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(d) Criteria for a new rental period. If an interruption in the use of equipment continues for more than 60 consecutive days plus the days remaining in the rental month in which use ceases, a new rental period begins if the supplier submits all of the following information—

1. A new prescription.
2. New medical necessity documentation.
3. A statement describing the reason for the interruption and demonstrating that medical necessity in the prior episode ended.

(e) Beneficiary moves. A permanent or temporary move made by a beneficiary does not constitute an interruption in the period of continuous use.

(f) New equipment. (1) If a beneficiary changes equipment or requires additional equipment based on a physician’s prescription, and the new or additional equipment is found to be necessary, a new period of continuous use begins for the new or additional equipment. A new period of continuous use does not begin for base equipment that is modified by an addition.

2. A new period of continuous use does not begin when a beneficiary changes from one stationary oxygen equipment modality to another or from one portable oxygen equipment modality to another.

(g) New supplier. If a beneficiary changes suppliers, a new period of continuous use does not begin.

(h) Oxygen equipment furnished after the 36-month rental period. A new period of continuous use does not begin under any circumstance in the case of oxygen equipment furnished after the 36-month rental period in accordance with §414.220(f) until the end of the reasonable useful lifetime established for such equipment in accordance with §414.210(f).


§414.320 Special payment rules for transcutaneous electrical nerve stimulators (TENS).

(a) General payment rule. Except as provided in paragraph (b) of this section, payment for TENS is made on a purchase basis with the purchase price determined using the methodology for purchase of inexpensive or routinely purchased items as described in §414.220. The payment amount for TENS computed under §414.220(c)(2) is reduced according to the following formula:

1. Effective April 1, 1990—the original payment amount is reduced by 15 percent.
2. Effective January 1, 1991—the reduced payment amount in paragraph (a)(1) is reduced by 15 percent.
3. Effective January 1, 1994—the reduced payment amount in paragraph (a)(1) is reduced by 45 percent.

(b) Exception. In order to permit an attending physician time to determine whether the purchase of the TENS is medically appropriate for a particular patient, two months of rental payments may be made in addition to the purchase price. The rental payments are equal to 10 percent of the purchase price.

[57 FR 57692, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995]

Subpart E—Determination of Reasonable Charges Under the ESRD Program

§414.300 Scope of subpart.

This subpart sets forth criteria and procedures for payment of the following services furnished to ESRD patients:

(a) Physician services related to renal dialysis.
(b) Physician services related to renal transplantation.
(c) Home dialysis equipment, supplies, and support services.
(d) Epoetin (EPO) furnished by a supplier of home dialysis equipment and supplies to a home dialysis patient for use in the home.

otherwise covered by the Medicare program and if they are considered reasonable and medically necessary in accordance with section 1862(a)(1)(A) of the Act.

(b) Scope and applicability—(1) Scope. This section pertains to physician services furnished to the following patients:

(i) Outpatient maintenance dialysis patients who dialyze—

(A) In an independent or hospital-based ESRD facility, or

(B) At home.

(ii) Hospital inpatients for which the physician elects to continue payment under the monthly capitation payment (MCP) method described in §414.314.

(2) Applicability. These provisions apply to routine professional services of physicians. They do not apply to administrative services performed by physicians, which are paid for as part of a prospective payment for dialysis services made to the facility under §413.170 of this chapter.

(c) Definitions. For purposes of this section, the following definitions apply:

Administrative services are physician services that are differentiated from routine professional services and other physician services because they are supervision, as described in the definition of “supervision of staff” of this section, or are not related directly to the care of an individual patient, but are supportive of the facility as a whole and of benefit to patients in general. Examples of administrative services include supervision of staff, staff training, participation in staff conferences and in the management of the facility, and advising staff on the procurement of supplies.

Dialysis session is the period of time that begins when the patient arrives at the facility and ends when the patient departs from the facility. In the case of home dialysis, the period begins when the patient prepares for dialysis and generally ends when the patient is disconnected from the machine. In this context, a dialysis facility includes only those parts of the building used as a facility. It does not include any areas used as a physician’s office.

Medical direction, in contrast to supervision of staff, is a routine professional service that entails substantial direct involvement and the physical presence of the physician in the delivery of services directly to the patient. Routine professional services include all physicians’ services furnished during a dialysis session and all services listed in paragraph (d) of this section that meet the following requirements:

(1) They are personally furnished by a physician to an individual patient.

