

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 § 414.102(c).

(2) If within 5 years of establishing fee schedule amounts using supplier or commercial prices, the supplier or commercial prices decrease by less than 15 percent, a one-time adjustment to the fee schedule amounts is made using the new prices. The new supplier or commercial prices would be used to establish the new fee schedule amounts in the same way that the older prices were used, including application of the deflation formula in paragraph (c)(1) of this section.

[84 FR 60806, Nov. 8, 2019]

Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

§ 414.200 Purpose.

This subpart implements sections 1834(a), (h) and (i) of the Act by specifying how payments are made for the purchase or rental of new and used durable medical equipment, prosthetic and orthotic devices, and surgical dressings for Medicare beneficiaries.

[78 FR 72253, Dec. 2, 2013]

§ 414.202 Definitions.

For purposes of this subpart, the following definitions apply:

Complex rehabilitative power-driven wheelchair means a power-driven wheelchair that is classified as—

(1) Group 2 power wheelchair with power options that can accommodate rehabilitative features (for example, tilt in space); or

(2) Group 3 power wheelchair.

Covered item update means the percentage increase in the consumer price index for all urban consumers (U.S. city average) (CPI-U) for the 12-month period ending with June of the previous year.

Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:

(1) Can withstand repeated use.

(2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

(3) Is primarily and customarily used to serve a medical purpose.

(4) Generally is not useful to an individual in the absence of an illness or injury.

(5) Is appropriate for use in the home.

Prosthetic and orthotic devices means—

(1) Devices that replace all or part of an internal body organ, including ostomy bags and supplies directly related to ostomy care, and replacement of such devices and supplies;

(2) One pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens; and

(3) Leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the beneficiary's physical condition.

The following are neither prosthetic nor orthotic devices—

(1) Parenteral and enteral nutrients, supplies, and equipment;

(2) Intraocular lenses;

(3) Medical supplies such as catheters, catheter supplies, ostomy bags, and supplies related to ostomy care that are furnished by an HHA as part of home health services under § 409.40(e) of this chapter;

(4) Dental prostheses.

§ 414.210

Region means, for the purpose of implementing § 414.210(g), geographic areas defined by the Bureau of Economic Analysis in the United States Department of Commerce for economic analysis purposes, and, for the purpose of implementing § 414.228, those contractor service areas administered by CMS regional offices.

Rural area means, for the purpose of implementing § 414.210(g), a geographic area represented by a postal zip code if at least 50 percent of the total geographic area of the area included in the zip code is estimated to be outside any metropolitan area (MSA). A rural area also includes a geographic area represented by a postal zip code that is a low population density area excluded from a competitive bidding area in accordance with the authority provided by section 1847(a)(3)(A) of the Act at the time the rules at § 414.210(g) are applied.

[57 FR 57689, Dec. 7, 1992, as amended at 75 FR 73622, Nov. 29, 2010; 76 FR 70314, Nov. 10, 2011; 79 FR 66262, Nov. 6, 2014]

§ 414.210 General payment rules.

(a) *General rule.* For items furnished on or after January 1, 1989, except as provided in paragraphs (c), (d), and (g) of this section, Medicare pays for durable medical equipment, prosthetics and orthotics, including a separate payment for maintenance and servicing of the items as described in paragraph (e) of this section, on the basis of 80 percent of the lesser of—

(1) The actual charge for the item;

(2) The fee schedule amount for the item, as determined in accordance with the provisions of §§ 414.220 through 414.232

(b) *Payment classification.* (1) The carrier determines fee schedules for the following classes of equipment and devices:

(i) Inexpensive or routinely purchased items, as specified in § 414.220.

(ii) Items requiring frequent and substantial servicing, as specified in § 414.222.

(iii) Certain customized items, as specified in § 414.224.

(iv) Oxygen and oxygen equipment, as specified in § 414.226.

(v) Prosthetic and orthotic devices, as specified in § 414.228.

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(vi) Other durable medical equipment (capped rental items), as specified in § 414.229.

(vii) Transcutaneous electrical nerve stimulators (TENS), as specified in § 414.232.

(2) CMS designates the items in each class of equipment or device through its program instructions.

(c) *Exception for certain HHAs.* Public HHAs and HHAs that furnish services or items free-of-charge or at nominal prices to a significant number of low-income patients, as defined in § 413.13(a) of this chapter, are paid on the basis of 80 percent of the fee schedule amount determined in accordance with the provision of §§ 414.220 through 414.230.

(d) *Prohibition on special limits.* For items furnished on or after January 1, 1989 and before January 1, 1991, neither CMS nor a carrier may establish a special reasonable charge for items covered under this subpart on the basis of inherent reasonableness as described in § 405.502(g) of this chapter.

(e) *Maintenance and servicing*—(1) *General rule.* Except as provided in paragraph (e)(3) of this section, the carrier pays the reasonable and necessary charges for maintenance and servicing of beneficiary-owned equipment. Reasonable and necessary charges are those made for parts and labor not otherwise covered under a manufacturer's or supplier's warranty. Payment is made for replacement parts in a lump sum based on the carrier's consideration of the item. The carrier establishes a reasonable fee for labor associated with repairing, maintaining, and servicing the item. Payment is not made for maintenance and servicing of a rented item other than the maintenance and servicing fee for oxygen equipment described in paragraph (e)(2) of this section or for other durable medical equipment as described in § 414.229(e).

(2) *Maintenance and servicing payment for certain oxygen equipment furnished after the 36-month rental period from January 1, 2009 through June 30, 2010.* The carrier makes a maintenance and servicing payment for oxygen equipment other than liquid and gaseous equipment (stationary and portable) as follows: