American Orthotic & Prosthetic Association

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Office of the Inspector General
Attn: Daniel R. Levinson
Department of Health & Human Services
330 Independence Ave., SW
Washington, DC 20201

Laurence Wilson
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RE: OIG Report "Medicare Supplier Acquisition Costs for L0631 Back Orthoses"

Dear Mr. Levinson:

During December 2012, the Department of Health and Human Services, Office of the Inspector General (OIG), published its report "Medicare Supplier Acquisition Costs for L0631 Back Orthoses."[1] This report details an OIG study and analysis of Medicare billings for HCPCS code L0631[2], and includes the OIG's recommendations and findings. The purpose of this letter is express concern relative to the OIG's recommendations to the Centers for Medicare and Medicaid Services (CMS) that resulted from this study.

Background

For this study, the OIG selected a random sampling of claims for spinal orthoses coded L0631, which were delivered to Medicare patients during the one year period beginning July 1, 2010. Suppliers were asked to provide the acquisition cost of the device provided, inclusive of any discounts, rebates, fees or additional charges. Suppliers were also asked to describe the services they provided to Medicare patients associated with the provision of the L0631 spinal orthosis, including the fitting of and any adjustments to the device. The study did not appear to account for the type of supplier (e.g., medical supply company, physician, certified orthosist/accredited orthotic facility, etc.) that provided and billed for the device. We have secured Medicare data, which is attached, which we believe provides important perspectives relative to the shifts in volume of claims and the relative role of different types of providers with respect to these changes between 2008 and 2011.

[1] https://oig.hhs.gov/oei/reports/oei-03-11-00600.pdf

[2] The HCPCS assigns the following definition to L0631: *Lumbar-sacral orthosis, sagittal control, with rigid anterior and posterior panels, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavity pressure to reduce load on the intervertebral discs, includes straps, closures, may including padding, shoulder straps, pendulous abdomen design, prefabricated, includes fitting and adjustment.*

HCPCS code L0631 describes a prefabricated spinal orthosis (brace.) According to the Local Coverage Determination that the OIG cites in its study[3], a prefabricated orthosis is *"...one which is manufactured in quantity without a specific patient in mind. It is preformed with a shape that generally conforms to the body part. A prefabricated orthosis may be trimmed, bent, molded..., or otherwise modified for use by a specific patient (i.e., custom fitted). A preformed orthosis is considered prefabricated even if it requires the attachment of straps and/or the addition of a lining and/or other finishing work. Multiple measurements may be taken of the body part to determine which stock size of a prefabricated orthosis will provide the best fit..."* The placement of an orthosis into the prefabricated category decidedly *does not imply* that it is a device that may be taken from a shelf and handed to a patient "as-is", or that it should be purchased by the patient in a retail-type transaction. It should further be noted that Medicare Part B payment for code L0631 is contingent upon the supplier obtaining a compliant prescription from a physician.

The OIG's stated reason for embarking on this study of Medicare billings for code L0631 is a doubling in the number claims submitted and the amounts allowed for paid claims from 2008 to 2011. We note that the OIG did not appear to account for the increase in Medicare enrollees[4] during that time period.

The OIG notes that L0631 may be used to bill for a variety of spinal orthoses, and that acquisition costs for the orthoses that may be coded L0631 vary according to the manufacturer and model number of the device. However, the OIG makes no comment on the detail of the orders received. L0631 is a lumbo-sacral orthosis ("LSO".) There are 13 lumbo-sacral orthoses codes from which to choose when a physician prescription is written as "LSO" and over 40 codes from which to choose if the order is written as "back brace". These codes can represent hundreds of different products. The current process allows: 1) the supplier to go back to the physician and obtain a detailed written order to validate which back brace is desired (by code); or 2) the appropriately licensed or certified clinician to determine the most appropriate device for the patient with a sufficiently detailed prescription. The OIG draws no correlations to the appropriateness of device provided to the patient and the type of supplier who provided it; given the relatively low number of Certified Orthotists involved in this scope (9% of claims), as well as the undisclosed number of certified fitters, this is problematic.

