HCPCS ALPHA-NUMERIC EDITORIAL PANEL
Business Address: Cooperating Parties:

CMS/CMM Centers for Medicare and Medicaid Services
7500 Security Boulevard C5-08-27 Blue Cross/Blue Shield Association
Baltimore, MD 21244-1850 Health Insurance Association of America

HCPCS CODE MODIFICATION PROCESS
RE: The 2005 HCPCS Update

The Healthcare Common Procedure Coding System (HCPCS) contains alpha-numeric codes used to identify those coding categories not included in the American Medical Association's CPT-4 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. They will assist in determining if a current National HCPCS Code exists which describes the product category.

You may submit a recommendation for review and consideration for establishment of a code, change to a code or the discontinuation of a code according to the enclosed format. Please prepare a cover letter outlining your code request and a brief summary of why the code modification is needed. When submitting the recommendation, identify one code or group of similar code requests (i.e., group requests in the same packet if the same documentation would be submitted for each recommendation) per submission packet. In addition to providing the information according to the format, please include descriptive material, which you think would be helpful in furthering the National Panel's understanding of the medical benefits of the item for which a coding modification is being recommended. Please submit the original request with supporting documentation and, to expedite review, include the original and 35 complete copies of your recommendation information packet for distribution and review. We also request that these information packets be limited to no more than 40 pages each, and please **do not** submit requests in 3 ring binders. The completed, signed and dated recommendation 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.

When the recommendation is received, it is distributed to the HCPCS National Panel and the Centers for Medicare and Medicaid Services (CMS) HCPCS Workgroup. The items are placed on the National Panel Agenda for review and National Coding decisions. At CMS the items are placed on an agenda and reviewed at a regularly scheduled meeting of the CMS HCPCS Workgroup. The Workgroup, comprised of representatives of the major components of CMS, meets monthly to determine CMS's recommendations to the National Panel pertaining to HCPCS coding issues.

CMS recommendations are referred to the Alpha-Numeric Editorial Panel, an interagency committee established for the purpose of making decisions pertaining to additions, deletions and changes to the Alpha-Numeric HCPCS. This Panel, which meets three times a year, is comprised of representatives of the Blue Cross/Blue Shield Association, the Health Insurance Association of America and the Centers for Medicare and Medicaid Services. Decisions of the Panel must be unanimous in order for a change to be made. Final decisions for the year 2005 modifications will be released in October 2004.

To be considered for inclusion in the year 2005 HCPCS update, completed recommendation packets must be received no later than COB Thursday, April 1, 2004. The HCPCS coding review process is an ongoing continuous process. The review cycle runs from April 2nd through the following April 1st. 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 as incomplete 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 April 2, 2004 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, National Panel Coordinator at (410) 786-4561; or Felicia Eggleston, HCPCS Workgroup Coordinator, via E-Mail HCPCS@cms.hhs.gov or telephone (410) 786-9287.

Healthcare Common Procedure Coding System (HCPCS)

Alpha-Numeric Coding Recommendation Format for the 2005 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 a 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 an assessment by any other agency or recognized medical body, provide a copy of the results of that assessment.

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 then explain in detail 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 for 2005 Update

INFORMATION SUPPORTING CODING MODIFICATION RECOMMENDATION

1. Identify the Item (product or drug) for which a Level II HCPCS Code is being requested by:

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. Describe the item fully in general terminology. (What is it? What does it do? How is it used? etc.)(Descriptive booklets, brochures, package inserts, as well as copies of published peer-review 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.

4. 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.

5. When was the item/product brought to market?

(**Note** all products must have 6 months of marketing experience prior to submitting a request for coding consideration and following FDA approval for marketing.)

6. Is the item/product primarily and customarily used to serve a medical purpose?

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

8. Is this product prescribed by a health care professional? If Yes - Who prescribes the product and in what setting is the product prescribed?

9. Where do beneficiaries obtain the product? (Pharmacy, equipment supplier, MD…)

10. Is the item durable, i.e., can it withstand repeated use?
11. How is the product currently being billed to insurance companies?

12. List any codes used by any third party payer to process claims for the item.

13. Why are the current code categories inadequate to describe the item? Explain fully.

14. How are you currently marketing this product or service? (Describe market distribution, i.e., nationally, east coast only, etc.)

15. Does Medicare currently pay for this item?

16. What is the total volume in sales and/or rental for the six months of marketing experience (United States only) prior to submitting the request for coding consideration? (Medicare, Medicaid and private business) (Do not estimate or provide projections - the information provided must represent actual volume of sales for the drug/product for the specific period of time indicated.)

17. Of the volume identified in #16, 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: _____
Hospital Inpatient Facilities: _____
Hospital Outpatient Facility: _____
Other- (identify):
TOTAL ANNUAL VOLUME OF USE: 100%

18. What is the wholesale cost of the item?

19. What is the retail cost of the item?

20. List any other manufacturers or suppliers of similar items.
(If a drug - list other drugs by trade name marketed under the same active ingredient category/generic name.)

21. Identify the difference between this item and that of competitors. (Include item cost, material or difference, and clinical studies specific to 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 manufacturer of the item identified in this recommendation is not identified above, please also provide the Name, Address and telephone number of the manufacturer.

9/09/03FYE