

HCPCS LEVEL II CODE MODIFICATION REQUEST PROCESS

RE: The 2007 HCPCS Update

The Healthcare Common Procedure Coding System (HCPCS) Level II contains alphanumeric codes used to identify items (and sometimes, services) that are not included in the HCPCS Level I (American Medical Association's CPT) code set.

As a preliminary step in the process for recommending a modification to the alpha-numeric coding system, for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), contact the Statistical Analysis Durable Medical Equipment Regional Contractor (SADMERC) HCPCS Helpline at 877-735-1326. Under contract to CMS, the SADMERC provides assistance in determining if a current National HCPCS Code exists which describes the product category. For Medicare, contact the local Medicare 3rd Party Payer. For private sector health insurance systems, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed.

You may submit a recommendation for review and consideration for the establishment of a code, change to a code, or the discontinuation of a code, according to the enclosed, standard format. Please prepare a cover letter outlining your code request and a brief summary of why the code modification is needed. In addition to providing the information according to the format, please include descriptive material, which you think would be helpful in furthering our understanding of the medical benefits of the item for which a coding modification is being recommended. Submit the original request with supporting documentation and, to expedite distribution and review, please also include 35 complete copies of your recommendation information packet. At this time, we are not able to accommodate electronic requests, and all request must be submitted on paper.

In order to ensure timely review of your materials, it is necessary to limit your recommendations to no more than 40 pages. Applications exceeding 40 page will not be accepted and must be trimmed to no more than 40 pages and resubmitted by the applicant by the application deadline. The completed, signed and dated format, FDA (approval letter or explanation of exemption), supporting documentation, product brochures and/or booklets should be bundled securely to ensure that all the information submitted is distributed intact to all reviewers. Please note that FDA approval for drug coding applications may be submitted after the initial application but no later than March 31st. Each side of a page, including brochures, booklets and any other inclusions, counts a page in calculating the 40 page limit. Please **do not use** bulky materials, such as 3-ring binders, to fasten recommendation materials, as this may result in difficulties distributing materials to reviewers. To ensure that applications are not overlooked separate applications should be submitted in different packages.

We do not require or ask for samples. However, many applicants ask if they can send product samples, video tapes or compact discs. If it is practical and feasible for an applicant to submit a sample with their application, they may voluntarily do so, however, it becomes

the property of CMS to keep or dispose of as the agency sees fit. If the applicant chooses to send samples, video tapes, or compact discs, please send no more than 3.

When the recommendation is received, it is distributed to all reviewers. The items are placed on HCPCS Meeting Agendas and reviewed at regularly scheduled meetings by a panel whose membership includes representatives of Medicaid, Medicare, and Private Insurers.

All external requests, (e.g. requests not generated internally) will be placed on a Public Meeting Agenda. The HCPCS Public Meetings provide an open forum for interested parties to make oral presentations or to submit written comments in response to published preliminary coding decisions. A Federal Register notice will be published to announce dates, times and the location of the public meetings. We will also have posted at this website www.cms.hhs.gov/medicare/hcpcs dates, times, agendas, preliminary coding recommendations, registration information and guidelines for participation in HCPCS Public Meetings. Although the Public Meetings are not decision-making meetings, they provide an opportunity for applicants and the general public to react to preliminary coding decisions and share additional information with decision makers, prior to final decisions.

All applicants will be notified, in writing, of the final decision on their application by mid-November 2006, and all modifications to the HCPCS codes set will be incorporated into the 2007 HCPCS Level II Annual update. The Update will be published on the official HCPCS worldwide [website@www.cms.hhs.gov/medicare/hcpcs/default.asp](http://www.cms.hhs.gov/medicare/hcpcs/default.asp) by mid November, 2006.

To be considered for inclusion in the year 2007 HCPCS update, completed recommendation packets must be received no later than COB Tuesday, January 3, 2006. The HCPCS coding review process is an ongoing, continuous process. Requests may be submitted at anytime throughout the year 2005, and up to January 3, 2006. Early submissions are strongly encouraged. Requests that are complete are reviewed and processed on a first come, first served basis. At CMS' discretion, incomplete recommendations may be returned or held until required information, as notified, is provided and the request complete. The then complete code request/recommendation will be entered into the review cycle.

Recommendations received or completed on or after January 4, 2006 and those requiring additional review will be considered for inclusion in a later HCPCS update. Applications exceeding the 40-page limit are not acceptable.

If you have questions regarding the process, 1) review documents on website at www.cms.hhs.gov/medicare/hcpcs, 2) submit an inquiry to HCPCS@cms.hhs.gov please contact Trish Brooks, at (410) 786-4561; Felicia Eggleston, at (410) 786-9287 or phone HCPCS staff: Jennifer Carver at (410) 786-6610 or Gloria Knight at (410) 784-4598.

Healthcare Common Procedure Coding System (HCPCS)

Alpha-Numeric Coding Recommendation Format for the 2007 Update

Instructions:

1. Please **sign and date** each recommendation. Be certain to provide the name, complete address and direct telephone number of the person to be contacted regarding this recommendation. We use this information to contact applicants regarding upcoming meetings, questions regarding applications, and to make notifications of the status of applications.

