



September 28, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare
& Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-8013

Dear Administrator Verma,

As Administrator, you know the grave toll of diabetes has had on our country's health. The American Podiatric Medical Association (APMA) and the American Orthotic and Prosthetic Association (AOPA) are taking the unusual step of writing this joint letter to you today because the misguided interpretation of Medicare's coding system is now threatening to heighten the risks of diabetes complications to America's veterans—an especially high risk subpopulation- as well as to its Medicare population. We write referring to some recent, very troubling actions by Medicare payment contractors with respect to claims for diabetic foot inserts (HCPCS code A5513), which is used to describe a custom molded diabetic shoe insert. We are specifically concerned about a troublesome term in the descriptor for A5513—"molded to patient model." These actions also equally impact veterans, with their substantial prevalence of diabetes, receiving care from the Department of Veterans Affairs (VA).

Historically, the best method to achieve a "molded to patient model" fit for a diabetic foot insert was to create a physical model of the patient's foot through the use of a negative impression, which was filled with plaster to create a model, or through the use of computer aided design/computer-aided manufacturing (CAD/CAM) technology, which would utilize multiple digital scans of a patient's foot to create a positive model of that foot by carving a model from a foam block. Technological advancements in CAD/CAM technology have eliminated the need to create a physical model of the patient's foot to obtain a custom molded diabetic insert. Technology now allows the same digital scans that were previously used to create a physical model of the foot to instead directly mill a diabetic insert that matches the plantar surface of the patient's foot with levels of accuracy equal to or exceeding methods that involve heating the insert material and then molding it over the model of the foot.

Unfortunately, the strict interpretation of the term "molded to patient model" by the Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Medical Directors forces manufacturers of custom molded diabetic foot inserts to use less advanced technology in their fabrication process. The Centers for Medicare & Medicaid Services (CMS) continually stresses the importance of innovation through technology—we even have an annual Medicare fee reduction attributed as the 'productivity adjustment' underscoring the need to improve efficiency in "how." Eliminating access to this technology is not in the best interest of federal health programs or their beneficiaries.

The term "molded to patient model" is, in many respects, yesterday's term. Today, practitioners use a scanner and get equal or better results with less annoyance to the patient. We understand how the MACs may feel constrained by those four words--but interrupting the delivery of needed care because of this serves no purpose and could have serious negative patient care consequences. It is important to note that since the VA follows CMS on these types of matters, the adverse result will impact veterans equally.

This can be resolved easily if someone at CMS tells the MACs—"it is OK to pay claims on codes where the descriptor includes the words "molded to patient model," even if those words are not strictly enforced, so long as the objective of the words is satisfied--namely, getting a device that has been fabricated to match the patient's anatomy, that is fitted properly.' These four words and their implication potentially limiting appropriate patient care is a big concern for podiatrists, orthotists and pedorthists alike that could be easily resolved to patients' benefit by CMS signaling "it's OK" to the MACs.

According to recent coding clarification published by the DME MACs and PDAC, custom molded diabetic inserts fabricated without the use of a physical model of the patient's foot must be billed under the non-covered HCPCS code A9270.¹ The Pricing, Data Analysis and Coding Contractor ("PDAC") announced on August 10, 2017, that it will begin a coding redetermination project for HCPCS code A5513 products and that the new policy will take effect in May 2018.²

The DME MAC's new interpretation of A5513 will discourage technological innovation and force suppliers to use less efficient and less effective processes in fabricating custom molded foot orthoses. As stated above, CMS already applies a "productivity adjustment" to the annual inflation based increase of the Medicare O&P fee schedule that is intended to recognize efficiencies that come from technological developments and, thereby, adjust Medicare providers' reimbursement downward to reflect these efficiencies.³

CMS is ignoring the purpose of the productivity adjustment and imposing a double penalty on practitioners that seek to increase productivity by utilizing advanced technology,

¹ *Id.*

² CGS, *Correct Coding – A5513 Product Coding Redetermination Project* (Aug. 10, 2017), <https://www.cgsmedicare.com/jb/pubs/news/2017/08/cope4087.html>.

³ Patient Protection and Affordable Care Act, Pub. 111-148, § 3401, 124 Stat. 119, 480 (2010).

