

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 for the 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