

§ 410.45 Rural health clinic services: Scope and conditions.

(a) Medicare Part B pays for the following rural health clinic services, if they are furnished in accordance with the requirements and conditions specified in part 405, subpart X, and part 491 of this chapter:

(1) Physicians' services.

(2) Services and supplies furnished as an incident to physicians' professional services.

(3) Nurse practitioner and physician assistant services.

(4) Services and supplies furnished as an incident to nurse practitioners' or physician assistants' services.

(5) Visiting nurse services.

(b) Medicare pays for rural health clinic services when they are furnished at the clinic, at a hospital or other medical facility, or at the beneficiary's place of residence.

§ 410.46 Physician and other practitioner services furnished in or at the direction of an IHS or Indian tribal hospital or clinic: Scope and conditions.

(a) Medicare Part B pays, in accordance with the physician fee schedule, for services furnished in or at the direction of a hospital or outpatient clinic (provider-based or free-standing) that is operated by the Indian Health Service (IHS) or by an Indian tribe or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act). These services are subject to the same situations, terms, and conditions that would apply if the services were furnished in or at the direction of a hospital or clinic that is not operated by IHS or by an Indian tribe or tribal organization. Payments include health professional shortage areas incentive payments when the requirements for these incentive payments in § 414.42 of this chapter are met.

(b) Payment is not made under this section to the extent that Medicare otherwise pays for the same services under other provisions.

(c) Payment is made under these provisions for the following services:

(1) Services for which payment is made under the physician fee schedule

in accordance with part 414 of this chapter.

(2) Services furnished by non-physician practitioners for which payment under Part B is made under the physician fee schedule.

(3) Services furnished by a physical therapist or occupational therapist, for which payment under Part B is made under the physician fee schedule.

(d) Payments under these provisions will be paid to the IHS or tribal hospital or clinic.

[66 FR 55329, Nov. 1, 2001]

§ 410.47 Pulmonary rehabilitation program: Conditions for coverage.

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

Individualized treatment plan means a written plan tailored to each individual patient that includes all of the following:

(i) A description of the individual's diagnosis.

(ii) The type, amount, frequency, and duration of the items and services furnished under the plan.

(iii) The goals set for the individual under the plan.

Medical director means the physician who oversees the pulmonary rehabilitation program at a particular site.

Outcomes assessment means an evaluation of progress as it relates to the individual's rehabilitation which includes the following:

(i) Evaluations, based on patient-centered outcomes, which must be measured by the physician or program staff at the beginning and end of the program. Evaluations measured by program staff must be considered by the physician in developing and/or reviewing individualized treatment plans.

(ii) Objective clinical measures of exercise performance and self-reported measures of shortness of breath and behavior.

Physician means a doctor of medicine or osteopathy as defined in section 1861(r)(1) of the Act.

Physician-prescribed exercise means aerobic exercise combined with other types of exercise (such as conditioning, breathing retraining, step, and strengthening) as determined to be appropriate for individual patients by a physician.

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Psychosocial assessment means an evaluation of an individual's mental and emotional functioning as it relates to the individual's rehabilitation or respiratory condition which includes an assessment of those aspects of an individual's family and home situation that affects the individual's rehabilitation treatment, and psychosocial evaluation of the individual's response to and rate of progress under the treatment plan.

Pulmonary rehabilitation means a physician-supervised program for COPD and certain other chronic respiratory diseases designed to optimize physical and social performance and autonomy.

Supervising physician means a physician that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under pulmonary rehabilitation programs.

(b) *General rule*—(1) *Covered conditions*. Medicare Part B covers pulmonary rehabilitation for beneficiaries:

(i) With moderate to very severe COPD (defined as GOLD classification II, III and IV), when referred by the physician treating the chronic respiratory disease;

(ii) Who have had confirmed or suspected COVID-19 and experience persistent symptoms that include respiratory dysfunction for at least four weeks;

(iii) Additional medical indications for coverage for pulmonary rehabilitation may be established through a national coverage determination (NCD).

(2) *Components*. Pulmonary rehabilitation must include all of the following:

(i) Physician-prescribed exercise during each pulmonary rehabilitation session.

(ii) Education or training that is closely and clearly related to the individual's care and treatment which is tailored to the individual's needs and assists in achievement of goals toward independence in activities of daily living, adaptation to limitations and improved quality of life. Education must include information on respiratory problem management and, if appropriate,

brief smoking cessation counseling.

