American Orthotic & Prosthetic Association

DME MAC Guidance for Split Code Orthoses: OTS Vs. Custom Fitted Vs. Custom Fabricated

The Centers for Medicare and Medicaid Services (CMS) with the release of the 2014 HCPCS codes created a new subset of prefabricated codes, 55 in total, which they deemed to be off-the-shelf (OTS) orthoses. They also created a series of 23 "split codes" or orthoses that can be provided either off the shelf or customized to fit a specific patient by an individual with expertise. The creation of the split codes and the OTS codes raised many questions, including who will make the decision whether an orthosis requires proper fitting by a trained individual or can be delivered as an off the shelf item without additional fitting and training, and what documentation will be required to support claims for services that require proper fitting by a qualified individual?

The Durable Medical Equipment Medicare Administrative Contractors (DME MACs) have the responsibility to develop coverage criteria or policies that must be met in order to justify claim payment and medical necessity. With the creation of the new subset of prefabricated orthoses, it was expected that the DME MACs would revise the existing medical policies to establish when items should be delivered as OTS and when the items require fitting by an individual with expertise. The DME MACs have not released revised policies but they have released a correct coding directive and provided some other additional clarifications. Below is a summary of the key points of DME MAC correct coding announcement and the full announcement may be accessed by clicking here.

"An item that is prefabricated and requires minimal self-adjustment for fitting at the time of delivery, and this fitting doesn't require the expertise/knowledge of a qualified practitioner is considered an OTS orthosis." This is not new information, but the announcement did specify that the adjustment of straps/closures and any bending/trimming for final fit or comfort at the time of delivery would constitute minimal self-adjustment."

"An item that is prefabricated and requires substantial modification for fitting at the time of delivery in order to provide an individualized fit to the patient is considered a custom fitted item." The announcement defines substantial as any changes made to achieve an individual fit, such as requiring the item to be trimmed, bent, molded (with or without heat) or any other alterations beyond self-adjustment, and the changes are done by a qualified practitioner.

The announcement did clarify who is considered a qualified practitioner, and as such is allowed to provide custom fit items. "Qualified practitioners are:

* Licensed physicians.
* Licensed physical or occupational therapists.
* Licensed in orthotics or prosthetics by the state in which the item is supplied when the state requires the licensing of orthotics and prosthetics practitioners.
* In states that do not require licensing of orthotics and prosthetics practitioners, a qualified practitioner must be specifically trained and educated to provide or manage the provision of custom fabricated orthotics, and is certified by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or is an individual who has equivalent specialized training in the provision of custom fabricated orthoses."

CMS believes this list is consistent with qualified provider language first published in the BIPA 2000 legislation as well as previous information published on the CMS website in December of 2013.

Most importantly the announcement provides guidance on who decides when an OTS, custom fit or custom fabricated item is required and what type of documentation you should have in your records.

The announcement indicates that **the ordering physician will be the one in charge of determining which item is provided to the patient**. The announcement states that the supplier must provide the item that is specified by the ordering physician, for example the type of orthosis and the method of fitting and/or fabrication. The announcement also says that you may refer to the policies or supplier manuals for additional information and guidance, so this indicates that while the orthotist may work with the physician to help decide which type of orthosis is required, the physician will have to indicate on the order what type of orthosis is necessary.

Lastly, the announcement states that, "the records must indicate/justify the need of the custom fitted item over the OTS item." This can be achieved by documenting the type of fabrication methods used, the type of materials used, type of modifications/alterations provided at the time of fitting and at the time of delivery, and lastly document who fabricated and fit the item including their credentials (i.e. are they a qualified practitioner).

There are still questions which remain unanswered: Are claims going to be reviewed manually? Will policy, once it is developed, or these new correct coding directives be applied retroactively? What is the role of the PDAC in all of this; will PDAC revise its existing coding verifications for these products?

AOPA will continue to press CMS and the DME MACs for answers to the questions not answered by this release, and any new questions and concerns that arise, and make sure that AOPA member's best interests are properly addressed, including some areas we are reviewing for accuracy and consistency with the statutes which define CMS' authority on these issues.

Off-the-Shelf Orthoses and Competitive Bidding Update

The creation of the new split codes, primarily the off-the-shelf codes, set the stage for CMS to include HCPCS codes which include the term "off the shelf" in their descriptors in a future round of competitive bidding. The potential for inclusion of OTS orthoses in future rounds of competitive bidding is obviously a major concern for AOPA and the O&P industry. The recent publication of the Advanced Notice of Proposed Rulemaking (ANPRM) regarding implementation of a national competitive bidding program by 2016 represents a significant development in the potential for inclusion of OTS orthoses as a product category subject to competitive bidding. AOPA will submit comments on this issue and encourages its members to submit comments as well. The ANPRM may be viewed here.

The term "off-the-shelf orthoses" is statutorily defined as "orthoses described in section 1861(s)(9) of the [Social Security] Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit a beneficiary. Medicare in their regulations altered the definition OTS, by changing the definition of "minimal self-adjustment" to mean any adjustment made by the beneficiary, a caretaker for the beneficiary, or the supplier of the device and does not require the services of a certified orthotist or an individual who has specialized training. AOPA has voiced its serious concerns regarding CMS' expansion of the term "off-the-shelf" from the statutory definition which requires "minimal self-adjustment" to include adjustments provided by the "beneficiary, caregiver, or supplier" through multiple meetings and correspondence with CMS officials.

AOPA continues to seek regulatory refinements to ensure that the term "off-the-shelf orthoses" is appropriately defined and that only those items which meet the statutory definition of OTS are the only ones considered eligible to be included in future rounds of the competitive bidding program. Other important questions arising under this latest announcement would be: (1) how will the authorization for physicians as qualified providers be interpreted, namely, will activities by an otherwise unqualified employee in physician offices purporting to operate "under the supervision of a physician" who never actually has any interaction with the patient about the orthoses be considered as still meeting the qualified provider requirement; and (2) exploration of this announcement's introduction of the new term "substantial" as the threshold for the requirement for a qualified provider-this is a much higher bar than the term "minimal self-adjustment" already articulated in the statute as the threshold.

If you wish to help AOPA in ensuring that only those items which meet the true definition of off-the-shelf are included as eligible for inclusion in any future rounds of competitive bidding consider attending the 2014 AOPA Policy Forum April 2-4 in Washington, DC; and have your voice heard on Capitol Hill.

Questions regarding the DME MAC Correct Coding announcement may be directed to Joe McTernan at jmcternan@aopanet.org or Devon Bernard at dbernard@aopanet.org.

American Orthotic & Prosthetic Association
330 John Carlyle Street, Suite 200
Alexandria, VA 22314