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means meet the definition of items and services that may be covered and 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 parenteral or enteral nutrients, supplies, and equipment covered under the prosthetic device benefit, splints and casts or other devices used for reductions of fractures or dislocations, or IOLs inserted in a physician's office covered under the prosthetic device benefit.

(2) If a preliminary determination is made that the item or service is parenteral or enteral nutrients, supplies, and equipment covered under the prosthetic device benefit, splints and casts or other devices used for reductions of fractures or dislocations, or IOLs inserted in a physician's office covered under the prosthetic device benefit, 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 73910, Dec. 28, 2021]

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]

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§ 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.

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.

(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:

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(i) For the first 6-month period following the date on which the 36-month rental period ends in accordance with § 414.226(a)(1) of this subpart, no payments are made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period for 30 minutes of labor for routine maintenance and servicing of the equipment in the beneficiary's home (including an institution used as the beneficiary's home).

(iii) The supplier must visit the beneficiary's home (including an institution used as the beneficiary's home) to inspect the equipment during the first month of the 6-month period.

(3) *Exception to maintenance and servicing payments.* For items purchased on or after June 1, 1989, no payment is made under the provisions of paragraph (e)(1) of this section for the maintenance and servicing of:

(i) Items requiring frequent and substantial servicing, as defined in § 414.222(a);

(ii) Capped rental items, as defined in § 414.229(a), that are not beneficiary-owned in accordance with § 414.229(d), § 414.229(f)(2), or § 414.229(h); and

(iii) Capped rental items, as defined in § 414.229(a), that are not beneficiary-owned in § 414.229(d), § 414.229(f)(2), or § 414.229(h); and

(iv) Oxygen equipment, as described in § 414.226.

(4) *Supplier replacement of beneficiary-owned equipment based on accumulated repair costs.* A supplier that transfers title to a capped rental item to a beneficiary in accordance with § 414.229(f)(2) is responsible for furnishing replacement equipment at no cost to the beneficiary or to the Medicare program if the carrier determines that the item furnished by the supplier will not last for the entire reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1). In making this determination, the carrier may consider whether the accumulated costs of repair exceed 60 percent of the cost to replace the item.

(5) *Maintenance and servicing payment for certain oxygen equipment furnished after the 36-month rental period and on or after July 1, 2010.* For oxygen equipment other than liquid and gaseous equip-

ment (stationary and portable), the carrier makes payment as follows:

(i) For the first 6-month period following the date on which the 36-month rental period ends in accordance with § 414.226(a)(1) of this subpart, no payments are made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period for routine maintenance and servicing of the equipment in the beneficiary's home (including an institution used as the beneficiary's home).

(iii) Payment for maintenance and servicing is made based on a reasonable fee not to exceed 10 percent of the purchase price for a stationary oxygen concentrator. This payment includes payment for maintenance and servicing of all oxygen equipment other than liquid or gaseous equipment (stationary or portable).

(iv) The supplier must visit the beneficiary's home (including an institution used as the beneficiary's home) to inspect the equipment during the first month of the 6-month period.

(f) *Payment for replacement of equipment.* If an item of DME or a prosthetic or orthotic device paid for under this subpart has been in continuous use by the patient for the equipment's reasonable useful lifetime or if the carrier determines that the item is lost, stolen, or irreparably damaged, the patient may elect to obtain a new piece of equipment.

(1) The reasonable useful lifetime of DME or prosthetic and orthotic devices is determined through program instructions. In the absence of program instructions, carriers may determine the reasonable useful lifetime of equipment but in no case can it be less than 5 years. Computation is based on when the equipment is delivered to the beneficiary, not the age of the equipment.

(2) If the beneficiary elects to obtain replacement oxygen equipment, payment is made in accordance with § 414.226(a).

(3) If the beneficiary elects to obtain a replacement capped rental item, payment is made in accordance with § 414.229(a)(2) or (a)(3).

(4) For all other beneficiary-owned items, if the beneficiary elects to obtain replacement equipment, payment is made on a purchase basis.

(g) *Application of Competitive Bidding Information and Limitation of Inherent Reasonableness Authority.* For items furnished on or after January 1, 2011, the fee schedule amounts may be adjusted, and for DME items furnished on or after January 1, 2016, the fee schedule amounts shall be adjusted, based on information on the payment determined as part of implementation of the programs under subpart F, of this part, excluding information on the payment determined in accordance with the special payment rules at §414.409. In the case of such adjustments, the rules at §405.502(g) and (h) of this chapter shall not be applied. The methodologies for adjusting fee schedule amounts are provided below. In any case where application of these methodologies results in an increase in the fee schedule amount, the adjustment to the fee schedule amount is not made.

(1) *Payment adjustments for areas within the contiguous United States using information from competitive bidding programs.* For an item or service subject to the programs under subpart F of this part, the fee schedule amounts for such item or service for areas within the contiguous United States shall be adjusted as follows:

(i) CMS determines a regional price for each state in the contiguous United States and the District of Columbia equal to the un-weighted average of the single payment amounts for an item or service established in accordance with §414.416 for competitive bidding areas that are fully or partially located in the same region that contains the state or District of Columbia.

(ii) CMS determines a national average price equal to the un-weighted average of the regional prices determined under paragraph (g)(1)(i) of this section.

(iii) A regional price determined under paragraph (g)(1)(i) of this section cannot be greater than 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section nor less than 90 percent of the national average price determined under paragraph (g)(1)(ii) of this section.

(iv) The fee schedule amount for all areas within a state that are not defined as rural areas for purposes of this subpart is adjusted to the regional price determined under paragraphs (g)(1)(i) and (iii) of this section.

(v) For items and services furnished before February 28, 2022, the fee schedule amount for all areas within a state that are defined as rural areas for the purposes of this subpart is adjusted to 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section.

(2) Payment adjustments for areas outside the contiguous United States and for items furnished on or after February 28, 2022 in rural areas within the contiguous United States using information from competitive bidding programs.

(i) For an item or service subject to the programs under subpart F, the fee schedule amounts for areas outside the contiguous United States (Alaska, Hawaii, and U.S. territories) for items and services furnished from January 1, 2016, through December 31, 2020 are reduced to the greater of—

(A) The average of the single payment amounts for the item or service for CBAs outside the contiguous United States.

(B) 110 percent of the national average price for the item or service determined under paragraph (g)(1)(ii) of this section.

