

- 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 outpatient prospective payment system. Payment is not based on current fee schedules or other payment methodologies.
- 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.
- When the originating site is a critical access hospital, contractors make payment separately from the cost-based reimbursement methodology.
- The originating site facility fee for telehealth services is not a Federally qualified health center (FQHC) and rural health clinic (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.
- 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 originating site facility fee regardless of geographic location. The geographic cost index (GPCI) should not be applied to the originating site facility fee. This fee is statutorily set and is not subject to the geographic payment adjustments authorized under the physician fee schedule.

280 – Preventive and Screening Services

(Rev. 1, 10-01-03)

See §50.4.4.2 for coverage requirements for PPV, hepatitis B vaccine, and Influenza Virus vaccine.

See Medicare Claims Processing Manual, Chapter 18, "Preventive and Screening Services," for coverage requirements for the following

- §40 for screening pelvic examinations,
- §50 for prostate cancer screening test and procedures.

280.1 – Glaucoma Screening

(Rev. 1, 10-01-03)

B-01-46, A-01-13, A-01-105, B3-4184-4184.9

A - Conditions of Coverage

The regulations implementing the Benefits Improvements and Protection Act of 2000, §102, provide for annual coverage for glaucoma screening for beneficiaries in the following high risk categories:

- Individuals with diabetes mellitus;
- Individuals with a family history of glaucoma; or
- African-Americans age 50 and over.

Medicare will pay for glaucoma screening examinations where they are furnished by or under the direct supervision in the office setting of an ophthalmologist or optometrist, who is legally authorized to perform the services under State law.

Screening for glaucoma is defined to include:

- A dilated eye examination with an intraocular pressure measurement; and
- A direct ophthalmoscopy examination, or a slit-lamp biomicroscopic examination.

Payment may be made for a glaucoma screening examination that is performed on an eligible beneficiary after at least 11 months have passed following the month in which the last covered glaucoma screening examination was performed.

The following HCPCS codes apply for glaucoma screening:

G0117 - Glaucoma screening for high risk patients furnished by a physician; and

G0118 - Glaucoma screening for high risk patients furnished under the direct supervision of a physician.

The type of service for the above G codes is: TOS Q.

For providers who bill intermediaries, applicable types of bill for screening glaucoma services are 13X, 22X, 23X, 71X, 73X, 75X, and 85X. The following revenue codes should be reported when billing for screening glaucoma services:

- Comprehensive outpatient rehabilitation facilities (CORFs), critical access hospitals (CAHs), skilled nursing facilities (SNFs), independent and provider-based RHCs and free standing and provider-based FQHCs bill for this service under revenue code 770. CAHs electing the optional method of payment for outpatient services report this service under revenue codes 96X, 97X, or 98X.

- Hospital outpatient departments bill for this service under any valid/appropriate revenue code. They are not required to report revenue code 770.

B - Calculating the Frequency

Once a beneficiary has received a covered glaucoma screening procedure, the beneficiary may receive another procedure after 11 full months have passed. To determine the 11-month period, start the count beginning with the month after the month in which the previous covered screening procedure was performed.

C - Diagnosis Coding Requirements

Providers bill glaucoma screening using screening ("V") code V80.1 (Special Screening for Neurological, Eye, and Ear Diseases, Glaucoma). Claims submitted without a screening diagnosis code may be returned to the provider as unprocessable.

D - Payment Methodology

1 - Carriers

Contractors pay for glaucoma screening based on the Medicare physician fee schedule. Deductible and coinsurance apply. Claims from physicians or other providers where assignment was not taken are subject to the Medicare limiting charge (refer to the Medicare Claims Processing Manual, Chapter 12, "Physician/Nonphysician Practitioners," for more information about the Medicare limiting charge).

2 - Intermediaries

Payment is made for the facility expense as follows:

- Independent and provider-based RHC/free standing and provider-based FQHC - payment is made under the all inclusive rate for the screening glaucoma service based on the visit furnished to the RHC/FQHC patient;
- CAH - payment is made on a reasonable cost basis unless the CAH has elected the optional method of payment for outpatient services in which case, procedures outlined in the Medicare Claims Processing Manual, Chapter 3, §30.1.1, should be followed;
- CORF - payment is made under the Medicare physician fee schedule;
- Hospital outpatient department - payment is made under outpatient prospective payment system (OPPS);
- Hospital inpatient Part B - payment is made under OPPS;
- SNF outpatient - payment is made under the Medicare physician fee schedule (MPFS); and
- SNF inpatient Part B - payment is made under MPFS.

Deductible and coinsurance apply.

E - Special Billing Instructions for RHCs and FQHCs

Screening glaucoma services are considered RHC/FQHC services. RHCs and FQHCs bill the contractor under bill type 71X or 73X along with revenue code 770 and HCPCS codes G0117 or G0118 and RHC/FQHC revenue code 520 or 521 to report the related visit. Reporting of revenue code 770 and HCPCS codes G0117 and G0118 in addition to revenue code 520 or 521 is required for this service in order for CWF to perform frequency editing.

Payment should not be made for a screening glaucoma service unless the claim also contains a visit code for the service. Therefore, the contractor installs an edit in its system to assure payment is not made for revenue code 770 unless the claim also contains a visit revenue code (520 or 521).

280.2 - Colorectal Cancer Screening

(Rev. 1, 10-01-03)

B3-4180

280.2.1 - Covered Services and HCPCS Codes

See Business Requirements at http://cms.hhs.gov/manuals/pm_trans/R3BP.pdf

(Rev. 3, 12-19-03)

B3-4180.1

Medicare covers colorectal cancer screening test/procedures for the early detection of colorectal cancer for the HCPCS codes indicated.

A. Effective for Services Furnished On or After January 1, 1998:

G0107 - Colorectal cancer screening; fecal-Occult blood test, 1-3 simultaneous determinations;

G0104 - Colorectal cancer screening; flexible sigmoidoscopy;

G0105 - Colorectal cancer screening; colonoscopy on individual at high risk;

G0106 - Colorectal cancer screening barium enema; alternative to GO104, screening sigmoidoscopy;

G0120 - Colorectal cancer screening barium enema; alternative to GO105, screening sigmoidoscopy.

B. Effective for Services Furnished On or After July 1, 2001:

G0121 - Colorectal Cancer Screening; Colonoscopy on Individual Not Meeting Criteria for High Risk

C. Effective for Services Furnished On or After January 1, 2004:

G0328 - Colorectal cancer screening; fecal-occult blood test, immunoassay, 1-3 simultaneous determinations.

280.2.2 - Coverage Criteria

(Rev. 3, 12-19-03)

B3-4180.2

The following are the coverage criteria for these screenings:

A. Screening Fecal-Occult Blood Tests (FOBT) (Codes G0107 & G0328)

Effective for services furnished on or after January 1, 2004, one screening FOBT (code G0107 **or** G0328) is covered for beneficiaries who have attained age 50, at a frequency of once every 12 months (i.e., at least 11 months have passed following the month in which the last covered screening FOBT was done). Screening FOBT means: (1) a guaiac-based test for peroxidase activity in which the beneficiary completes it by taking samples from two different sites of three consecutive stools **or**, (2) a immunoassay (or immunochemical) test for antibody activity in which the beneficiary completes the test by taking the appropriate number of samples according to the specific manufacturer's instructions. This expanded coverage is in accordance with revised regulations at 42 CFR 410.37(a)(2) that includes " other tests determined by the Secretary through a national coverage determination." This screening requires a written order from the beneficiary's attending physician. (The term "attending physician" is defined to mean a doctor of medicine or osteopathy (as defined in §1861(r)(1) 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.)

B. Screening Flexible Sigmoidoscopies (code G0104)

For claims with dates of service on or after January 1, 2002, carriers pay for screening flexible sigmoidoscopies (Code G0104) for beneficiaries who have attained age 50 when these services were performed by a doctor of medicine or osteopathy, or by a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in §1861(aa)(5) of the Act and in the Code of Federal Regulations at 42 CFR 410.74, 410.75, and 410.76) at the frequencies noted below. For claims with dates of service prior to January 1, 2002, pay for these services under the conditions noted only when they are performed by a doctor of medicine or osteopathy.

