

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 on a regular basis as an individual, in one of the following practice types: a solo practice, partnership, or group practice; or as an employee of one of these.

(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; 76 FR 73470, Nov. 28, 2011; 77 FR 69363, Nov. 16, 2012; 79 FR 68002, Nov. 13, 2014; 82 FR 4578, Jan. 13, 2017; 83 FR 60073, Nov. 23, 2018]

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

Notwithstanding the exclusion from coverage of vaccines (see § 411.15 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 individuals with intellectual disabilities;

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

(v) Homosexual men;

(vi) Illicit injectable drug abusers;

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

(viii) Persons diagnosed with diabetes mellitus.

(2) *Intermediate risk groups.* (i) Staff in institutions for individuals with intellectual disabilities and classroom employees who work with individuals with intellectual disabilities;

(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

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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; 77 FR 69363, Nov. 16, 2012; 87 FR 70223, Nov. 18, 2022]

§ 410.64 Additional preventive services.

(a) Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of “preventive services” under § 410.2, 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

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in making such national coverage determinations.

[73 FR 69933, Nov. 19, 2008, as amended at 75 FR 73615, Nov. 29, 2010]

§ 410.66 Emergency outpatient services furnished by a nonparticipating hospital and services furnished in a foreign country.

Conditions for payment of emergency inpatient services furnished by a nonparticipating U.S. hospital and for services furnished in a foreign country are set forth in subparts G and H of part 424 of this chapter.

[71 FR 48136, Aug. 18, 2006]

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

(a) *Basis and scope—* (1) *Basis.* This section implements sections 1861(jjj), 1861(s)(2)(HH), 1833(a)(1)(CC) and 1834(w) of the Act which provide for coverage of opioid use disorder treatment services furnished by an opioid treatment program and the payment of a bundled payment under Part B to an opioid treatment program for opioid use disorder treatment services that are furnished to a beneficiary during an episode of care beginning on or after January 1, 2020.

(2) *Scope.* This section sets forth the criteria for an opioid treatment program, the scope of opioid use disorder treatment services, and the methodology for determining the bundled payments to opioid treatment programs for furnishing opioid use disorder treatment services.

(b) *Definitions.* For purposes of this section, the following definitions apply:

Episode of care means a one-week (contiguous 7-day) period.

Opioid treatment program means an entity that is an opioid treatment program (as defined in § 8.2 of this title, or any successor regulation) that meets the requirements described in paragraph (c) of this section.

Opioid use disorder treatment service means one of the following items or services for the treatment of opioid use disorder that is furnished by an opioid