(ii) For an item or service subject to the programs under subpart F of this part, the fee schedule amounts for areas outside the contiguous United States for items and services furnished on or after February 28, 2022, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b-5(g)(1)(B)), whichever is later, is adjusted to equal the sum of—

(A) Fifty percent of the greater of the average of the single payment amounts for the item or service for CBAs outside the contiguous United States or 110 percent of the national average price for the item or service determined under paragraph (g)(1)(ii) of this section; and

(B) Fifty percent of the fee schedule amount for the area in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for durable medical equipment and supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment.

(iii) For an item or service subject to the programs under subpart F of this part, the fee schedule amounts for rural areas within the contiguous United States for items and services furnished on or after February 28, 2022, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, is adjusted to equal the sum of—

(A) Fifty percent of 110 percent of the national average price for the item or service determined under paragraph (g)(1)(ii) of this section; and

(B) Fifty percent of the fee schedule amount for the area in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for durable medical equipment and supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment.

(3) *Payment adjustments for items and services included in no more than ten competitive bidding programs.* Notwithstanding paragraph (g)(1) of this section, for an item or service that is included in ten or fewer competitive bidding programs as defined at §414.402, the fee schedule amounts applied for all areas within and outside the contiguous United States are reduced to 110 percent of the un-weighted average of the single payment amounts from the ten or fewer competitive bidding programs for the item or service in the areas where the ten or fewer competitive bidding programs are in place.

(4) *Payment adjustments using data on items and services included in competitive bidding programs no longer in effect.* In the case where adjustments to fee schedule amounts are made using any

of the methodologies described, other than paragraph (g)(10) of this section, if the adjustments are based solely on single payment amounts from competitive bidding programs that are no longer in effect, the single payment amounts are updated before being used to adjust the fee schedule amounts. The single payment amounts are updated based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) from the mid-point of the last year the single payment amounts were in effect to the month ending 6 months prior to the date the initial fee schedule reductions go into effect. Following the initial adjustments to the fee schedule amounts, if the adjustments continue to be based solely on single payment amounts from competitive bidding programs that are no longer in effect, the single payment amounts used to reduce the fee schedule amounts are updated every 12 months using the percentage change in the CPI-U for the 12-month period ending 6 months prior to the date the updated payment adjustments would go into effect.

(5) *Adjusted payment amounts for accessories used with different types of base equipment.* In situations where a HCPCS code that describes an item used with different types of base equipment is included in more than one product category in a CBA under competitive bidding, a weighted average of the single payment amounts for the code is computed for each CBA based on the total number of allowed services for the item on a national basis for the code from each product category prior to applying the payment adjustment methodologies in this section.

(6) *Adjustments of single payment amounts resulting from price inversions under the DMEPOS Competitive Bidding Program.* (i) In situations where a price inversion defined in §414.402 occurs under the DMEPOS Competitive Bidding Program in a competitive bidding area (CBA) following a competition for a grouping of similar items identified in paragraph (g)(6)(ii) of this section, prior to adjusting the fee schedule amounts under paragraph (g) of this section the single payment amount for each item in the grouping of similar items in the CBA is adjusted to be

equal to the weighted average of the single payment amounts for the items in the grouping of similar items in the CBA.

(ii) The groupings of similar items subject to this rule include—

(A) Hospital beds (HCPCS codes E0250, E0251, E0255, E0256, E0260, E0261, E0290, E0291, E0292, E0293, E0294, E0295, E0301, E0302, E0303, and E0304).

(B) Mattresses and overlays (HCPCS codes E0277, E0371, E0372, and E0373)

(C) Power wheelchairs (HCPCS codes K0813, K0814, K0815, K0816, K0820, K0821, K0822, and K0823).

(D) Seat lift mechanisms (HCPCS codes E0627 and E0629).

(E) TENS devices (HCPCS codes E0720 and E0730).

(F) Walkers (HCPCS codes E0130, E0135, E0141, and E0143).

(iii) The weight for each item (HCPCS code) used in calculating the weighted average described in paragraph (g)(6)(ii) of this section is equal to the proportion of total nationwide allowed services furnished in calendar year 2012 for the item (HCPCS code) in the grouping of similar items, relative to the total nationwide allowed services furnished in calendar year 2012 for each of the other items (HCPCS codes) in the grouping of similar items.

(7) *Payment adjustments for mail order items furnished in the Northern Mariana Islands.* The fee schedule amounts for mail order items furnished to beneficiaries in the Northern Mariana Islands are adjusted so that they are equal to 100 percent of the single payment amounts established under a national mail order competitive bidding program. Beginning on or after the date that the Northern Mariana Islands are included under a national mail order competitive bidding program, the fee schedule adjustment methodology under this paragraph no longer applies.

(8) *Updating adjusted fee schedule amounts.* The adjusted fee schedule amounts are revised each time a single payment amount for an item or service is updated following one or more new competitions and as other items are added to programs established under Subpart F of this part.

(9) *Transition rules.* The payment adjustments described above are phased in as follows:

(i) For applicable items and services furnished with dates of service from January 1, 2016 through December 31, 2016, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.

(ii) For items and services furnished with dates of service from January 1, 2017, through May 31, 2018, the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

(iii) For items and services furnished in rural areas and non-contiguous areas (Alaska, Hawaii, and U.S. territories) with dates of service from June 1, 2018 through December 31, 2020 or through the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b-5(g)(1)(B)), whichever is later, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.

(iv) For items and services furnished in areas other than rural or noncontiguous areas with dates of service from June 1, 2018 through March 5, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

(v) For items and services furnished in areas other than rural or noncontiguous areas with dates of service from March 6, 2020, through the remainder of the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b-5(g)(1)(B)), based on the fee schedule amount for the area is equal to 75 percent of the adjusted payment amount established under this section and 25 percent of the unadjusted fee schedule amount. For items and services furnished in areas other than rural or noncontiguous areas with dates of service from the expiration date of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b-5(g)(1)(B)), through December 31, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

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(vi) For items and services furnished in all areas with dates of service on or after February 28, 2022, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act, whichever is later, based on the fee schedule amount for the area is equal to the adjusted payment amount established under paragraph (g) of this section.