For services furnished from January 1, 1998, through June 30, 2001, inclusive

Once every 48 months (i.e., at least 47 months have passed following the month in which the last covered screening flexible sigmoidoscopy was done).

For services furnished on or after July 1, 2001

Once every 48 months as calculated above **unless** the beneficiary does not meet the criteria for high risk of developing colorectal cancer (refer to §280.2.3) **and** the beneficiary has had a screening colonoscopy (code G0121) within the preceding 10 years. If such a beneficiary has had a screening colonoscopy within the preceding 10 years, then he or she can have covered a screening flexible sigmoidoscopy only after at least 119 months have passed following the month that he/she received the screening colonoscopy (code G0121).

NOTE: If during the course of a screening flexible sigmoidoscopy a lesion or growth is detected which results in a biopsy or removal of the growth, the appropriate diagnostic procedure classified as a flexible sigmoidoscopy with biopsy or removal should be billed and paid rather than code G0104.

C. Screening Colonoscopies for Beneficiaries at High Risk of Developing Colorectal Cancer (Code G0105)

The carrier must pay for screening colonoscopies (code G0105) when performed by a doctor of medicine or osteopathy at a frequency of once every 24 months for beneficiaries at high risk for developing colorectal cancer (i.e., at least 23 months have passed following the month in which the last covered G0105 screening colonoscopy was performed). Refer to §280.2.3 for the criteria to use in determining whether or not an individual is at high risk for developing colorectal cancer.

NOTE: If during the course of the screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the growth, the appropriate diagnostic procedure classified as a colonoscopy with biopsy or removal should be billed and paid rather than code G0105.

D. Screening Colonoscopies Performed on Individuals Not Meeting the Criteria for Being at High-Risk for Developing Colorectal Cancer (Code G0121)

Effective for services furnished on or after July 1, 2001, screening colonoscopies (code G0121) are covered when performed under the following conditions:

1. On individuals not meeting the criteria for being at high risk for developing colorectal cancer (refer to §280.2.3);
2. At a frequency of once every 10 years (i.e., at least 119 months have passed following the month in which the last covered G0121 screening colonoscopy was performed); and
3. If the individual would otherwise qualify to have covered a G0121 screening colonoscopy based on the above (see §§280.2.2.D.1 and 2) **but** has had a covered screening flexible sigmoidoscopy (code G0104), then the individual may have a covered G0121 screening colonoscopy only after at least 47 months have passed following the month in which the last covered G0104 flexible sigmoidoscopy was performed.

NOTE: If during the course of the screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the growth, the appropriate diagnostic procedure classified as a colonoscopy with biopsy or removal should be billed and paid rather than code G0121.

E. Screening Barium Enema Examinations (codes G0106 and G0120)

Screening barium enema examinations are covered as an alternative to either a screening sigmoidoscopy (code G0104) or a screening colonoscopy (code G0105) examination. The same frequency parameters for screening sigmoidoscopies and screening colonoscopies above apply.

In the case of an individual aged 50 or over, payment may be made for a screening barium enema examination (code G0106) performed after at least 47 months have passed following the month in which the last screening barium enema or screening flexible sigmoidoscopy was performed. For example, the beneficiary received a screening barium enema examination as an alternative to a screening flexible sigmoidoscopy in January 1999. The count starts beginning February 1999. The beneficiary is eligible for another screening barium enema in January 2003.

In the case of an individual who is at high risk for colorectal cancer, payment may be made for a screening barium enema examination (code G0120) performed after at least 23 months have passed following the month in which the last screening barium enema or the last screening colonoscopy was performed. For example, a beneficiary at high risk for developing colorectal cancer received a screening barium enema examination (code G0120) as an alternative to a screening colonoscopy (code G0105) in January 2000. The count starts beginning February 2000. The beneficiary is eligible for another screening barium enema examination (code G0120) in January 2002.

