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(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; 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.

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(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, 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 treatment program that meets the requirements described in paragraph (c) of this section.

(i) Opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act for use in treatment of opioid use disorder.

(ii) Dispensing and administration of opioid agonist and antagonist treatment medications, if applicable.

(iii) Substance use counseling by a professional to the extent authorized under State law to furnish such services including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During a Public Health Emergency, as defined in § 400.200 of this chapter, or for services furnished after the end of such emergency, in cases where audio/video communication technology is not available to the beneficiary, the counseling services may be furnished using audio-only telephone calls if all other applicable requirements are met.

(iv) Individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law), including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During a Public Health Emergency, as defined in § 400.200 of this chapter, or for services furnished after the end of such emergency, in cases where audio/video communication technology is not available to the beneficiary, the therapy services may be furnished using audio-only telephone calls if all other applicable requirements are met.

(v) Toxicology testing.

(vi) Intake activities, including initial medical examination services required under § 8.12(f)(2) of this title and initial assessment services required under § 8.12(f)(4) of this title. Services to initiate treatment with buprenorphine may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. In cases where audio-video communications technology is not available to the beneficiary, services to initiate treatment with buprenorphine may be furnished using audio-only telephone calls if all other applicable requirements are met.

(vii) Periodic assessment services required under § 8.12(f)(4) of this title, that are furnished during a face-to-face encounter, including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During the Public Health Emergency, as defined in § 400.200 of this chapter, and through the end of CY 2023, in cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met.

(viii) Opioid antagonist medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act for the emergency treatment of known or suspected opioid overdose and overdose education furnished in conjunction with opioid antagonist medication.

(c) *Requirements for opioid treatment programs.* To participate in the Medicare program and receive payment, an opioid treatment program must meet all of the following:

(1) Be enrolled in the Medicare program.

(2) Have in effect a certification by the Substance Abuse and Mental Health Services Administration (SAMHSA) for the opioid treatment program.

(3) Be accredited by an accrediting body approved by the SAMHSA.

(4) Have in effect a provider agreement under part 489 of this title.

(d) *Bundled payments for opioid use disorder treatment services furnished by opioid treatment programs.* (1) CMS will establish categories of bundled payments for opioid treatment programs for an episode of care as follows:

(i) Categories for each type of opioid agonist and antagonist treatment medication;

(ii) A category for medication not otherwise specified, which will be used for new FDA-approved opioid agonist or antagonist treatment medications for which CMS has not established a category; and

(iii) A category for episodes of care in which no medication is provided.

(2) The bundled payment for episodes of care in which a medication is provided consists of payment for a drug component, reflecting payment for the applicable FDA-approved opioid agonist or antagonist medication in the patient's treatment plan, and a non-drug component, reflecting payment for all other opioid use disorder treatment services reflected in the patient's treatment plan (including dispensing/administration of the medication, if applicable). The payments for the drug component and non-drug component are added together to create the bundled payment amount. The bundled payment for episodes of care in which no medication is provided consists of a single payment amount for all opioid use disorder treatment services reflected in the patient's treatment plan (excluding medication and dispensing/administration of medication).

(i) *Drug component.* The payment for the drug component for an episode of care will be determined as follows, using the most recent data available at time of ratesetting for the applicable calendar year:

(A) *Implantable and injectable medications.* For implantable and injectable medications, the payment is determined using the methodology set forth in section 1847A of the Act, except that the payment amount must be 100 percent of the ASP, if ASP is used; and the payment must be 100 percent of the wholesale acquisition cost (WAC), if WAC is used.

(B) *For oral medications.* (1) Except as provided under paragraph (d)(2)(i)(B)(2) of this section, if ASP data are available, the payment amount is 100 percent of ASP, which will be determined based on ASP data that have been calculated consistent with the provisions in part 414, subpart J of this chapter and voluntarily submitted by drug manufacturers. If ASP data are not available, the payment amount for methadone will be based on the TRICARE rate and for buprenorphine will be calculated using the National Average Drug Acquisition Cost.

(2) For CY 2022, the payment amount for methadone is the payment amount determined under paragraph (d)(2)(i)(B)(1) of this section for methadone in CY 2021. For CY 2023 and subsequent years, the payment amount for methadone will be based on the payment amount determined under paragraph (d)(2)(i)(B)(1) of this section for methadone in CY 2021 and updated by the PPI for Pharmaceuticals for Human Use (Prescription).

(C) *Exception.* For the drug component of bundled payments in the medication not otherwise specified category under paragraph (d)(1)(iii) of this section, the payment amount is based on the applicable methodology under paragraphs (d)(2)(i)(A) and (B) of this section (applying the most recent available data for such new medication), or invoice pricing until the necessary data become available.

(ii) *Non-drug component.* The payment for CY 2020 for the non-drug component of the bundled payment for an episode of care is the sum of:

(A) The CY 2019 Medicare physician fee schedule non-facility rates for the following items and services:

(1) Psychotherapy, 30 minutes with patient

(2) Group psychotherapy

(3) Alcohol and/or substance (other than tobacco) abuse structured assessment and brief intervention at the non-physician practitioner rate.

(4) For administration of an injectable medication, if applicable, drug administration (Therapeutic, prophylactic).

(5) For the insertion, removal, or insertion and removal of the implantable

medication, if applicable, the applicable rate.

(B) For dispensing oral medication, if applicable, an approximation of the average dispensing fees under state Medicaid programs.

