

colorectal cancer as described in paragraph (a)(3) of this section, after at least 23 months have passed following the month in which the last screening colonoscopy was performed, or, as provided in paragraphs (h) and (i) of this section, the last screening barium enema was performed.

(3) In the case of an individual who is not at high risk for colorectal cancer as described in paragraph (a)(3) of this section but who has had a screening flexible sigmoidoscopy performed, payment may be made for a screening colonoscopy only after at least 47 months have passed following the month in which the last screening flexible sigmoidoscopy was performed.

(h) *Conditions for coverage of screening barium enemas.* Medicare Part B pays for a screening barium enema if it is ordered in writing by the beneficiary's attending physician.

(i) *Limitations on coverage of screening barium enemas.* (1) In the case of an individual age 45 or over who is not at high risk of colorectal cancer, payment may be made for a screening barium enema examination performed after at least 47 months have passed following the month in which the last screening barium enema or screening flexible sigmoidoscopy was performed.

(2) In the case of an individual who is at high risk for colorectal cancer, payment may be made for a screening barium enema examination performed after at least 23 months have passed following the month in which the last screening barium enema or the last screening colonoscopy was performed.

(j) *Expansion of coverage of colorectal cancer screening tests.* Effective January 1, 2022, colorectal cancer screening tests include a planned screening flexible sigmoidoscopy or screening colonoscopy that involves the removal of tissue or other matter or other procedure furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

(k) *A complete colorectal cancer screening.* Effective January 1, 2023, colorectal cancer screening tests include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. The frequency limitations de-

scribed for screening colonoscopy in paragraph (g) of this section shall not apply in the instance of a follow-on screening colonoscopy test described in this paragraph.

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**§ 410.38 Durable medical equipment, prosthetics, orthotics and supplies (DMEPOS): Scope and conditions.**

(a) *General scope.* Medicare Part B pays for durable medical equipment, including ventilators, oxygen equipment, hospital beds, and wheelchairs, if the equipment is used in the patient's home or in an institution that is used as a home.

(b) *Institutions that may not qualify as the patient's home.* An institution that is used as a home may not be a hospital or a CAH or a SNF as defined in sections 1861(e)(1), 1861(mm)(1) and 1819(a)(1) of the Act, respectively.

(c) *Definitions.* As used in this section:

(1) *Physician* has the same meaning as in section 1861(r)(1) of the Act.

(2) *Treating practitioner* means physician as defined in section 1861(r)(1) of the Act, or physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

(3) *DMEPOS supplier* means an entity with a valid Medicare supplier number, including an entity that furnishes items through the mail.

(4) *Written Order/Prescription* is a written communication from a treating practitioner that documents the need for a beneficiary to be provided an item of DMEPOS.

(5) *Face-to-face encounter* is an in-person or telehealth encounter between the treating practitioner and the beneficiary.

(6) *Power mobility device (PMD)* means a covered item of durable medical equipment that is in a class of wheelchairs that includes a power wheelchair (a four-wheeled motorized vehicle whose steering is operated by an electronic device or a joystick to control direction and turning) or a power-operated vehicle (a three or four-wheeled

motorized scooter that is operated by a tiller) that a beneficiary uses in the home.

(7) *Master List of DMEPOS items Potentially Subject to Face-To-Face Encounter and Written Orders Prior to Delivery and/or Prior Authorization Requirements, also referred to as “Master List,”* are items of DMEPOS that CMS has identified in accordance with sections 1834(a)(11)(B) and 1834(a)(15) of the Act. The criteria for this list are specified in § 414.234 of this chapter. The Master List shall serve as a library of DMEPOS items from which items may be selected for inclusion on Required Face-to-Face Encounter and Written Order Prior to Delivery List and/or the Required Prior Authorization List.

(8) *Required Face-to-Face Encounter and Written Order Prior to Delivery List* is a list of DMEPOS items selected from the Master List and subject to the requirements of a Face-to-Face Encounter and Written Order Prior to Delivery. The list of items is published in the FEDERAL REGISTER and posted on the CMS website. The list is effective no less than 60 days following its publication. When selecting items from the Master List, CMS may consider factors such as operational limitations, item utilization, cost-benefit analysis, emerging trends, vulnerabilities identified in official agency reports, or other analysis.

(d) *Conditions of Payment.* The requirements described in this paragraph (d) are conditions of payment applicable to DMEPOS items.

(1) *Written Order/Prescription.* All DMEPOS items require a written order/prescription for Medicare payment. Medicare Contractors shall consider the totality of the medical records when reviewing for compliance with standardized written order/prescription elements.

