



Application for Code Verification Review

The application is being submitted:

For a new product, not previously coded by PDAC.

For a product previously submitted for review in which the application was rejected. Provide DCN number from rejected application: _____

For a previously reviewed product that has been modified since initial review. Provide DCN number from previous application (if available): _____

For a product previously reviewed by PDAC in which the 45-day timeframe for submitting a reconsideration has lapsed.

Note: This application will now be considered a new application for this product.

Provide DCN Number from previous application: _____

Section A - Manufacturer Information

Manufacturer Name:		Manufacturer Point of Contact:	
Email Address:		Telephone Number:	
Mailing Address:			
City:	State:	Zip:	
Website Address:			
Country:			

Correspondence will be sent to the Manufacturer's e-mail address unless indicated below:

Please send correspondence to the e-mail address listed below for Designated Representative in the United States.

The following contact information must be completed by the Designated Representative, if different from the Manufacturer information listed above.

U.S. Designated Representative Name:		Company Name:	
Email Address:		Telephone Number:	
Mailing Address:	City:	State:	Zip:
Website Address:	Country: United States		



Section B - Product Information

Provide the requested information below to be entered into the Product Classification List (PCL). If additional space is needed, add a supplementary page indicating the corresponding section and question the information relates to.

Product name:
Model Number (write "NONE" if there is no model number):
Does the product need a PCL Comment for Model Number explanation to clarify size, color, height, etc.? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please provide a comment to be entered into the Product Classification List (PCL). (Example of comment: XX in Model Number indicates size). Comment:
Is a product sample required to be submitted per instructions on PDAC Website? <input type="checkbox"/> Yes <input type="checkbox"/> No
Is a product sample being submitted with this application? <input type="checkbox"/> Yes <input type="checkbox"/> No

Product Description and Details

Is this product pre-market? <input type="checkbox"/> Yes <input type="checkbox"/> No
Is this product for home use? <input type="checkbox"/> Yes <input type="checkbox"/> No
Provide a detailed and complete description of the product. Include all functional information, beneficiary instructions, and any manufacturing information that supports the requested code(s):
List all standard component(s) included in the base product (i.e. power cords, batteries, arm rests, etc.), if applicable:

HCPCS Code(s)

List the HCPCS code(s) requested for the product(s) and a detailed explanation for the code(s) selected. If unsure which HCPCS code(s) to request, write "UNSURE" in HCPCS Code Field. Attach additional pages as necessary.

HCPCS Code	Explanation

If previously coded by other insurers or agencies, provide the code(s) assigned:

Food and Drug Administration (FDA) Information

Most Current Year of Registration:	Establishment Registration Number:	510K Number:
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- FDA Manufacturer Name listed on FDA registration **must** match the manufacturer name listed in Section A
- A copy or screen shot of the manufacturer's current year FDA Establishment Registration and Device Listing from the FDA's website AND the 510K Number (if applicable) **MUST** be submitted with the application.
- Enteral Nutrition does not apply.



Section C - Product Specific Information

Prior to completing Section C and application submission, review all appropriate DME MAC policy related material (DME MAC LCD, coding and policy articles, etc.).

Locate, complete and attach Section C for the product type being submitted. This appendix can be located on the [Applications page](#). Section C **must** be attached or the application will be rejected.

Prosthesis applications are not required to submit a Section C. Attach any additional documentation and/or photographs to support your requested code.

For Power Mobility Devices, attach a completed PDAC Test Report-for Performance Testing for Power Wheelchairs form. This is located on the [Applications page](#). The form is required and the application will be rejected if not attached.

Section D - Authorized Signature

The certification **must** be signed by a person in one of the following offices: owner, general partner, chief executive officer, president, chief financial officer, chief operating officer, executive vice-president, or a similar title that clearly shows that the signer holds a position of status and authority within the organization comparable to those offices. In the case of a signature by someone lacking any of the foregoing, the signature **must** be accompanied by a copy of a resolution of the organization's board of directors, certified by the organization's secretary, that the organization has authorized the signer to execute the certification.

I certify that the foregoing statements are true and correct and to the best of my personal knowledge. I understand that the information being provided will be used by the U.S. Department of Health and Human Services and its contractors to make decisions that may affect claims payments under the Medicare program. I further understand that if the information provided is untrue, I may be subject to sanctions, including civil money penalties and debarment from federal programs. If I become aware that any information in this application is untrue, incorrect, or incomplete; I agree to notify the PDAC of this fact immediately.

I agree, in order to support correct coding of the subject product, that should there be a change in product name, a change in model number, or any substantial change in design, construction or performance, I will submit relevant information and documentation to the PDAC for consideration within thirty (30) day of such change. I also agree that should there be a change in the submitter identification as set forth in Section A, I will submit the correct information to the PDAC within thirty (30) days of such change. I also agree to submit product information to the PDAC upon the PDAC's request to ensure the continued correct coding of the subject product.

Authorized official name: _____

Authorized official title: _____

Signature: _____ Date: _____