

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C5-09-14
Baltimore, Maryland 21244-1850



Healthcare Common Procedure Coding System (HCPCS) Level II Code Modification Request Process 2019 Update

The Healthcare Common Procedure Coding System (HCPCS) Level II contains alpha-numeric codes used to identify items (and sometimes, services) that are not included in the HCPCS Level I (American Medical Association's CPT) code set.

As a preliminary step in the process for recommending a modification to the HCPCS Level II coding system, it may be helpful for you to contact 3rd party payers for Medicare, Medicaid, and private insurers to determine if, in their determination, existing HCPCS codes identify the item.

You may submit a recommendation to establish, revise, or discontinue a code, using the attached standard format. Please prepare a cover letter outlining your code request and a brief summary of why the code modification is needed. In addition to providing the information according to the format, please include descriptive material, which you think would be helpful in furthering CMS' understanding of the medical benefits of the product for which a coding modification is being recommended.

Please submit *1 original request* signed in ink with supporting documentation, *plus 35 copies* of your entire original recommendation information packet (36 applications in total). Receipt of the copies helps expedite distribution to HCPCS workgroup members. CMS does not accept hand-delivery of applications. The application must be sent in paper form through the mail at the address indicated in these instructions. At this time, CMS is not able to accommodate applications that are submitted electronically. CMS does not have an e-mail authentication process in place for applicants that assures the privacy of sensitive and/or proprietary information within an application submitted as an electronic attachment. In addition, electronic submission does not function as a place holder for late paper submissions.

In order to ensure timely review of your materials, it is necessary to limit your recommendations to no more than 40 pages. **Completed applications must include the application questions unedited and exactly as they are written in the application, as well as your answers to all of the questions.**

Applications exceeding 40 pages will not be accepted, with the following exception: Applicants making a claim of "significant therapeutic distinction" to distinguish a product from its current coding in an existing code category (refer to question 7c on the application) may need to exceed the 40-page limit in order to submit relevant substantiating clinical information. In these cases *only*, the applicant may exceed the 40-page limit *only* for relevant substantiating clinical information. The clinical information must be attached to the original application as well as all 35 copies.

Each side of a page, including brochures, booklets, and any other inclusions, counts as one page in calculating the 40 page limit. The completed, signed, and dated format, including required FDA clearance (approval letter or explanation of exemption), and package insert and any other supporting documentation, such as, but not limited to, product brochures and/or booklets, are all included in the 40-page application limit. All pages of each application must be fastened securely to ensure that it arrives and can be distributed intact. Staples are the preferred method of fastening materials. Please **do not use paper clips or bulky materials** like 3-ring binders to fasten materials, as this may result in difficulties distributing materials to reviewers. Submission of un-fastened, loose pages, separated only by colored sheets of paper, is also not acceptable.

Applicants may submit more than one HCPCS application. To ensure that additional applications are not overlooked, each separate application should be mailed in a separate package. If multiple related applications are being submitted, it would be helpful to specify this in the cover letters of the related applications.

CMS does not require or ask for product samples. However, many applicants ask if they may send product samples, video tapes, or compact discs as a supplement to their application. If it is practical and feasible for an applicant to submit a sample with their application, they may voluntarily do so; however, it becomes the property of CMS to keep or dispose of as the agency sees fit. If the applicant chooses to send samples, video tapes, or compact discs, please send no more than three.

CMS' Review and Reconsideration Process, Public Notice, and Opportunities for Public Input

All timely and complete recommendations are distributed to all reviewers; placed on HCPCS Meeting Agendas and reviewed at regularly scheduled meetings by a panel whose membership includes representatives of all government and non-government insurance sectors, including Medicaid, Medicare, the private insurance sector, and the Department of Veteran's Affairs.

