

Crosswalk Document

The instrument collection and instructions entitled *Healthcare Common Procedure Coding System (HCPCS) - Level II Code Modification Request Process* contain revisions to dates, as well as, editorial revisions to content to provide clarity to the applicants. The dates and deadlines are changed annually to reflect the upcoming coding cycle because the HCPCS process is an ongoing process and the HCPCS code set is updated annually. In addition, the instructions that precede the instrument collection have been revised to remove information that is duplicated in questions that are on the information collection.

Below are revisions that have been made to the questions on the instrument collection.

Question #4 of the instrument collection is revised to require additional information about the durability of the product(s). CMS needs this information in order to identify categories of new durable medical equipment subject to the procedures established in accordance with the mandate of section 531(b) of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA 2000), Public Law 106-554, for obtaining public consultation on preliminary coding and payment determinations for these items. This information is readily available from the manufacturers of these items and other individuals submitting requests for changes to the HCPCS.

Revised Question 4. Is the item durable, if so, explain how it can withstand repeated use. Specify whether the entire item or only certain components of the item can withstand repeated use.

4a.) Is the item durable, if so, explain how it can withstand repeated use?

Specify whether the entire item or only certain components of the item can withstand repeated use:

4b.) If the entire item can withstand repeated use, then please specify the length of the time that the item can withstand repeated use.

4c.) If only certain components of the device can withstand repeated use, then please identify the individual components and the length of the time that the individual components can withstand repeated use.

4d.) Please provide detailed information on the warranty of the device such as the parts included under the warranty, the length of the warranty and the parts excluded from the warranty. In addition, please specify if the device includes any disposable components and the expected life or the replacement frequency recommended for the disposable components.

Revised Question 11.

- 11a.) Provide the date that the item/product was cleared for marketing by the FDA. If the product is exempt from FDA review and classification, please explain the basis for the exemption.
- b.) Attach copy of the FDA approval letter including the 510(k) summary for those items that are approved using the 510(k) process. Also, if an item is cleared using the 510(k) process, identify the HCPCS codes, if applicable, that describe the predicate products listed in the 510(k) submission and explain why these codes do not adequately describe the item that is the subject of the HCPCS recommendation. In other words, if an item is listed as being substantially equivalent to another item(s) in an application for FDA marketing clearance, why is it not equivalent or comparable for coding purposes?
- c.) For drugs and biologicals only: In order for an application for a code for a drug/biological can be considered timely and complete: FDA approval documentation may be submitted after the code application, but no later than March 31, 2012, provided all other application materials are complete and submitted by the deadline of January 3, 2012, and provided the application for marketing approval has been submitted to the FDA by September 30, 2011. Applicants awaiting FDA clearance for drugs or biologicals at the January 3rd submission deadline must submit with the application documentation evidencing submission for FDA approval, along with the date the application was submitted to the FDA.

Question #13 of the instrument collection was also revised to require answers for all applicants, including those who are submitting HCPCS Level II modification requests for drugs and biological. The HCPCS workgroup's decisions are influenced by the setting(s) in which certain drugs or biological products would be administered. HCPCS Level II codes are used to describe items that are used outside the physician's office. This information is considered as part of the decision tree criteria for code determinations. In addition, due to the new interpretation of section 1847A of the Social Security Act, there are new criteria used to code drugs and biologicals and the percentage of use across various settings are necessary to implement such criteria.

Revised Question 13. Identify the percent of use of the item across the following settings. For drugs/biological, provide the percentage of use for the setting(s) in which this product is or would be administered.

Physician's Office: _____

Freestanding Ambulatory Care Clinics: _____

Patient's Home by patient: _____

Patient's Home by Health Care Provider: _____

Nursing Home/Skilled Nursing Facility: _____

Hospital Inpatient Facilities: _____

Hospital Outpatient Facility: _____

Other- (identify): _____

TOTAL VOLUME OF USE ACROSS ALL SETTINGS SHOULD EQUAL 100%