

§ 410.39

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- (ii) Item of DME ordered.
- (iii) Signature of the prescribing practitioner.
- (iv) Prescribing practitioner NPI.
- (v) The date of the order.

(5) *Supplier's order and documentation requirements.* (i) A supplier must maintain the written order and the supporting documentation provided by the physician, physician assistant, nurse practitioner, or clinical nurse specialist and make them available to CMS upon request for 7 years from the date of service consistent with § 424.516(f) of this chapter.

(ii) Upon request by CMS or its agents, a supplier must submit additional documentation to CMS or its agents to support and substantiate that a face-to-face encounter has occurred.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 57688, Dec. 7, 1992; 58 FR 30668, May 26, 1993; 70 FR 50946, Aug. 26, 2005; 71 FR 17030, Apr. 5, 2006; 77 FR 69362, Nov. 16, 2012]

§ 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.

(b) *Condition for coverage of screening digital rectal examinations.* Medicare Part B pays for a screening digital rectal examination if it is performed by the beneficiary's physician, or by the beneficiary's physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife as defined in paragraphs (a)(4) or (a)(5) of this section who is authorized to perform this service under State law.

(c) *Limitation on coverage of screening digital rectal examinations.* (1) Payment may not be made for a screening digital rectal examination performed for a man age 50 or younger.

(2) For an individual over 50 years of age, payment may be made for a screening digital rectal examination only if the man has not had such an examination paid for by Medicare during the preceding 11 months following the month in which his last Medicare-covered screening digital rectal examination was performed.

(d) *Condition for coverage of screening prostate-specific antigen blood tests.* Medicare Part B pays for a screening prostate-specific antigen blood test if it is ordered by the beneficiary's physician, or by the beneficiary's physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife as defined in paragraphs (a)(4) or (a)(5) of this section who is authorized to order this test under State law.

(e) *Limitation on coverage of screening prostate-specific antigen blood test.* (1) Payment may not be made for a screening prostate-specific antigen blood test performed for a man age 50 or younger.

(2) For an individual over 50 years of age, payment may be made for a screening prostate-specific antigen blood test only if the man has not had such an examination paid for by Medicare during the preceding 11 months following the month in which his last Medicare-covered screening prostate-specific antigen blood test was performed.

[64 FR 59440, Nov. 2, 1999, as amended at 65 FR 19331, Apr. 11, 2000]

§ 410.40 Coverage of ambulance services.

(a) *Basic rules.* Medicare Part B covers ambulance services if the following conditions are met:

(1) The supplier meets the applicable vehicle, staff, and billing and reporting requirements of § 410.41 and the service meets the medical necessity and origin and destination requirements of paragraphs (d) and (e) of this section.

(2) Medicare Part A payment is not made directly or indirectly for the services.

(b) *Levels of service.* Medicare covers the following levels of ambulance service, which are defined in § 414.605 of this chapter:

(1) Basic life support (BLS) (emergency and nonemergency).

(2) Advanced life support, level 1 (ALS1) (emergency and non-emergency).

(3) Advanced life support, level 2 (ALS2).

(4) Paramedic ALS intercept (PI).

(5) Specialty care transport (SCT).

(6) Fixed wing transport (FW).

(7) Rotary wing transport (RW).

(c) *Paramedic ALS intercept services.* Paramedic ALS intercept services must meet the following requirements:

(1) Be furnished in an area that is designated as a rural area by any law or regulation of the State or that is located in a rural census tract of a metropolitan statistical area (as determined under the most recent Goldsmith Modification). (The Goldsmith Modification is a methodology to identify small towns and rural areas within large metropolitan counties that are isolated from central areas by distance or other features.)

(2) Be furnished under contract with one or more volunteer ambulance serv-

ices that meet the following conditions:

(i) Are certified to furnish ambulance services as required under § 410.41.

(ii) Furnish services only at the BLS level.

(iii) Be prohibited by State law from billing for any service.

(3) Be furnished by a paramedic ALS intercept supplier that meets the following conditions:

(i) Is certified to furnish ALS services as required in § 410.41(b)(2).

(ii) Bills all the beneficiaries who receive ALS intercept services from the entity, regardless of whether or not those beneficiaries are Medicare beneficiaries.

(d) *Medical necessity requirements—(1) General rule.* Medicare covers ambulance services, including fixed wing and rotary wing ambulance services, only if they are furnished to a beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided in order for the billed service to be considered medically necessary. Nonemergency transportation by ambulance is appropriate if either: the beneficiary is bed-confined, and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or, if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. Thus, bed confinement is not the sole criterion in determining the medical necessity of ambulance transportation. It is one factor that is considered in medical necessity determinations. For a beneficiary to be considered bed-confined, the following criteria must be met:

(i) The beneficiary is unable to get up from bed without assistance.

(ii) The beneficiary is unable to ambulate.

(iii) The beneficiary is unable to sit in a chair or wheelchair.

(2) *Special rule for nonemergency, scheduled, repetitive ambulance services.*