

(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-cov-

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

Non-physician certification statement means a statement signed and dated by an individual which certifies that the medical necessity provisions of paragraph (e)(1) of this section are met and who meets all of the criteria in paragraphs (i) through (iii) of this definition. The statement need not be a stand-alone document and no specific format or title is required.

(i) Has personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished;

(ii) Who must be employed:

(A) By the beneficiary's attending physician; or

(B) By the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported;

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(iii) Is among the following individuals, with respect to whom all Medicare regulations and all applicable State licensure laws apply:

- (A) Physician assistant (PA).
- (B) Nurse practitioner (NP).
- (C) Clinical nurse specialist (CNS).
- (D) Registered nurse (RN).
- (E) Licensed practical nurse (LPN).
- (F) Social worker.
- (G) Case manager.
- (H) Discharge planner.

Physician certification statement means a statement signed and dated by the beneficiary's attending physician which certifies that the medical necessity provisions of paragraph (e)(1) of this section are met. The statement need not be a stand-alone document and no specific format or title is required.

(b) *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 (e) and (f) of this section.

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

(c) *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).

(d) *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 iden-

tify 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 services 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.

(e) *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.*

(i) Medicare covers medically necessary nonemergency, scheduled, repetitive ambulance services if the ambulance provider or supplier, before furnishing the service to the beneficiary, obtains a physician certification statement dated no earlier than 60 days before the date the service is furnished.

(ii) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to CMS. The ambulance service must meet all program coverage criteria including vehicle and staffing requirements. While a signed physician certification statement (PCS), does not alone demonstrate that transportation by ground ambulance was medically necessary, the PCS and additional documentation from the beneficiary's medical record may be used to support a claim that transportation by ground ambulance is medically necessary. The PCS and additional documentation must provide detailed explanations, that are consistent with the beneficiary's current medical condition, that explains the beneficiary's need for transport by an ambulance, as described at § 410.41(a), that includes observation or other services rendered by qualified ambulance personnel, as described in § 410.41(b).

(3) *Special rule for nonemergency ambulance services that are either unscheduled or that are scheduled on a nonrepetitive basis.* Medicare covers medically necessary nonemergency ambulance services that are either unscheduled or that are scheduled on a nonrepetitive basis under one of the following circumstances:

(i) For a resident of a facility who is under the care of a physician if the ambulance provider or supplier obtains a physician certification statement within 48 hours after the transport.

(ii) For a beneficiary residing at home or in a facility who is not under the direct care of a physician. A physician certification is not required.

(iii) If the ambulance provider or supplier is unable to obtain a signed physician certification statement from the beneficiary's attending physician, a non-physician certification statement must be obtained.

(iv) If the ambulance provider or supplier is unable to obtain the required physician or non-physician certification statement within 21 calendar days following the date of the service, the ambulance provider or supplier must document its attempts to obtain the requested certification and may then submit the claim. Acceptable documentation includes a signed return receipt from the U.S. Postal Service or other similar service that evidences that the ambulance supplier attempted to obtain the required signature from the beneficiary's attending physician or other individual named in paragraph (e)(3)(iii) of this section.

(v) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to the contractor. The presence of the physician or non-physician certification statement or signed return receipt does not alone demonstrate that the ambulance transport was medically necessary. All other program criteria must be met in order for payment to be made.

(f) *Origin and destination requirements.* Medicare covers the following ambulance transportation:

(1) From any point of origin to the nearest hospital, CAH, rural emergency hospital (REH), or SNF that is capable of furnishing the required level and type of care for the beneficiary's illness or injury. The hospital or CAH or REH must have available the type of physician or physician specialist needed to treat the beneficiary's condition.

(2) From a hospital, CAH, REH, or SNF to the beneficiary's home.

(3) From a SNF to the nearest supplier of medically necessary services not available at the SNF where the beneficiary is a resident, including the return trip.

(4) For a beneficiary who is receiving renal dialysis for treatment of ESRD, from the beneficiary's home to the nearest facility that furnishes renal dialysis, including the return trip.

(5) During a Public Health Emergency, as defined in § 400.200 of this chapter, a ground ambulance transport from any point of origin to a destination that is equipped to treat the condition of the patient consistent with

any applicable state or local Emergency Medical Services protocol that governs the destination location. Such destinations include, but are not limited to, alternative sites determined to be part of a hospital, critical access hospital, REH (effective January 1, 2023), or skilled nursing facility, community mental health centers, federally qualified health centers, rural health clinics, physician offices, urgent care facilities, ambulatory surgical centers, any location furnishing dialysis services outside of an ESRD facility when an ESRD facility is not available, and the beneficiary's home.

(g) *Specific limits on coverage of ambulance services outside the United States.* If services are furnished outside the United States, Medicare Part B covers ambulance transportation to a foreign hospital only in conjunction with the beneficiary's admission for medically necessary inpatient services as specified in subpart H of part 424 of this chapter.

[64 FR 3648, Jan. 25, 1999, as amended at 65 FR 13914, Mar. 15, 2000; 67 FR 9132, Feb. 27, 2002; 77 FR 69362, Nov. 16, 2012; 84 FR 63187, Nov. 15, 2019; 85 FR 19286, Apr. 6, 2020; 87 FR 70223, Nov. 18, 2022; 87 FR 72285, Nov. 23, 2022]

§ 410.41 Requirements for ambulance providers and suppliers.

(a) *Vehicle.* A vehicle used as an ambulance must meet the following requirements:

(1) Be specially designed to respond to medical emergencies or provide acute medical care to transport the sick and injured and comply with all State and local laws governing an emergency transportation vehicle.

(2) Be equipped with emergency warning lights and sirens, as required by State or local laws.

(3) Be equipped with telecommunications equipment as required by State or local law to include, at a minimum, one two-way voice radio or wireless telephone.

(4) Be equipped with a stretcher, linens, emergency medical supplies, oxygen equipment, and other lifesaving emergency medical equipment as required by State or local laws.

(b) *Vehicle staff.* A vehicle furnishing ambulance services must be staffed by at least two people who meet the re-

quirements of state and local laws where the services are being furnished, and at least one of the staff members must, for:

(1) *BLS vehicles.* (i) Be certified at a minimum as an emergency medical technician-basic by the State or local authority where the services are furnished; and

(ii) Be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle;

(2) *ALS vehicles.* (i) Meet the requirements of paragraph (b)(1) of this section; and

(ii) Be certified as a paramedic or an emergency medical technician, by the State or local authority where the services are being furnished, to perform one or more ALS services.

(c) *Billing and reporting requirements.* An ambulance supplier must comply with the following requirements:

(1) Bill for ambulance services using CMS-designated procedure codes to describe origin and destination and indicate on claims form that the physician certification statement or non-physician certification statement is on file, if required.

(2) Upon a carrier's request, complete and return the ambulance supplier form designated by CMS and provide the Medicare carrier with documentation of compliance with emergency vehicle and staff licensure and certification requirements in accordance with State and local laws.

(3) Upon a carrier's request, provide additional information and documentation as required.

[64 FR 3648, Jan. 25, 1999, as amended at 80 FR 71373, Nov. 16, 2015; 84 FR 63188, Nov. 15, 2019]

§ 410.42 Limitations on coverage of certain services furnished to hospital outpatients.

(a) *General rule.* Except as provided in paragraph (b) of this section, Medicare Part B does not pay for any item or service that is furnished to a hospital outpatient (as defined in § 410.2) during an encounter (as defined in § 410.2) by an entity other than the hospital unless the hospital has an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to its patients. As used