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CMS Responds to Concerns Regarding Custom Fabricated Diabetic Inserts

November 27, 2017

The Centers for Medicare and Medicaid Services (CMS) has proposed a change to the DMEPOS Quality Standards that addresses the concern regarding the recent DME MAC/PDAC interpretation of the term **"molded to patient model"** when used to describe custom fabricated diabetic shoe inserts. The proposed change to the quality standards allows for the creation of a digital positive model of the patient's foot using CAD/CAM technology that is then used to direct mill a custom fabricated insert based on the digital model.

In July, 2017, the DME MACs and PDAC issued a joint bulletin that stated that in order to meet the definition of **"molded to patient model" contained in the descriptor for A5513, diabetic inserts must be fabricated over a physical model of the patient's foot.** The bulletin went on to state that digital or virtual models that were used to direct mill custom inserts are not considered a positive model and inserts fabricated using this technique do not meet the code requirements of A5513 and therefore, must be billed as A9270, a statutorily non-covered HCPCS code. On September 28, 2017, AOPA and the American Podiatric Medical Association (APMA) submitted a joint letter to CMS expressing their concern over this bulletin as it represented a significant threat to the use of advanced technology to provide better clinical service. In addition to working directly with the APMA, AOPA worked closely with the O&P Alliance, Representative Wenstrup's (R-OH) office, his staff, and the House VA Subcommittee on Health to make sure that this issue remained at the forefront of the discussion.

On November 2, 2017, CMS announced a proposed change to the DMEPOS Quality standards that would include the use of digital or virtual models to direct mill custom diabetic inserts as an acceptable method to meet the definition of **"molded to patient model" contained in the code language for A5513.** CMS will hold an Open Door Forum call on November 28, 2017 at 2:00 pm EST to allow experts to discuss the proposed changes to the DMEPOS Quality Standards and will accept comments on the proposed changes through December 11, 2017. Comments on the proposed changes may be sent to CMS via e-mail at ReducingProviderBurden@cms.hhs.gov.

CMS has indicated that it intends to finalize the proposed changes by January 1, 2018.