(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

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, including 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