

occupational therapy, or speech-language pathology services to be furnished to the individual, and indicates the diagnosis and anticipated goals.

(d) *Changes in the plan.* Any changes in the plan—

(1) Are made in writing and signed by one of the following:

- (i) The physician.
- (ii) The physical therapist who furnishes the physical therapy services.
- (iii) The occupational therapist who furnishes the physical therapy services.
- (iv) The speech-language pathologist who furnishes the speech-language pathology services.

(v) A registered professional nurse or a staff physician, in accordance with oral orders from the physician, physical therapist, occupational therapist, or speech-language pathologist who furnishes the services.

(vi) A nurse practitioner, a clinical nurse specialist, or a physician assistant.

(2) The changes are incorporated in the plan immediately.

(e) *Review of the plan.* (1) The physician reviews the plan as often as the individual's condition requires, but at least every 30 days.

(2) Each review is dated and signed by the physician who performs it.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 54 FR 38680, Sept. 20, 1989; 54 FR 46614, Nov. 6, 1989. Redesignated at 56 FR 8854, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 63 FR 58907, Nov. 2, 1998]

§ 410.62 Outpatient speech-language pathology services: Conditions and exclusions.

(a) *Basic rule.* Medicare Part B pays for outpatient speech pathology services if they meet the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine or osteopathy.

(2) They are furnished under a written plan of treatment that—

- (i) Is established by a physician or, effective January 1, 1982, by either a physician or the speech pathologist who will provide the services to the particular individual;
- (ii) Is periodically reviewed by a physician; and

(iii) Meets the requirements of § 410.63.

(3) They are furnished by a provider as defined in § 489.2 of this chapter or by others under arrangements with, or under the supervision of, a provider.

(b) *Outpatient speech pathology services to certain inpatients of a hospital, CAH, or SNF.* Medicare Part B pays for outpatient speech pathology services furnished to an inpatient of a hospital, CAH, or SNF who requires them but has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

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

(d) *Limitation.* After 1998, outpatient speech-language pathology services are subject to the limitation in § 410.60(e).

[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]

§ 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).

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(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.* 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.

[55 FR 22790, Jun. 4, 1990; 55 FR 31186, Aug. 1, 1990]

§410.64 Services related to cardiac pacemakers and pacemaker leads.

(a) *Requirement.* (1) Physicians or providers that request or receive payment for the implantation, removal, or replacement of permanent cardiac pacemakers and pacemaker leads, must submit to HCFA the information required for the pacemaker registry.

(2) The required information is set forth under 21 CFR part 805 of the FDA regulations and must be submitted in accordance with general instructions issued by HCFA.

(b) *Denial of payment.* If HCFA finds that a physician or provider has failed to comply with paragraph (a) of this section, HCFA will deny payment for the implantation, removal, or replacement of any permanent cardiac pacemaker or pacemaker lead, effective 45 days after sending the physician or provider written notice in accordance with paragraph (c) of this section.

(c) *Notice of denial of payment.* The notice of denial of payment—

(1) States the reasons for the determination;

(2) Grants the physician or provider 45 days from the date of the notice to submit the information or evidence showing that the determination is in error; and

(3) Informs the physician or provider of its right to hearing.

(d) *Right to hearing.* If the denial of payment goes into effect at the expiration of the 45-day period, it constitutes an "initial determination" subject to administrative and judicial review under part 498 of this chapter.

[56 FR 8841, Mar. 1, 1991]

§410.66 Emergency outpatient services furnished by a nonparticipating hospital and services furnished in Mexico or Canada.

Conditions for payment of emergency outpatient services furnished by a nonparticipating U.S. hospital and for services furnished in Mexico or Canada are set forth in subparts G and H of part 424 of this chapter.

[53 FR 6634, Mar. 1, 1988; 53 FR 12945, Apr. 20, 1988]

§410.68 Antigens: Scope and conditions.

Medicare Part B pays for—

(a) Antigens that are furnished as services incident to a physician's professional services; or

(b) A supply of antigen sufficient for not more than 12 weeks that is—

(1) Prepared for a patient by a doctor of medicine or osteopathy who has examined the patient and developed a plan of treatment including dosage levels; and

(2) Administered—