

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd).

Subpart B—Medical and Other Health Services

■ 2. Section 410.30 is amended by revising paragraph (b) to read as follows:

§ 410.30 Prescription drugs used in immunosuppressive therapy.

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(b) *Eligibility.* For drugs furnished on or after December 21, 2000, coverage is available only for prescription drugs used in immunosuppressive therapy, furnished to an individual who received an organ or tissue transplant for which Medicare payment is made, provided the individual is eligible to receive Medicare Part B benefits.

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■ 3. Section 410.47 is added to read as follows:

§ 410.47 Pulmonary rehabilitation program: Conditions for coverage.

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

Individualized treatment plan means a written plan established, reviewed, and signed by a physician every 30 days, that describes all of the following:

- (i) The individual's diagnosis.
- (ii) The type, amount, frequency, and duration of the items and services under the plan.
- (iii) The goals set for the individual under the plan.

Medical director means the physician who oversees or supervises the PR program.

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

- (i) Beginning and end evaluations, based on patient-centered outcomes, which are conducted by the physician at the start and end of the program.
- (ii) Objective clinical measures of effectiveness of the PR program for the

individual patient, including 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 physical activity, including aerobic exercise, prescribed and supervised by a physician that improves or maintains an individual's pulmonary functional level.

Psychosocial assessment means a written evaluation of an individual's mental and emotional functioning as it relates to the individual's rehabilitation or respiratory condition.

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 under the PR program.

(b) *Beneficiaries who may be covered.*

(1) Medicare covers pulmonary rehabilitation for beneficiaries with moderate to very severe COPD (defined as GOLD classification II, III and IV), when referred by the physician treating the chronic respiratory disease.

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

(c) *Components.* Pulmonary rehabilitation includes all of the following components:

(1) *Physician-prescribed exercise.* This physical activity includes techniques such as exercise conditioning, breathing retraining, step, and strengthening exercises. Some aerobic exercise must be included in each pulmonary rehabilitation session.

(2) *Education or training.* (i) Education or training closely and clearly related to the individual's care and treatment which is tailored to the individual's needs.

(ii) Education includes information on respiratory problem management and, if appropriate, brief smoking cessation counseling.

(iii) Any education or training prescribed must assist in achievement of individual goals towards independence in activities of daily living, adaptation to limitations and improved quality of life.

(3) *Psychosocial assessment.* The psychosocial assessment must meet the criteria as defined in paragraph (a) of this section and includes:

(i) An assessment of those aspects of an individual's family and home situation that affects the individual's rehabilitation treatment.

(ii) A psychosocial evaluation of the individual's response to and rate of progress under the treatment plan.

(4) *Outcomes assessment.* The outcomes assessment must meet the criteria as defined in paragraph (a) of this section.

(5) *Individualized treatment plan.* The individualized treatment plan must be established, reviewed, and signed by a physician, who is involved in the patient's care and has knowledge related to his or her condition, every 30 days.

(d) *Settings.* (1) Medicare Part B pays for a pulmonary rehabilitation in the following settings:

(i) Physician's offices.

(ii) Hospital outpatient settings.

(2) All settings must have the following available for immediate use and accessible at all times:

(i) 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.

(ii) A physician must be immediately available and accessible for medical consultations and emergencies at all times when services are being provided 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.

(e) *Physician standards.* Medicare Part B pays for pulmonary rehabilitation services for PR programs supervised by a physician who meets the following requirements—

(1) Is responsible and accountable for the pulmonary rehabilitation program, including oversight of the PR staff.

(2) Is involved substantially, in consultation with staff, in directing the progress of the individual in the program including direct patient contact related to the periodic review of his or her treatment plan.

(3) Has expertise in the management of individuals with respiratory pathophysiology, and cardiopulmonary training and/or certification including basic life support.

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

(f) *Limitations on coverage: Sessions.* Medicare Part B pays for services provided in connection with a pulmonary rehabilitation exercise

program for up to 36 sessions, no more than two sessions per day. Up to an additional 36 sessions may be approved by the Medicare contractor, based on medical necessity in accordance with section 1862(a)(1)(A) of the Act.

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

■ 4. Section 410.48 is added to read as follows:

§ 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 hospice 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 the need for dialysis which includes, but not limited to, the following topics:

(i) Prevention and treatment of cardiovascular disease.

(ii) Prevention and treatment of diabetes.

(iii) Hypertension management.

(iv) Anemia management.

(v) Bone disease and disorders of calcium and phosphorus metabolism management.

(vi) Symptomatic neuropathy management.

(vii) Impairments in functioning and well-being.

(2) The prevention of uremic complications which includes, but not limited to, the following topics:

(i) Information on how the kidneys work and what happens when the kidneys fail.

(ii) Understanding if remaining kidney function can be protected, preventing disease progression, and realistic chances of survival.

(iii) Diet and fluid restrictions.

(iv) Medication review, including how each medication works, possible side effects and minimization of side effects, the importance of compliance, and informed decision-making if the patient decides not to take a specific drug.

(3) Therapeutic options, treatment modalities, and settings, including a discussion of the advantages and disadvantages of each treatment option and how the treatments replace the kidney, which includes, but not limited to, the following topics:

(i) Hemodialysis, both at home and in-facility.

(ii) Peritoneal dialysis (PD), including intermittent PD, continuous ambulatory PD, and continuous cycling PD, both at home and in-facility.

(iii) All dialysis access options for hemodialysis and peritoneal dialysis.

(iv) Transplantation.

(4) Opportunities for beneficiaries to actively participate in the choice of therapy and be tailored to meet the needs of the individual beneficiary involved which includes, but not limited to, the following topics:

(i) Physical symptoms.

(ii) Impact on family and social life.

(iii) Exercise.

(iv) The right to refuse treatment.

(v) Impact on work and finances.

(vi) The meaning of test results.

(vii) Psychological impact.

(5) Qualified persons must develop outcomes assessments designed to measure beneficiary knowledge about chronic kidney disease and its treatment.

(i) The outcomes assessments serve to assess program effectiveness of preparing the beneficiary to make informed decisions about their healthcare options related to chronic kidney disease.

(ii) The outcomes assessments serve to assess the program's effectiveness in meeting the communication needs of underserved populations, including persons with disabilities, persons with limited English proficiency, and persons with health literacy needs.

(iii) The assessment must be administered to the beneficiary during a kidney disease education session.

(iv) The outcomes assessments must be made available to CMS upon request.

(e) *Limitations for coverage of kidney disease education services.* (1) Medicare Part B makes payment for up to 6 sessions of kidney disease patient education services.

(2) A session is 1 hour long and may be provided individually or in group settings of 2 to 20 individuals who need not all be Medicare beneficiaries.

(f) *Effective date.* Medicare Part B covers kidney disease patient education services for dates of service on or after January 1, 2010.

■ 5. Section 410.49 is added to read as follows: