HCPCS Level II Application Information and Instructions

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.

1. You may submit an application to establish, revise, or discontinue a code using the following standard application form. In addition to providing all the requested 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 item or service for which a coding modification is being requested. Specific application completion instructions are embedded within the application for clarification.

2. The applicant's response selections determine the relevancy of subsequent questions and as such certain subsequent items will be enabled/disabled (grayed out) based on the applicant's response to previous questions.

3. All fields are required unless marked optional. If a question does not appear to apply, provide a detailed explanation as to why it does not apply. "N/A" by itself, without additional explanation, will be considered a non-response, and will make the application incomplete. Incomplete submittals will not be accepted.

4. The information entered in the application/request will begin to automatically save after selecting the "Next" button for the first time. The applicant will be logged out automatically if idle for more than 15 minutes. The applicant may continue the application where they left off at the prior session.

5. Primary and Secondary contact information along with the Manufacturer's information is required. Only the applicant's attestation/signature is required for the application submission.

6. Any applicant who is dissatisfied with CMS' final HCPCS Level II coding decision may resubmit a new request in a subsequent coding cycle in accordance with the CMS policy. Any resubmitted applications must include information about the prior request as required in the application.

7. New information is helpful but not a requirement for first resubmission with the following exception: when CMS refers an applicant to the AMA or any other agency as a result of a prior application and a request for the same item or service is resubmitted in a subsequent cycle, the applicant is required to provide information that they followed up on CMS' request and report the outcome within the resubmission. For any subsequent resubmissions (after the first resubmission), for the same item or service, previously unavailable information or additional explanation is required, that supports the request and may be helpful in informing CMS with regard to why CMS' prior decision should be changed.

8. Effective for all HCPCS Level II coding cycles beginning on or after January 1, 2020, required documentation of final FDA marketing authorization of FDA-regulated items or services must be included with the code application and submitted by the application deadline.

9. Once an application has been submitted, it cannot be modified or edited. However, applicants can initiate additional information submission or ask questions via the form in the "Contact" section under the Resources for HCPCS Level II. In case CMS requires additional information, CMS staff will reach out to the applicant via the Medicare Electronic Application Request Information System™ (MEARIS™) "Request for Information (RFI)" feature.

10. Applicants have the option to withdraw a submitted application at any point before the deadline.

11. A separate application is required for each coding action requested, even if they are related. Request for series of codes or coding actions, even if related, are considered separate coding actions and therefore, require separate applications.

☐ **I acknowledge that I have read the instructions**

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Applicant Information

Please note *that the MEARIS™ website can only be accessed by individuals who are located in the United States.*

Who is the party requesting the HCPCS Level II code? (e.g. the manufacturer, distributor, healthcare organization/entity)

Name (this is the applicant)

Provide contact information for the applicant.

The contact listed here will be included as a contact for this application.

First name | Middle name (optional) | Last name

Organization | Occupation/Job Title

Email address | Country: United States

US Phone Number | Extension (optional)

Ex. 1234567890

Mailing address line 1

Mailing address line 2 (optional)

City | State | Zip code

Applicant Type: Other

Describe "Other"

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Who is the primary contact?

☐ Same as Applicant Contact

First name | Middle name (optional) | Last name

Organization | Occupation/Job Title

US Phone Number
Ex. 1234567890

Extension (optional)

Email address

Country
United States

Mailing address line 1

Mailing address line 2 (optional)

City | State | Zip code

Relationship
Other

Describe "Other"

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Who is the secondary contact?

☐ Same as Applicant Contact

First name | Middle name (optional) | Last name

Organization | Occupation/Job Title

US Phone Number
Ex. 1234567890

Extension (optional)

Email address

Country
United States

Mailing address line 1

Mailing address line 2 (optional)

City | State | Zip code

Relationship
Other

Describe "Other"

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Provide the manufacturer's details

Is there a manufacturer for the item or service that is the subject of this HCPCS Level II code application?

(•) Yes ( ) No

Manufacturing Company

Representative Occupation/Job Title

First name (optional)

Middle name (optional)

Last name (optional)

Manufacturer's Email address

Country
United States

US Phone Number
Ex. 1234567890

Extension (optional)

Mailing address line 1

Mailing address line 2 (optional)

City

State

Zip code

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Provide the manufacturer's details

Is there a manufacturer for the item or service that is the subject of this HCPCS Level II code application?

- ○ Yes
- ◉ No

Explain why?