FACTS--WHY ACTION IS NEEDED: One in four individuals with diabetes will develop a foot ulcer.⁴ Infections and ulcers may result in lower-limb amputation.⁵ In 2014, an estimated 7.2 million hospital discharges reported diabetes among individuals 18 years of age or older in the United States, and these discharges included approximately 108,000 lower-extremity amputations. The cost of diabetes in the U.S. amounts to \$176 billion in direct medical costs. According to the American Diabetes Association, in 2012, Medicare spent approximately \$103.84 *billion* on diabetes care and only a fraction of that amount, \$71.66 *million*, was spent on HCPCS code A5513. The percentage spend for molded to patient model diabetic inserts compared to the total Medicare spend for diabetes care amounted to 0.07%.

We have appended to this letter a spreadsheet tracking the utilization of A5513 for the sample year 2012. Podiatrists lead all categories of providers in utilization of this code at 618,966 units billed. Orthotic and prosthetic (O&P) providers accounted for 505,952 units, and pedorthists accounted for 13,726 units. Clearly, members of both APMA and AOPA have a significant stake in this issue. More importantly, Medicare beneficiaries and veterans served by podiatrists and O&P providers are significantly at risk for diabetic ulcers, and ultimately for amputation, if care is not maintained up to standard. The costs of quality care are low, and the risk to patients, if appropriate care is neglected, is great.

TWO WAYS TO A SOLUTION: (1) CMS should focus to a greater extent on performance and outcome of the orthotic treatment itself, and less on the process used to achieve that result; and/or (2) CMS should use its authority to intervene in this year's HCPCS coding update to initiate its own action to modify the language for all codes that include the words "molded to patient model" or similar language, to instead read "custom fabricated from patient model". The descriptor for HCPCS code A5513 could be changed from "custom *molded* from model of patient's foot" to "custom *fabricated* from model of patient's foot." This change would allow manufacturers who produce custom fabricated inserts through the direct milling process to meet the requirements of the revised HCPCS code. It does not appear that the DMEPOS Quality Standards would impose any impediment on our proposed actions on A5513, as APMA and AOPA are cognizant of, and endorse the position stated in the letter submitted by the O&P Alliance which in significant detail clarifies that A5513 is not subject to the Quality Standards. Both alternatives should maintain coverage and reimbursement of custom diabetic foot inserts under HCPCS code A5513.

A virtual model from a digital scan of a patient's foot qualifies under the phrase "model of patient's foot" used in HCPCS code A5513, and that the term "custom molded" includes direct shaping of a finished diabetic foot insert from the virtual model through the use of CAD/CAM or similar technology.

⁴ APMA, *The Real Cost of Diabetes*, <https://www.apma.org/files/APMA%5FTodaysPodiatrist%5FInfographic%5F8%2E5x11%5FNOCROPS%2D2.pdf> (last visited Sep. 1, 2017).

⁵ Johns Hopkins Univ. Evidence-Based Practice Ctr., *Preventing Complications and Treating Symptoms of Diabetic Peripheral Neuropathy*, COMP. EFFECTIVENESS REV. 1 (Mar. 2017), https://ahrq-ehc-application.s3.amazonaws.com/media/pdf/diabetic-neuropathy_research-2017.pdf.

APMA and AOPA urge your action to resolve expeditiously the recent turmoil relating to payment policy on A5513, to assure the millions of Medicare beneficiaries, Veterans and those with other coverage, e.g., in the private sector, that coverage for diabetic shoe inserts is assured into the future, based on device performance as opposed to any specific manufacturing process, and that diabetic patients will not be asked to pay the cost of inserts out-of-pocket as the PDAC interim action suggests. Thank you for your consideration of this matter, and we would be pleased to discuss this matter further as you may desire.

Very truly yours,



Ira Kraus, DPM, President
American Podiatric Medical Association



Michael Oros, President
American Orthotic & Prosthetic Association

cc: Rep. Pat Tiberi
Rep. Brad Wenstrup
Demetrios Kouzoukas
Carla DiBlasio
Kim Brandt
Laurence Wilson
George Mills
Elizabeth Richter
Melanie Combs-Dyer