Concerns

The OIG found an average acquisition cost of $191 for each L0631 back orthosis included in the study, with an average allowable of $919. Although the description for code L0631 includes fitting and adjustment services, the OIG's data shows that for one-third of claims the supplier did not report providing fitting and/or adjustment services; these findings may not have documented those simple but important processes that

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[3] https://www.noridianmedicare.com/dme/coverage/docs/lcds/current_articles/spinal_orthoses_tlso_and_lso.htm

[4] http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareMedicaidStatSupp/2012.html

clinicians consider intrinsic to the provision of any device. Based on the relatively low acquisition cost of a device alone, when compared with its Medicare allowable, the OIG has recommended to CMS that it use supplier acquisition cost information to lower the Medicare fee schedule amount for L0631.

The OIG recommendations that L0631 should be considered for either a payment based on average acquisition cost (on the internet), or be included in competitive bidding Is contrary to established standard of care, contrary to the description of concurrent clinical services for these devices, and would be very detrimental to Medicare benenficiaries receiving this device.

a. Where Do Claims Volume and Growth Reside; Current Quality Standards Are Not Implemented as to All Provider Categories

Analysis of Medicare paid claims data show that the largest single component of claims (61,495) for L0631 from 2008 until 2011 were submitted by suppliers who designated themselves as medical supply companies without certified orthotists or prosthetists on staff. Additional data analysis indicates that during the period from 2008 until 2011, the largest percentage based increases in the provision of orthoses described by L0631 have not been from providers with orthotists or prosthetists on staff but rather by other provider types, specifically physicians (52%) and Occupational and Physical Therapists (53%). CMS has the legislative authority to apply quality standards to health professionals who provide orthotic devices, including L0631. At this point, and in conjunction with specific provisions included in MIPPA, CMS has exercised that authority to apply 'quality standards' as to medical suppliers, but has, for the present, exempted physicians, orthotists and prosthetists, physicial therapists and occupational therapists from those same quality standards.

Current Medicare regulations require that medical supply companies maintain compliance with Medicare Quality Standards through a mandatory accreditation requirement. Appendix C of the Medicare Quality Standards require that, "The provision of custom fabricated or custom fitted devices (i.e., other than off-the-shelf items) requires access to a facility with the equipment necessary to fulfill the supplier's responsibility to provide follow-up treatment, including modification, adjustment, maintenance, and repair of the item(s). Individuals supplying the item(s) set out in this appendix must possess certification and/or licensing and specialized education, training, and experience in fitting."

While AOPA is not challenging the ability of other providers to provide orthoses described by L0631, efforts should be made to ensure that required fitting anf follow up procedures are followed in order to ensure the best possible outcome for Medicare beneficiaries.

b. Presently, Congress Has Authorized CMS to Condict Competitive Bidding Only as to Off-the-Shelf Orthotics as Defined in the Statute, and the Proposal to Incorporate L0631 for Competitive Bidding as if this Device Met the Statutory Definition Would Both Violate the Law and Prove Contrary to Existing Standard of Care, and Be Detrimental to Medicare Beneficiaries

As previously stated in its comments to CMS AOPA strongly disagrees with the inclusion of orthoses described by L0631 in future rounds of competitive bidding as they are not designed

to be provided to Medicare beneficiaries without proper fitting, adjustment, and follow up care from a qualified health care professional. The statutory definition of an off the shelf orthosis is one that can be fit with "minimal self adjustment". On several occasions, both in person and in writing,AOPA has demonstrated to CMS, supported by peer-reviewed publications/literature, why the inclusion of L0631 in any competitive bidding program would not only be contrary to the statutory definition of an off the shelf orthosis, but of at least equivalent importance, may create potential harm to Medicare beneficiaries through the provision of improperly fit devices.

c. Any Attempt to Set the Reimbursement for L0631 Based on Supplier Acquisition Cost Would Completely Ignore the Fact that the Clinical Component of Fitting, Trimming and Adjustment is Defined Incorporated into the Fee, Is Currently Provided in the Majority of Cases Where the Device is Delivered, and Eliminating it Would be Detrimental to Medicare Beneficiaries and Their Quality of Care

AOPA believes that the use of supplier acquisition cost as the sole grounds for determining the appropriateness of Medicare reimbursement for any orthosis is fundamentally flawed. The cost of the device itself represents a small portion of the overall service that includes the fitting, adjustment and required follow up care necessary to ensure that the orthosis functions properly and according to the specific medical need of the patient. We maintain that any supplier that bills Medicare for a code that includes payment for fitting and clinical patient care *without providing or making such services available,* is defrauding Medicare. These codes, as well as the reimbursement associated with them, properly reflect the standard of care; namely, that these devices are delivered in conjunction with an established series of clinical services.

