

§ 414.240

42 CFR Ch. IV (10–1–23 Edition)

additional attributes and features. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code are established in accordance with paragraph (c) of this section.

(c) *Use of supplier or commercial price lists.* (1) Fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price.

(i) The annual deflation factors are specified in program instructions and are based on the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period, as calculated using the following formula: ((base CPI-U minus current CPI-U) divided by current CPI-U) plus one.

(ii) The deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Act for DME, section 1834(h)(4) of the Act for prosthetic devices, prosthetics, orthotics, and therapeutic shoes and inserts, and section 1834(i)(1)(B) of the Act for surgical dressings.

(2) If within 5 years of establishing fee schedule amounts using supplier or commercial prices, the prices decrease by less than 15 percent, a one-time adjustment to the fee schedule amounts is made using the new prices. The new prices would be used to establish the new fee schedule amounts in the same way that the older prices were used, in-

cluding application of the deflation formula in paragraph (c)(1) of this section.

[84 FR 60808, Nov. 8, 2019]

§ 414.240 Procedures for making benefit category determinations and payment determinations for new durable medical equipment, prosthetic devices, orthotics and prosthetics, surgical dressings, and therapeutic shoes and inserts.

(a) *Definitions.* For the purpose of this subpart—

Benefit category determination means a national determination regarding whether an item or service meets the Medicare definition of durable medical equipment at section 1861(n) of the Act, a prosthetic device at section 1861(s)(8) of the Act and further defined under section 1834(h)(4) of the Act, an orthotic or leg, arm, back or neck brace, a prosthetic or artificial leg, arm or eye at section 1861(s)(9) of the Act, is a surgical dressing, or is a therapeutic shoe or insert subject to sections 1834(a), (h), or (i) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute.

(b) *General rule.* The procedures for determining whether new items and services addressed in a request for a HCPCS Level II code(s) or by other means meet the definition of items and services paid for in accordance with this subpart are as follows:

(1) At the start of a HCPCS coding cycle, CMS performs an analysis to determine if the item or service is statutorily excluded from coverage under Medicare under section 1862 of the Act, and, if not excluded by statute, whether the item or service is durable medical equipment, a prosthetic device as further defined under section 1834(h)(4) of the Act, an orthotic or prosthetic, a surgical dressing, or a therapeutic shoe or insert.

(2) If a preliminary determination is made that the item or service is durable medical equipment, a prosthetic device, an orthotic or prosthetic, a surgical dressing, or a therapeutic shoe or insert, CMS makes a preliminary payment determination for the item or service.

(3) CMS posts preliminary benefit category determinations and payment

determinations on *CMS.gov* approximately 2 weeks prior to a public meeting.

(4) After consideration of public consultation provided at a public meeting on preliminary benefit category determinations and payment determinations for items and services, CMS establishes the benefit category determinations and payment determinations for items and services through program instructions.

[86 FR 73911, Dec. 28, 2021]

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.

[55 FR 23441, June 8, 1990, as amended at 56 FR 43710, Sept. 4, 1991; 59 FR 1285, Jan. 10, 1994]

§414.310 Determination of reasonable charges for physician services furnished to renal dialysis patients.

(a) *Principle.* Physician services furnished to renal dialysis patients are subject to payment if the services are 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.