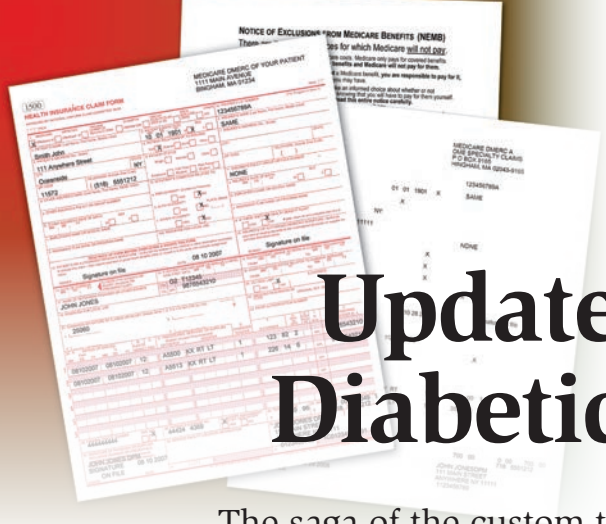

Update on Custom Diabetic Foot Inserts

The saga of the custom therapeutic shoe insert code concludes.

BY PAUL KESSELMAN, DPM

In the April 2018 issue of *Podiatry Management*, this column provided a review of Medicare's policy coverage changes of custom diabetic foot inserts. At the time that column was written, the issue of the fee schedule differential between those custom fabricated inserts manufactured using a milling process (K0903) and those manufactured via the molding process (A5513) was not yet resolved. During summer and fall of 2017, Medicare steadfastly issued several policy statements declaring there would be at least a 30% differential between the two inserts with the milled device (K0903) being paid at a significantly lower rate than the custom molded device (A5513). This has now been resolved (see below).

There also continues confusion from the supplier community about the validation process required by Medicare for these two inserts. This column will serve to provide a very brief synopsis and clarification of all these issues.

As of April 1, 2018, Medicare has instituted several new coding rules regarding "custom inserts" for patients with diabetes. There is a transitional period for some of the rules noted below. It is important for every supplier of custom inserts for patients with diabetes to understand the following:

1) All custom fabricated inserts must be made from a block of raw materials of specific thickness and durometer (density). This is a requirement of both the Price Data Analysis Contractor (PDAC) and Appendix C of CMS' Quality Standards. There is no transitional period for this.

2) Devices with current validation letters from the PDAC which have not recently been updated with a new effective date of 2018 and indicative of no end date will all have their validations rescinded by August 1, 2018. The reason for this is that all custom inserts are currently required to provide detailed work flows illustrating certain aspects of the fabrication process. Most imporant is whether devices are manufactured from a virtual scanned image using a milling process or whether the devices were actually custom fabricated using a positive mold of the patient's foot.

3) The PDAC will be assigning either the A5513 code to those using a custom molding process (positive physical mold) or K0903 to indicate whether the device was made using a millling process.

4) Devices currently validated as A5513 which are not custom molded over a physical model of the patient's foot from either a scan, foam, or cast impression, as of April 1, 2018 service dates (date dispensed) should now be billed as K0903 (see limitations below).

5) Devices which are custom milled do not require PDAC validation until service dates of August 1, 2018. That is, any custom inserts manufactured via the milling process may be billed as K0903 so long as the manufacturer has submitted an application for K0903 validation. This so-called "self-designation" is in effect through July1, 2018.

As of April 1, 2018, Medicare has instituted several new coding rules regarding "custom inserts" for patients with diabetes.

6) Both types of custom fabricated inserts, A5513 (custom molded) and K0903 (custom milled) will require a new validation letter without an end date by August 1, 2018, indicating they conform with these new regulations.

7) No matter which type of custom fabricated insert is manufactured, the supplier must take a negative impression of the patient's foot (via scan, foam box, or cast impression) which is then used by the fabricating facility to either create a positive mold or virtual positive.

8) The fabricating laboratory can use a virtual image derived from the supplier's scan to create a positive

Continued on page 50

Inserts *(from page 49)*

mold, or the negative physical impression provided by the supplier may be used to produce a positive mold over which the custom inserts (A5513) can be produced.

