HCPCS LEVEL II CODE MODIFICATION REQUEST PROCESS
RE: The 2006 HCPCS Update

The Healthcare Common Procedure Coding System (HCPCS) Level II contains alpha-numeric codes used to identify those coding categories not included in the American Medical Association's CPT codes.

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), is to 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.

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.

In order to ensure timely review of your materials, it is necessary to limit your recommendations to no more than 40 pages. The completed, signed and dated format, FDA (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, should be calculated into 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 be sure that we do not overlook any applications, it would be helpful if you submit different applications 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. At this time, we are not able to accommodate electronic requests, and all request must be submitted on paper. 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 the HCPCS Agenda for review and National Coding decisions. The items are placed on

an agenda and reviewed at regularly scheduled meetings by a panel whose membership includes representatives of Medicaid, Medicare, and Private Insurers.

All external requests will be placed on a Public Meeting Agenda. These meetings provide an open forum for interested parties to make oral presentations or to submit written comments in response to 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/default.asp 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 2005, and all modifications to the HCPCS codes set will be incorporated into the 2006 HCPCS Level II Annual update. The Update will be published on the official HCPCS worldwide website@www.cms.hhs.gov/medicare/hcpcs/default.asp by mid November, 2005.

To be considered for inclusion in the year 2006 HCPCS update, completed recommendation packets must be received no later than COB Monday, January 3, 2005. The HCPCS coding review process is an ongoing, continuous process. Requests may be submitted at anytime throughout the year. Early submissions are strongly encouraged. Requests that are complete are reviewed and processed on a first come, first served basis. 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 on or after January 4, 2005 and those requiring additional review will be considered for inclusion in a later HCPCS update.**

If you have questions regarding the process, please contact Cindy Hake, HCPCS Chairperson at (410) 786-3404; Trish Brooks, at (410) 786-4561; Felicia Eggleston, at HCPCS@cms.hhs.gov or telephone (410) 786-9287, or Jennifer Carver at (410) 786-6610.

Healthcare Common Procedure Coding System (HCPCS)

Alpha-Numeric Coding Recommendation Format for the 2006 Update

Instructions:

1. Please **sign and date** each recommendation. Be certain to provide the name, address and telephone number of the person to be contacted regarding this recommendation.

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.

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 be returned for clarification. This will delay the review process.

4. Submit Coding Recommendations to:

Felicia Eggleston, 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. 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:

2. Please circle the HCPCS category from the following list, which most accurately describes the category for the item identified in question #1:
Medical/Surgical Supplies Dialysis Supplies and Equipment
Ostomy/Urological Supplies Surgical Dressing Prosthetic Orthotic
Enteral/Parenteral Nutrition Durable Medical Equipment Blood/Blood Products
Drug Biologic Radiopharmaceutical Vision Hearing
Other (please indicate/provide category)_____

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

4. 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.
Drug products must include, A) indications for use, B) action, C) dosage and route of administration, D) package insert and, E) how supplied.

5. Describe how the item/product is primarily and customarily used to serve a medical purpose?

6. Identify similar products and their manufacturers.
(If a drug - list other drugs by trade name marketed under the same active ingredient category/generic name.)

7. a) List any insurers that pay for this product and any codes that are currently being billed 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 6. (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.)

8. Have you previously requested a national coverage determination through CMS for this product or service? If yes, provide the date of your application, and the decision, if rendered.

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 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.

12. When was the item/product brought to market in the United States? (**Note** all non-drug items must have 3 months of marketing experience prior to submitting a request for coding consideration.) Prior to submitting the request for coding consideration, what is the total number of units sold in the U.S. and the total dollar amount in sales (Medicare, Medicaid and private business)? State agency applicants report the total number of units purchased by Medicaid and the total dollar amount paid. Do not estimate or provide projections - the information provided must represent actual volume of sales for the product for the period of time indicated. For drugs, the requirement to submit marketing data is waived.

13. Of the volume identified in #12, what is the percent of use in the following settings:
Physician's Office: _____
Freestanding Ambulatory Care Clinics: _____
Patient's Home by patient: _____
Patient's Home by Health Care Provider: _____
Nursing Home/Skilled Nursing Facility: _____ (total)
    Medicare Part A _____
    Medicare Part B _____
Hospital Inpatient Facilities: _____
Hospital Outpatient Facility: _____
Other- (identify): _____
TOTAL VOLUME OF USE SHOULD EQUAL 100%

14. What is the Manufacturer's Suggested Retail Price (MSRP) of the item?

HCPCS Coding Recommendation submitted by:

Name:
Name of Corporation/Organization:
Complete Mailing Address:
Telephone Number:
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.

_____Date:_____

Signature

*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.