A TOPIC AOPA IS WORKING ON THAT IS IMPORTANT TO THE FUTURE OF YOUR BUSINESS

Why Should We Be Upset About How CMS Identifies Off The Shelf Orthotics and Their New Coding Alternatives for 23 OTS Orthotic Codes?

Despite AOPA efforts over the past three years to require CMS to adhere to the statutory definition of OTS orthotics as requiring only "minimal self adjustment by the patient," CMS continues its effort to expand that definition beyond the law's provisions.

The Core of the Issue

How CMS defines OTS is a critical issue should CMS ever decide to implement competitive bidding on those devices or to otherwise make major changes impacting reimbursements for off-the-shelf orthotics. An even more important question is what patient harm may occur if some devices don't have the necessary evaluation and fitting expertise of a qualified provider? Another big issue is the documentation required and from whom to establish medical necessity and then how will the "gotcha" RAC audit games play out?

Why Is It Important To You?

In addition to concerns about patient welfare if appropriate evaluation and treatment are not in the hands of a qualified provider, a very important issue for you is whether you will get paid and by whom. If by Medicare, will you be vulnerable to RAC audits and possible claw backs based on the determination of medical necessity? Finally, who is vested with the decision making power of whether the patient needs an OTS device or a custom fit device—you with a mastery of the field or a physician with perhaps at best six hours of classroom knowledge of orthotics.

What Is AOPA Doing About This?

When CMS first released an initial list of 62 (subsequently reduced to 55 in August 2013) orthotic codes defined as off the shelf on its website in February of 2012 AOPA undertook a careful examination of each code and provided CMS a code by code 492 page analysis. The document included relevant literature searches and other evidence to support AOPA's view that only 13 of the codes clearly met the statutory definition of "minimal self adjustment" by the patient. Since that time numerous meetings with CMS officials and Administrator Tavenner have done little to resolve the huge difference. But even more troubling is the CMS continued effort to expand the definition of what is an OTS device. Most recently the DME MAC Medical Directors added a new standard—"substantial modification." Unless a device requires "substantial modification" it will be considered OTS. Ambiguity prevails!

This latest CMS OTS interpretation prompted AOPA to write a letter to Laurence Wilson, Director of Chronic Care Policy Group for CMS, on April 2, 2014 in which AOPA expressed concern over the introduction of the "substantial modification" standard to define what is and what is not an OTS device. AOPA's letter rallied the O&P Alliance to follow up by generating its own letter on April 29, 2014 to the DME MACs consistent with the AOPA concerns. The Alliance letter reiterated strong objections to the new standard noting that, "The O&P Alliance continues to believe that CMS and its contractors are misreading the federal statutory definition of off-the-shelf orthotics." The letter suggested CMS use a more realistic approach that would define non OTS devices as those requiring use of a tool or other equipment that a typical Medicare beneficiary would not possess; requires range of motion control modifications; and requires assembly or adjustment to prevent skin integrity issues and facilitate proper functioning. This is clearly beyond "minimal self adjustment." The letter further suggested CMS adopt a clear standard such as "anything that goes beyond minimal self adjustment' is not an OTS device. Nothing could be clearer!

> **"An even more important question is what patient harm may occur if some devices don't have the necessary evaluation and fitting expertise of a qualified provider?"**

AOPA's April 2nd letter to Laurence Wilson also drove home this need for clarification noting, "The term 'substantial modification' would necessarily infer that there is some ground between 'minimal self adjustment' and 'substantial modification.' But of course there is none—any device which cannot be used by the patient with 'minimal self-adjustment' falls inexorably, at least, into the next adjacent level of complexity, i.e., custom fitted—there is no place in between, and so the term "substantial modification' must be removed from any consideration as contrary to the statute, confusing and unreasonable and inappropriate."

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The Alliance letter also addressed the audit problems particularly if and when CMS implements competitive bidding on OTS orthotics by pointing out, "The decision as to whether to provide the patient with an OTS device or a custom fitted orthosis is often not known until the provider or supplier directly assesses the patient, which always occurs after the physician prescribes orthotic intervention. Therefore requiring explicit documentation in the physician's records as to whether such orthotic treatment must be custom fit or OTS is not practical or reasonable." The Alliance recommended that, "the records of the credentialed orthotic supplier should be accepted to support the medical necessity of custom fit orthoses instead of OTS devices."

The letter also focused on the "widespread confusion in the physician and provider/supplier communities as a result of applying competitive bidding to OTS orthoses that are described by two different—but similar—HCPCS codes, one that is affected by competitive bidding and one that is not."

The Bottom Line

The concerns over continued CMS overreach certainly drive the AOPA and O&P Alliance effort on OTS competitive bidding but it is part of a larger pattern that would have serious and long term impact on your ability to be fairly reimbursed for the services you provide. Dating back to January, AOPA's Board established a three-step process to help prepare for this troubling CMS interest in expanding the statutory definition of off-the-shelf orthotics beyond "minimal self-adjustment" and to anticipate confusion, disputes and audits challenging medical necessity for custom-fitted devices. CMS could be expected to argue that the OTS device without any clinical services would have been just fine. The three AOPA steps include:

1. Educating members about the new codes, how they might be used, and urging members, if they provide any clinical services to use the custom-fitted code, even though, at least for the time being, CMS has removed any economic reason to code as custom-fitted vs. OTS. Substantial analysis of Medicare data and what providers deliver which codes in what volume is also underway.
2. To encourage a multi-disciplinary task force including physicians, therapists and orthotists to look at the OTS situation and address issues relating to documentation, need for custom-fitting/clinical care, as well as the continuity of care for these orthotic patients as they move through the three health professional groups who typically make up the mobility team for orthotic patients. This group met April 15, 2014 with encouraging results in developing what will ultimately be guidelines for distinguishing OTS and determining medical necessity.
3. To try to encourage and assist the development of a patient voice relating to devices which CMS insists on categorizing as off-the-shelf orthotics.

This pattern of ignoring the statutes whether it is for defining OTS or initiating new policy without the proper notice and comment opportunity as required by the Administrative Procedure Act requires a "watchdog" role in which AOPA must continue to lead. It's a role someone or some organization must play and as our April letter observed, it's to your advantage "by making it your personal cause to make sure everyone you know in O&P is helping carry the load."

Very truly yours,

Thomas F. Fise, JD
AOPA Executive Director