The screening barium enema must be ordered in writing after a determination that the test is the appropriate screening test. Generally, it is expected that this will be a screening double contrast enema unless the individual is unable to withstand such an exam. This means that in the case of a particular individual, the attending physician must determine that the estimated screening potential for the barium enema is equal to or greater than the screening potential that has been estimated for a screening flexible sigmoidoscopy, or for a screening colonoscopy, as appropriate, for the same individual. The screening single contrast barium enema also requires a written order from the beneficiary's attending physician in the same manner as described above for the screening double contrast barium enema examination.

280.2.3 - Determining Whether or Not the Beneficiary is at High Risk for Developing Colorectal Cancer

(Rev. 1, 10-01-03)

B3-4180.3

A. Characteristics of the High Risk Individual

An individual at high risk for developing colorectal cancer has one or more of the following:

- A close relative (sibling, parent, or child) who has had colorectal cancer or an adenomatous polyp;
- A family history of familial adenomatous polyposis;
- A family history of hereditary nonpolyposis colorectal cancer;
- A personal history of colorectal cancer;
- A personal history of adenomatous polyps;
- Inflammatory bowel disease, including Crohn's Disease, and ulcerative colitis.

B. Partial List of ICD-9-CM Codes Indicating High Risk

Listed below are some examples of diagnoses that meet the high risk criteria for colorectal cancer. This is not an all-inclusive list. There may be more instances of conditions which may be coded and could be at the medical directors' discretion.

- **Personal History**
  - V10.05 - Personal history of malignant neoplasm of large intestine
  - V10.06 - Personal history of malignant neoplasm of rectum, rectosigmoid junction, and anus
- **Chronic Digestive Disease Condition**
  - 555.0 - Regional enteritis of small intestine
  - 555.1 - Regional enteritis of large intestine
  - 555.2 - Regional enteritis of small intestine with large intestine
  - 555.9 - Regional enteritis of unspecified site
  - 556.0 - Ulcerative (chronic) enterocolitis
  - 556.1 - Ulcerative (chronic) ileocolitis
  - 556.2 - Ulcerative (chronic) proctitis
  - 556.3 - Ulcerative (chronic) proctosigmoiditis
  - 556.8 - Other ulcerative colitis
  - 556.9 - Ulcerative colitis, unspecified (nonspecific PDX on the MCE)
- **Inflammatory Bowel**
  - 558.2 - Toxic gastroenteritis and colitis
  - 558.9 - Other and unspecified noninfectious gastroenteritis and colitis

280.2.4 - Determining Frequency Standards

(Rev. 1, 10-01-03)

B3-4180.4

To determine the 11, 23, 47, and 119-month periods, the count starts beginning with the month after the month in which a previous test/procedure was performed.

EXAMPLE: The beneficiary received a fecal-occult blood test in January 2000. The carrier starts its count beginning with February 2000. The beneficiary is eligible to receive another blood test in January 2001 (the month after 11 full months have passed).

280.2.5 - Noncovered Services

(Rev. 1, 10-01-03)

B3-4180.5

The following noncovered HCPCS codes are used to allow claims to be billed and denied for beneficiaries who need a Medicare denial for other insurance purposes for the dates of service indicated:

A. From January 1, 1998 Through June 30, 2001, Inclusive

Code G0121 (colorectal cancer screening; colonoscopy on an individual not meeting criteria for high risk) should be used when this procedure is performed on a beneficiary who does NOT meet the criteria for high risk. This service should be denied as noncovered because it fails to meet the requirements of the benefit for these dates of service. The beneficiary is liable for payment. Note that this code is a covered service for dates of service on or after July 1, 2001.

B. On or After January 1, 1998

Code G0122 (colorectal cancer screening; barium enema) should be used when a screening barium enema is performed NOT as an alternative to either a screening colonoscopy (code G0105) or a screening flexible sigmoidoscopy (code G0104). This service should be denied as noncovered because it fails to meet the requirements of the benefit. The beneficiary is liable for payment.