(iii) Psychosocial assessment.

(iv) Outcomes assessment.

(v) An individualized treatment plan detailing how components are utilized for each patient. The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.

(3) *Settings*. (i) Medicare Part B pays for pulmonary rehabilitation in the following settings:

(A) A physician's office.

(B) A hospital outpatient setting.

(ii) All settings must have the following:

(A) A physician immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician meets the requirements for direct supervision for physician office services, at § 410.26 of this subpart; and for hospital outpatient services at § 410.27 of this subpart.

(B) The necessary cardio-pulmonary, emergency, diagnostic, and therapeutic life-saving equipment accepted by the medical community as medically necessary (for example, oxygen, cardiopulmonary resuscitation equipment, and defibrillator) to treat chronic respiratory disease.

(c) *Medical director standards*. The physician responsible for a pulmonary rehabilitation program is identified as the medical director. The medical director, in consultation with staff, is involved in directing the progress of individuals in the program and must possess all of the following:

(1) Expertise in the management of individuals with respiratory pathophysiology.

(2) Cardiopulmonary training in basic life support or advanced cardiac life support.

(3) Be licensed to practice medicine in the State in which the pulmonary rehabilitation program is offered.

(d) *Supervising physician standards*. Physicians acting as the supervising physician must possess all of the following:

(1) Expertise in the management of individuals with respiratory pathophysiology.

(2) Cardiopulmonary training in basic life support or advanced cardiac life support.

(3) Be licensed to practice medicine in the State in which the pulmonary rehabilitation program is offered.

(e) *Limitations on coverage:* The number of pulmonary rehabilitation sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the Medicare Administrative Contractor.

(f) *Effective date.* Coverage for pulmonary rehabilitation program services is effective January 1, 2010.

[74 FR 62002, Nov. 25, 2009, as amended at 86 FR 65662, Nov. 19, 2021]

§ 410.48 Kidney disease education services.

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

Kidney disease patient education services means face-to-face educational services provided to patients with Stage IV chronic kidney disease.

Physician means a physician as defined in section 1861(r)(1) of the Act.

Qualified person means either of the following healthcare entities that meets the qualifications and requirements specified in this section to provide kidney disease patient education services—

(i) One of the following healthcare professionals who furnishes services for which payment may be made under the physician fee schedule:

(A) Physician (as defined in section 1861(r)(1) of the Act).

(B) Physician assistant as defined in section 1861(aa)(5) of the Act and § 410.74 of this subpart).

(C) Nurse practitioner as defined in section 1861(aa)(5) of the Act and § 410.75 of this subpart).

(D) Clinical nurse specialist (as defined in section 1861(aa)(5) of the Act and § 410.76 of this subpart),

(ii)(A) A hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hos-

pice that is located in a rural area as defined in § 412.64(b)(ii)(C) of this chapter; or

(B) A hospital or critical access hospital that is treated as being rural under § 412.103 of this chapter.

Renal dialysis facility means a unit, which is approved to furnish dialysis service(s) directly to end-stage renal disease (ESRD) patients, as defined in § 405.2102 of this chapter.

Stage IV chronic kidney disease means kidney damage with a severe decrease in glomerular filtration rate (GFR) quantitatively defined by a GFR value of 15–29 ml/min/1.73m², using the Modification of Diet in Renal Disease (MDRD) Study formula.

(b) *Covered beneficiaries.* Medicare Part B covers outpatient kidney disease patient education services if the beneficiary meets all of the conditions and requirements of this subpart, including all of the following:

(1) Is diagnosed with Stage IV chronic kidney disease.

(2) Obtains a referral from the physician (as defined in section 1861(r)(1) of the Act) managing the beneficiary's kidney condition.

(c) *Qualified person.* (1) Medicare Part B covers outpatient kidney disease patient education services provided by a qualified person as defined in paragraph (a) of this section and must be able to properly receive Medicare payment under part 424 of this chapter.

(2) A qualified person does not include either of the following:

(i) A hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency or hospice if kidney disease patient education services are provided outside of a rural area as defined in § 412.64(b)(ii)(C) of this chapter unless the services are furnished in a hospital or critical access hospital that is treated as being in a rural area under § 412.103 of this chapter.

(ii) A renal dialysis facility, as defined in § 405.2102 of this chapter.

(d) *Standards for content of kidney disease patient education services.* The content of the kidney disease patient education services includes the following:

(1) The management of comorbidities including for the purpose of delaying