Healthcare Common Procedure Coding System (HCPCS) Level II Code Modification Application Preview

The following is an overview of the questions you may be asked in order to complete your HCPCS Level II application in MEARIS™. The application is broken into multiple sections. You must provide your response to the questions under each section, if applicable. You will have the ability to review and edit the information you entered before submitting your HCPCS Level II application in MEARIS™.

Contact Info Section

1. Provide information below for the Primary, Secondary, Consultant, and Manufacturer contact.
    a. First Name, Middle Name (optional), Last Name, Manufacturing Company, Organization, Organization/Job Title, US Phone Number, Extension (optional), Email address, Country, Mailing Address, City, State, zip code.

Request Info Section

1. HCPCS Level II Code Request
    a. Request new code
    b. Revise existing code
    c. Delete existing code
2. Provide a summary of your code request.
3. Applications associated with this request.
    a. Is this application a repeat application? If so, then:
        i. Provide prior application number, submission year, what was the decision made on the previous application.
        ii. You will have the ability to upload attachments related to New information/supporting information (optional).

Item or Service Info Section

1. Provide the details of the Item or Service for which the code is being requested.
2. 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.
    a. Drugs or Biologicals
    b. Non-drug, Non-biological Item or Service
3. Select a HCPCS Level II sub-category for Drugs or Biologicals.
    a. Blood/Blood Products
    b. Drugs
    c. Biologicals
    d. Radiopharmaceutical
    e. Other
        i. If selected "Other", then Describe the category to which this item or service belongs to.
4. Select a HCPCS Level II sub-category for Non-drug, Non-biological Item or Service.
    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. Vision
   j. Other
      i. If selected "Other", then describe the category to which this item or service belongs to.
5. Provide additional details of the item or service for which the code is being requested.
   a. Trade or Brand name
   b. FDA Classification
   c. General Item or Service Name or Generic Name (active ingredient)
6. Describe the Item or Service fully in general terminology.
   a. How is the item or service supplied? (How packaged).
   b. Describe the item or service's patient population for whom the item or service is clinically indicated.
   c. Does the item have a national drug code? If yes, provide the code.
7. How is the item or service primarily and customarily used to serve a medical purpose?
8. Provide durability information.
   a. Can the item be rented and used by successive patients?
   b. Does the item have an expected lifetime of at least three years?
9. Provide warranty details.
   a. 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.
10. Marketing Information
    a. Is the item or service currently marketed and available for use and purchase in United States?
    b. Provide the date the item or service was first marketed in the United States.
    c. Date of first sale in the United States.
11. Medical Use
    a. Is this item or service useful in the absence of an illness or injury?
    b. Explain why or why not.
12. Upload descriptive booklets, brochures, package inserts, and other marketing materials pertaining to this product.

Significant Therapeutic Distinction Section

1. Identify similar items or services.
   a. Add item or service
   b. Enter details of each similar items or services and click to add them to the list.

i. Item or service / drug trade name
ii. Manufacturer
iii. 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.
iv. Are you making a claim of significant therapeutic distinction?
v. Provide the best available information related to your claim.
vi. Attach all clinical studies to support the above Significant Therapeutic Distinction (optional).

Billing Section

1. List any third-party payers that pay for this item or service.
2. List any codes that are currently being billed to those payers for this item or service.
3. 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.

FDA Info Section

1. Prescription Information
    a. Is this item or service prescribed by a health care professional?
    b. As per the FDA label, who is this item or service prescribed by?
    c. As per the FDA label, in what setting(s) is this item or service prescribed?
2. Provide FDA Information.
    a. Is the item or service exempt from FDA review and classification?
    b. Provide the date that the item or service was cleared for marketing by the FDA.
    c. Please explain the basis for the FDA exemption.
    d. Please specify the FDA marketing authorization pathway (e.g., 510(k), BLA, Breakthrough, DeNovo, NDA etc.).
    e. 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).
    f. Attach applicable files:
        i. 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.
        ii. Attach a copy of the final dated marketing authorization as published by the FDA.
        iii. Attach a copy of the cover sheet that was submitted to the FDA with the request for marketing authorization.

iv. Attach a copy of the final FDA approved package insert as published by the FDA.
v. 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.

Setting of Use Section

1. Identify Setting of Use.
    a. Provide the percent of use for the setting in which the item or service is or would be used or administered. Total percentage of use across all settings should equal 100%.
        i. Physician's Office
        ii. Freestanding Ambulatory Care Clinics
        iii. Patient's Home by patient
        iv. Patient's Home by Health Care Provider
        v. Nursing Home/Skilled Nursing Facility
        vi. Hospital Inpatient Facilities
        vii. Hospital Outpatient Facilities
        viii. Other (Identify)

Summary Section

1. This displays a summary of all the information that was asked and answered.
2. You will have the ability to review and edit any section of information that you entered.
3. There will be an Attestation section at the bottom of the Summary Section that you will need to check off.
    a. I attest that the information provided in this HCPCS Level II code application and any other supporting information/documentation is true and accurate to the best of my knowledge.
4. You will be able to submit your application and will receive a confirmation page as well as a confirmation email that your application has been received by CMS.
5. Your primary and secondary contacts will be added to the Team and will receive an email letting them know that they have been identified as a primary or secondary contact.
6. The primary and secondary contact will have the ability to access the MEARIS™ system and the application(s) that are associated with the Team that you created.