2. Please provide documentation of the item's current classification by the Food and Drug Administration (FDA). Include a copy of the cover page from the initial FDA application and **a copy of the FDA's determination, notification/approval letter**. If the item identified in this recommendation is a drug, identify the drug category (active ingredient)/generic name of the drug. If the item identified in this recommendation is health care device or product, identify the device/product(s) that have been determined to be substantially equivalent by FDA. (If this item is not classified by the FDA, please explain the basis for exemption.) If the drug/product/service has been subject to and assessment by any other agency or recognized medical body, provide a copy of the results of that assessment.

Note: Documentation of FDA approval of a drug may be submitted after the coding application but no later than March 31st as long as all other requested information is complete and submitted by the deadline.

3. Please note: **All requested information must be supplied before your recommendation for modifications to the HCPCS coding system can be considered.** The following questions may be transferred to a word processor/computer to allow space to respond fully and completely. All questions must be answered. "N/A" is not an acceptable response. If the question does not appear to apply, provide a detailed explanation as to why it doesn't apply. Incomplete submittals will not be accepted.

4. Submit Coding Recommendations to:

Felicia Eggleston, CMS HCPCS Workgroup Coordinator
Centers for Medicare and Medicaid Services
C5-08-27
7500 Security Blvd
Baltimore, Maryland 21244-1850

Alpha-Numeric HCPCS Coding Recommendation Format

INFORMATION SUPPORTING CODING MODIFICATION RECOMMENDATION

1. For the purpose of publication on our request list and public meeting agenda on the HCPCS website, please provide a brief summary (not to exceed **300 words**) of your request. In this summary, please specify your request to modify the HCPCS code set: (e.g. number of new codes requested, recommended language; revise a code (provide old language and recommended language), discontinue a code). The name of the product, description, function, and the reason why existing codes do not adequately describe your product. For drugs, include the indications for use, action, dosage and route of administration, and how supplied. Text that exceeds the 300-word limit may be truncated and not appear on our published summary, therefore, it is important to provide a concise summary within the 300-word limit.

2. Identify the Item (product or drug) 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 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/Biologic

K) Radiopharmaceutical

L) Vision

M) Hearing

N) Other (please indicate/provide category) _____

4. Is the item durable, i.e., can it withstand repeated use?

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 peer-reviewed 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.

For drugs, include: A) indications for use, B) action, C) dosage and route of administration, D) package insert and, E) how supplied. FDA approval documentation for drugs may be submitted up to March 31st of the current coding cycle, as long as all other application materials are complete and submitted by the deadline.

6. Describe how the item/product is primarily and customarily used to serve a medical Purpose.

7. Identify similar products and their manufacturers.

(If a drug - list other drugs by trade name marketed under the same active ingredient category/generic name.)

8. Answer each of the questions A), B), and C) below:

A) List any insurers that pay for this product and any codes that are currently being billed to those insurers for this product.

B) Explain why existing code categories are inadequate to describe the item.

C) Identify significant differences between this item and other products listed in question 7. (Include differences in item cost; material; product design; how it is used; differences in function/treatment provided to a patient; clinical indication; and clinical outcome. Include peer-reviewed clinical evidence that substantiates your comments.)

9. Is this product prescribed by a health care professional? If yes - who prescribes the product and in what setting(s) is the product prescribed?

10. Is the item useful in the absence of an illness or injury? Explain:

11. Provide the date that the item/product was approved for marketing by the FDA.

Attach copy of the FDA approval letter. If the product is exempt from FDA review and classification, please explain the basis for the exemption. Note: Documentation of FDA approval for drugs may be submitted after the coding application but no later than March 31st, 2006.

12. When was the item/product marketed in the United States?

(**Note** Marketing data is not required for drugs. For all non-drug items, the applicant must submit 3 months of marketing experience following the FDA approval date.) 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 (Medicare, Medicaid and private business)? Do not estimate or provide projections - the information provided must represent actual volume of sales for the product for the period of time indicated.

13. Identify the percent of use of the item across the following settings. This question must be answered for all items, including drugs. In the case of drugs that have not yet been marketed, provide information regarding anticipated use.

- 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 Facility: _____
- Other- (identify): _____

TOTAL VOLUME OF USE ACROSS ALL SETTINGS SHOULD EQUAL 100%

14. What is the Manufacturer's Suggested Retail Price (MSRP) or list price of the item? This question must be answered for all items, including drugs. In the case of drugs that have not yet been marketed, provide information regarding planned MSRP upon expected near term FDA approval.

HCPCS Coding Recommendation submitted by:

- 2. * Please provide a **complete** mailing address and direct dial phone number. We use this information to contact applicants regarding upcoming meetings, questions regarding applications, and to make notifications of the status of applications.

- Name:
- Name of Corporation/Organization:
- Mailing Address:
- Street:
- City, State, Zip
- Telephone Number (ext.):
- FAX Number:
- E-Mail Address:

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

Signature

Date:_____

If the applicant is not the manufacturer, the applicant must include with the application a signed document from the manufacturer certifying that the manufacturer supports the application and that the information describing the product is accurate.

10/2005 FYE