(C) One fourth of the sum of the CY 2019 Clinical Laboratory Fee Schedule rate for two drug tests, presumptive, capable of being read by direct optical observation only and for a drug test, definitive, 1–7 drug classes.

(iii) *No medication provided episodes of care.* The bundled payment amount for CY 2020 for an episode of care in which no medication is provided is based on the non-drug component rate for an episode of care in which a drug is dispensed or administered, not including any amounts reflecting the cost of dispensing or administration of a drug.

(iv) *Increased level of psychotherapy.* For CY 2023 and subsequent years, the payment for the non-drug component of the bundled payment for an episode of care under paragraph (d)(2) of this section is adjusted to reflect the CY 2019 Medicare physician fee schedule non-facility rate for psychotherapy, 45 minutes with patient.

(3) At least one OUD treatment service described in paragraphs (b)(1) through (5) of this section must be furnished to bill for the bundled payment for an episode of care.

(4) Adjustments will be made to the bundled payment for the following:

(i) If the opioid treatment program furnishes:

(A) Counseling or therapy services in excess of the amount specified in the beneficiary's treatment plan and for which medical necessity is documented in the medical record, an adjustment will be made for each additional 30 minutes of counseling or individual therapy furnished during the episode of care.

(B) Intake activities described in paragraph (b)(6) of this section, an adjustment will be made when intake activities are furnished.

(C) Periodic assessments described in paragraph (b)(7) of this section, an adjustment will be made when this service is furnished.

(D) Additional take home supply of oral drugs of up to 21 days, in increments of 7 days, an adjustment will be

made when oral medications are dispensed.

(E) Take-home supply of opioid antagonist medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug and Cosmetic Act for the emergency treatment of known or suspected opioid overdose and overdose education furnished in conjunction with opioid antagonist medication, an adjustment will be made when these medications are dispensed. This adjustment will be limited to once every 30 days, except when a further take home supply of these medications is medically reasonable and necessary. The opioid treatment program must document in the medical record the reason(s) for the exception. The amount of the drug component of the adjustment will be determined using the methodology in paragraph (d)(2)(i) of this section. The amount of the non-drug component of the adjustment will be determined based on the CY 2020 Medicare payment rate for CPT code 96161.

(ii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be geographically adjusted using the Geographic Adjustment Factor described in §414.26 of this subchapter. For purposes of this adjustment, OUD treatment services that are furnished via an OTP mobile unit will be treated as if they were furnished at the physical location of the OTP registered with the Drug Enforcement Administration (DEA) and certified by SAMHSA.

(iii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be updated annually using the Medicare Economic Index described in §405.504(d) of this subchapter.

(5) Payment for medications delivered, administered or dispensed to a

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beneficiary as part of the bundled payment or an adjustment to the bundled payment under paragraph (d)(4)(i) of this section is considered a duplicative payment if a claim for delivery, administration or dispensing of the same medications for the same beneficiary on the same date of service was also separately paid under Medicare Part B or Part D. CMS will recoup the duplicative payment made to the opioid treatment program.

(6) For purposes of the adjustment to the bundled payment under paragraph (d)(4)(i)(A) of this section, after the end of the Public Health Emergency as defined in § 400.200 of this chapter, when services are furnished using audio-only technology the practitioner must certify, in a form and manner specified by CMS, that they had the capacity to furnish the services using two-way, audio/video communication technology, but used audio-only technology because audio/video communication technology was not available to the beneficiary.

(e) *Beneficiary cost-sharing.* A beneficiary copayment amount of zero will apply.

[84 FR 63189, Nov. 15, 2019, as amended at 85 FR 19286, Apr. 6, 2020; 85 FR 27620, May 8, 2020; 85 FR 85026, Dec. 28, 2020; 86 FR 65664, 66036, Nov. 19, 2021; 87 FR 70224, Nov. 18, 2022]

§ 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 months 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—

(i) In accord with the plan of treatment developed by the doctor of medicine or osteopathy who prepared the antigen; and

(ii) By a doctor of medicine or osteopathy or by a properly instructed person under the supervision of a doctor of medicine or osteopathy.

[54 FR 4026, Jan. 27, 1989, as amended at 65 FR 65440, Nov. 1, 2000]

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§ 410.69 Services of a certified registered nurse anesthetist or an anesthesiologist's assistant: Basic rule and definitions.

(a) *Basic rule.* Medicare Part B pays for anesthesia services and related care furnished by a certified registered nurse anesthetist or an anesthesiologist's assistant who is legally authorized to perform the services by the State in which the services are furnished.

(b) *Definitions.* For purposes of this part—

Anesthesia and related care means those services that a certified registered nurse anesthetist is legally authorized to perform in the state in which the services are furnished.

Anesthesiologist's assistant means a person who—

(1) Works under the direction of an anesthesiologist;

(2) Is in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on nonphysician anesthetists; and

(3) Is a graduate of a medical school-based anesthesiologist's assistant educational program that—

(A) Is accredited by the Committee on Allied Health Education and Accreditation; and

(B) Includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.

Anesthetist includes both an anesthesiologist's assistant and a certified registered nurse anesthetist.

Certified registered nurse anesthetist means a registered nurse who:

(1) Is licensed as a registered professional nurse by the State in which the nurse practices;

(2) Meets any licensure requirements the State imposes with respect to nonphysician anesthetists;

(3) Has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and

(4) Meets the following criteria: