Healthcare Common Procedure Coding System (HCPCS) Level II Code Modification Application Instructions for the 2021 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 code set. The HCPCS Level I code set includes the Current Procedural Terminology (CPT) code set, which is owned and maintained by the American Medical Association.

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 that you think would be helpful in furthering CMS' understanding of the medical benefits of the product for which a coding modification is being requested.

Until further notice, all applications to CMS' Level II HCPCS coding program must be submitted electronically via our secure mailbox. Paper applications sent to CMS will not be processed. Please electronically submit all HCPCS code requests to our electronic mailbox, using the detailed instructions at Item # 7 under "Instructions" (below). 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 included. FDA package inserts also are not counted against 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.

Applicants may submit more than one HCPCS application. Each separate application should be submitted in a separate email. If multiple related applications are being submitted, it would be helpful to specify this in the cover letters of the related applications.

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Until further notice, due to limited access to the CMS building under current COVID-19 Public Health Emergency, CMS does not have a means to accept product samples.

<u>CMS' Review Process, Public Notice, and Opportunities for Public Input:</u>

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 shared with 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 CMS' 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 discontinued the practice of mailing 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.

<u>Application Deadlines:</u>

<u>Application Deadlines for Quarterly Coding Cycles for Drugs and Biological Products:</u>

First quarterly cycle application deadline: 11:59 PM January 4, 2021
Second quarterly cycle application deadline: 11:59 PM April 1, 2021
Third quarterly cycle application deadline: To Be Announced
Fourth quarterly cycle application deadline: To Be Announced

<u>Application Deadlines for Bi-Annual Coding Cycles for DMEPOS and other Non-Drug and Non-Biological Items:</u>

First bi-annual cycle application deadline: 11:59 PM January 4, 2021

Second bi-annual cycle application deadline: To Be Announced

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.

<u>Instructions</u>

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.

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, 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 2021 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. Until further notice, all applications to CMS' Level II HCPCS coding program must be submitted electronically via our secure mailbox. Paper applications sent to CMS will not be processed. Please electronically submit all HCPCS code requests to our new mailbox, using the following instructions:

    *   Create a PDF document, both Word and Libre Office will save documents as PDF files
    *   The files must be zipped with a passphrase with AES 256 encryption if they contain any proprietary or personally identifiable information
    *   In PKZip, set the security options to AES 256 passphrase. 7Zip can also be used to encrypt the zip files using AES 256 passphrase
    *   Enter the passphrase in the dialogue box to encrypt the files
    *   Attachments must be less than 100M. Split size will create multi part zip files which can be sent in separate messages
    *   Send the passphrase in a separate email from the zip files to the email address below
    *   The applications should be emailed to : HCPCS_Level_II_code_applications@cms.hhs.gov
    *   The e-mail box (above) may also be used to notify CMS staff of problems with electronic application submissions. Staff will be available to respond during normal business hours
    *   CMS staff will e-mail confirmation of applications received.

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.

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; 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. 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.

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.

    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 US?
   B)   Date the product was first marketed in the US. Note: for drugs and biologicals, the date of first sale is also required. Non-drug items that are not regulated by the FDA are required to be marketed in the US for the application to be considered complete.

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 US primary contact with US 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