THE ORTHOTIC AND
PROSTHETIC ALLIANCE

1501 M Street, NW, 7th Floor
Washington, DC 20005
Phone: 202-466-6550
Fax: 202-785-1756
Email: opalliance@gmail.com

Inclusion of Off-the-Shelf Orthotics (OTS) in Round Two of the CMS DMEPOS Competitive Acquisition Program ("Competitive Bidding")

Overview

The DMEPOS Competitive Acquisition (hereinafter referred to as "Competitive Bidding") Program was authorized by Congress through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA 2003"). The MMA 2003 requires that CMS replace the current Medicare fee schedule payment methodology for selected items of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) with a competitive bid process in selected area throughout the country. The intent of the competitive bidding program is to improve the effectiveness of the Medicare methodology for setting DMEPOS payment amounts, ostensibly resulting in a reduction of beneficiary out-of-pocket expenses and a cost savings to the Medicare program, while maintaining beneficiary access to quality items and services.

MMA 2003 exempts from competitive bidding all prosthetics and orthotics other than "off-the-shelf" orthotics. The basis for this broad exemption for orthotic and prosthetic care is the clinical, service-oriented, and customized nature or orthotics and prosthetics which does not lend itself well to easy comparison as do many DME-based commodity items. Section 302(b)(2) of the MMA 2003 authorizes the items included in the competitive bidding program as durable medical equipment and supplies as well as "other equipment and supplies (described in Sec. 1842(s)(2)(D)) other than parenteral nutrients, equipment, and supplies" and off-the-shelf orthotics described in 1861(s)(9) of the Social Security Act. In addition, Section 302(b)(3) allows the Secretary to exempt rural areas as well as "items and services for which the application of competitive acquisition is not likely to result in significant savings."

Round One of the DMEPOS Competitive Bidding Program began earlier this year in nine competitive bidding areas (CBAs), and includes nine DMEPOS categories. The categories include such items as power mobility devices, hospital beds and accessories, oxygen and mail order diabetic supplies. DMEPOS items in Round 1 moved from DMEPOS fee schedule reimbursement to Competitive Bidding single payment amounts effective for dates of service on or after January 1, 2011.

Competitive Bidding Round Two

The Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA") authorized designation of 91 additional metropolitan statistical areas (MSAs) that will be included in Round Two of DMEPOS competitive bidding. The specific CBAs within those MSAs have not yet been announced. Further, there has been no official announcement regarding the DMEPOS services that will be included in Round Two. However, during the April 11, 2011, Program Advisory and Oversight Committee ("PAOC"), CMS announced that off-the-shelf ("OTS") orthotics are potential items for inclusion in Round Two of the program.

CMS stated at the April PAOC meeting that during 2009, OTS orthotics were the ninth highest DMEPOS spend category with $212 million in annual expenditures, accounting for 2.8% of all DMEPOS spending. However, because of recent coding and coverage changes, OTS orthotics have likely dropped in rank and in annual expenditures. As a result, CMS should reassess whether the savings to be achieved by competitive bidding of OTS orthotics is worth the investment of federal resources to include these devices in the Program.

2002 Competitive Bidding Demonstration Project

Between February 2001 and December 2002, CMS conducted a Competitive Bidding demonstration project in the San Antonio, Texas area. Included as part of this study were oxygen equipment and supplies; hospital beds and accessories; wheelchairs and accessories; off-the-shelf orthotics (described in the evaluation of the study as "general orthotics"); and nebulizer drugs. A total of 51 suppliers participated in the demonstration project and eight of those suppliers provided "general orthotics."

A subsequent evaluation of the demonstration project concentrated on five areas:

1. Medicare expenditures;
2. Beneficiary access;
3. Quality and product selection;
4. Market competitiveness; and
5. Administrative feasibility of the reimbursement system.

The CMS evaluation of the demonstration project noted that although Medicare's policy objectives in terms of savings, access, quality, competition, and administrative feasibility were largely realized for most of the service areas, then Secretary of Health and Human Services Tommy Thompson, in his final report to Congress, concluded that general orthotics were "not well suited" to competitive bidding based largely on the lack of savings achieved in this product category. The study concluded:

> "We believe that the product category of general orthotics is not as well-suited for competitive bidding as oxygen equipment and supplies, hospital beds and accessories, wheelchairs and accessories, and nebulizer drugs. We reach this conclusion primarily on the basis of the relatively low potential for savings in the product category." (RTI International, Final Evaluation Report, Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS, p. 253 (November 2003).)

OTS Orthotics Coding Changes Reduce Potential Impact of Inclusion in Round Two of Competitive Bidding

The proposed inclusion of OTS orthotics in competitive bidding has been authorized by statute since 2003. However, subsequent to passage of legislation authorizing and, subsequently, modifying competitive bidding, CMS has implemented a number of changes to the orthotic benefit that further reduce the potential for savings of including OTS orthotics in Round Two.

- Many of the codes that would have fallen within the OTS category initially have been deleted by CMS. They include:

    - L0210: Thoracic rib belt
    - L1800: Knee orthosis, elastic with stays, prefabricated
    - L1815: Knee orthosis, elastic or other elastic type material, with condylar pads, prefab
    - L1825: Knee orthosis, elastic knee cap, prefabricated
    - L1901: Ankle orthosis, elastic, prefabricated
    - L3651: Shoulder orthosis, single shoulder, elastic, prefabricated
    - L3652: Shoulder orthosis, double shoulder, elastic, prefabricated
    - L3700: Elbow orthosis, elastic with stays, prefabricated
    - L3701: Elbow orthosis, elastic, prefabricated
    - L3909: Wrist orthosis, elastic, prefabricated
    - L3911: Wrist hand finger orthosis, elastic, prefabricated

- The Alpha-Numeric HCPCS Workgroup created a new code category, A4466, into which devices that are primarily elastic in nature have been placed.