All external recommendations (i.e., requests not generated internally) will be placed on a Public Meeting Agenda together with the preliminary HCPCS coding decision. The HCPCS Public Meetings provide an open forum for interested parties to make oral presentations or to submit written comments in response to published preliminary coding decisions. The announcement of the dates, times, and the location of the public meetings will be published in the Federal Register. In addition, the dates, times, agendas, preliminary coding recommendations, meeting registration information, and guidelines for participation in HCPCS Public Meetings will be posted on CMS' official Level II HCPCS website at www.cms.gov/medhcpcsgeninfo. Although the Public Meetings are not decision-making meetings, they provide an opportunity for applicants and the general public to react to preliminary coding decisions and share additional information with decision makers prior to final decisions. As such, CMS' Public Meeting process provides a reconsideration opportunity.

For applications that are completed and submitted timely, applicants will receive written notification of the final decision on their application by mid-November 2018. All modifications to the HCPCS codes set will be incorporated into the 2019 HCPCS Level II Annual update, which will be published on CMS' official HCPCS Level II website at www.cms.gov/medhcpcsgeninfo by mid-November 2018. A summary of all external applications, including CMS' final decisions and rationale, will also be published on the same website.

Application Deadline

To be considered for inclusion in CMS' 2019 Annual HCPCS update, completed application packets must be received no later than close of business (COB) on Thursday, January 4, 2018. The HCPCS coding review process is an ongoing, continuous process. Only complete and timely requests will be accepted. Requests for the 2018-2019 coding cycle may be submitted at any time following the 2017 application deadline and up to January 4, 2018. Early submissions are strongly encouraged.

Recommendations received or completed after COB on January 4, 2018 will not be processed for the 2018-2019 coding cycle. Applications exceeding the 40-page limit are not acceptable, with a single exception as noted on page 1 of these instructions and in question 7c of this application.

For additional detailed information regarding the HCPCS coding process or the application process, you may: 1) review documents on CMS' website at www.cms.gov/medhpcsgeninfo; 2) submit an inquiry to the HCPCS mailbox at HCPCS@cms.hhs.gov; or 3) contact CMS' HCPCS staff: Nathan Helman at (410) 786-4602, Judi Wallace at (410) 786-319, Kimberlee Combs Miller at (410) 786-6707, or Cynthia Hake at (410) 786-3404.

Instructions

1. Please **sign and date** each recommendation. Be certain to provide the name, complete mailing address, *direct* telephone number, fax number, and e-mail address of the applicant. CMS uses this information to contact applicants regarding upcoming meetings, questions regarding applications, and to make notifications of the status of applications. Please be sure that your system can receive emails from cms.hhs.gov.
2. When the applicant is not the manufacturer, a representative of the manufacturer must *also* sign the application and provide their contact information, as instructed at question 14b and 14c of the application. The manufacturer's attestation and signature must be part of the original application and may not be an addendum page or separately submitted.
3. Foreign applicants (i.e., those residing outside the U.S.) must provide a primary U.S. contact with U.S. contact information.
4. Please provide documentation of the item's current classification by the Food and Drug Administration (FDA). Include unredacted copies of the following documents: the cover page from the initial FDA application, the FDA's determination, the notification/approval letter or updated registration (whichever is appropriate), and the FDA approved package insert. If the drug/biological/product/service has been subject to an assessment by any other agency or recognized medical body, provide a copy of the results of that assessment.

Documentation of FDA market approval of a FDA-regulated drug or biological may be submitted after the coding application but no later than March 31st 2018, provided that all other requested information is complete and submitted by the application deadline.

5. All requested information must be supplied before your recommendation for modifications to the HCPCS coding system can be considered. All application questions in CMS' format must be transferred to your application exactly as they appear in CMS' Coding Recommendation format. All questions must be answered fully. If a question does not appear to apply, provide a detailed explanation as to why it does not apply. **“N/A” responses are considered a non-response**, and will make the application incomplete. Incomplete submittals will not be accepted.
6. Repeat applications must include information within the application that is new and different from the prior application(s) that is intended to overcome a prior decision. In addition, please make it clear in your cover letter that this is a repeat application, and highlight any new/different information in the application.
7. Submit Coding Recommendations to:

Cynthia Hake, Director, CMS' National Level II HCPCS Coding Program
Centers for Medicare and Medicaid Services
C5-09-14
7500 Security Blvd
Baltimore, Maryland 21244-1850



