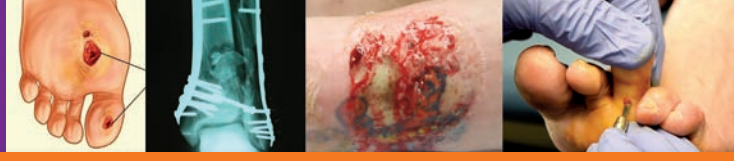

The Story Behind HCPCS Code A5513

CMS almost caused diabetic inserts to technologically regress.

BY PAUL KESSELMAN, DPM

As this issue is dedicated to diabetes, it is relevant to reprint parts of a letter submitted to *PM News* on August 18, 2017 regarding HCPCS code A5513 (custom-molded inserts for patients with diabetes). This letter provided significant details regarding a change to the requirements for custom therapeutic shoe inserts. This installment of DME for DPMs provides sections of that letter with some updated information and a prediction of where we may be headed come the Spring of 2018.

Background

In mid-July 2017, the DME MAC and PDAC issued a joint bulletin concerning A5513 (custom inserts for patients with diabetes). This bulletin stipulated that only those custom inserts manufactured with raw materials using either a physical positive mold or those molded directly against the patient's foot are the accepted methods for fabrication. It further spelled out that those manufactured in any other fashion (e.g., custom milling via the use of virtual positive images) were unacceptable.

Lastly, the bulletin indicated that suppliers could be held responsible and could be required to refund any payments made by Medicare (effective immediately) if the custom inserts were found to have been fabricated in any fashion other than by either of the two aforementioned methods. It is an understatement to say that this created a significant amount of anger, frustration, and logistical issues for all entities involved in providing custom inserts to patients.

Primarily, most central fabricating laboratories use digital data to direct mill custom-fabricated devices. The PDAC was aware that these devices were produced in this manner because the manufacturers spelled out those manufacturing processes in their PDAC applications and the PDAC issued validation letters for inserts which are direct milled. The PDAC bulletin suddenly stated a reversal of course by stipulating the current processes were "illegal". This created a significant problem for all involved.

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Secondly, for the labs, this required a change to "old" physical molds (a significant expense), and in this digital age, a backwards step (akin to going from Fed Ex to the Pony Express). This new policy now requires all manufacturers to submit a new application for each model using an old process (another expense).

Thirdly, there has been no scientific proof that using a virtual positive impression (computer model derived from a negative impression, no matter the process) is an inferior process to those produced with a physical model.

Finally, HCPCS code A5513 does not contain a requirement for a physical model in its definition. A5513 in its long description requires a model of the patient's foot (note the absence of the word "physical". The definition has clearly been misinterpreted to require a physical model by the DME MAC and CMS due to another irrational government policy.)

The reason for this sudden policy enforcement (and code interpretation) is that CMS decided to implement a longstanding section from the Supplier Quality Standards written more than a decade ago. The current document (1) as it references custom-molded devices contains few changes from the original version released in 2006. As with other government documents, it is possible the 2006 edition originated before the turn of the century (long before today's sophisticated scanning and molding/printing systems).

Pages 14-15 of the current version provide a workflow for cus-

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tom-molded devices to be fabricated from a digital or physical negative (scan, negative cast or foam) impression. Thus the manner in which most podiatrists/orthotists/pedorthists take their impression(s) is not affected by this policy. That is, one may continue to take impressions of patients by any of the above approved methods.

Quality Standards

The Quality Standards do not mention anything about manufacturing devices directly from a virtual positive image (which probably did not exist in 2000 and thus was ignored again last year). It does provide workflow for a positive digital image to construct a positive model rectification of the patient's body part. This essentially means that the computer positive is used to create a physical model over which the device must be created. This simply is an additional step which is not only unnecessary but as with every production process, leaves room for production errors at the lab. It is interesting to note that the Quality Standards do not actually stipulate that use of digital images to manufacture are prohibited. Thus, one can imagine this was either an oversight or simply ignorance of the process more than 15 years ago.

As one can imagine, this policy change did not go unnoticed by those organizations representing manufacturers and suppliers as this policy change caused considerable confusion. This apparently hastily-considered policy implementation (without hearings, comment periods, etc.) also created a number of logistical obstacles for Medicare agencies.

Many manufacturers hold PDAC validation letters which were not revoked by the July bulletin. Left as is, the resulting expensive legal nightmare for Medicare would be a public embarrassment for CMS and their agencies. They would be in for a legal argument they could likely not have won.

More important for the public, had this been enforced, an acute patient access crisis would have ensued lasting for months. Back orders would have resulted due to only a very limited number of manufacturers who either have: been hand-fabricating devices with vacuum presses and physical molds; those recently receiving approval for this old process; manufacturing devices which had long been discontinued under an old validation process; and lastly those orthotic and prosthetic (O&P) shops directly molding against the patient's foot (rare in podiatry). The reality is that these limited number of manufacturers could never have been able to put even the smallest dent in the number of orders needed to be filled on a daily basis.

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Someone with common sense (perhaps within CMS or Noridian) finally prevailed, having realized that their new policy had many unintended consequences. On August 10, 2017, the DME MAC issued another joint bulletin (perhaps as face-saving), putting a temporary (although limited) resolution to the crisis. It appears now that all A5513 PDAC validations will NOT be revoked until June 1, 2018. This gives manufacturers time to submit a new PDAC validation application incorporating this "new" requirement, albeit old technology. The bulletin stipulates there will be no grandfathering—i.e., those A5513 products with a current PDAC validation will be subject to a new application process and will NOT be given a pass beyond May 31, 2018.

Some suppliers have suggested that they would be avoiding this problem altogether by switching to all heat molded (A5512) inserts as a short-term solution until all the dust settled. But there are two excellent reasons to avoid this temptation:

Providing those patients at the highest risk and deserving of a custom insert (especially those who are doing well with a custom insert) and then switching to an off-the-shelf insert could create additional problems. Switching to a heat-molded insert may result in a patient either suffering a recurrence or worsening condition. A patient who had a successfully resolved problem with a custom insert and who now develops a new issue as the result of a heat-molded insert could also result in a potential liability for the supplier.

The second concern is that of those watching your practice patterns at Medicare, especially if you switch from a high volume of higher-paid custom inserts to a high volume of lower-paid heat-molded inserts. This trend may trigger the auditors at the various DME MAC, RAC, etc. agencies to initiate a post-payment audit for previously dispensed custom inserts. It certainly would be interesting to read chart documentations which suddenly do a 180-degree change after many years and now suddenly only document the need for a heat-molded insert.

For claims with dates of service prior to and including May 31, 2018, the current PDAC validation letters remain valid despite the recent policy announcements, and they are NOT revoked.

The following suggestions may help you in considering what to do regarding your continued use of your

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vendor(s) for custom inserts (A5513):

Since this new regulation does not become effective until June 1, 2018, most of the major custom insert manufacturers are currently working on complying with the new regulation and submitting new PDAC validations. Simultaneously, there is a collaborative effort between these manufacturers, APMA and AOPA, to either postpone or cancel the implementation of the new policy. Thus, at this time, there is no need to stop providing custom inserts (A5513) with the same vendors you currently use.

For claims with dates of service prior to and including May 31, 2018, the current PDAC validation letters remain valid despite the recent policy announcements, and they are NOT revoked. These letters will remain effective for DOS of May 31, 2018 and prior even if you submit the claims after May 31, 2018.

It bears repeating that claims for custom inserts with PDAC validation letters revoked on June 1, 2018 will not adversely impact payment for those claims as long as the dates of service are prior to and inclusive of May 31, 2018, no matter when submitted.

Claims with service dates on or after June 1, 2018 will be subject to new validation letters.

At the time this article is being composed, AOPA, APMA, PFA, and others have held many joint meetings, and each has met with Congressional delegations. The next step is for these organizations and for Congressional delegations to meet with CMS officials. The rationale for going the CMS route and political routes are simple. This appears to be a CMS initiative and the DME MAC medical directors appear to be taking the position that they did not create this issue and are powerless to correct it. Hopefully, by later this year or early next year, this issue will be resolved permanently.

The Twenty-First Century Cures Act

It is of paramount importance for CMS officials to understand that the Quality Standards are in direct opposition to the Twenty First Century Cures Act. This act requires penalties for use of old technology when more modern sophisticated technology exists (digital x-ray, for example). It also precludes CMS contractors (Medicare Payers) from implementing policies which do not embrace modern technology. The current conundrum is that CMS wishes medical professionals to embrace modern technology only on a selective basis, with no rationale other than a dusty old policy.

Even if you don't provide therapeutic shoes/inserts, this is a very important issue deserving of your attention. It has the potential to impact many other areas of your practice beyond shoes/inserts, including non-Medicare beneficiaries.

Universally, almost all orthotic manufacturers incorporate digital technology and convert your physical negatives (foams or casts) to a virtual positive. These digital positives are then used in a modern milling method

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for fabrication of inserts, orthotics, toe fillers, etc. Those of you who use scanners should know that your virtual images are almost never converted into physical positives. This, no doubt, would be a huge backwards step, but that is exactly what this policy is mandating.

The current Medicare policy requirements are a throwback to yesteryear and would result in requiring almost every lab to re-tool at an inordinate cost, forcing them to use technology they long ago abandoned. If adapted by private third-party insurance, it would impact your ability to provide orthotics to the non-Medicare population. If allowed to stand, this would also impact L5000 (toe fillers) for Medicare and non-Medicare patients alike, despite the fact that toe fillers do not require a PDAC validation. This could even have the potential to drive costs for orthotics upwards as many manufacturers attempt to recoup their investment in outdated technology, while others may go out of business.

CMS Rationale

One might ask what besides the Quality Standards motivated CMS to institute this policy?

1) Is Medicare spending an excessive amount of dollars on A5513? This is not the case. In 2015, the cost of A5513 was <.1% of the MCR budget and A5513 is ~.07% of spending on DM. So placing a stricter spending limit on A5513 would not save the Federal goverment anything worthwhile. In fact, attempting to enforce an absurd policy might likely cost the goverment more than it could ever save.

2) Is there is a study which proves that digital-created devices are less medically efficient? The answer is NO! Manufacturers across the country are universal in their agreement that producing devices via computer technology and direct milling is quicker, perhaps more efficient and precise than the old-fashioned method.

3) Is there is a study which proves that direct-milled devices are cheaper to produce than those produced manually with a positive physical model? There is universal agreement among manufacturers that one cannot assume that direct-milled devices are cheaper to produce than those produced via positive physical models.

Equipment, labor and OSHA costs for direct milling may be equivalent to producing devices derived from a physical positive model. Direct milling requires extremely expensive equipment (each assembly line costs on average a minimum of $40K for hardware, software, and milling equipment). This cost does not include maintenance costs for computers or other equipment and also requires highly-skilled higher-paid technicians to work these systems than those who produce hand-made devices.

Both methods of production also require low-cost manual labor to complete the fabrication process. This includes the addition of special accommodations and other corrections that a computer cannot accomplish. Computers and 3D technology can also be argued to produce better devices with nuances not otherwise possible with manual techniques.

If a computer can perform those tasks more rapidly with less room for errors, then why should CMS stand in the way of utilizing a more efficient process? The Quality Standards are severely outdated and need to be rewritten. The days of 3D printing are upon us and the Quality Standards, if not rewritten, may continue to stand in the way of further evolution of modern manufacturing techniques.

My prediction (and wish) is:

1) For the parties still being identified at CMS to come to understand (by virtue of educational meetings with APMA, AOPA, etc.) that enforcing the "Quality Standards" as they apply to custom-molded devices is contrary to quality care and the 21st Century Cures Act.

2) CMS will institute a one-year (or more) stay on implementation of the August 2017 policy requirements.

3) CMS will assemble a panel of educated parties to rewrite the Quality Standards to bring them up-to-date with modern manufacturing techniques.

As a final note on therapeutic shoes, DME MAC Regions B, C and D are no longer conducting widespread pre-payment audits on diabetic footwear. Region A is likely to discontinue shortly as well. This should not be a reason to let your guard down with your documentation. There is a shift regarding widespread pre-payment audits, to targeting high frequent billers of specific codes and the provision of educational forums (whether in person or via web based-forums) to increase compliance. One should continue to follow stringent documentation requirements of the LCD, as post-payment recoupment via other CMS agencies is increasing. **PM**

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References

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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.