HCPCS Application Intake Screenshots

Page 1

CMS.gov

HCPCS Level II Code Modification Application 2021 Update

Summary of Recommendation

1) Summary
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 3000 characters).

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.

Next

CMS.gov

HCPCS Level II Code Modification Application 2021 Update

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

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 peerreviewed 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

Previous

Next

CMS.gov

HCPCS Level II Code Modification Application 2021 Update

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.

Drop files or click here to upload

Previous

Next

CMS.gov

HCPCS Level II Code Modification Application 2021 Update

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

Previous

Next

CMS.gov

HCPCS Level II Code Modification Application 2021 Update

Prescription Information

9) A) Is this product prescribed by a health care professional?

- ○ Yes
- ○ No

Previous Next

CMS.gov

HCPCS Level II Code Modification Application 2021 Update

Medical Use

10) A) Is this product useful in the absence of an illness or injury?

- ○ Yes
- ○ No

B) Explain why or why not

Previous Next

CMS.gov

HCPCS Level II Code Modification Application 2021 Update

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.

Drop files or click here to upload

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).

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, 2019, provided that all other application materials are complete and submitted by the deadline of January 7, 2019, and provided that the application for marketing approval has been submitted to the FDA by September 30, 2018. Applicants awaiting FDA clearance at the January 7th 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 than March 31, 2019. The revised application must include FDA clearance documentation (as specified above), as well as complete responses to all questions that were pending FDA clearance.

Drop files or click here to upload

Previous

Next

CMS.gov

HCPCS Level II Code Modification Application 2021 Update

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.

Previous Next

CMS.gov

HCPCS Level II Code Modification Application 2021 Update

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 Office	0 %
Freestanding Ambulatory Care Clinics	0 %
Patient Home by patient	0 %
Patient Home by Health Care Provider	0 %
Nursing Home/Skilled Nursing Facility	0 %
Hospital Inpatient Facilities	0 %
Hospital Outpatient Facilities	0 %
Other Setting 1 *	0 %
Other Setting 2 *	0 %
Total	0 %

Previous Next

CMS.gov

HCPCS Level II Code Modification Application 2021 Update

Supplemental Documents

Attach additional documents relevant to your application here.

Use this section exclusively for providing supplemental information only. Documents required as part of a response to individual application questions must be attached at the appropriate question or the application will be considered incomplete.

Drop files or click here to upload

Previous

Next

CMS.gov

HCPCS Level II Code Modification Application 2021 Update

Required Signature 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 Name

Name of Corporation/Organization

Mailing Address

Direct-dial Phone and Extension

Fax

Email

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

- ○ Yes
- ○ No

Previous

Next

CMS.gov

HCPCS Level II Code Modification Application 2021 Update

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

× SIGN HERE

clear

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.

Previous Next