

§410.63

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(3) They are furnished by one of the following:

(i) A provider as defined in §489.2 of this chapter, or by others under arrangements with, and under the supervision of, a provider.

(ii) A speech-language pathologist in private practice as described in paragraph (c) of this section.

(iii) Incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform speech-language pathology services under State law. When a speech-language pathology service is provided incident to the services of a physician, physician assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that apply to speech-language pathology and speech-language pathologists, except that a license to practice speech-language pathology services in the State is not required.

(b) *Special provisions for services furnished by speech-language pathologists in private practice.* Medicare Part B pays for outpatient speech-language pathology services furnished to an inpatient of a hospital, CAH, or SNF who requires the services but has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

(c) *Special provisions for services furnished by speech-language pathologists in private practice—(1) Basic qualifications.* In order to qualify under Medicare as a supplier of outpatient speech-language pathology services, each individual speech-language pathologist in private practice must meet the following requirements:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of speech-language pathology by the State in which he or she practices, and practice only within the scope of his or her license and/or certification.

(ii) Engage in the private practice of speech-language pathology as an individual, in one of the following practice types:

(A) An unincorporated solo practice.

(B) An unincorporated partnership or unincorporated group practice.

(C) An unincorporated solo practice, partnership, or group practice, or a professional corporation or other incorporated speech-language pathology practice.

(D) An employee of a physician group.

(E) An employee of a group that is not a professional corporation.

(iii) Bill Medicare only for services furnished in one of the following:

(A) A speech-language pathologist's private practice office space that meets all of the following:

(1) 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 and during the hours that the therapist engages in practice at that location.

(2) The space must be owned, leased, or rented by the practice, and used for the exclusive purpose of operating the practice.

(B) A patient's home not including any institution that is a hospital, a CAH, or a SNF.

(iv) Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

(d) *Excluded services.* No service is included as an outpatient speech-language pathology service if it is not included as an inpatient hospital service if furnished to a hospital or CAH inpatient.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 56 FR 8852, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 58 FR 30668, May 26, 1993; 63 FR 58907, Nov. 2, 1998; 69 FR 66422, Nov. 15, 2004; 73 FR 69933, Nov. 19, 2008]

§410.63 Hepatitis B vaccine and blood clotting factors: Conditions.

Notwithstanding the exclusion from coverage of vaccines (see §405.310 of this chapter) and self-administered drugs (see §410.29), the following services are included as medical and other health services covered under §410.10, subject to the specified conditions:

(a) *Hepatitis B vaccine: Conditions.* Effective September 1, 1984, hepatitis B vaccinations that are reasonable and necessary for the prevention of illness for those individuals who are at high or

intermediate risk of contracting hepatitis B as listed below:

(1) *High risk groups.* (i) End-Stage Renal Disease (ESRD) patients;

(ii) Hemophiliacs who receive Factor VIII or IX concentrates;

(iii) Clients of institutions for the mentally retarded;

(iv) Persons who live in the same household as a hepatitis B carrier;

(v) Homosexual men;

(vi) Illicit injectable drug abusers; and

(vii) Pacific Islanders (that is, those Medicare beneficiaries who reside on Pacific islands under U.S. jurisdiction, other than residents of Hawaii).

(2) *Intermediate risk groups.* (i) Staff in institutions for the mentally retarded and classroom employees who work with mentally retarded persons;

(ii) Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work (including workers who work outside of a hospital and have frequent contact with blood or other infectious secretions); and

(iii) Heterosexually active persons with multiple sexual partners (that is, those Medicare beneficiaries who have had at least two documented episodes of sexually transmitted diseases within the preceding 5 years).

(3) *Exception.* Individuals described in paragraphs (a) (1) and (2) of this section are not considered at high or intermediate risk of contracting hepatitis B if they have undergone a prevaccination screening and have been found to be currently positive for antibodies to hepatitis B.

(b) *Blood clotting factors: Conditions.* Effective July 18, 1984, blood clotting factors to control bleeding for hemophilia patients competent to use these factors without medical or other supervision, and items related to the administration of those factors. The amount of clotting factors covered under this provision is determined by the carrier based on the historical utilization pattern or profile developed by the carrier for each patient, and based on consideration of the need for a reasonable reserve supply to be kept in the home in the event of emergency or unforeseen circumstance.

(c) *Blood clotting factors: Furnishing Fee.* (1) Effective January 1, 2005, a furnishing fee of \$0.14 per unit of clotting factor is paid to entities that furnish blood clotting factors unless the costs associated with furnishing the clotting factor are paid through another payment system, for example, hospitals that furnish clotting factor to patients during a Part A covered inpatient hospital stay.

(2) The furnishing fee for blood clotting factors furnished in 2006 or a subsequent year is be equal to the furnishing fee paid the previous year increased by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.

[55 FR 22790, June 4, 1990; 55 FR 31186, Aug. 1, 1990, as amended at 69 FR 66422, Nov. 15, 2004]

§ 410.64 Additional preventive services.

(a) Medicare Part B pays for additional preventive services not otherwise described in this subpart that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following:

(1) Reasonable and necessary for the prevention or early detection of illness or disability.

(2) Recommended with a grade of A or B by the United States Preventive Services Task Force.

(3) Appropriate for individuals entitled to benefits under part A or enrolled under Part B.

(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations.

[73 FR 69933, Nov. 19, 2008]