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 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 official 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 rulemaking.

(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