Provide response

0 / 3000

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HCPCS Level II Code Request

- (●) Request New Code
- ( ) Revise Existing Code
- ( ) Delete Existing Code

HCPCS Level II Code (optional)

Suggested language for this code (optional)

Provide response

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For the purpose of publication on CMS request list and public meeting agenda on the HCPCS Level II website, please provide a concise summary of your request

* CMS may edit your summary prior to publication

The summary should be arranged in the form of a cohesive paragraph in the mentioned sequence.

Your request to modify the HCPCS Level II code set (e.g. recommended language or revisions to an existing code, including old language and recommended language or discontinuation of a code);
The name and description of the item or service;
The function of the item or service;
The reason why existing codes do not adequately describe the item or service;

The following information is required for drugs and biologicals (should be uniform across the application) and as applicable for non-drug, non-biological Items and Services.

Indications for use;
Action;
Dosage;
Route of administration; and
How packaged.

Provide response

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Applications associated with this request

Is this a repeat application?

(•) Yes ( ) No

Prior Application Number (optional)

Submission Year (optional)

Decision

Why applicant disagrees with the decision?

Provide response

0 / 3000

If an applicant is referred back to CMS by the AMA or any other agency, the applicant is required to submit the referral for CMS to consider the code request re-submission complete.

Attachments related to new information/supporting information (optional)

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Applications associated with this request

Attachments related to new information/supporting information (optional)

Previously Uploaded Files

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Provide the details of the Item or Service for which the code is being requested

CMS may move the request into another category, if deemed appropriate, after evaluation.

Please check one HCPCS Level II category from the following list, which you believe most accurately describes the item or service identified as the subject of this request.

- (●) Drugs or Biologicals
- ( ) Non-drug, Non-biological Item or Service

Select a HCPCS Level II subcategory for Drugs or Biologicals

Other

Describe the category to which this item or service belongs to

Provide response

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Provide additional details of the item or service for which the code is being requested

Response is mandatory for all drugs and biologicals and as applicable for all other items or services. Where not applicable, please type NA and explain your answer.

Identify the item or service (drug/ biological or non-drug, non-biological) for which a HCPCS Level II code is being requested.

Trade or Brand Name

FDA Classification

General Item or Service Name or Generic Drug Name (active ingredient)

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Describe the Item or Service fully in general terminology

Response is mandatory for all drugs and biologicals and as applicable for all other items or services. Where not applicable, please type NA and explain your answer.

What is the item or service?

Provide response

0 / 3000

What does the item or service do and how? (Function and mechanism of action)

Provide response

0 / 3000

How is the item or service used? (Indications for use, dosage, route of administration)

Provide response

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Describe the Item or Service fully in general terminology

Responses must include Mechanism of action, Indications for use, Dosage, Route of administration for all drugs and biologicals and as applicable for all other items or services. Where not applicable, please type NA and explain your answer.

How is the item or service supplied? (How packaged)

Provide response

0 / 3000

Describe the item or service's patient population for whom the item or service is clinically indicated

Provide response

0 / 3000

Does the item have a national drug code?

- (●) Yes
- ( ) No

Please enter the associated drug codes in the next field.

Note: You can enter multiple drug codes by separating them with a comma, or pressing enter after entering the drug code.

National Drug Code

Refer to the National Drug Code Directory for Information regarding NDCs

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How is the item or service primarily and customarily used to serve a medical purpose?

Provide response

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Provide durability information

Where not applicable, please type NA and explain your answer.

In order to help us determine whether the item can be considered Durable Medical Equipment under Medicare Part B, please answer the following questions:

Can the item be rented and used by successive patients?

Provide response

0 / 3000

Does the item have an expected lifetime of at least three years?

Provide response

0 / 3000

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Provide warranty details

Where not applicable, please type NA and explain your answer

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

Provide response

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Marketing Information

Applications for non-drug, non-biological items that are not regulated by the FDA and also not yet available in the U.S. market will be considered incomplete and will not be processed.

Is the item or service currently marketed and available for use and purchase in United States?

(●) Yes ( ) No

Provide the date the item or service was first marketed in the United States

Date

Response mandatory for drugs and biologicals for the request to be considered complete.

Date of first sale in the United States

Date

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Medical Use

Is this item or service useful in the absence of an illness or injury?

(•) Yes ( ) No

Explain why or why not

Provide response

0 / 3000

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Upload descriptive booklets, brochures, package inserts, and other marketing materials pertaining to this product

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Application Help

Upload descriptive booklets, brochures, package inserts, and other marketing materials pertaining to this product

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Identify similar items or services

Are there any items or services similar to this item or service?

