

(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.

[74 FR 62003, Nov. 25, 2009]

§ 410.49 Cardiac rehabilitation program and intensive cardiac rehabilitation program: Conditions of coverage.

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

Cardiac rehabilitation (CR) means a physician-supervised program that furnishes physician prescribed exercise, cardiac risk factor modification, psychosocial assessment, and outcomes assessment.

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.

Intensive cardiac rehabilitation (ICR) program means a physician-supervised program that furnishes cardiac rehabilitation and has shown, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in paragraph (c) of this section.

Intensive cardiac rehabilitation site means a hospital outpatient setting or physician's office that is providing intensive cardiac rehabilitation utilizing an approved ICR program.

Medical director means a physician that oversees or supervises the cardiac rehabilitation or intensive cardiac rehabilitation program at a particular site.

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

- (i) Minimally, assessments from the commencement and conclusion of cardiac rehabilitation and intensive cardiac rehabilitation, based on patient-centered outcomes which must be measured by the physician immediately at the beginning of the program and at the end of the program.
- (ii) Objective clinical measures of exercise performance and self-reported measures of exertion 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 (that is, strengthening, stretching) as determined to be

appropriate for individual patients by a physician.

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

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 cardiac rehabilitation and intensive cardiac rehabilitation programs.

(b) *General rule*—(1) *Covered beneficiary rehabilitation services*. Medicare part B covers cardiac rehabilitation and intensive cardiac rehabilitation program services for beneficiaries who have experienced one or more of the following:

- (i) An acute myocardial infarction within the preceding 12 months;
- (ii) A coronary artery bypass surgery;
- (iii) Current stable angina pectoris;
- (iv) Heart valve repair or replacement;
- (v) Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting;
- (vi) A heart or heart-lung transplant.
- (vii) For cardiac rehabilitation only, other cardiac conditions as specified through a national coverage determination.

(2) *Components of a cardiac rehabilitation program and an intensive cardiac rehabilitation program*. Cardiac rehabilitation programs and intensive cardiac rehabilitation programs must include all of the following:

- (i) Physician-prescribed exercise each day cardiac rehabilitation items and services are furnished.
- (ii) Cardiac risk factor modification, including education, counseling, and behavioral intervention, tailored to the patients' individual needs.
- (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 cardiac rehabilitation and intensive cardiac rehabilitation in one of the following settings:

(A) A physician's office.

(B) A hospital outpatient setting.

(ii) All settings must have 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.

(c) *Standards for an intensive cardiac rehabilitation program.* (1) To be approved as an intensive cardiac rehabilitation program, a program must demonstrate through peer-reviewed, published research that it has accomplished one or more of the following for its patients:

(i) Positively affected the progression of coronary heart disease.

(ii) Reduced the need for coronary bypass surgery.

(iii) Reduced the need for percutaneous coronary interventions;

(2) An intensive cardiac rehabilitation program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in 5 or more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services:

(i) Low density lipoprotein.

(ii) Triglycerides.

(iii) Body mass index.

(iv) Systolic blood pressure.

(v) Diastolic blood pressure.

(vi) The need for cholesterol, blood pressure, and diabetes medications.

(3) A list of approved intensive cardiac rehabilitation programs, identified through the national coverage determination process, will be posted to the CMS Web site and listed in the FEDERAL REGISTER.

(4) All prospective intensive cardiac rehabilitation sites must apply to enroll as an intensive cardiac rehabilitation program site using the designated forms as specified at § 424.510 of this chapter. For purposes of appealing an adverse determination concerning site approval, an intensive cardiac rehabilitation site is considered a supplier (or prospective supplier) as defined in § 498.2 of this chapter.

(d) *Standards for the physician responsible for cardiac rehabilitation program.* A physician responsible for a cardiac rehabilitation program or intensive cardiac rehabilitation programs is identified as the medical directors. The medical director, in consultation with staff, are involved in directing the progress of individuals in the program, must possess all of the following:

(1) Expertise in the management of individuals with cardiac 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 cardiac rehabilitation program is offered.

(e) *Standards for supervising-physicians.* Physicians acting as the supervising-physician must possess all of the following:

(1) Expertise in the management of individuals with cardiac 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 cardiac rehabilitation program is offered.

(f) *Limitations for coverage of cardiac rehabilitation programs.* (1) *Cardiac Rehabilitation:* The number of cardiac rehabilitation program 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 contractor under section 1862(a)(1)(A) of the Act.

(2) *Intensive Cardiac Rehabilitation:* Intensive cardiac rehabilitation program sessions are limited to 72 1-hour sessions (as defined in section 1848(b)(5) of

§ 410.50

the Act), up to 6 sessions per day, over a period of up to 18 weeks.

[74 FR 62003, Nov. 25, 2009]

§ 410.50 Institutional dialysis services and supplies: Scope and conditions.

Medicare Part B pays for the following institutional dialysis services and supplies if they are furnished in approved ESRD facilities:

(a) All services, items, supplies, and equipment necessary to perform dialysis and drugs medically necessary and the treatment of the patient for ESRD and, as of January 1, 2011, renal dialysis services as defined in § 413.171 of this chapter.

(b) Routine dialysis monitoring tests (i.e., hematocrit and clotting time) used by the facility to monitor the patients' fluids incident to each dialysis treatment, when performed by qualified staff of the facility under the direction of a physician, as provided in § 494.130 of this chapter, even if the facility does not meet the conditions for coverage of services of independent laboratories in part 494 of this chapter.

(c) Routine diagnostic tests.

(d) Epoetin (EPO) and its administration.

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 43709, Sept. 4, 1991; 59 FR 1285, Jan. 10, 1994; 73 FR 20474, Apr. 15, 2008; 75 FR 49197, Aug. 12, 2010]

§ 410.52 Home dialysis services, supplies, and equipment: Scope and conditions.

(a) Medicare Part B pays for the following services, supplies, and equipment furnished to an ESRD patient in his or her home:

(1) Purchase or rental, installation, and maintenance of all dialysis equipment necessary for home dialysis, and reconditioning of this equipment. Dialysis equipment includes, but is not limited to, artificial kidney and automated peritoneal dialysis machines, and support equipment such as blood pumps, bubble detectors, and other alarm systems.

(2) Items and supplies required for dialysis, including (but not limited to) dialyzers, syringes and needles, forceps, scissors, scales, sphygmomanometer with cuff and stethoscope, alcohol

42 CFR Ch. IV (10–1–12 Edition)

wipes, sterile drapes, and rubber gloves.

(3) Home dialysis support services furnished by an approved ESRD facility, including periodic monitoring of the patient's home adaptation, emergency visits by qualified provider or facility personnel, any of the tests specified in paragraphs (b) through (d) of § 410.50, personnel costs associated with the installation and maintenance of dialysis equipment, testing and appropriate treatment of water, and ordering of supplies on an ongoing basis.

(4) On or after July 1, 1991, erythropoiesis-stimulating agents for use at home by a home dialysis patient and, on or after January 1, 1994, by a dialysis patient, if it has been determined, in accordance with § 494.90(a)(4) of this chapter, that the patient is competent to use the drug safely and effectively.

(b) Home dialysis support services specified in paragraph (a)(3) of this section must be furnished in accordance with a written treatment plan that is prepared and reviewed by a team consisting of the individual's physician and other qualified professionals. (Section 494.90 of this chapter contains details on patient plans of care).

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 43709, Sept. 4, 1991; 59 FR 26959, May 25, 1994; 73 FR 20474, Apr. 15, 2008]

§ 410.55 Services related to kidney donations: Conditions.

Medicare Part B pays for medical and other health services covered under this subpart that are furnished in connection with a kidney donation—

(a) If the kidney is intended for an individual who has end-stage renal disease and is entitled to Medicare benefits; and

(b) Regardless of whether the donor is entitled to Medicare.

§ 410.56 Screening pelvic examinations.

(a) *Conditions for screening pelvic examinations.* Medicare Part B pays for a screening pelvic examination (including a clinical breast examination) if it is performed by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act), or by a certified nurse midwife (as defined in section