(i) *Elements.* A written order/prescription must include the following elements:

(A) Beneficiary Name or Medicare Beneficiary Identifier (MBI).

(B) General Description of the item.

(C) Quantity to be dispensed, if applicable.

(D) Order Date.

(E) Treating Practitioner Name or National Provider Identifier (NPI).

(F) Treating Practitioner Signature.

(ii) *Timing of the Written Order/Prescription.*

(A) For PMDs and other DMEPOS items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the written order/prescription must be communicated to the supplier prior to delivery.

(B) For all other DMEPOS, the written order/prescription must be communicated to the supplier prior to claim submission.

(2) *Items Requiring a Face-to-Face Encounter.* For PMDs and other DMEPOS items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the treating practitioner must document and communicate to the DMEPOS supplier that the treating practitioner has had a face-to-face encounter with the beneficiary within the 6 months preceding the date of the written order/prescription.

(i) The encounter must be used for the purpose of gathering subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.

(ii) If it is a telehealth encounter, the requirements of §§ 410.78 and 414.65 of this chapter must be met.

(3) *Documentation:* A supplier must maintain the written order/prescription and the supporting documentation provided by the treating practitioner and make them available to CMS and its agents upon request.

(i) Upon request by CMS or its agents, a supplier must submit additional documentation to CMS or its agents to support and/or substantiate the medical necessity for the DMEPOS item.

(ii) The face-to-face encounter must be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, progress notes, treatment plans or other sources of information that may be appropriate). The supporting documentation must include subjective and objective beneficiary specific information used for diagnosing, treating, or managing a

clinical condition for which the DMEPOS is ordered.

(4) *Refills*—(i) *Definitions*. As used in this paragraph (d):

*Date of service* (for refilled items) means either—

(1) The date of delivery for the DMEPOS item; or

(2) For items rendered via delivery or shipping service, the shipping date.

*Refills* mean DMEPOS products that are provided on a recurring basis secondary to a medically necessary DMEPOS order.

*Shipping date* means—

(1) The date the delivery/shipping service label is created; or

(2) The date that the item is retrieved for delivery. These dates must not demonstrate significant variation.

(ii) *Documentation*. The DMEPOS supplier must document contact with the beneficiary or their representative to verify the refill is needed. This documentation must include both of the following:

(A) Evidence of the beneficiary or their representative's affirmative response of the need for supplies, which should be obtained as close to the expected end of the current supply as possible. Contact and affirmative response must be within 30 calendar days from the expected end of the current supply.

(B)(i) For shipped items, the beneficiary name, date of contact, the item requested, and an affirmative response from the beneficiary, indicative of the need for refill, prior to dispensing the product; or

(2) For items obtained in-person from a retail store, the delivery slip signed by the beneficiary or their representative or a copy of the itemized sales receipt is sufficient documentation of a request for refill.

(iii) *Delivery of DMEPOS items provided on a recurring basis*. The date of service for DMEPOS items provided on a recurring basis must be no earlier than 10 calendar days before the expected end of the current supply.

(e) *Suspension of face-to-face encounter and written order prior to delivery requirements*. CMS may suspend face-to-face encounter and written order prior to delivery requirements generally or for a particular item or items at any time and without undertaking rule-

making, except those items for which inclusion on the Master List was statutorily imposed.

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#### § 410.39 Prostate cancer screening tests: Conditions for and limitations on coverage.

(a) *Definitions*. As used in this section, the following definitions apply:

(1) *Prostate cancer screening tests* means any of the following procedures furnished to an individual for the purpose of early detection of prostate cancer:

(i) A screening digital rectal examination.

(ii) A screening prostate-specific antigen blood test.

(iii) For years beginning after 2002, other procedures CMS finds appropriate for the purpose of early detection of prostate cancer, taking into account changes in technology and standards of medical practice, availability, effectiveness, costs, and other factors CMS considers appropriate.

(2) *A screening digital rectal examination* means a clinical examination of an individual's prostate for nodules or other abnormalities of the prostate.

(3) *A screening prostate-specific antigen blood test* means a test that measures the level of prostate-specific antigen in an individual's blood.

(4) A physician for purposes of this provision means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act) who is fully knowledgeable about the beneficiary, and who would be responsible for explaining the results of the screening examination or test.

(5) A physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife for purposes of this provision means a physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife (as defined in sections 1861(aa) and 1861(gg) of the Act) who is fully knowledgeable about the beneficiary, and who would be responsible for explaining the results of the screening examination or test.