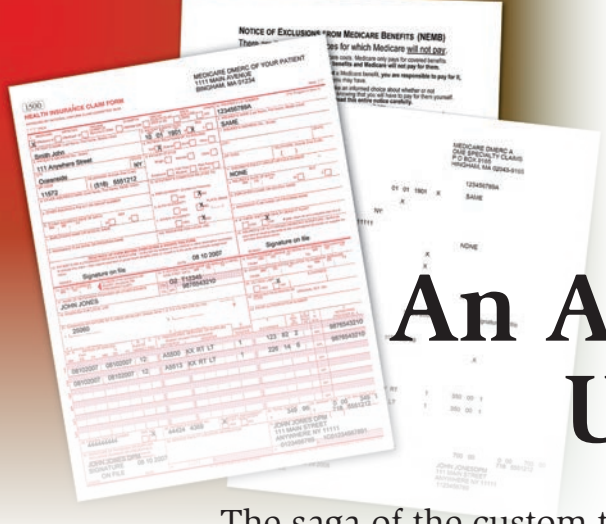

An A5513 Code Update

The saga of the custom therapeutic shoe insert code continues.

BY PAUL KESSELMAN, DPM

This article is written with a heavy heart during the initial days following the passing of my teacher, mentor, and dear friend Dr. Harry Goldsmith. I will forever be in his debt for the time and patience he showed in sharing his vast expertise, not just with me, but with generations of his colleagues. My grandfather used to say, the highest compliment you could extend on someone was "Zy a mench" (Be a person of integrity and honor). Harry was the embodiment of that expression and more. I'm sure he will be watching us all from a first class seat high above. May Harry rest in peace and his memory live forever.

The saga of the custom therapeutic shoe insert code which first reared its ugly head in the summer of 2017 seems to be showing no signs of slowing down. In early 2018, there seemed to be weekly bulletin updates from various CMS agencies on this issue, some contradicting previously issued policies. Fee scheduling complexities and inconsistencies have also been raised and are currently being addressed at the highest level of CMS. Some of the changes sought by CMS also appear to have run afoul of other Federal agencies (i.e., the FDA) and are currently being appealed.

This month's bulletin will try to make some sense out of all of the above issues and more as the saga of custom therapeutic shoe inserts goes on.

Due to the complexities of the issues involved, a very simplified question and answer format based on the top issues of confusion is presented. The responses are based on what is known during the first two weeks of February 2018. There remains significant fluidity despite a looming self-imposed CMS deadline of April 1, 2018. The reader is advised to regularly check with other sources such as *PM News*, APMA News Blasts, and CMS and DME MAC bulletins for further updates.

The saga of the custom therapeutic shoe insert code which first reared its ugly head in the summer of 2017 seems to be showing no signs of slowing down.

Fact 1: A5513 will continue to be a valid code after April 1, 2018 and for the foreseeable future.

Comment: After April 1, 2018, A5513 will only be able to be used to describe custom inserts which are manufactured when an actual positive physical model is part of the manufacturing process.

After April 1, 2018, any custom insert manufactured using a milled process must be billed using the new K0093 code (for diabetics only, multiple density insert, made by direct carving with CAM technology from a rectified CAD model created from a digitized scan of the patient, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore a 35 durometer or higher, includes arch filler and other shaping material, custom fabricated, each).

Fact 2: The fee schedule for A5513 is $43.56 per insert and will remain the same after April 1, 2018.

Comment: The fee schedule implementation for the new K0093 code will have no effect on the fee schedule for other HCPCS codes covered under the Therapeutic Shoe Program for Patients with Diabetes.

Fact 3: Products coded as A5513 and K0093 will require new validations.

Comment: All custom therapeutic insert devices which received product validation letters for A5513 are required to be re-validated by the PDAC no later than July 31, 2018. The previous May 31, 2018 date has been extended for PDAC convenience. If custom inserts are not re-validated by the July 31, 2018 deadline, the correct code to be used in these circumstances will be A0629 (non-covered insert).

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Fact 4: Effective April 1, 2018, any product which received a PDAC verification for A5513 but was manufactured via the computerized custom milling process, must be billed with the K0093 code.

Comment: This is true for custom inserts even if they were previously validated as A5513. The PDAC has provided a four-month grace period for manufacturers to obtain new validations coded as K0093. As of August 1, 2018, only those custom-milled products PDAC validated as K0093 may be billed as K0093. If a product was not newly validated by the PDAC by August 1, 2018, then it must be billed under the non-covered item or service code A9270.