(10) *Payment adjustments for items and services furnished in former competitive bidding areas during temporary gaps in the DMEPOS CBP.* During a temporary gap in the entire DMEPOS CBP and/or National Mail Order CBP, the fee schedule amounts for items and services that were competitively bid and furnished in areas that were competitive bidding areas at the time the program(s) was in effect are adjusted based on the SPAs in effect in the competitive bidding areas on the last day before the CBP contract period of performance ended, increased by the projected percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) for the 12-month period ending on the date after the contract periods ended. If the gap in the CBP lasts for more than 12 months, the fee schedule amounts are increased once every 12 months on the anniversary date of the first day of the gap period based on the projected percentage change in the CPI-U for the 12-month period ending on the anniversary date.

[57 FR 57689, Dec. 7, 1992, as amended at 71 FR 65932, Nov. 9, 2006; 73 FR 69936, Nov. 19, 2008; 73 FR 80304, Dec. 31, 2008; 74 FR 62009, Nov. 25, 2009; 79 FR 66262, Nov. 6, 2013; 81 FR 77965, Nov. 4, 2016; 83 FR 21925, May 11, 2018; 83 FR 57070, Nov. 14, 2018; 85 FR 27623, May 8, 2020; 86 FR 73911, Dec. 28, 2021; 87 FR 199, Jan. 4, 2022]

§ 414.220 Inexpensive or routinely purchased items.

(a) *Definitions.* (1) *Inexpensive equipment* means equipment the average purchase price of which did not exceed \$150 during the period July 1986 through June 1987.

(2) *Routinely purchased equipment* means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987.

(3) *Accessories.* Effective January 1, 1994, accessories used in conjunction

with a nebulizer, aspirator, or ventilator excluded from § 414.222 meet the definitions of “inexpensive equipment” and “routinely purchased equipment” in paragraphs (a)(1) and (a)(2) of this section, respectively.

(b) *Payment rules.* (1) Subject to the limitation in paragraph (b)(3) of this section, payment for inexpensive and routinely purchased items is made on a rental basis or in a lump sum amount for purchase of the item based on the applicable fee schedule amount.

(2) Effective January 1, 1994, payment for ostomy supplies, tracheostomy supplies, urologicals, and surgical dressings not furnished as incident to a physician’s professional service or furnished by an HHA is made using the methodology for the inexpensive and routinely purchased class.

(3) The total amount of payments made for an item may not exceed the fee schedule amount recognized for the purchase of that item.

(c) *Fee schedule amount for 1989 and 1990.* The fee schedule amount for payment of purchase or rental of inexpensive or routinely purchased items furnished in 1989 and 1990 is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for inexpensive or routinely purchased items that were furnished during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier’s allowed charges for the item. A separate determination of an average reasonable charge is made for rental equipment, new purchased equipment, and used purchased equipment.

(2) The carrier adjusts the amount determined under paragraph (c)(1) of this section by the change in the level of the CPI-U for the 6-month period ending December 1987.

(d) *Updating the local payment amounts for years after 1990.* For each year subsequent to 1990, the local payment amounts of the preceding year are increased or decreased by the covered item update. For 1991 and 1992, the covered item update is reduced by 1 percentage point.

(e) *Calculating the fee schedule amounts for years after 1990.* For years after 1990, the fee schedule amounts are

equal to the national limited payment amount.

(f) *Calculating the national limited payment amount.* The national limited payment amount is computed as follows:

(1) The 1991 national limited payment amount is equal to:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

(ii) The sum of 67 percent of the local payment amount plus 33 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average of all local payment amounts; or

(iii) The sum of 67 percent of the local payment amount plus 33 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average of all local payment amounts.

(2) The 1992 national limited payment amount is equal to:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

(ii) The sum of 33 percent of the local payment amount plus 67 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average; or

(iii) The sum of 33 percent of the local payment amount plus 67 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average.

(3) For 1993, the national limited payment amount is equal to one of the following:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts.

(ii) 100 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average of all local payment amounts.

(iii) 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average of all local payment amounts.

(4) For 1994 and subsequent years, the national limited payment amount is equal to one of the following:

(i) If the local payment amount is not in excess of the median, nor less than 85 percent of the median, of all local payment amounts—100 percent of the local payment amount.

(ii) If the local payment amount exceeds the median—100 percent of the median of all local payment amounts.

(iii) If the local payment amount is less than 85 percent of the median—85 percent of the median of all local payment amounts.

(g) *Payment for surgical dressings.* For surgical dressings furnished after December 31, 1993, the national limited payment amount is computed based on local payment amounts using average reasonable charges for the 12-month period ending December 31, 1992, increased by the covered item updates for 1993 and 1994.

[57 FR 57689, Dec. 7, 1992, as amended at 60 FR 35497, July 10, 1995]

§ 414.222 Items requiring frequent and substantial servicing.

(a) *Definition.* Items requiring frequent and substantial servicing in order to avoid risk to the beneficiary's health are the following:

(1) Ventilators (except those that are either continuous airway pressure devices or respiratory assist devices with bi-level pressure capability with or without a backup rate, previously referred to as "intermittent assist devices with continuous airway pressure devices").

(2) Continuous and intermittent positive pressure breathing machines.

(3) Continuous passive motion machines.

(4) Other items specified in CMS program instructions.

(5) Other items identified by the carrier.

(b) *Payment rule.* Rental payments for items requiring frequent and substantial servicing are made on a monthly basis, and continue until medical necessity ends.

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(c) *Fee schedule amount for 1989 and 1990.* The fee schedule amount for items requiring frequent and substantial servicing is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for rental of items requiring frequent and substantial servicing that were furnished during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item.

(2) The carrier adjusts the amounts determined under paragraph (c)(1) of this section by the change in the level of the CPI-U for the 6-month period ending December 1987.

(d) *Updating the fee schedule amounts for years after 1990.* For years after 1990, the fee schedules are determined using the methodology contained in paragraphs (d), (e), and (f) of § 414.220.

(e) *Transition to other payment classes.* For purposes of calculating the 15-month rental period, beginning January 1, 1994, if an item has been paid for under the frequent and substantial servicing class and is subsequently paid for under another payment class, the rental period begins with the first month of continuous rental, even if that period began before January 1, 1994. For example, if the rental period began on July 1, 1993, the carrier must use this date as beginning the first month of rental. Likewise, for purposes of calculating the 10-month purchase option, the rental period begins with the first month of continuous rental without regard to when that period started. For example, if the rental period began in August 1993, the 10-month purchase option must be offered to the beneficiary in May 1994, the tenth month of continuous rental.

(f) *Multi-function ventilators*—(1) Definition. For the purpose of this paragraph (f), a multi-function ventilator is a ventilator as defined in paragraph (a)(1) of this section that also performs medically necessary functions for the patient at the same time that would otherwise be performed by one or more different items classified under § 414.220, § 414.226, or § 414.229.