280.3 - Screening Mammography

(Rev. 1, 10-01-03)

A3-3660.10, B3-4601.1

Section 4163 of the Omnibus Budget Reconciliation Act of 1990 added §1834(c) of the Act to provide for Part B coverage of mammography screening performed on or after January 1, 1991. The term "screening mammography" means a radiologic procedure provided to an asymptomatic woman for the purpose of early detection of breast cancer and includes a physician's interpretation of the results of the procedure. Unlike diagnostic mammographies, there do not need to be signs, symptoms, or history of breast disease in order for the exam to be covered.

A doctor's prescription or referral is not necessary for the procedure to be covered. Payment may be made for a screening mammography furnished to a woman at her direct request, and based on a woman's age and statutory frequency parameter.

Section 4101 of the Balanced Budget Act (BBA) of 1997 provides for annual screening mammographies for women over 39 and waives the Part B deductible. Coverage applies as follows:

Age	Screening Period
Less than 35 years old	No payment may be made for a screening mammography performed on a woman under 35 years of age.
35-39	(Baseline). Pay for only one screening mammography performed on a woman between her 35th and 40th birthday.
Over age 39	For a woman over 39, pay for a screening mammography performed after 11 full months have passed following the month in which the last screening mammography was performed.

To determine the 11-month period, intermediaries and carriers start counting beginning with the month after the month in which a previous screening mammography was performed.

EXAMPLE: If Mrs. Smith received a screening mammography examination in January 1998, begin counting the next month (February 1998) until 11 months have elapsed. Payment can be made for another screening mammography in January 1999.

See the Medicare Claims Processing Manual, Chapter 18, "Preventive and Screening Services," §30, for billing and payment instructions.

280.4 - Screening Pap Smears

(Rev. 1, 10-01-03)

A3-3628.1, B3-4603.1

Effective, January 1, 1998, §4102 of the Balanced Budget Act (BBA) of 1997 (P.L. 105-33) amended §1861(nn) of the Act (42 USC 1395X(nn)) to include coverage every three years for a screening Pap smear or more frequent coverage for women:

1. At high risk for cervical or vaginal cancer; or
2. Of childbearing age who have had a Pap smear during any of the preceding three years indicating the presence of cervical or vaginal cancer or other abnormality.

Effective July 1, 2001, the Consolidated Appropriations Act of 2001 (P.L. 106-554) modifies §1861(nn) to provide Medicare coverage for biennial screening Pap smears. Specifications for frequency limitations are defined below.

For claims with dates of service from January 1, 1998, through June 30, 2001, screening Pap smears are covered when ordered and collected by a doctor of medicine or osteopathy (as defined in §1861(r)(1) of the Act), or other authorized practitioner (e.g., a certified nurse midwife, physician assistant, nurse practitioner, or clinical nurse specialist, who is authorized under State law to perform the examination) under one of the following conditions.

- The beneficiary has not had a screening Pap smear test during the preceding three years (i.e., 35 months have passed following the month that the woman had the last covered Pap smear ICD-9-CM code V76.2 is used to indicate special screening for malignant neoplasm, cervix); or

- There is evidence (on the basis of her medical history or other findings) that she is of childbearing age and has had an examination that indicated the presence of cervical or vaginal cancer or other abnormalities during any of the preceding three years; and at least 11 months have passed following the month that the last covered Pap smear was performed; or
- She is at high risk of developing cervical or vaginal cancer ICD-9-CM code V15.89, other specified personal history presenting hazards to health) and at least 11 months have passed following the month that the last covered screening Pap smear was performed. The high risk factors for cervical and vaginal cancer are:

Cervical Cancer High Risk Factors

- Early onset of sexual activity (under 16 years of age);
- Multiple sexual partners (five or more in a lifetime);
- History of a sexually transmitted disease (including HIV infection); and
- Fewer than three negative or any Pap smears within the previous seven years.

Vaginal Cancer High Risk Factors

- DES (diethylstilbestrol) - exposed daughters of women who took DES during pregnancy

The term "woman of childbearing age" means a woman who is premenopausal, and has been determined by a physician, or qualified practitioner, to be of childbearing age, based on her medical history or other findings. Payment is not made for a screening Pap smear for women at high risk or who qualify for coverage under the childbearing provision more frequently than once every 11 months after the month that the last screening Pap smear covered by Medicare was performed.

