HCPCS LEVEL II CODE MODIFICATION REQUEST PROCESS
RE: The 2012 HCPCS Update

The Healthcare Common Procedure Coding System (HCPCS) Level II contains alpha-numeric 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 HCPCS Level II coding system, it may be helpful for you to contact 3rd party payers for Medicare, Medicaid and private insurers to determine if, in their determination, existing HCPCS codes identify the item.

You may submit a recommendation to establish, revise or discontinue a code, using the attached, 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 originals requests and copies 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. **PLEASE INCLUDE BOTH QUESTIONS AND ANSWERS ON YOUR APPLICATION** Applications exceeding 40 pages will not be accepted and must be trimmed to no more than 40 pages and resubmitted by the applicant by the application deadline. Applicants making a claim of significant therapeutic distinction to distinguish a product from an existing code category may find a need to exceed the 40-page limit in order to submit relevant substantiating clinical information. In these cases only, the applicant may provide one reference copy of each article in addition to 35 copies of the application. Each side of a page, including brochures, booklets and any other inclusions, counts as page in calculating the 40 page limit. 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. 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 as a supplement to their application. 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) that are completed by the applicable deadline 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 post on CMS' official HCPCS website at www.cms.hhs.gov/medicare/hcpcs the 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 2011, and all modifications to the HCPCS codes set will be incorporated into the 2012 HCPCS Level II Annual update. The Update will be published on the official HCPCS worldwide website @www.cms.hhs.gov/medhcpcsgeninfo by mid November, 2011.

To be considered for inclusion in the year 2012 HCPCS update, completed recommendation packets must be received no later than close of business (COB) Monday, January 3, 2011. The onus is on the applicant to ensure timely delivery of materials. The HCPCS coding review process is an ongoing, continuous process. Requests may be submitted at anytime throughout the year 2010, and up to January 3, 2011. 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 is completed. Only complete code requests are entered into the review cycle. Applications for products/services that are not yet available on the U.S. market will be considered incomplete. **Recommendations received or completed on or after COB January 3, 2011 and those requiring additional review will be considered for inclusion in a later HCPCS update. Applications exceeding the 40-page limit are not acceptable with the single exception as noted on page 1 of these instructions and in question 7c of this application.**

For additional information regarding the HCPCS coding process or the application process, you may: 1) review documents on website at www.cms.hhs.gov/medhcpcsgeninfo ; 2) submit an inquiry to HCPCS@cms.hhs.gov; or 3) contact CMS HCPCS staff Felicia Eggleston, at (410) 786-9287; Jennifer Carver at (410) 786-6610; or Geneva Harkness at (410) 786-6951.

Healthcare Common Procedure Coding System (HCPCS)
Alpha-Numeric Coding Recommendation Format for the 2012 Update
Instructions:
1. Please **sign and date** each recommendation. Be certain to provide the name, complete address, direct telephone number, and email address 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. Please be sure that your system can receive emails from cms.hhs.gov.
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 or biological, identify the drug category, active ingredient and generic name of the drug or biological. If the item identified in this recommendation is a health care device or product, identify the specific device(s)/product(s) that have been determined by the FDA to be substantially equivalent. If this item is not classified by the FDA, please explain the basis for exemption. If the drug/biological/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. Note: Documentation of FDA approval of a drug or biological may be submitted after the coding application but no later than March 31st, provided 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. Applications for products/services that are not yet available on the U.S. market will be considered incomplete. 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

The purpose of question 1 is for the applicant to state the nature of the request and to explain in a brief summary exactly what is being requested and why.

1. For the purpose of publication on our request list and public meeting agenda on the HCPCS website, please provide a brief summary of your request (not to exceed **300 words**). 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). Include 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. CMS may edit your summary prior to publication.

The purpose of questions 2-6 is to gather information about the product, including purpose, functionality, clinical indications, and appropriate HCPCS category.

2. Identify the Item (product or drug/biological) 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:
D) Drug or Biological Y/N

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/Biological
__ K) Radiopharmaceutical
__ L) Vision

__ M) Hearing
__ N) Other (please indicate/provide category)_____

4. Is the item durable, if so, explain how it can withstand repeated use? Specify whether the entire item or only certain components of the item can withstand repeated use.

4a.) If the entire item can withstand repeated use, then please specify the length of the time that the item can withstand repeated use.

4b.) If only certain components of the device can withstand repeated use, then please identify the individual components and the length of the time that the individual components can withstand repeated use.

4c) Please provide detail 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.

CMS needs this information in order to identify categories of new durable medical equipment subject to the procedures established in accordance with the mandate of section 531(b) of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA 2000), Public Law 106-554, for obtaining public consultation on preliminary coding and payment determinations for these items. This information is readily available from the manufacturers of these items and other individuals submitting requests for changes to the HCPCS.