(2) *Payment rule.* Effective for dates of service on or after January 1, 2019, the monthly rental fee schedule amount for a multi-function ventilator de-

scribed in paragraph (f)(1) of this section is equal to the monthly rental fee schedule amount for the ventilator established in paragraph (c) and paragraph (d) of this section plus the average of the lowest monthly cost for one additional function determined under paragraph (f)(3) of this section and the monthly cost of all additional functions determined under paragraph (f)(3) of this section, increased by the annual covered item updates of section 1834(a)(14) of the Act.

(3) *Monthly cost for additional functions.* (i) For functions performed by items classified under this section prior to 1994, the monthly cost is equal to the monthly rental fee schedule amount established in paragraphs (c) and (d) of this section increased by the covered item update of section 1834(a)(14) of the Act.

(ii) For functions performed by items classified under § 414.220, the monthly cost is equal to the fee schedule amount for purchased equipment established in § 414.220(c), (d), (e), and (f), adjusted in accordance with § 414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment.

(iii) For functions performed by items classified under § 414.226, the monthly cost is equal to the monthly payment amount established in § 414.226(e) and (f), adjusted in accordance with § 414.210(g), multiplied by 36 and divided by 60 months or total number of months of the reasonable useful lifetime of the oxygen equipment.

(iv) For functions performed by items classified under § 414.229, the monthly cost is equal to the purchase price established in § 414.229(c), adjusted in accordance with § 414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment.

[57 FR 57690, Dec. 7, 1992, as amended at 60 FR 35497, July 10, 1995; 71 FR 4525, Jan. 27, 2006; 83 FR 57071, Nov. 14, 2018]

§ 414.224 Customized items.

(a) *Criteria for a customized item.* To be considered a customized item for payment purposes under paragraph (b) of this section, a covered item (including a wheelchair) must be uniquely constructed or substantially modified for a

specific beneficiary according to the description and orders of a physician and be so different from another item used for the same purpose that the two items cannot be grouped together for pricing purposes.

(b) *Payment rule.* Payment is made on a lump sum basis for the purchase of a customized item based on the carrier's individual consideration and judgment of a reasonable payment amount for each customized item. The carrier's individual consideration takes into account written documentation on the costs of the item including at least the cost of labor and materials used in customizing an item.

[56 FR 65998, Dec. 20, 1991, as amended at 58 FR 34919, June 30, 1993]

§414.226 Oxygen and oxygen equipment.

(a) *Payment rules—(1) Oxygen equipment.* Payment for rental of oxygen equipment is made based on a monthly fee schedule amount during the period of medical need, but for no longer than a period of continuous use of 36 months. A period of continuous use is determined under the provisions in §414.230.

(2) *Oxygen contents.* Payment for purchase of oxygen contents is made based on a monthly fee schedule amount until medical necessity ends.

(b) *Monthly fee schedule amount for items furnished prior to 2007.* (1) Monthly fee schedule amounts are separately calculated for the following items:

(i) Stationary oxygen equipment and oxygen contents (stationary and portable oxygen contents).

(ii) Portable oxygen equipment only.

(iii) Stationary and portable oxygen contents only.

(iv) Portable oxygen contents only.

(2) For 1989 and 1990, the monthly fee schedule amounts are the local payment amounts determined as follows:

(i) The carrier determines the base local average monthly payment rate equal to the total reasonable charges for the item for the 12-month period ending December 1986 divided by the total number of months for all beneficiaries receiving the item for the same period. In determining the local average monthly payment rate, the following limitations apply:

(A) Purchase charges for oxygen systems are not included as items classified under paragraph (b)(1)(i) of this section.

(B) Purchase charges for portable equipment are not included as items classified under paragraph (b)(1)(ii) of this section.

(ii) The carrier determines the local monthly payment amount equal to 0.95 times the base local average monthly payment amount adjusted by the change in the CPI-U for the six-month period ending December 1987.

(3) For 1991 through 2006, the fee schedule amounts for items described in paragraphs (b)(1)(iii) and (iv) of this section are determined using the methodology contained in §414.220(d), (e), and (f).

(4) For 1991 through 2006, the fee schedule amounts for items described in paragraphs (b)(1)(i) and (ii) of this section are determined using the methodology contained in §414.220(d), (e), and (f).

(5) For 2005 and 2006, the fee schedule amounts determined under paragraph (b)(4) of this section are reduced using the methodology described in section 1834(a)(21)(A) of the Act.

(c) *Monthly fee schedule amount for items furnished from 2007 through 2018.*

(1) For 2007, national limited monthly payment rates are calculated and paid as the monthly fee schedule amounts for the following classes of items:

(i) Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).

(ii) Portable equipment only (gaseous or liquid tanks).

(iii) Oxygen generating portable equipment only.

(iv) Stationary oxygen contents only.

(v) Portable oxygen contents only.

(2) The national limited monthly payment rate for items described in paragraph (c)(1)(i) of this section is equal to the weighted average fee schedule amount established under paragraph (b)(5) of this section reduced by \$1.44.

(3) The national limited monthly payment rate for items described in paragraph (c)(1)(ii) of this section is equal to the weighted average of the

fee schedule amounts established under paragraph (b)(5) of this section.

(4) The national limited monthly payment rate for items described in paragraph (c)(1)(iii) of this section is equal to the national limited monthly payment rate established under paragraph (c)(5) of this section, multiplied by 24, and divided by 36.

(5) The national limited monthly payment rate for items described in paragraphs (c)(1)(iv) and (c)(1)(v) of this section is equal to 50 percent of the weighted average fee schedule amounts established under paragraph (b)(3) of this section for items described in paragraph (b)(1)(iii) of this section.

(6) For 2008 through 2018, CMS makes an annual adjustment to the national limited monthly payment rate for items described in paragraph (c)(1)(i) of this section to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.

(d) *Application of monthly fee schedule amounts for items furnished from 2007 through 2018.* (1) The fee schedule amount for items described in paragraph (c)(1)(i) of this section is paid when the beneficiary rents stationary oxygen equipment.

(2) Subject to the limitation set forth in paragraph (g)(2) of this section, the fee schedule amount for items described in paragraphs (c)(1)(ii) and (c)(1)(iii) of this section is paid when the beneficiary rents portable oxygen equipment.

