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SUBMITTED VIA ELECTRONIC MAIL

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Re: Off-the-Shelf Orthotics Medical Policy

Dear Drs. Brennan, Hughes, Hoover and Moynihan:

On behalf of the Orthotic & Prosthetic Alliance (O&P Alliance), a coalition of the five major national orthotic and prosthetic organizations representing over 10,000 O&P professionals and 3,000 accredited O&P facilities, we are writing to follow up on your joint DME MAC correct coding guidance issued on March 27, 2014 entitled, "Definitions Used for Off-the-Shelf Versus Custom Fitted Prefabricated Orthotics (Braces)-Revised" (hereafter referred to as "joint guidance").

The O&P Alliance shares a number of key concerns involving this new policy raised in a letter by the American Orthotic and Prosthetic Association sent on April 2, 2014 to Laurence Wilson of CMS. But before detailing those continuing concerns, we would like to first acknowledge those aspects of the joint guidance we support and highlight some areas we believe are in need of additional clarification.

1. Linking Qualifications with the Level of Orthotic Complexity:

First and foremost, we appreciate that this policy guidance specifically incorporates key aspects of Section 427 of the Beneficiary Improvement and Protection Act of 2000 (BIPA). By referencing ABC and BOC as the agencies appropriate to certify orthotists to provide orthoses other than off-the-shelf (OTS) orthoses, the DME MACs have explicitly linked qualifications of the provider or supplier with the complexity of the orthosis provided. The O&P Alliance has been advocating this position for many years and has repeatedly encouraged CMS to implement this structure, as dictated by federal statute (i.e., BIPA, Section 427). The joint guidance also accommodates the provision of more complex or customized orthoses (i.e., custom fit orthoses) by individuals with "equivalent specialized training in the provision of orthoses" which, we believe, acknowledges that appropriate providers and suppliers other than certified orthotists will be permitted to continue providing certain custom fit orthoses to patients.

Since the joint DME MAC communication clearly and appropriately defines ABC and BOC as the organizations that confer certification in orthotics and since both ABC and BOC have "deemed" status as accrediting agencies for DMEPOS accreditation, the O&P Alliance believes this joint guidance delineating the level of adjustment for custom fit orthoses carries weight, reduces ambiguity, and should be incorporated in follow up communications and/or within LCDs/Policy articles. Additionally, since ABC and BOC have been deemed as organizations that confer orthotic certification under the authority of federal law, it is reasonable to expect these organizations to establish published guidelines on what constitutes an individual functioning in the orthotic field with "equivalent specialized training."

2. "Substantial Modification"

The O&P Alliance continues to believe that CMS and its contractors are misreading the federal statutory definition of "off-the-shelf orthotics" at Section 1847(a)(2)(C) of the Social Security Act by dramatically expanding the scope of OTS orthotics. Congressional intent to limit OTS orthotics to those requiring "minimal self-adjustment" has been interpreted by CMS and its contractors over the years to include adjustments made by persons other than the patient (ie., caretakers and certain suppliers). The joint guidance introduces a new concept to this expansive interpretation: that of "substantial modification." Under the joint guidance, unless an orthosis requires substantial modification to fit the device to the patient, it will be considered OTS.

We repeat our objection that this standard goes well beyond the letter and spirit of the federal law and Congressional intent. There is a wide range of ambiguity between orthoses that require "minimal self-adjustment" and those that require "*substantial* modification" by a qualified provider. To overcome our consistent objection to CMS's expansive interpretation of OTS orthotics, we believe CMS and you, as DME MAC Medical Directors, would clarify matters considerably if you were to adopt "anything beyond 'minimal self-adjustment'" as the standard, rather than "substantial modification." We, therefore, request that you eliminate the new term "substantial modification" when defining what is and is not considered OTS orthotics.

Additionally, to help further clarify the demarcation between OTS and other orthoses, we suggest that you publish additional guidance as to when an adjustment rises to the level of requiring clinical expertise and is, thereby, considered custom-fit. For example, such delineation could involve any one of the following:

1) Requires the use of a tool or other equipment that the typical Medicare beneficiary would not have access to or own. This may include but is not limited to special wrenches, cutting or finishing equipment, heating elements, and drilling or shaping tools;

2) Requires the control of range of motion through the use of items such as turnbuckles, joint controls/limiters, motion control straps or stays, which (although they may be bent by hand) require the assessment of position to conform to acceptable positioning for the patient condition or physician order; and,

3) Requires the assembly or adjustment of the orthosis to align with anatomical joint axes to minimize the risk of, or prevent, skin integrity issues and facilitate proper functioning.