2019 Alpha-Numeric HCPCS Coding Recommendation Format

Summary of Recommendation

- 1.) For the purpose of publication on CMS' request list and public meeting agenda on the HCPCS website, please provide a concise summary of your request (not to exceed **300 words**). Please organize the summary in the following sequence: A) your request to modify the HCPCS code set (e.g., number of new codes requested, including recommended language; or revise a code, including old language and recommended language; or discontinue a code); B) the name and description of the product; C) the function of the product; and D) the reason why existing codes do not adequately describe the product. In addition, for drugs and biologics only, please also include the following: E) indications for use; F) action; G) dosage; H) route of administration; and I) how supplied. Note that text that exceeds the 300 word limit may be truncated and not appear on CMS' published summary. CMS may edit your summary prior to publication.

Product Information

- 2.) Identify the Item (product or drug/biological) for which a Level II HCPCS Code is being requested.
 - A) Trade or Brand Name:
 - B) General Product Name or Generic Drug Name (active ingredient):
 - C) FDA classification:

- 3.) Please check one HCPCS category from the following list, which in your estimation most accurately describes the item identified in question #1:
 - A) Medical/Surgical Supplies
 - B) Dialysis Supplies and Equipment
 - C) Ostomy/Urological Supplies
 - D) Surgical Dressing
 - E) Prosthetic
 - F) Orthotic
 - G) Enteral/Parenteral Nutrition
 - H) Durable Medical Equipment
 - I) Blood/Blood Products
 - J) Drug/Biological
 - K) Radiopharmaceutical
 - L) Vision
 - M) Hearing
 - N) Other (please indicate/provide category) _____

4. A) 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.
 - B) If the entire item can withstand repeated use, then please specify the length of the time that the item can withstand repeated use.
 - C) 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.
 - D) 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.
- 5.) Describe the item fully in general terminology. What is it? What does it do? How is it used? Describe the patient population for whom the product is clinically indicated. Descriptive booklets, brochures, package inserts, as well as copies of published peer-reviewed articles on the item may be included in the information packet submitted for review, but they do not replace the requirement to fully respond to this question and fully describe the item.

Responses for drugs and biologicals must include: A) indications for use, B) action, C) dosage and route of administration, D) package insert, E) how supplied, F) National Drug Code (NDC), if one exists.

- 6.) Describe how the product is primarily and customarily used to serve a medical purpose.

Significant Therapeutic Distinction

7. A) Identify similar items and their manufacturers. If the item is a drug, then list other drugs by trade name that are marketed under the same active ingredient category/generic name.
- B) Identify significant differences between this item and other products listed above. Include differences in item cost; material; product design; how it is used; different mechanism of operation, differences in function/treatment provided to a patient; clinical indication; and clinical outcome.
- C) *Complete question 7C only if you are making a claim of significant therapeutic distinction.* Claims of significant therapeutic distinction when compared to the use of other, similar items that would otherwise share a code, must be described in detail. Articulate the clinical theory behind the claim, including differences in the product or its operation as it compares to currently coded products. Specify how the product results in a significantly improved medical outcome or significantly superior clinical outcome. (Please refer to the HCPCS decision tree for definitions and additional information.)

Provide the best available information related to your claim. Include copies of all articles that result from your systematic analysis of the available literature. Information submitted should be as complete as possible. Unfavorable articles should be provided with any appropriate rebuttal or explanation. It is acceptable to exceed the 40-page limit of this application only if the additional pages contain clinical information that substantiate a claim of significant therapeutic distinction. When this occurs, the original application and all clinical documentation must be included in each of the 36 copies submitted to CMS.

Payment and Billing Information

8. A) List any 3rd party payers that pay for this product
- B) List any codes that are currently being billed to those payers for this product.
- C) Explain why existing code categories are inadequate to describe the product.

Prescription Information

9. A) Is this product prescribed by a health care professional?
- B) If yes, who prescribes the product, and in what setting(s) is it prescribed?