(3) The fee schedule amount for items described in paragraph (c)(1)(iv) of this section is paid when the beneficiary—

(i) Owns stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents; or

(ii) Rents stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(4) The fee schedule amount for items described in paragraph (c)(1)(v) of this section is paid when the beneficiary—

(i) Owns portable oxygen equipment described in (c)(1)(ii) of this section;

(ii) Rents portable oxygen equipment described in paragraph (c)(1)(ii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section and does not rent stationary oxygen equipment; or

(iii) Rents portable oxygen equipment described in paragraph (c)(1)(ii) of this section after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(e) *Monthly fee schedule amount for items furnished for years after 2018.* (1) For 2019, national limited monthly payment rates are calculated and paid as the monthly fee schedule amounts for the following classes of items:

(i) Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).

(ii) Portable gaseous equipment only.

(iii) Portable liquid equipment only.

(iv) Oxygen generating portable equipment only.

(v) Stationary oxygen contents only.

(vi) Portable oxygen contents only, except for portable liquid oxygen contents for prescribed flow rates greater than four liters per minute.

(vii) Portable liquid oxygen contents only for prescribed flow rates of more than 4 liters per minute.

(2) The monthly payment rate for items described in paragraphs (e)(1)(i), (ii), (iv), (v), and (vi) of this section are determined using the applicable methodologies contained in § 414.210(g).

(3) The monthly payment rate for items described in paragraph (e)(1)(iii) of this section is determined initially based on the monthly payment rate for items described in paragraph (e)(1)(iv) of this section and is subsequently adjusted using the applicable methodologies contained in § 414.210(g).

(4) The monthly payment rate for items described in paragraph (e)(1)(vii) of this section is determined initially based on 150 percent of the monthly payment rate for items described in paragraph (e)(1)(vi) of this section and is subsequently adjusted using the applicable methodologies contained in § 414.210(g).

(5) Beginning in 2019, CMS makes an annual adjustment to the monthly payment rate for items described in paragraphs (e)(1)(i) through (e)(1)(vii) of

this section to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.

(f) *Application of monthly fee schedule amounts for items furnished for years after 2018.* (1) The fee schedule amount for items described in paragraph (e)(1)(i) of this section is paid when the beneficiary rents stationary oxygen equipment.

(2) Subject to the limitation set forth in paragraph (g)(2) of this section, the fee schedule amount for items described in paragraphs (e)(1)(ii), (iii), and (iv) of this section is paid when the beneficiary rents portable oxygen equipment.

(3) The fee schedule amount for items described in paragraph (e)(1)(v) of this section is paid when the beneficiary—

(i) Owns stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents; or

(ii) Rents stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(4) The fee schedule amount for items described in paragraph (e)(1)(vi) of this section is paid when the beneficiary—

(i) Owns portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section; or Code of Federal Regulations/Title 42—Public Health/Vol. 3/2017–10–0166

(ii) Rents portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section and does not rent stationary oxygen equipment; or

(iii) Rents portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(5) The fee schedule amount for items described in paragraph (e)(1)(vii) of this section is paid when the beneficiary has a prescribed flow rate of more than 4 liters per minute and—

(i) Owns portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section; or Code of Federal Regulations/Title 42—Public Health/Vol. 3/2017–10–0166

(ii) Rents portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section and does not rent stationary oxygen equipment; or

(iii) Rents portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(g) *Volume adjustments.* (1) The fee schedule amount for an item described in paragraph (c)(1)(i) of this section is adjusted as follows:

(i) If the attending physician prescribes an oxygen flow rate exceeding four liters per minute, the fee schedule amount is increased by 50 percent, subject to the limit in paragraph (g)(2) of this section.

(ii) If the attending physician prescribes an oxygen flow rate of less than one liter per minute, the fee schedule amount is decreased by 50 percent.

(2) If portable oxygen equipment is used and the prescribed oxygen flow rate exceeds four liters per minute, the total fee schedule amount recognized for payment is limited to the higher of—

(i) The sum of the monthly fee schedule amount for the items described in paragraphs (c)(1)(i) and (c)(1)(ii) or (c)(1)(iii) of this section; or

(ii) The adjusted fee schedule amount described in paragraph (g)(1)(i) of this section.

(3) In establishing the volume adjustment for those beneficiaries whose physicians prescribe varying flow rates, the following rules apply:

(i) If the prescribed flow rate is different for stationary oxygen equipment than for portable oxygen equipment, the flow rate for the stationary equipment is used.

(ii) If the prescribed flow rate is different for the patient at rest than for the patient at exercise, the flow rate for the patient at rest is used.

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(iii) If the prescribed flow rate is different for nighttime use and daytime use, the average of the two flow rates is used.

(h) *Furnishing oxygen and oxygen equipment after the 36-month rental cap.* (1) The supplier that furnishes oxygen equipment for the 36th continuous month during which payment is made under this section must—

(i) Continue to furnish the equipment during any period of medical need for the remainder of the reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1); or

(ii) Arrange for furnishing the oxygen equipment with another supplier if the beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment.

(2) The supplier that furnishes liquid or gaseous oxygen equipment (stationary or portable) for the 36th continuous month during which payment is made under this section must—

(i) Continue to furnish the oxygen contents necessary for the effective use of the liquid or gaseous equipment during any period of medical need for the remainder of the reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1); or

(ii) Arrange for furnishing the oxygen contents with another supplier if the beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment.

(i) *Additional supplier requirements for rentals that begin on or after January 1, 2007.* (1) The supplier that furnishes oxygen equipment for the first month during which payment is made under this section must continue to furnish the equipment for the entire 36-month period of continuous use, unless medical necessity ends or—

(i) The item becomes subject to a competitive acquisition program implemented in accordance with section 1847(a) of the Act;

(ii) The beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment;

(iii) The beneficiary elects to obtain oxygen equipment from a different sup-

plier prior to the expiration of the 36-month rental period; or

(iv) CMS or the carrier determines that an exception should apply in an individual case based on the circumstances.

(2) Oxygen equipment furnished under this section may not be replaced by the supplier prior to the expiration of the reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1) unless:

(i) The supplier replaces an item with the same, or equivalent, make and model of equipment because the item initially furnished was lost, stolen, irreparably damaged, is being repaired, or no longer functions;

(ii) A physician orders different equipment for the beneficiary. If the order is based on medical necessity, then the order must indicate why the equipment initially furnished is no longer medically necessary and the supplier must retain this order in the beneficiary's medical record;

(iii) The beneficiary chooses to obtain a newer technology item or upgraded item and signs an advanced beneficiary notice (ABN); or

(iv) CMS or the carrier determines that a change in equipment is warranted.