Fact 5: The Quality Standards as adopted in January 2018 provide an update to the previously released standards of 2016. The Quality Standards did not go far enough in resolving the questions regarding the use of digital technology to obtain impressions and/or manufactured inserts.

Comment: CMS was gracious enough to allow several key leaders of APMA and the American Orthotic and Prosthetic Association (AOPA) to address these issues during a conference call in early January 2018. The discussion primarily involved whether a scan of a physical impression would be allowed as part of the workflow (as this was not specifically stipulated in the January 2018 Quality Standards). Recent DME and PDAC bulletins have verified this workflow to be one of several acceptable methods by which to capture an image of the patient's foot. While the Quality Standards were not updated to allow for this most common of methods by which to obtain a digital image, all the DME MAC contractors issued clarification bulletins approving this process. CMS did indicate it was willing to address this issue sometime in a future update of the Quality Standards.

Fact 6: The custom-fabricated and custom-milled devices are often impossible to distinguish from one another and are often functional equivalents.

Most HCPCS codes do not specify manufacturing processes, as this normally is within the purview of the FDA.

Comment: The fuss is based on the initial absence of digital technology in the Quality Standards. It would seem that now that this is resolved, this fuss is really much ado about nothing, other than the fee schedule.

It is the opinion of many in the industry that CMS has taken some liberties in dictating the specifications of the manufacturing process. Most HCPCS codes do not specify manufacturing processes, as this normally is within the purview of the FDA. Several organized medical associations are engaged in discussions with several Federal agencies to determine if CMS has overstepped its bounds. (See also Fact 8). Further clarification on this issue cannot currently be determined.

Fact 7: At the present time, the fee schedule to be implemented on April 1, 2018 for K0093 is $38.67 per insert. This is 14% less than the fee for A5513, which is $43.56 per insert.

Comment: This fee differential was initially released by CMS in November 2017 and is currently being appealed to very high levels within CMS. The rationale provided by CMS for this fee differential was that the workflow for the supplier is substantially different and the new code also does not follow the strict fee schedule regulations of the Therapeutic Shoe Program. Additionally, CMS offered that new codes are subject to complex Consumer Price Index (CPI) formulas. Neither of the above explanations appear logical to many experts.

Fact 8: You are reading this after April 1, 2018 by which time CMS had stipulated the new code and fee for K0093 be used.

Comment: At the time this article is composed, there is a proposed 14% fee differential between K0093 and A5513. One should check for updates on this issue to see what if anything has changed since early February 2018. It is possible that this deadline was imposed only to conform with the regularly scheduled quarterly HCPCS fee updates issued by CMS. Perhaps this deadline will be extended to September 1, 2018. Further updates or delays may be announced by mid-March 2018.

Fact 9: The cost to my practice to make these two different types of devices (milled vs. molded) are the same. Yet there is a fee differential for two products which look and function the same.

If a product was not newly validated by the PDAC by August 1, 2018, then it must be billed under the non-covered item or service code A9270.

Comment: CMS and their "experts" were actually presented with two products (one custom-molded and the other custom-milled) at a recent meeting with the American Orthotic and Prosthetic Association. CMS experts could not distinguish one device from the other as both appeared identical. This is exactly why the fee differential proposed

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by CMS should not be allowed to be implemented and is currently being reviewed.

All of this turmoil could easily have been avoided by modifying the HCPCS A5513 code to replace "custom molded" with "custom fabricated".

Fact 10: Code Explosion Regulations preclude CMS from having different fees for HCPCS codes, which initially were derived from the same code.

Comment: This policy has been quoted as one fact for the appeal of any fee differential between A5513 and K0093. By assigning a different reimbursement schedule to A5513 and K0093, it appears CMS is violating one its own policies.

Conclusion

It is possible that CMS will delay implementation of the fee reduction. It would be quite ironic if CMS simply pays the same fee for both codes (at the current A5513). All of this turmoil could easily have been avoided by modifying the HCPCS A5513 code to replace "custom-molded" with "custom-fabricated". This would have been a simple matter for the HCPCS Common Work Group to resolve.

This simple fix in the narrative could have avoided the requirement(s) that manufacturers submit new applications for insert coding if their applications indicated the insert was made for a single patient. It would have saved the contractors and taxpayers (us) and manufacturers hundreds of thousands of man hours and hundreds of thousands of dollars.

So much for simplification. As usual, stay tuned for updates. **PM**

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.