(•) Yes ( ) No

Multiple items or services can be added to the list.

Click the button to add a similar item or service

Add item or service

Explain why there are no similar items or services

Provide response

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Enter details of each similar items or services and click to add them to the list

If the item is a drug, then list other drugs, by trade name, that contain the same active ingredient.

Item or Service/Drug Trade Name

Manufacturer

Identify significant differences between this item and your item or service. Include differences in item cost; material; item design; how it is used; mechanism of operation, function/treatment provided to a patient; clinical indication; and clinical outcome.

Answer

0 / 3000

Are you making a claim of significant therapeutic distinction?

(•) Yes ( ) No

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 item or service or its operation as it compares to the other similar items or services. Specify how the item or service results in a significantly improved medical outcome or significantly superior clinical outcome. Provide the best available information related to your claim.

Answer

0 / 3000

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. Applicants are urged to mention/ highlight the section or pages that contain information relevant to their request in the submitted articles or clinical studies to help CMS understand the applicants' claim of Significant Therapeutic Distinction made in the request.

Attach all clinical studies to support the above Significant Therapeutic Distinction (optional):

Add/Edit File(s)

Cancel

Save

Application Help

Enter details of each similar items or services and click to add them to the list

If the item is a drug, then list other drugs, by trade name, that contain the same active ingredient.

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. Applicants are urged to mention/ highlight the section or pages that contain information relevant to their request in the submitted articles or clinical studies to help CMS understand the applicants' claim of Significant Therapeutic Distinction made in the request.

Attach all clinical studies to support the above Significant Therapeutic Distinction (optional):

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Application Help

Provide billing information for this Item or Service

List any third party payers that pay for this item or service

List of third party payers

0 / 3000

List any codes that are currently being billed to those payers for this item or service

List of codes

0 / 3000

Explain why existing code categories are inadequate to describe the item or service. If a third party payer has an existing policy with regard to reporting this item or service on claims submitted to them, please include that policy

Provide response

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Prescription Information

Is this item or service prescribed by a health care professional?

(●) Yes ( ) No

As per the FDA label, who is this item or service prescribed by?

Prescriber details

0 / 3000

As per the FDA label, in what setting(s) is this item or service prescribed?

Provide response

0 / 3000

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Provide FDA Information

Is the item or service exempt from FDA review and classification?

(●) Yes ( ) No

Provide the date that the item or service was cleared for marketing by the FDA

Date

Please explain the basis for the FDA exemption

Basis of FDA exemption

0 / 3000

Please specify the FDA marketing authorization pathway (e.g. 510 k, BLA, Breakthrough, DeNovo, NDA etc)

Provide response

0 / 3000

When cleared by 510(k), applicant needs to identify the predicate product(s).

Please identify the predicate product(s) as well as the HCPCS Level II codes that describe the predicate product(s), as applicable. Explain why the existing HCPCS Level II codes for the predicate product(s) do not adequately describe the product that is the subject of this HCPCS Level II 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? (optional)

Provide response

0 / 3000

Attach applicable files:

1. Provide proof of item or service establishment registration, verification of HCT/P subject to section 361 of the Public Health Service Act (PHS Act) and 21 CFR 1271, if applicable.
2. Attach a copy of the final dated marketing authorization as published by the FDA
3. Attach a copy of the cover sheet that was submitted to the FDA with the request for marketing authorization.
4. Attach a copy of the final FDA approved package insert as published by the FDA.
5. If the item or service has been subject to an assessment by any other agency or recognized medical body, provide a copy of the results of that assessment.

Add/Edit File(s)

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Provide FDA Information

Attach applicable files:

1. Provide proof of item or service establishment registration, verification of HCT/P subject to section 361 of the Public Health Service Act (PHS Act) and 21 CFR 1271, if applicable.
2. Attach a copy of the final dated marketing authorization as published by the FDA
3. Attach a copy of the cover sheet that was submitted to the FDA with the request for marketing authorization.
4. Attach a copy of the final FDA approved package insert as published by the FDA.
5. If the item or service has been subject to an assessment by any other agency or recognized medical body, provide a copy of the results of that assessment.

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Identify setting of use

Provide physical setting type and not ownership or insurer type. Round the percent of use for the setting to the nearest whole number.

Provide the percent of use for the setting in which the item or service is or would be used or 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 Facilities:	%
Other(Identify):	%
TOTAL PERCENTAGE OF USE ACROSS ALL SETTINGS SHOULD EQUAL 100%	%

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