Comparing the composite cost of a device and the requisite series of clinical services versus the cost at which a similarly described device *alone* may be purchased on the internet is just as invalid as comparing the cost of an artificial hip joint versus the cost of the surgical intervention and hospitalization associated with a total hip replacement. Further, the placement of L0631 into the prefabricated category of orthoses, rather than the off-the-shelf category[5], lends further evidence that clinical intervention in the fitting, customization and follow-up care for users of the L0631 back brace is not only expected, but necessary. We see no indication that the OIG looked for any follow-up visits in this study (we are asking a data question we don't have the answer to, but they might—where will we be if they say, actually our data show that 80% of these patients had no follow-up care?).

A failure to document and report fitting and adjustment services does not necessarily indicate that none occurred. These services are not required to be documented under any CMS policy. To assume that they did not occur may be inaccurate. Many clinicians only document any services that are out of the norm during the provision of a device; thus the one-third of devices which have no reporting of fitting and adjustment may be high compared with what occurred with each beneficiary.

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[5] 42 U.S.C. § 1395w-3(a)(2)(C) requiring "minimal self-adjustment"

Based upon a review of the devices reported, 23 of the devices within the study do not match the coding of the PDAC, a requirement provided by policy. While this represented approximately only 3% (point estimate), the OIG did not factor this into the exclusion criteria or assumptions of cost of devices.

According to the OIG report regarding Fitting and Adjustment, two-thirds of the devices reported included the provision of fitting and adjustment services. The OIG recommendations relating to either shifting to average acquisition cost or competitive bidding of this device simply ignores the clinical facts that fitting and adjustment services are needed for satisfactory patient care, and that such fitting and adjustment has been appropriately provided by clinical personnel in at least two-thirds of the cases tracked by the OIG's own admission. This, coupled with the fact that a combined total of 81% of devices were provided on the premises of the facility or directly to the beneficiary by staff (presumably home or nursing home, etc.,) further reinforces that a large majority of these devices must be provided by qualified individuals and not simply shipped or delivered without any clinical intervention.

In its recommendations, the OIG offered two methods by which CMS could lower the Medicare fee schedule amount for L0631: CMS could invoke its inherent reasonable authority, or include L0631 in DMEPOS Competitive Bidding. While CMS did not concur with utilizing inherent reasonableness to make fee schedule adjustments, it did agree that including L0631 as part of DMEPOS competitive bidding may be appropriate.

Including L0631 back braces as part of DMEPOS competitive bidding would require that the code be reclassified and placed in the off-the-shelf category of devices. As discussed above, the descriptor for L0631 specifically includes a component for fitting and adjustment, and can include any number of modifications before the device is suitable for a particular patient. By definition, an off-the-shelf device requires "*minimal self-adjustment.*" The report does show a statistically significant number of delivery events (again, at least two-thirds, and possibly more) that **did** include instruction and required adjustments beyond the patient's knowledge. Subsequently characterizing all delivery events as not requiring instruction ignores the necessity of documented adjustments that were required by the study's own findings. As the current code descriptor shows, devices that may be code L0631 require a clinical component that simply does not exist with devices that may be appropriately adjusted by the patient prior to wearing. We are vehemently opposed to the classification of L0631 as (1) an off-the-shelf device; (2) if it were appropriate for a payment linked to average acquisition cost (ignoring entirely the clinical services of trimming and adjusting that ARE both needed and are customarily provided); and/or (3) appropriate for competitive bidding under the current statutory standard. Providing this device in any of those three permutations, without the necessary clinical care, fitting and adjustment would violate the provider's ethical obligation to the patient as it would be detrimental to good quality patient care..

We would, however, encourage CMS to acknowledge the importance of clinical intervention in the provision of L0631 back braces, and instead require the fitting and

delivery of such devices be done by properly trained and certified clinical personnel. Those personnel may be a certified orthotist, an orthotics fitter working under the supervision of a certified orthotist, or a physician.

In conclusion, while AOPA understands the concern of the OIG regarding the increased utilization and costs associated with orthoses described by L0631, it believes that a systematic reduction in reimbursement rates either through inherent reasonableness authority or inclusion of L0631 in future rounds of competitive bidding will lead to lower quality of care for Medicare beneficiaries.

Sincerely,

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