B – For Claims with Dates of Service on or After July 1, 2001

When the beneficiary does not qualify for a more frequently performed screening Pap smear as noted in items 1 and 2 above, contractors pay for the screening Pap smear only after at least 23 months have passed following the month during which the beneficiary received her last covered screening Pap smear. All other coverage and payment requirements remain the same.

See the Medicare Claims Processing Manual, Chapter 18, "Preventive and Screening Services," for billing procedures.

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 undertaken for the sole purpose of correcting a subluxated 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) pigmentary changes (discoloration) skin texture (thin, 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 existing claims processing practices which may include review of carrier's history and medical consultation as well as physician contacts.

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

Codes and policies for routine foot care and supportive devices for the feet are not exclusively for the use of podiatrists. These codes must be used to report foot care services regardless of the specialty of the physician who furnishes the services. Carriers must instruct physicians to use the most appropriate code available when billing for routine foot care.

300 - Diabetes Self-Management Training Services

(Rev. 13, 05-13-04)

Section 4105 of the Balanced Budget Act of 1997 permits Medicare coverage of diabetes *self-management training (DSMT)* services when these services are furnished by a certified provider who meets certain quality standards. This program is intended to educate beneficiaries in the successful self-management of diabetes. The program includes instructions in self-monitoring of blood glucose; education about diet and exercise; an insulin treatment plan developed specifically for the patient who is insulin-dependent; and motivation for patients to use the skills for self-management.

Diabetes self-management training services may be covered by Medicare only if the *treating* physician or *treating* qualified nonphysician practitioner who is managing the beneficiary's diabetic condition certifies that such services are needed. The referring physician or qualified nonphysician practitioner must maintain the plan of care in the beneficiary's medical record and documentation substantiating the need for training on an individual basis when group training is typically covered, if so ordered. *The order must also include a statement signed by the physician that the service is needed as well as the following:*

- *The number of initial or follow-up hours ordered (the physician can order less than 10 hours of training);*
- *The topics to be covered in training (initial training hours can be used for the full initial training program or specific areas such as nutrition or insulin training); and*
- *A determination that the beneficiary should receive individual or group training.*

The provider of the service must maintain documentation in file that includes the original order from the physician and any special conditions noted by the physician.

When the training under the order is changed, *the training order/referral* must be signed by the physician or qualified nonphysician practitioner treating the beneficiary and maintained in the beneficiary's file *in the DSMT's program records.*

NOTE: *All entities billing for DSMT under the fee-for-service payment system or other payment systems, facilities, federally qualified health centers (FQHCs), End-Stage Renal Disease (ESRD), rural health clinics (RHCs) or managed care organizations must meet all national coverage requirements.*

300.1 - Beneficiaries Eligible for Coverage and Definition of Diabetes

(Rev. 13, 05-13-04)

Medicare Part B covers 10 hours of initial training for a beneficiary who has been diagnosed with diabetes.

Diabetes is diabetes mellitus, a condition of abnormal glucose metabolism diagnosed using the following criteria;

- *a fasting blood sugar greater than or equal to 126 mg/dL on two different occasions;*

- *a 2 hour post-glucose challenge greater than or equal to 200 mg/dL on 2 different occasions; or*

- *a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.*

Documentation that the beneficiary is diabetic is maintained in the beneficiary's medical record.

Beneficiaries are eligible to receive follow-up training each calendar year following the year in which they have been certified as requiring initial training *or they may receive follow-up training when ordered even if Medicare does not have documentation that initial training has been received. In that instance, contractors shall not deny the follow-up service even though there is no initial training recorded.*

300.2 - Certified Providers

(Rev. 13, 05-13-04)

PM AB -02-151, B-01-40

A designated certified provider bills for DSMT provided by an accredited DSMT program. Certified providers must submit a copy of their accreditation certificate to the contractor. The statute states that a "certified provider" is a physician or other individual or entity designated by the Secretary that, in addition to providing outpatient self-management training services, provides other items and services for which payment may be made under title XVIII, and meets certain quality standards. The CMS is designating all providers and suppliers that bill Medicare for other individual services such as hospital outpatient departments, renal dialysis facilities, physicians and durable medical equipment suppliers as certified. *All suppliers/providers who may bill for other Medicare services or items and who represent a DSMT program that is accredited as meeting quality standards can bill and receive payment for the entire DSMT program.. Registered dietitians are eligible to bill on behalf of an entire DSMT program on or after January 1, 2002, as long as the provider has obtained a Medicare provider number. A dietitian may not be the sole provider of the DSMT service.*

The CMS will not reimburse services *on a fee-for-service basis* rendered to a beneficiary if they are:

- An inpatient in a hospital or skilled nursing facility (SNF);

- In hospice care;

- A resident in a nursing home; or

- An outpatient in a rural health clinic (RHC) or (FQHC)
  NOTE: While separate payment is not made for this service to RHCs or FQHCs, the service is covered but is considered included in the encounter rate.

All *DSMT programs* must be accredited as meeting quality standards by a CMS approved national accreditation organization. *Currently, CMS recognizes the American Diabetes Association and the Indian Health Service as approved national accreditation organizations. Programs without accreditation by a CMS-approved national accreditation organization are not covered. Certified providers may be asked to submit updated accreditation documents at any time or to submit outcome data to an organization designated by CMS.*

Enrollment of DMEPOS Suppliers

DMEPOS suppliers are reimbursed for diabetes training through local carriers. In order to file claims for *DSMT*, a DMEPOS supplier must be enrolled in the Medicare program with the National Supplier Clearinghouse (NSC). The supplier must also meet the quality standards of a CMS-approved national accreditation organization as stated above. *DMEPOS suppliers must obtain a provider number from the local carrier in order to bill for DSMT.*

The carrier requires a completed Form CMS-855, along with an *accreditation* certificate as part of the provider application process. After it has been determined that the quality standards are met, a billing number is assigned to the supplier. Once a supplier has received a *provider identification (PIN)* number, the supplier can begin receiving reimbursement for this service.

Carriers should contact the National Supplier Clearinghouse (NSC) according to the instruction in Pub 100-8, the Medicare Program Integrity Manual, Chapter 10, "Healthcare Provider/Supplier Enrollment," to verify an applicant is currently enrolled and eligible to receive direct payment from the Medicare program.

The applicant is assigned specialty 87.

Any DMEPOS supplier that has its billing privileges deactivated or revoked by the NSC will also have the billing number deactivated by the carrier.

300.3 - Coding Frequency of Training

(Rev. 13, 05-13-04)

A – Coding

The following HCPCS codes are used for DSMT:

- *G0108 - Diabetes outpatient self-management training services, individual, per 30 minutes.*
- *G0109 - Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes.*

The type of service for these codes is 1.

B - Initial Training

Medicare will cover initial training that meets the following conditions:

- Is furnished to a beneficiary who has not previously received initial or follow-up training under HCPCS G0108 or G0109.

- Is furnished within a continuous 12-month period.

- Does not exceed a total of 10 hours *for the initial training*. The 10 hours of training can be done in any combination of 1/2 hour increments. They can be spread over the 12-month period or less.

- With the exception of 1 hour *of individual training*, training is *usually* furnished in a group setting who need not all be Medicare beneficiaries.

- *The one hour of individual training may be used for any part of the training including insulin training.*

- Is furnished in increments of no less than one-half hour.

C - Individual Training

Medicare covers training on an individual basis for a Medicare beneficiary under any of the following conditions:

- No group session is available within two months of the date the training is ordered;

- The beneficiary's physician (or qualified nonphysician practitioner) documents in the beneficiary's medical record that the beneficiary has special needs resulting from conditions, such as severe vision, hearing or language limitations *or other such special conditions as identified by the treating physician or non-physician practitioner*, that will hinder effective participation in a group training session; or

- The physician orders additional insulin training.

- The need for individual training must be identified by the physician or non-physician practitioner in the referral.

NOTE: If individual training has been provided to a Medicare beneficiary and subsequently the carrier or intermediary determines that training should have been provided in a group, down-coding the reimbursement from individual to the group level and provider education would be the appropriate actions instead of denying the service as billed.

