DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C5-15-12
Baltimore, Maryland 21244-1850

Healthcare Common Procedure Coding System (HCPCS) Level II Code Modification Application Instructions for the 2020 Coding Cycle

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

You may submit an application to establish, revise, or discontinue a code using the attached standard application form. 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 in these instructions, 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 requested.

Please submit *1 original request* signed in ink with supporting documentation, *plus 25 copies* of your entire original application packet (26 applications in total). Receipt of the copies helps expedite distribution to HCPCS workgroup members. In order to ensure timely review of your materials, it is necessary to limit your applications 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.**

An application in which the applicant makes a claim of "significant therapeutic distinction" may exceed the 40-page limit to submit relevant substantiating clinical information that distinguishes a product from other, similar products (refer to question 7c on the application). The clinical information must be attached to the original application as well as all 25 copies. FDA package inserts also are not included in the 40-page limit. In these two cases *only*, the applicant may exceed the 40-page limit.

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 application, including required FDA clearance (approval letter or explanation of exemption), 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 results in difficulties distributing materials to reviewers.

Applicants may submit more than one HCPCS application. To ensure that additional applications are not overlooked, each separate application should be included 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 applications. If it is practical and feasible for an applicant to submit a sample with the application, the applicant may voluntarily do so; however, it becomes the property of CMS to keep or dispose of consistent with agency records management policy. If the applicant chooses to send samples, video tapes, or compact discs, please send no more than three.

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

Please refer to CMS' document titled "HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) LEVEL II CODING PROCEDURES", published on CMS' HCPCS web site at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html for detailed information regarding 2020 implementation of shorter and more frequent HCPCS coding cycles.

All timely and complete applications are distributed to all federal participants in the CMS HCPCS workgroup. All applications for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and other non-drug and non-biological items will be placed on a Public Meeting Agenda together with a preliminary HCPCS coding recommendation. 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 locations of the public meetings will be published in the Federal Register. In addition, the dates, times, agendas, preliminary coding recommendations, meeting registration information, and other pertinent information for participation in HCPCS Public Meetings will be posted on CMS' official HCPCS Level II web site at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html . Although the Public Meetings are not decision-making meetings, they provide an opportunity for applicants and the general public to react to preliminary coding recommendations and share additional information prior to final decisions.

All modifications to the HCPCS codes set will be published on CMS' official HCPCS Level II web site at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html. Beginning in 2020, CMS will no longer mail HCPCS coding decision letters to individual applicants. Rather, a summary of all applications, including CMS' final coding decisions and rationale, will be published on CMS' HCPCS Level II web site at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html.

Application Deadlines:

In order to ensure arrival of completed application packets by the due date, applicants should postmark their mailing no later than 7 calendar days before the application deadline. For applications that are being hand delivered, the applications must be received by 4:00 PM on the application deadline or the applications will not be processed and should be submitted in a

subsequent coding cycle. Applications exceeding the 40-page limit will not be accepted, with the exception noted on page 1 of these instructions regarding question 7c of this application.

Application deadlines for quarterly coding cycles for drugs and biological products:

First quarterly cycle application deadline:	4:00 PM January 6, 2020
Second quarterly cycle application deadline:	4:00 PM April 6, 2020
Third quarterly cycle application deadline:	4:00 PM June 29, 2020
Fourth quarterly cycle application deadline:	4:00 PM September 21, 2020

Application deadlines for bi-annual coding cycles for DMEPOS and other non-drug and non-biological items:

First bi-annual cycle application deadline:	4:00 PM January 6, 2020
Second bi-annual cycle application deadline:	4:00 PM June 29, 2020

For additional detailed information regarding the HCPCS coding process or the application process, you may: 1) review documents on CMS' web site at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html; 2) submit an inquiry to the HCPCS mailbox at HCPCS@cms.hhs.gov; or 3) contact CMS' HCPCS staff:

Kimberlee Combs Miller	(410) 786-6707 or Kimberlee.combs-miller@cms.hhs.gov
Irina Akelaitis	(410) 786-4602 or Irina.akelaitis@cms.hhs.gov
Felicia Kyeremeh	(410) 786-1898 or Felicia.kyeremeh@cms.hhs.gov
Sundus Ashar	(410) 786-0750 or Sundus.ashar1@cms.hhs.gov
William Walker	(410) 786-5023 or William.walker@cms.hhs.gov

Instructions

1. **Sign and date** each original application. 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, ask questions regarding applications, and provide notifications of the status of applications. Please be sure that your system can receive emails from cms.hhs.gov.