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 and biologicals, include: A) indications for use, B) action, C) dosage and route of administration, D) package insert and, E) how supplied.

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

The purpose of question 7 is to assist CMS in determining whether there is an existing HCPCS code category that describes your product. The question also provides information regarding any functional or operational differences between this product and similar products and if those differences result in a significant therapeutic distinction.

7A) Identify similar products and their manufacturers.
(If a drug - list other drugs by trade name marketed under the same active ingredient category/generic name.)

7B) Identify significant differences between this item and other products listed above. (Include differences in item cost; material; product design; how it is used; different mechanism of operation, differences in function/treatment provided to a patient; clinical indication; and clinical outcome.)
7C) Complete item 7C only if you are making a claim of significant therapeutic distinction). Claims of significant therapeutic distinction when compared to the use of other, similar items, must be described in detail. Articulate the clinical theory behind the claim, including differences in the product or its operation as it compares to currently coded products. Specify how the product results in a significantly improved medical outcome or significantly superior clinical outcome. (Please refer to the HCPCS decision tree for additional information.) Provide the best available information related to your claim. Include copies of all articles that result from your systematic analysis of the available literature. Information submitted should be as complete as possible. Unfavorable articles should be provided with any appropriate rebuttal or explanation. If the articles submitted cause you to exceed the overall 40-page limit, then submit one reference copy of each article and 35 copies of the application.

The purpose of question 8 is to identify how the product is currently being reimbursed and why existing codes do not adequately describe the item.

8. Answer each of the questions A), B), and C) below:
A) List any 3rd party payers that pay for this product
B) List any codes that are currently being billed to those payers for this product.
C) Explain why existing code categories are inadequate to describe the item.

The purpose of questions 9& 10 is to find out who prescribes the item and whether it can be used if there is no illness or injury.

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

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

The purpose of question 11 is to confirm FDA approval. FDA approval is required for all products unless they are deemed exempt by the FDA. The FDA classification of products is one of the factors considered by CMS when grouping like items into existing code categories. CMS needs this information in order to gain valuable insight regarding the comparability of the item that is the subject of the request for change to the HCPCS to other items currently classified under the HCPCS. This information is readily available from the manufacturers of these items and other individuals submitting requests for changes to the HCPCS and is necessary in order to determine if the request should be granted or rejected in order to meet the needs of Medicare, Medicaid and other payers.

11. Provide the date that the item/product was approved for marketing by the FDA. Attach copy of the FDA approval letter including the 510K summary for those items that are approved using the 510K process. If an item is approved using the 510K process identify the HCPCS codes, if applicable, that describe the predicate products listed in the 510K submission and explain why these codes do not adequately describe the item that is the subject of the HCPCS recommendation. If an item is listed as being substantially equivalent to another item(s) for FDA purposes, why is it not equivalent or comparable for coding purposes? If the product is exempt from FDA review and classification, please explain the basis for the exemption. Note: For drugs and biologicals only: FDA approval documentation may be submitted after the code application, but no later than March 31, 2011, provided all other application materials are complete and submitted by the deadline, and provided the application for marketing approval has been submitted to the FDA by September 30, 2010. Applicants awaiting FDA approval for drugs or biologicals at the January 3rd submission deadline must submit with the application documentation evidencing submission for FDA approval, along with the date the application was submitted to the FDA. For all non-drug and biological items, the applicant must submit 3 months of marketing experience following the FDA approval date.

Question 12 is necessary in order for CMS to assess the administrative burden associated with making a modification to the code set.

12. When was the item/product marketed in the United States?
Note Marketing data is not required for drugs and biologicals, however; the date of first sale is required. 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 insurance)? Do not estimate or provide projections - the information provided must represent actual volume of sales for the product for the period of time indicated.

Question 13 is necessary in order for CMS to assess appropriateness of inclusion in the HCPCS Level II code set as well as assess the administrative burden associated with making a modification to the code set. For drugs and biologicals this question is necessary to determine if a HCPCS Level II code is warranted. The setting for which a drug would be administered factors into the determination for a code because HCPCS Level II codes describe items that are used outside of the physician's office.

13. Identify the percent of use of the item across the following settings for all non-drugs/biologicals. For drugs/biological, provide the percentage of use for the setting(s) in which this product is or would be administered or prescribed and administered.

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%

Questions 14 is necessary to ensure that the appropriate pricing and payment is assigned for the product.

14. What is the Manufacturer's Suggested Retail Price (MSRP) or list price of the item? This question must be answered for all items, except drugs/biologicals.

HCPCS Coding Recommendation submitted by:
* 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 and extension:
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 of Applicant

Is applicant the manufacturer? Y/N If not, the manufacturer must sign the following attestation:

I attest that the information describing the product is accurate.

_____Date:_____
Signature of Manufacturer

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1042**. The time required to complete this information collection is estimated to average 11 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.