

§ 414.230

(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 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.

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(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 (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 an average monthly rental fee schedule of \$50 (adjusted annually for inflation using consumer price index for all urban consumers (CPI-U), and