



**American Orthotic &
Prosthetic Association**

November 15, 2013

Mr. Laurence Wilson
Director
Chronic Care Policy Group
Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear Laurence,

This will follow-up both on the meeting which you and your team had with representatives of the O&P Alliance on August 26, and on my follow-up email to you dated 8/28. It has come to my attention recently that the annual announcement of new HCPCS codes to take effect on January 1, 2014 has been delayed a bit this year, and it seems that the target date is now sometime toward the end of November. Before that announcement is etched into stone with the formal release, I want to re-state AOPA's sense that the plans being advanced for the "exploding" of codes and follow-up to position off-the-shelf (OTS) orthotic devices for possible eventual competitive bidding has very significant gaps, AND that it would be very prudent for CMS to make modifications in any "final" OTS list before the HCPCS announcement.

Specifically, this letter will formalize our request that, at minimum 26 codes slated for the OTS list/exploding of codes treatment be removed from the OTS list and recognized: (1) as virtually always requiring clinical care, and (2) as NOT meeting the terms of the statutory definition for OTS devices, i.e., not being capable of being used by the patient with "minimal self-adjustment." Prior communications have included interpretation of the legal definition and position that both the statute and sound patient outcomes demand recognition of clinical care as prerequisite for these devices, and I will not recite that again here. You will recall that in July, 2012, we had physically presented many of these devices in a meeting with you and your staff, demonstrated how they are used and adjusted, presented medical literature underscoring the indispensability of clinical care with these devices, and citing the specific instructions included in manufacturer labeling for device use as being incompatible, actually indecipherable for safe and effective use by the patient in the absence of concomitant clinical care by the orthotist or comparable health professional. Sadly, save for one pediatric device, the OTS list CMS published ignored all of that explication, and improperly asserted that all these devices would be on your OTS list—this is a conclusion which we believe cannot withstand scrutiny or challenge.

The following are the specific devices/codes that we are formally petitioning be eliminated from OTS treatment. There may be others that should also be omitted—these are simply the most egregious ones where irreparable harm to Medicare beneficiaries would result if the OTS policy were implemented.

L0172	L0174	L0456	L0466	L0468	L0623
L0625	L0626	L0627	L0628	L0630	L0631
L0633	L0637	L0639	L1810	L1832	L1850
L3670	L3675	L3807	L3915	L3923	L4360
L4386	L4396				

We believe our meeting on August 26 demonstrated that there are multiple, serious flaws in the pathway suggested by CMS to explode codes and otherwise advance barriers to patient access to the care needed for effective use of these devices. Among others, serious shortcomings highlighted then included:

- Who could determine when clinical care required for the 23 exploded OTS codes
- How that health professional would be paid (ABN?)
- How absence of clinical care would impact patient health

Thank you for your consideration of this request to avert very significant damage and risk of injury to Medicare beneficiaries, and recognition of the legitimate parameters of the statutory definition in any roll-out and code modifications relating to off-the-shelf-orthotics. Please let us know if we can be of assistance in your expedited review of our request/petition.

Very truly yours,



Thomas F. Fise
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cc: Thomas A. Scully, Esquire