9) From the impression (scan, foam box or cast) the laboratory can produce a virtual positive over which the custom milled insert (K0903) can be produced.

10) After July 31, 2018, any custom insert which does not conform with the above policy changes should be coded as A9270 (non-covered item).

11) A5512 (pre-fabricated heat molded inserts) are not affected by these policy changes.

12) The most important takeaways from all of the above are that:

A) Most custom fabricated inserts on the market today are manufactured using the milling process.

B) It is important during this transition phase (April 1, 2018 through July 31, 2018) that you confirm that your laboratory has submitted an application to the PDAC. During this time laboratories may "self-designate" their devices in accordance with the workflow on the PDAC application (custom milled—K0903 or custom molded—A5513).

C) Self-designation will disappear on August 1, 2018, by which time the PDAC DMEC website will take precedence. That is, if by August 1, 2018 (assuming the deadline has not changed), if the device is not newly validated by the PDAC, then the device can no longer be submitted to your DME MAC as either K0903 or A5513.

Since suppliers are ultimately responsible for their own billing, your office should request written confirmation from your vendor, laboratory, or fabricating entity regarding the appropriate fabrication process for their inserts. Most vendors, distributors, and manufacturers are more than willing to share a copy of their PDAC validation letters or copies of verification of submission. Since validation letters are frequently added and rescinded, PDAC maintains an online website dedicated to the validity of product coding. This can be found at https://www.dmepdac.com/.

Search for the button entitled "Search DMECS for Codes and Fees". Then select the last button on the left entitled: Search "DMEPOS Classification List"

Copies of web announcements, advertisements from publications, etc. are not necessarily reliable forms of coding confirmation.

If at all possible, have one person in your office responsible for maintaining this information in a downloaded pdf file.

As of August 2018, all custom inserts will require new open ended validation letters.

As for the Medicare fee schedule issue, in mid-March 2018, CMS announced there would be no fee differential between those inserts manufactuted via the molding process (A5513) and those custom fabricated devices manufactured via the milling process. The nationwide fee for both these devices would continue to be reimbursed at: $43.56 per insert.

Furthermore, this clarification was accompanied by a huge capitulation by Medicare stating that they could find no difference in the medical effectiveness between the two types of devices. The simple fact was that CMS officials could not differentiate between the two types of inserts.

APMA, AOPA, and several other organizations submitted countless documents and met with senior CMS officials as well as Congressman Brad Wenstrup, the latter who provided instrumental support. All should be commended for their contributions to this successful effort.

As for non-Medicare, third-party payers, it is too soon to say whether they will pay for K0903 at the same rate as A5513, or even accept the K0903 code as valid. Providers are urged to contact their non-Medicare providers for more information. Certainly critical to this issue will be how these non-Medicare claims are handled as Medicare secondary crossover claims.

In summary, there is no financial incentive to use the wrong HCPCS code when billing custom fabricated inserts to Medicare. Those manufactured with a physical mold should be coded as A5513; those manufactured with a milled process K0903 (so long as the device has either been validated or the manufacturer has submitted an application). Inserts currently validated by the PDAC as A5513 but manufactured via a milling process should be coded as K0903 (assuming the manufacturer has submitted an application to PDAC). As of August 2018, all custom inserts will require new open-ended validation letters. It is uncertain how this may affect non-Medicare carriers' payments and the processing of Medicare secondary cross-over claims. **PM**

Sources

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10436.pdf

https://www.cgsmedicare.com/jc/pubs/news/2018/0218/cope6148.html

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html

Dr. Kesselman is in private practice in NY. He is certified by the ABPS and is a founder of the Academy of Physicians in Wound Healing. He is also a member of the Medicare Provider Communications Advisory Committee for several Regional DME MACs (DMERCs). He is a noted expert on durable medical equipment (DME) for the podiatric profession, and an expert panelist for Codingline.com. He is a medical advisor and consultant to many medical manufacturers.