2. When an application is submitted on behalf of the manufacturer, the manufacturer must *also* sign the application and provide the manufacturer's contact information, as instructed at question 14b and 14c of the application.

3. It may be necessary for CMS to contact an applicant regarding an application. Foreign applicants (i.e., those residing outside the U.S.) are encouraged to provide a primary U.S. contact with U.S. contact information to ensure effective communication.

4. 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, 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.

Effective for all HCPCS coding cycles beginning on or after January 1, 2020, required documentation of final FDA market approval of FDA-regulated drugs or biological products must be included with the code application and submitted by the application deadline. CMS' delivery on its important goal, and stakeholder requests, to implement quarterly coding cycles for drugs and biological products necessitated procedural changes that balance the need to code more quickly against the amount of time necessary to process applications. Accordingly, CMS has eliminated the 3 month deadline extension for submission of FDA clearance documentation following the application deadline (as previously offered within the annual coding cycle). Under the newly implemented shorter coding cycles, all required FDA documentation is due by the application deadline. We note that, under this new process, the overall timeframe between FDA approval and HCPCS coding will generally be significantly shorter than in the prior annual coding cycle.

5. All requested information must be supplied before your application to modify the HCPCS coding system can be considered complete. All application questions must be transferred to your application exactly as they appear in this application. 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. For 2020 coding cycles, any applicant who is dissatisfied with CMS' final HCPCS coding decision may submit a new request in a subsequent coding cycle. Although new information is not a requirement of a new application, previously unavailable information or additional explanations that support the request may be helpful in informing CMS with regard to why CMS' prior decision should be changed.

7. Submit HCPCS code applications to:

   Cynthia Hake, Director, CMS' National HCPCS Level II Coding Program, and Deputy Director, CMS/CM/CCPG/DDP
   Centers for Medicare & Medicaid Services
   Mailstop: C5-09-14
   7500 Security Blvd
   Baltimore, Maryland 21244-1850

DEPARTMENT OF HEALTH & HUMAN SERVICES
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Healthcare Common Procedure Coding System (HCPCS)
Level II Code Modification Application

Attachment to Healthcare Common Procedure Coding System (HCPCS)
Level II Code Modification Application Instructions

1. For the purpose of publication on CMS' request list and public meeting agenda on the HCPCS web site, please provide a concise summary of your request (not to exceed **300 words**). CMS may edit your summary prior to publication, even if the summary does not 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 revisions to an existing code, including old language and recommended language; or discontinuation of 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 packaged. Note that text that exceeds the 300 word limit may be truncated and not appear on CMS' published summary.

Product Information

2. Identify the item (product or drug/biological) for which a HCPCS Level II 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. 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.

5. Describe how the product is primarily and customarily used to serve a medical purpose.

6. 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, 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, please identify the individual components and the length of the time that the individual components can withstand repeated use.

   D) 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.

<u>Significant Therapeutic Distinction</u>

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; mechanism of operation, 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, must be described in detail. Articulate the clinical theory behind the claim, including differences in the product or its operation as it compares to other similar 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 also 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 the original and each of 25 copies submitted to CMS.

Billing Information

8. A) List any third 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. If a third party payer has an existing policy with regard to reporting this product on claims submitted to them, please include that policy.

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? Please specify what the FDA label requires with regard to prescriber and setting.

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, and final FDA approved package insert. 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 application. 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?

Marketing

12.A) Is the product currently marketed and available for use and purchase in United States?
B) Date the product was first marketed in the United States. Note: for drugs and biologicals, the date of first sale is also required.

Setting of Use

13. Identify the percent of use of the item across the following settings. For drugs or biologicals, provide the percent 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 are encouraged to provide a U.S. primary contact with U.S. contact information to ensure effective communication. CMS uses this information to contact applicants regarding upcoming meetings, ask questions regarding applications, and provide notifications of the status of applications. Applicants are CMS' primary contacts for any information pertaining to HCPCS code applications.

Applicant's Name and Title:
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 application is accurate and correct to the best of my knowledge.

_____Date:_____
Signature of Applicant

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

YES [ ]

NO [ ]*

C) *If the applicant is submitting this application on behalf of a manufacturer, the manufacturer must provide the requested contact information, sign, and date the attestation (below).

Name and Title of Manufacturer's Representative:
Name of Manufacturing Company:
Mailing Address (street):
City, State, Zip
Direct Dial 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.

_____Date:_____
Signature of Manufacturer's Representative

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.