Medical Use

10. A) Is this product useful in the absence of an illness or injury?
- B) Explain why or why not.

FDA Information

11. A) Provide the date that the 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 and provide proof of product establishment registration, such as HCT/P or other registration, as applicable.
- B) Attach a copy of the cover sheet that was submitted to the FDA with the request for clearance. CMS does not accept redacted copies.
- C) Attach a copy of the final unredacted FDA approval letter, including the 510(k) summary for those items that are approved using the 510(k) process. CMS does not accept redacted copies. Also, if an item is cleared using the 510(k) process, identify the predicate product(s) listed in the 510(k) submission as well as the HCPCS codes that describe the predicate product(s). Explain why the existing HCPCS codes for the predicate product(s) do not adequately describe the product that is the subject of this 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?

For drugs and biologicals only: For a HCPCS code application for a drug/biological to be considered timely and complete, FDA approval documentation may be submitted after

the code application, but no later than March 31, 2018, provided that all other application materials are complete and submitted by the deadline of January 4, 2018, *and* provided that the application for marketing approval has been submitted to the FDA by September 30, 2017. Applicants awaiting FDA clearance at the January 4th submission deadline must include documentation evidencing submission for FDA approval, along with the date the application was submitted to the FDA. As soon as the drug or biological receives FDA clearance, a revised and complete application must be submitted to CMS immediately and in no case later March 31, 2018. The revised application (1 signed original, plus 35 copies) must include FDA clearance documentation (as specified above), as well as complete responses to all questions that were pending FDA clearance.

Marketing and Cost

12. A) When was the product marketed in the United States? Note: For drugs and biologicals, the date of first sale is required.
- B) For all products that are not drugs and not biologics, the applicant must submit 3 months of marketing experience following FDA clearance. This marketing experience must reflect sales in the US in the 3 months prior to submitting this coding recommendation. What is the total number of units sold in the U.S. and the total dollar amount in sales, including from Medicare, Medicaid, and private insurance? The information provided must represent actual volume of sales for the product for the period of time indicated. Estimations or projections are not acceptable and will be considered a non-response. Applications for any product that is not yet available on the U.S. market will be considered incomplete and not processed. Note: For drugs and biologicals *only*, information regarding the number of units sold is not required.
- C) What is the Manufacturer's Suggested Retail Price (MSRP) or list price of the item? This question must be answered for all items, **except drugs/biologicals**.

Setting of Use

- 13.) Identify the percent of use of the item across the following settings. For drugs or biologicals, provide the percentage of use for the setting in which the item 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%

Required Signatures and Contact Information

14. A) Please provide complete contact information for the applicant. Foreign applicants must provide a U.S. primary contact with U.S. contact information. CMS uses this information to contact applicants regarding upcoming meetings, questions regarding applications, and to make notifications of the status of applications. Applicants are CMS' primary contacts for any information pertaining to HCPCS code applications.

Applicant's Name:
Name of Corporation/Organization:
Mailing Address (street):
City, State, Zip
Direct dial Telephone Number and extension:
FAX Number:
E-Mail Address:

I attest that the information provided in this HCPCS coding recommendation is accurate and correct to the best of my knowledge.

Signature of Applicant Date: _____

- B) Is the applicant the manufacturer? Check one box below.

YES []

NO []*

- C) *If the applicant is NOT the manufacturer, the manufacturer must provide the requested contact information and sign and date the attestation (below.)

Name of Manufacturer's Representative:
Name of Manufacturing Company:
Mailing Address (street):
City, State, Zip
Telephone Number and extension:
FAX Number:
E-Mail Address:

I declare that the information in this application describing the product that is the subject of this application is true and accurate to the best of my knowledge.

Signature of Manufacturer's Representative Date: _____

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1042**. The time required to complete this information collection is estimated to average 11 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

CMS Disclaimer

Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact Cynthia Hake, Deputy Director of the Division of DMEPOS Policy (DDP) in the Center for Medicare (CM), at (410) 786-3404 or cynthia.hake@cms.hhs.gov.