3. Clarification of Documentation to Prevent Unnecessary Audit Risk

The O&P Alliance continues to be concerned with those aspects of the joint guidance that address documentation requirements, particularly if and when CMS implements competitive bidding of OTS orthotics. 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 and is expected to document the medical necessity of the orthosis in the medical record. 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.

Under the current policy, the supplier must contact the physician after the patient is assessed and rely on the physician to return to his or her patient's file to record detailed information involving the extent of modifications necessary to the orthosis actually provided to the patient. This requires considerable follow up by orthotists with the prescribing physicians to ensure the physician's records comport with what is clinically indicated and actually provided to the patient at the time of orthotic treatment. This constitutes a major workflow burden on the system and exposes providers and suppliers to extensive and unnecessary audit risk. Without such physician documentation, the orthotic supplier risks claims denials for reasons that are not under his or her control.

Contrary to prosthetic limb prescriptions, orthotic prescriptions are far more common, usually involve less complex and/or expensive devices and components, and do not require the assessment of a patient's functional level in order to justify medical necessity. Therefore, what a

physician can realistically be expected to record in the patient file—and the amount of time it takes—to justify an orthotic prescription should be distinguished from, and be significantly less comprehensive and less burdensome from the physician's standpoint, than what is expected as to prosthetics. We believe the clinical records of a certified orthotist (or other equivalently trained individual with specific orthotic expertise) should be part of the medical record in order to document the need for such modifications and/or adjustments once an initial physician prescription has been written. The detail of necessary adjustments made at the time the orthosist sees the patient will not always be included in the physician record and—in the absence of contradictory medical records from the physician—the records of the credentialed orthotic supplier should be accepted to support the medical necessity of custom fit orthoses instead of OTS devices.

The current policy with respect to orthotic documentation does not take into account the realities of providing orthotic care from a health systems perspective and, therefore, should be modified.

4. Implications for Competitive Bidding of OTS Orthotics

If CMS proceeds to competitively bid OTS orthoses using the newly bifurcated or "exploded" orthotic codes, a whole host of clinical, documentation, and administrative complications may occur as a result of the joint guidance. We would expect 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 very similar—HCPCS codes, one that is affected by competitive bidding and one that is not. For instance:

- Suppose a general practitioner (M.D.) prescribes an orthosis for a Medicare beneficiary and suggests several certified orthotists. The patient then selects a certified orthotist whose company does not have a competitively bid contract with Medicare for OTS orthotics. The certified orthotist determines that an OTS orthosis will be sufficient and a custom fit orthosis is not necessary and, therefore, will not be covered by Medicare. What happens? Will the patient be required to leave the orthotist's office without the required orthotic treatment? Will the patient have to return to the physician for guidance, contact a contracted supplier, and then potentially provide measurements and await a drop-shipped device in the mail?

- Suppose a physician prescribes an orthosis for a Medicare beneficiary and offers the patient a list of orthotic suppliers with competitively bid contracts. The supplier fits the patient with an OTS orthosis. The complexity of the patient's condition exceeds the ability of the OTS orthosis to address the patient's clinical needs and a misaligned and ill-fitting OTS orthosis leads to an exacerbation of the underlying condition and a skin breakdown. The patient returns to the physician, who, after additional and unnecessary expense to treat the skin breakdown, prescribes a more customized orthosis. Will Medicare cover the second custom fit or custom fabricated orthosis to treat the same condition that should have been addressed appropriately the first time

around? Will beneficiaries be forced to pay an additional 20% of the fee schedule amount for the subsequent orthosis?

We look forward to any additional clarifications you might offer to the issues raised in this letter, whether directly or through the publication of additional guidance. Again, we appreciate the fact that this policy guidance specifically incorporates key aspects of Section 427 of the Beneficiary Improvement and Protection Act of 2000. To contact the O&P Alliance directly, please call Peter Thomas, O&P Alliance Counsel, at your convenience at 202-872-6730 or Peter.Thomas@ppsv.com. Thank you for your consideration of our views.

Sincerely,

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