(3) Before furnishing oxygen equipment, the supplier must disclose to the beneficiary its intentions regarding whether it will accept assignment of all monthly rental claims for the duration of the rental period. A supplier's intentions could be expressed in the form of a written agreement between the supplier and the beneficiary.

[57 FR 57690, Dec. 7, 1992, as amended at 71 FR 65933, Nov. 9, 2006; 73 FR 69936, Nov. 19, 2008; 78 FR 72253, Dec. 2, 2013; 83 FR 57071, Nov. 14, 2018]

§ 414.228 Prosthetic and orthotic devices.

(a) *Payment rule.* Payment is made on a lump-sum basis for prosthetic and orthotic devices subject to this subpart.

(b) *Fee schedule amounts.* The fee schedule amount for prosthetic and orthotic devices is determined as follows:

(1) The carrier determines a base local purchase price equal to the average reasonable charge for items purchased during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item.

(2) The carrier determines a local purchase price equal to the following:

(i) For 1989 and 1990, the base local purchase price is adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(ii) For 1991 through 1993, the local purchase price for the preceding year is adjusted by the applicable percentage increase for the year. The applicable percentage increase is equal to 0 percent for 1991. For 1992 and 1993, the applicable percentage increase is equal to the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

(iii) For 1994 and 1995, the applicable percentage increase is 0 percent.

(iv) For all subsequent years the applicable percentage increase is equal to the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

(3) CMS determines the regional purchase price equal to the following:

(i) For 1992, the average (weighted by the relative volume of all claims among carriers) of the local purchase prices for the carriers in the region.

(ii) For 1993 and subsequent years, the regional purchase price for the preceding year adjusted by the applicable percentage increase for the year.

(4) CMS determines a purchase price equal to the following:

(i) For 1989, 1990 and 1991, 100 percent of the local purchase price.

(ii) For 1992, 75 percent of the local purchase price plus 25 percent of the regional purchase price.

(iii) For 1993, 50 percent of the local purchase price plus 50 percent of the regional purchase price.

(iv) For 1994 and subsequent years, 100 percent of the regional purchase price.

(5) For 1992 and subsequent years, CMS determines a national average purchase price equal to the unweighted average of the purchase prices determined under paragraph (b)(4) of this section for all carriers.

(6) CMS determines the fee schedule amount equal to 100 percent of the purchase price determined under paragraph (b)(4) of this section, subject to the following limitations:

(i) For 1992, the amount cannot be greater than 125 percent nor less than 85 percent of the national average purchase price determined under paragraph (b)(5) of this section.

(ii) For 1993 and subsequent years, the amount cannot be greater than 120 percent of the national average nor less than 90 percent of the national average purchase price determined under paragraph (b)(5) of this section.

(c) *Payment for therapeutic shoes.* The payment rules specified in paragraphs (a) and (b) of this section are applicable to custom molded and extra depth shoes, modifications, and inserts (therapeutic shoes) furnished after December 31, 2004.

[57 FR 57691, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995; 73 FR 69937, Nov. 19, 2008]

§ 414.229 Other durable medical equipment—capped rental items.

(a) *General payment rule.* Payment is made for other durable medical equipment that is not subject to the payment provisions set forth in § 414.220 through § 414.228 as follows:

(1) For items furnished prior to January 1, 2006, payment is made on a rental or purchase option basis in accordance with the rules set forth in paragraphs (b) through (e) of this section.

(2) For items other than power-driven wheelchairs furnished on or after January 1, 2006, payment is made in accordance with the rules set forth in paragraph (f) of this section.

(3) For power-driven wheelchairs furnished on or after January 1, 2006 through December 31, 2010, payment is made in accordance with the rules set forth in paragraphs (f) or (h) of this section.

(4) For power-driven wheelchairs that are not classified as complex rehabilitative power-driven wheelchairs, furnished on or after January 1, 2011, payment is made in accordance with the rules set forth in paragraph (f) of this section.

(5) For power-driven wheelchairs classified as complex rehabilitative

power-driven wheelchairs, furnished on or after January 1, 2011, payment is made in accordance with the rules set forth in paragraphs (f) or (h) of this section.

(b) *Fee schedule amounts for rental.* (1) For 1989 and 1990, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section subject to the following limitation: For 1989 and 1990, the fee schedule amount cannot be greater than 115 percent nor less than 85 percent of the prevailing charge, as determined under § 405.504 of this chapter, established for rental of the item in January 1987, as adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(2) For 1991 and subsequent years, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section for each of the first 3 months and 7.5 percent of the purchase price for each of the remaining months.

(3) For power-driven wheelchairs furnished on or after January 1, 2011, the monthly fee schedule amount for rental of equipment equals 15 percent of the purchase price recognized as determined under paragraph (c) of this section for each of the first 3 months and 6 percent of the purchase price for each of the remaining months.

(c) *Determination of purchase price.* The purchase price of other covered durable medical equipment is determined as follows:

(1) For 1989 and 1990. (i) The carrier determines a base local purchase price amount equal to the average of the purchase prices submitted on an assignment-related basis of new items supplied during the 6-month period ending December 1986.

(ii) The purchase price is equal to the base local purchase price adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(2) For 1991. (i) The local payment amount is the purchase price for the preceding year adjusted by the covered item update for 1991 and decreased by

the percentage by which the average of the reasonable charges for claims paid for all other items described in § 414.229, is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988.

(ii) The purchase price for 1991 is the national limited payment amount as determined using the methodology contained in § 414.220(f).

(3) *For years after 1991.* The purchase price is determined using the methodology contained in paragraphs (d) through (f) of § 414.220.

(d) *Purchase option.* Suppliers must offer a purchase option to beneficiaries during the 10th continuous rental month and, for power-driven wheelchairs, the purchase option must also be made available at the time the equipment is initially furnished.

(1) Suppliers must offer beneficiaries the option of purchasing power-driven wheelchairs at the time the supplier first furnishes the item. On or after January 1, 2011, this option is available only for complex rehabilitative power-driven wheelchairs. Payment must be on a lump-sum fee schedule purchase basis if the beneficiary chooses the purchase option. The purchase fee is the amount established in paragraph (c) of this section.

(2) Suppliers must offer beneficiaries the option of converting capped rental items (including power-driven wheelchairs not purchased when initially furnished) to purchased equipment during their 10th continuous rental month. Beneficiaries have one month from the date the supplier makes the offer to accept the purchase option.