D - Follow-Up Training

After receiving the initial training, Medicare covers follow-up training that meets the following conditions:

- Consists of no more than two hours individual or group training for a beneficiary each year;
- Group training consists of 2 to 20 individuals who need not all be Medicare beneficiaries;
- Is furnished any time in a calendar year following a year in which the beneficiary completes the initial training *(e.g., beneficiary completes initial training in November 2003 therefore the beneficiary is entitled to 2 hours of follow-up training beginning in January of 2004)*;
- Is furnished in increments of no less than one-half hour; and
- The physician (or qualified nonphysician practitioner) treating the beneficiary must document in the beneficiary's medical record *that the beneficiary is a diabetic.*

300.4 - Payment for DSMT

(Rev. 13, 05-13-04)

PM AB -02-151, B-01-40

Payment to providers for outpatient diabetes self-management training is based on rates established under the *Medicare* Physician Fee Schedule.

- Payment may only be made to any provider that bills Medicare for other individual Medicare Services;
- Payment may be made only for training sessions actually attended by the beneficiary and documented on attendance sheets;
- Other conditions for fee-for-service payment. The beneficiary must meet the following conditions if the provider is billing for initial training:
    - The beneficiary has not previously received initial *or follow-up* training for which Medicare payment was made under this benefit;
    - The beneficiary is not receiving services as an inpatient in a hospital, SNF, hospice, or nursing home; or
    - The beneficiary is not receiving services as an outpatient in an RHC or FQHC.

300.4.1 – Incident-To Provision

(Rev. 13, 05-13-04)

The "incident to" requirements of section 1861(s)(2)(A) of the Social Security Act do not apply to DSMT services. Section 1861 (s)(2)(S) of the Act authorizes DSMT in a stand alone provision. DSMT services are covered only if the physician or qualified non-physician practitioner who is managing the beneficiary's diabetic condition certifies that such services are needed and refers the patient to the DSMT program. The referral must be done under a comprehensive plan of care related to the beneficiary's diabetic condition. Training may be furnished by a physician, individual, or entity that meets the following conditions:

- *Furnishes other services for which direct Medicare payment may be made;*
- *May properly receive Medicare payment under 42CFR 424.73 or 424.80 which set forth prohibitions on assignment and reassignment of claims;*
- *Submits necessary documentation to, and is accredited by, an accreditation organization approved by CMS under 42CFR 410.142 to meet one of the sets of quality standards described in 42 CFR 410.144; and*
- *Provides documentation to CMS, as requested, including diabetes outcome measurements set forth at CFR 410.146.*
    - *Any certified providers or suppliers that provide other individual items or services under Medicare that meet CMS's quality standards and meet the conditions for CMS approval pursuant to 42 CFR 410.145, may receive reimbursement for diabetes training. Entities are more likely than individuals to bill for DSMT services. These certified providers must be currently receiving payment for other Medicare services.*

300.5 - Bill Processing Requirements

(Rev. 13, 05-13-04)

See Chapter 25 of the Medicare Claims Processing Manual for instructions for intermediaries, hospitals, and outpatient facilities.

See Chapter 26 of the Medicare Claims Processing Manual for instructions for carriers and physicians intermediaries, hospitals, and outpatient facilities.

Billing is to the "certified provider's" regular intermediary or carrier, i.e., there are no specialty contractors for this service. (See §300.2 above for definition of "certified provider" in this instance.

300.5.1 - Special Claims Processing Instructions for FIs

(Rev. 13, 05-13-04)

- *Coding and Payment Requirements*

The provider bills for DSMT on the CMS Form 1450 or its electronic equivalent.

The cost of the service is billed under revenue code 942 in FL 42 "Revenue Code." The provider will report HCPCS codes G0108 or G0109 in FL 44 "HCPCS/Rates." The definition of the HCPCS code used should be entered in FL 43 "Description."

- *Applicable Bill Types*

The appropriate bill types are 12x, 13x, 34x (can be billed if service is outside of the treatment plan), 72x, 74x, 75x, 83x and 85x.