Application Help

Who is the primary contact?

The applicant should be the primary 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

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Application Help

Who is the secondary contact?

A secondary contact is now also required, who will be contacted along with the primary contact, for notifications and/or requesting additional information related to the application.

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

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Application Help

Provide the manufacturer's details

Is the applicant a manufacturer of the item or service that is the subject of this code application?

(●) Yes ( ) No

If not the manufacturer explain why?

Provide response

0 / 3000

Manufacturing Company

Representative Occupation/Job Title

First name

Middle name (optional)

Last name

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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Application Help

HCPCS Code Request

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

HCPCS Code (optional)

Suggested language for this code (optional)

Provide response

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Application Help

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

* 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 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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Application Help

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)

Uploaded Files

No files to list. Use the button below to browse files on your local disk and select to upload.
Supported formats include PDF, word, excel, powerpoint, JPEG, PNG, and plain text files

Drag and drop files to upload or Browse Files

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Application Help

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 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 subcategory for Drugs or Biologicals

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Application Help

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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Application Help

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.

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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Next

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 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

National Drug Code

Refer to the National Drug List for information regarding NDC codes.

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Application Help

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

Provide response

0 / 3000

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Application Help

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?

Please explain

0 / 3000

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

Please explain

0 / 3000

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Application Help

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

0 / 3000

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Application Help

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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Application Help

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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Next

Application Help

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

Uploaded Files

No files to list. Use the button below to browse files on your local disk and select to upload.

Supported formats include PDF, word, excel, powerpoint, JPEG, PNG, and plain text files

Drag and drop files to upload or Browse Files

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Application Help

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

0 / 3000

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Enter details of each similar item or service 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.

Provide response

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 other similar items or services. 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.

Provide response

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)

Drag and drop files to upload or Browse Files

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Cancel

Save

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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Application Help

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 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 codes that describe the predicate product(s), as applicable. Explain why the existing HCPCS codes for the predicate product(s) do not adequately describe the item or service 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?

Provide response

0/3000

Attach applicable files:

1) 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.

Drag and drop files to upload or Browse Files

Supported formats include PDF, word, excel, powerpoint, JPEG, PNG, and plain text files

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Application Help

Identify setting of use

Provide physical setting type and not ownership or insurer type.

Provide the percent of use for the setting in which the item or service is or would be used or administered

Physicians Office:	%
Freestanding Ambulatory Care Clinics:	%
Patients Home by patient:	%
Patients Home by Health Care Provider:	%
Nusing 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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