- The PDAC, another CMS contractor, has redesignated several previously coded OTS items into this new category, essentially defining them as "supplies" rather than "orthoses." The PDAC continues to pursue this approach in their ongoing review of products for code classification.

- Medicare has determined that items falling into the category of A4466 are not medically necessary, and as such, are no longer covered services.

Based upon the coding and coverage changes noted above, far fewer OTS orthotics appear to be even available for competitive bidding under Round Two than under the San Antonio demonstration project. As such, OTS orthotics are not likely to meet the criteria for "significant savings" under the statute and, thus, should not be eligible for competitive bidding in Round Two of the Program. Essentially, the cost savings to Medicare has already been achieved via changes to coding and coverage criteria. In this case, items placed under A4466 no longer expend Medicare dollars, so the desired goal to cut expenses through use of the Competitive Bidding Program has effectively been achieved by deeming these devices as non-covered.

All of the orthoses described by the reclassified codes reflect items that require no adjustment on the part of the practitioner. These OTS devices should be clearly defined separately from other, more complex orthoses, where factors such as rigidity, design, sizing, adjustability, and follow up care place them into the category of *prefabricated* orthoses or *custom fabricated* orthoses, both of which require professional involvement and expertise.

OTS Orthotics Defined

Since the time of the 2002 Demonstration project, statutory language defining OTS orthotics has been enacted as follows:

> *OFF-THE-SHELF ORTHOTICS.—Orthotics described in section 1861(s)(9) for which payment would otherwise be made under section 1834(h) which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.* [MMA 2003, Section 302(b)(2).]

The operative language in this definition is the term "minimal self-adjustment." This language illustrates orthoses that can truly be purchased at a pharmacy or medical supply company, pulled from a box and effectively used with minimal adjustments made by the patient him or herself. Such self adjustment does not include the need for expertise in trimming, bending, molding, assembling, or customizing the orthosis to fit the individual. In short, this language describes a very low complexity device.

This statutory language further eliminates codes that were included in the general orthotics category of the 2001-2002 demonstration project. Coupled with the elastic-based orthoses that were recoded and reclassified by CMS in recent years, it is not clear which off-the-shelf orthoses are left for CMS to competitively bid. Again, this raises serious questions whether the application of competitive bidding to OTS orthotics, as they are now defined, is capable of achieving significant savings for CMS.

Clinical Considerations

In addition to the potential for savings, there are several clinical considerations to take into account when analyzing the appropriateness of including OTS orthotics in Round Two of the Competitive Bidding Program:

- An OTS code describes countless products and product variations where clinical judgment of the orthotist or physician determines what product variant is the most appropriate for the patient's needs. Bidding will likely narrow the choice of devices and variations to the lowest and least sophisticated devices, which are not clinically appropriate in all situations. The orthotic and prosthetic profession has accepted this wide variation in sophistication knowing that some products are not the best cost value in certain situations but are the best in clinical efficacy for the patient.

- Many OTS devices are dispensed along with a custom orthosis. It is not uncommon for a stroke patient requiring a custom ankle foot orthosis ("AFO") to also need an OTS wrist hand orthosis ("WHO") and shoulder subluxation orthosis. If OTS orthotics is included in Round Two and the patient is receiving care from an orthotist without a competitive bidding contract, this patient would be inconvenienced by the need to visit two different suppliers for their orthotic treatment needs.

- Most physicians rely on the O&P practitioner to determine if an OTS device, a prefabricated/custom fit orthosis, or a custom fabricated orthosis is indicated for the particular patient. Additionally, some Medicare coverage policies (e.g., AFOs) require documentation of an attempt to fit a non-custom device on a patient and a rationale as to why a non-custom

device will not work before coverage of a custom orthosis is justified. Including OTS orthotics in Round Two of competitive bidding will add complexity and unnecessary confusion to the orthotic treatment process.

- In an acute care setting, there often is a progression from custom fabricated orthoses to OTS type devices as the patient's condition improves. Therefore, separately bidding OTS devices would introduce an unnecessary interruption in the continuity of patient care.

Finally, many OTS orthoses are currently fitted in the acute setting. By competitively bidding these items, patients will be required to travel to a separate location to a supplier with a competitive bidding contract without the device, in order to receive orthotic care that is covered by Medicare. Instead of being fit safely and immediately, without necessitating travel and possible injury from unprotected movement, patients will be exposed to potential harm.

Conclusion

The analysis cited in this White Paper demonstrates numerous fiscal, clinical, and operational reasons why CMS should not include off-the-shelf orthotics in Round Two of the DMEPOS Competitive Acquisition Program. There is a serious question as to whether competitively bidding this small subcategory of orthotics will yield significant savings. CMS has already achieved Medicare savings in OTS orthotics through coding and coverage changes in the past several years. New statutory language restricts the range of orthoses that CMS can include in competitive bidding to only those appropriate for minimal self-adjustment. There are also a number of clinical situations that render inclusion of OTS orthotics very inconvenient, inefficient, and even unsafe for the Medicare patient.

For more information, contact Peter W. Thomas, JD, Counsel, Orthotic & Prosthetic Alliance, at 202-466-6550.