(i) If the beneficiary does not accept the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 15 months. After 15 months of rental payments have been paid, the supplier must continue to provide the item without charge, other than a charge for maintenance and servicing fees, until medical necessity ends or Medicare coverage ceases. A period of continuous use is determined under the provisions in § 414.230.

(ii) If the beneficiary accepts the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 13

months. On the first day after 13 continuous rental months during which payment is made, the supplier must transfer title to the equipment to the beneficiary.

(e) *Payment for maintenance and servicing.* (1) The carrier establishes a reasonable fee for maintenance and servicing for each rented item of other durable medical equipment. The fee may not exceed 10 percent of the purchase price recognized as determined under paragraph (c) of this section.

(2) Payment of the fee for maintenance and servicing of other durable medical equipment that is rented is made only for equipment that continues to be used after 15 months of rental payments have been made and is limited to the following:

(i) For the first 6-month period, no payments are to be made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period.

(3) Payment for maintenance and servicing DME purchased in accordance with paragraphs (d)(1) and (d)(2)(ii) of this section, is made on the basis of reasonable and necessary charges.

(f) *Rules for capped rental items furnished beginning on or after January 1, 2006.* (1) For items furnished on or after January 1, 2006, payment is made based on a monthly rental fee schedule amount during the period of medical need, but for no longer than a period of continuous use of 13 months. A period of continuous use is determined under the provisions in §414.230.

(2) The supplier must transfer title to the item to the beneficiary on the first day that begins after the 13th continuous month in which payments are made under paragraph (f)(1) of this section.

(3) Payment for maintenance and servicing of beneficiary-owned equipment is made in accordance with §414.210(e).

(g) *Additional supplier requirements for capped rental items that are furnished beginning on or after January 1, 2007.* (1) The supplier that furnishes an item for the first month during which payment is made using the methodology described in paragraph (f)(1) of this section must continue to furnish the

equipment until medical necessity ends, or the 13-month period of continuous use ends, whichever is earlier, unless—

(i) The item becomes subject to a competitive acquisition program implemented in accordance with section 1847(a) of the Act;

(ii) The beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment;

(iii) The beneficiary elects to obtain the equipment from a different supplier prior to the expiration of the 13-month rental period; or

(iv) CMS or the carrier determines that an exception should apply in an individual case based on the circumstances.

(2) A capped rental item furnished under this section may not be replaced by the supplier prior to the expiration of the 13-month rental period unless:

(i) The supplier replaces an item with the same, or equivalent, make and model of equipment because the item initially furnished was lost, stolen, irreparably damaged, is being repaired, or no longer functions;

(ii) A physician orders different equipment for the beneficiary. If the need for different equipment is based on medical necessity, then the order must indicate why the equipment initially furnished is no longer medically necessary and the supplier must retain this order in the beneficiary's medical record;

(iii) The beneficiary chooses to obtain a newer technology item or upgraded item and signs an advanced beneficiary notice (ABN); or

(iv) CMS or the carrier determines that a change in equipment is warranted.

(3) Before furnishing a capped rental item, the supplier must disclose to the beneficiary its intentions regarding whether it will accept assignment of all monthly rental claims for the duration of the rental period. A supplier's intentions could be expressed in the form of a written agreement between the supplier and the beneficiary.

(4) No later than two months before the date on which the supplier must transfer title to a capped rental item to the beneficiary, the supplier must

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disclose to the beneficiary whether it can maintain and service the item after the beneficiary acquires title to it. CMS or its carriers may make exceptions to this requirement on a case-by-case basis.

(h) *Purchase of power-driven wheelchairs furnished on or after January 1, 2006.* (1) Suppliers must offer beneficiaries the option to purchase power-driven wheelchairs at the time the equipment is initially furnished.

(2) Payment is made on a lump-sum purchase basis if the beneficiary chooses this option.

(3) On or after January 1, 2011, this option is available only for complex rehabilitative power-driven wheelchairs.

[57 FR 57691, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995; 71 FR 65934, Nov. 9, 2006; 75 FR 73622, Nov. 29, 2010]

§ 414.230 Determining a period of continuous use.

(a) *Scope.* This section sets forth the rules that apply in determining a period of continuous use for rental of durable medical equipment.

(b) *Continuous use.* (1) A period of continuous use begins with the first month of medical need and lasts until a beneficiary's medical need for a particular item of durable medical equipment ends.

(2) In the case of a beneficiary receiving oxygen equipment on December 31, 2005, the period of continuous use for the equipment begins on January 1, 2006.

(c) *Temporary interruption.* (1) A period of continuous use allows for temporary interruptions in the use of equipment.

(2) An interruption of not longer than 60 consecutive days plus the days remaining in the rental month in which use ceases is temporary, regardless of the reason for the interruption.

(3) Unless there is a break in medical necessity that lasts longer than 60 consecutive days plus the days remaining in the rental month in which use ceases, medical necessity is presumed to continue.

(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 § 414.226(h) until the end of the reasonable useful lifetime established for such equipment in accordance with § 414.210(h).

[56 FR 50823, Oct. 9, 1991, as amended at 57 FR 57111, Dec. 3, 1992; 71 FR 65935, Nov. 9, 2006; 73 FR 69937, Nov. 19, 2008; 83 FR 57072, Nov. 14, 2018]

§ 414.232 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]

§414.234 Prior authorization for items frequently subject to unnecessary utilization.

(a) *Definitions.* For the purpose of this section, the following definitions apply:

Prior authorization is a process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the item is furnished to the beneficiary and before the claim is submitted for processing.

Provisional affirmation is a preliminary finding that a future claim meets Medicare's coverage, coding, and payment rules.

Required Prior Authorization List is a list of DMEPOS items selected from the Master List and subject to the requirements of prior authorization as a condition of payment.

Unnecessary utilization means the furnishing of items that do not comply with one or more of Medicare's coverage, coding, and payment rules.