(2) They contribute directly to the diagnosis or treatment of an individual patient.

(3) They ordinarily must be performed by a physician.

Supervision of staff, in contrast to medical direction, is an administrative service that does not necessarily require the physician to be present at the dialysis session. It is a general activity primarily concerned with monitoring performance of and giving guidance to other health care personnel (such as nurses and dialysis technicians) who deliver services to patients.

(d) Types of routine professional services. Routine professional services include at least all of the following services when medically appropriate:

(1) Visits to the patient during dialysis, and review of laboratory test results, nurses’ notes and any other medical documentation, as a basis for—

(i) Adjustment of the patient’s medication or diet, or the dialysis procedure;

(ii) Prescription of medical supplies; and

(iii) Evaluation of the patient’s psychosocial status and the appropriateness of the treatment modality.

(2) Medical direction of staff in delivering services to a patient during a dialysis session.

(3) Pre-dialysis and post-dialysis examinations, or examinations that could have been furnished on a pre-dialysis or post-dialysis basis.

(4) Insertion of catheters for patients who are on peritoneal dialysis and do not have indwelling catheters.

(e) Payment for routine professional services. Beginning August 7, 1990, routine professional services furnished by physicians may be paid under either the “initial method” of payment described in §413.313, (if all of the physicians at the facility elect the initial
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§ 414.313 Initial method of payment.

(a) Basic rule. Under this method, the intermediary pays the facility for routine professional services furnished by physicians. Payment is in the form of an add-on to the facility’s composite rate payment, which is described in part 413, subpart H of this subchapter.

(b) Services for which payment is not included in the add-on payment. (1) Physician administrative services are considered to be facility services and are paid for as part of the facility’s composite rate.

(2) The carrier pays the physician or the beneficiary (as appropriate) under the reasonable charge criteria set forth in subpart E of part 405 of this chapter for the following services:
   (i) Physician services that must be furnished at a time other than during the dialysis session (excluding pre-dialysis and post-dialysis examinations and examinations that could have been furnished on a pre-dialysis or post-dialysis basis), such as monthly and semi-annual examinations to review health status and treatment.
   (ii) Physician surgical services other than insertion of catheters for patients who are on peritoneal dialysis and do not have indwelling catheters.
   (iii) Physician services furnished to hospital inpatients who were not admitted solely to receive maintenance dialysis.
   (iv) Administration of hepatitis B vaccine.

(c) Physician election of the initial method. (1) Each physician in a facility must submit to the appropriate carrier and intermediary that serve the facility a statement of election of the initial method of payment for all the ESRD facility patients that he or she attends.

(2) The initial method of payment applies to dialysis services furnished beginning with the second calendar month after the month in which all physicians in the facility elect the initial method and continues until the effective date of a termination of the election described in paragraph (d) of this section.

(d) Termination of the initial method.

(1) Physicians may terminate the initial method of payment by written notice to the carrier(s) that serves each physician and to the intermediary that serves the facility.

(2) If the notice terminating the initial method is received by the carrier(s) and intermediary—
   (i) On or before November 1, the effective date of the termination is January 1 of the year following the calendar year in which the notice is received by the carrier(s) and intermediary; or
   (ii) After November 1, the effective date of the termination is January 1 of the second year after the calendar year in which the notice is received by the carrier(s) and intermediary.

(e) Determination of payment amount. The factors used in determining the add-on amount are related to program experience. They are re-evaluated periodically and may be adjusted, as determined necessary by CMS, to maintain the payment at a level commensurate with the prevailing charges of other physicians for comparable services.

(f) Publication of payment amount. Revisions to the add-on amounts are published in the FEDERAL REGISTER in accordance with the Department’s established rulemaking procedures.


§ 414.314 Monthly capitation payment method.

(a) Basic rules. (1) Under the monthly capitation payment (MCP) method, the carrier pays an MCP amount for each patient, to cover all professional services furnished by the physician, except those listed in paragraph (b) of this section.

(2) The carrier pays the MCP amount, subject to the deductible and coinsurance provisions, to the physician if the physician accepts assignment or to the beneficiary if the physician does not accept assignment.

(3) The MCP method recognizes the need of maintenance dialysis patients for physician services furnished periodically over relatively long periods of