(b) *Master List of Items Potentially Subject to Face-To-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements.*(1) Master List Inclusion Criteria are as follows:

(i) Any DMEPOS items included in the DMEPOS Fee Schedule that have an average purchase fee of \$500 (ad-

justed annually for inflation using consumer price index for all urban consumers (CPI-U), and reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period)) or greater, or an average monthly rental fee schedule of \$50 (adjusted annually for inflation using consumer price index for all urban consumers (CPI-U), and reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period)) or greater, or are identified as accounting for at least 1.5 percent of Medicare expenditures for all DMEPOS items over a 12-month period that are:

(A) Identified as having a high rate of potential fraud or unnecessary utilization in an Office of Inspector General (OIG) or Government Accountability Office (GAO) report that is national in scope and published in 2015 or later, or

(B) Listed in the 2018 or later Comprehensive Error Rate Testing (CERT) Medicare Fee-for-Service (FFS) Supplemental Improper Payment Data report as having a high improper payment rate, or

(ii) The annual Master List updates shall include any items with at least 1,000 claims and 1 million dollars in payments during a recent 12-month period that are determined to have aberrant billing patterns and lack explanatory contributing factors (for example, new technology or coverage policies). Items with aberrant billing patterns would be identified as those items with payments during a 12-month timeframe that exceed payments made during the preceding 12-months, by the greater of:

(A) Double the percent change of all DMEPOS claim payments for items that meet the above claim and payment criteria, from the preceding 12-month period, or

(B) Exceeding a 30 percent increase in payment, or

(iii) Any item statutorily requiring a face-to-face encounter, a written order

prior to delivery, or prior authorization.

(2) The Master List is self-updating at a minimum annually, and is published in the FEDERAL REGISTER.

(3) DMEPOS items identified as having a high rate of fraud or unnecessary utilization in any of the following reports that are national in scope and meeting the payment threshold criteria set forth in paragraph (b)(1) of this section are added to the Master List:

(i) OIG reports published after 2020.

(ii) GAO reports published after 2020.

(iii) Listed in the CERT Medicare FFS Supplemental Improper Payment Data report(s) published after 2020 as having a high improper payment rate.

(4) Items are removed from the Master List after 10 years from the date the item was added to the Master List, unless the item was identified in an OIG report, GAO report, or having been identified in the CERT Medicare FFS Supplemental Improper Payment Data report as having a high improper payment rate, within the 5-year period preceding the anticipated date of expiration.

(5) Items that are discontinued or are no longer covered by Medicare are removed from the Master List.

(6) An item is removed from the list if the cost drops below the payment threshold criteria set forth in paragraph (b)(1)(i) of this section.

(7) An item is removed from the Master List and replaced by its equivalent when the Healthcare Common Procedure Coding System (HCPCS) code representing the item has been discontinued and cross-walked to an equivalent item.

(c) *Condition of payment*—(1) *Items requiring prior authorization.* CMS publishes in the FEDERAL REGISTER and posts on the CMS Prior Authorization Web site a list of items, the Required Prior Authorization List, that require prior authorization as a condition of payment.

(i) The Required Prior Authorization List specified in paragraph (c)(1) of this section is selected from the Master List. CMS may consider factors such as geographic location, item utilization or cost, system capabilities, emerging trends, vulnerabilities identified in of-

ficial agency reports, or other analysis and may implement prior authorization nationally or locally.

(ii) CMS may elect to limit the prior authorization requirement to a particular region of the country if claims data analysis shows that unnecessary utilization of the selected item(s) is concentrated in a particular region. CMS may elect to exempt suppliers from prior authorization upon demonstration of compliance with Medicare coverage, coding, and payment rules through such prior authorization process.

(iii) The Required Prior Authorization List is effective no less than 60 days after publication and posting.

(2) *Denial of claims.* (i) CMS or its contractors denies a claim for an item that requires prior authorization if the claim has not received a provisional affirmation.

(ii) Claims receiving a provisional affirmation may be denied based on either of the following:

(A) Technical requirements that can only be evaluated after the claim has been submitted for formal processing.

(B) Information not available at the time of a prior authorization request.

(d) *Submission of prior authorization requests.* A prior authorization request must do the following:

(1) Include all relevant documentation necessary to show that the item meets applicable Medicare coverage, coding, and payment rules, including those outlined in § 410.38 and all of the following:

(i) Written order/prescription.

(ii) Relevant information from the beneficiary's medical record.

(iii) Relevant supplier produced documentation.

(2) Be submitted before the item is furnished to the beneficiary and before the claim is submitted for processing.

(e) *Review of prior authorization requests.* (1) After receipt of a prior authorization request, CMS or its contractor reviews the prior authorization request for compliance with applicable Medicare coverage, coding, and payment rules.

(2) If applicable Medicare coverage, coding, and payment rules are met, CMS or its contractor issues a provisional affirmation to the requester.

(3) If applicable Medicare coverage, coding, and payment rules are not met, CMS or its contractor issues a non-affirmation decision to the requester.

(4) If the requester receives a non-affirmation decision, the requester may resubmit a prior authorization request before the item is furnished to the beneficiary and before the claim is submitted for processing.

(5) A prior authorization request for an expedited review must include documentation that shows that processing a prior authorization request using a standard timeline for review could seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function. If CMS or its contractor agrees that processing a prior authorization request using a standard timeline for review could seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function, then CMS or its contractor expedites the review of the prior authorization request and communicates the decision following the receipt of all applicable Medicare required documentation.

(f) *Suspension of prior authorization requests.* (1) CMS may suspend prior authorization requirements generally or for a particular item or items at any time and without undertaking rule-making.

(2) CMS provides notification of the suspension of the prior authorization requirements via—

- (i) FEDERAL REGISTER notice; and
- (ii) Posting on the CMS prior authorization Web site.

[80 FR 81706, Dec. 30, 2015, as amended at 84 FR 60807, Nov. 8, 2019]

§414.236 Continuity of pricing when HCPCS codes are divided or combined.

(a) *General rule.* If a new HCPCS code is added, CMS or contractors make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

(b) *Mapping fee schedule amounts based on different kinds of coding*

changes. When the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components must not be higher than the fee schedule amount for the original item. When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes. When the codes for the components of a single item are combined in a single global code, the fee schedule amounts for the new code are established by totaling the fee schedule amounts used for the components (that is, use the total of the fee schedule amounts for the components as the fee schedule amount for the global code). When the codes for several different items are combined into a single code, the fee schedule amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes.

[84 FR 60808, Nov. 8, 2019]

§414.238 Establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history.

(a) *General rule.* If a HCPCS code is new and describes items and services that do not have a fee schedule pricing history (classified and paid for previously under a different code), the fee schedule amounts for the new code are established based on the process described in paragraphs (b) or (c) of this section.

(b) *Comparability.* Fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: Physical components; mechanical components; electrical components; function and intended use; and

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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.