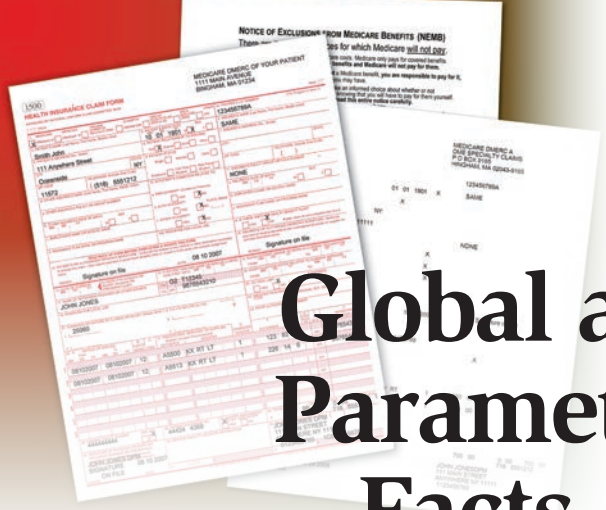

Global and Coverage Parameters for DME, Facts and Fiction

How frequently can you dispense specific DME products?

BY PAUL KESSELMAN, DPM

How frequently specific DME products may be provided to patients has been a popular question often raised at lectures and in many online forums. A recent *Codingline* question from a colleague raised the following question: "I just was doing a follow-up with a patient that I sent to an off-site orthotist for custom diabetic insoles and a hallux toe filler on the left orthotic. When I asked the patient if he got the three pairs of insoles (to be replaced quarterly), he told me no, he only got one pair. I called the orthotist's office to ask why that was, and they informed me that under the new Medicare guidelines "toe fillers" on orthotics makes them technically a prosthetic and Medicare will pay for only one pair a year. Has anyone else run across this issue?

The answer provided by the orthotist to the podiatrist was only partially correct, worthy of further explanation, and is the subject of this month's column: *Global and Coverage Parameters for DME, Facts and Fiction.*

In reviewing the above question, several key issues need to be addressed, the most important being that similar to CPT coding, there are global periods specific for each HCPCS device. There is no simple answer that applies to every HCPCS code. In addition, when one mixes HCPCS codes covered by different LCD policies, this often leads to confusion. Which device is covered and is this an issue of global or coverage parameters or is this related to Medically Unnecessary Edits (MUE)? Here are some common coverage issues which you should be aware of:

1) Diabetic patients who qualify for therapeutic shoes and who require a toe filler. This is a unique circumstance where patients may qualify under coverage for both policies (Therapeutic Shoe for Patients with Diabetes and Lower Limb Prosthesis). However, this does not infer that Medicare will provide coverage for both a custom insert and a toe filler for the same limb. Patients are not entitled to a pair of custom inserts if they are receiving a prosthetic toe filler (L5000). A patient cannot simultaneously use both types of devices on the identical anatomical site.

Medicare's policy under these circumstances is that it will pay for either an L5000 or an A5513 insert on one specific limb. That is, the foot receiving the toe filler will not also be reimbursed for custom inserts. Thus, in the above scenario, the orthotist's office was correct. A patient would be entitled to receive three custom inserts for the right foot (assuming she meets the medical necessity requirements for A5513) and a toe filler (L5000) on the left foot.

It is crucial to remember that the A5513 custom insert(for diabetic patients only) and L5000 are for very different devices, with coverage parameters in two different DME MAC policies. A5513 devices are described in the provision of the Therapeutic Shoes for Patients with Diabetes LCD, whereas coverage for L5000 (PARTIAL FOOT, SHOE INSERT WITH LONGITUDINAL ARCH, TOE FILLER) is described in the Lower Limb Prosthetics LCD.

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Other than simultaneous usage, these policies are mutually exclusive of each other, in particular regarding global and medical necessity issues. The orthotist's office was incorrect by stating that this was a "new policy" and by stating the patient automatically qualified for an L5000 (see #3).

More information on diabetics who may require therapeutic inserts and custom toe fillers may be found

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at: https://www.cgsmedicare.com/jc/pubs/news/2012/0512/cope19059.html

2) Non-diabetic patients with a transmetatarsal amputation almost certainly qualify for a toe filler. However, they would not qualify for shoes or any provision within the LCD describing therapeutic shoes. Thus these patients may require the same shoe as the diabetic patient. However, shoes provided in this scenario would be best addressed under the Orthopedic Footwear LCD. In this scenario, shoes would not be a covered service. One should refer to that policy for the appropriate HCPCS codes (L3215-L3640) for your patient.

3) Medical necessity for the toe filler is not automatically established in patients with a hallux (partial or complete) amputation. From the original question posed, there is an insufficient amount of clinical information to substantiate the need for a custom toe filler. A patient with a transmetatarsal amputation may automatically qualify for an L5000 (and possibly higher level) prosthetic. The patient with a single (hallux or lesser) toe amputation must demonstrate significant gait abnormalities in order to qualify for an L5000 code. The prescribing physician must document why a prosthetic device is required to provide stability. A patient with a single lesser toe amputation may almost never qualify for an L5000. However, a diabetic neuropathic patient with a complete (or nearly total) hallux amputation with deformities of the lessor digits may qualify for an L5000.

4) Custom therapeutic inserts are a calendar year benefit. No more than three inserts per foot will be covered per calendar year, with more limiting issues found in the Therapeutic Shoe for Patients with Diabetes LCD.

5) Toe fillers do not have a specific calendar year or specific time-limiting parameter. That is for devices described under the Lower Limb Prosthetic LCD. Prosthetic devices may be covered based on medical necessity. That is, there is no calendar year permit or "five year rule" as applies to AFO/KAFO (see below) devices, because L5000 (toe fillers) are not described in the AFO/LCD. Thus, none of the policy restrictions found in the AFO/KAFO LCD apply to L5000.

6) Therapeutic shoes, while covered by the DME MAC, are actually not DME and are a carve-out benefit covered by a Congressional Act. It is of particular importance to pay strict attention to the benefits and restrictions contained within this policy.

7) Medically Unnecessary Edits (MUE) are a complex set of rules similar to CCI. CMS sets limits on how many of a specific HCPCS code or codes may be provided to a beneficiary on one day.

Other DME Parameters to Consider

AFO/KAFO Policy

Most, if not all, AFO/KAFO devices (L1900-L4631) are subject to a five-year lifetime expectancy. This is also referred to as "Global Period" during which time a replacement device will under most circumstances not be covered. That is, Medicare will not pay for a replacement device within a five-year period if the replacement is required because of normal wear and tear (aka Irreparable Wear). This expectation, however, does not translate to devices not subject to the AFO/KAFO policy—therapeutic shoes, surgical dressings, and many other DMEPOS. Upon reviewing the AFO/KAFO policy, one should note that there are also provisions permitting exceptions to the five-year rule. These include:

1) Irreparable loss or damage: Replacement of a complete orthosis or component of an orthosis due to loss is covered if the device is still reasonable and necessary. Examples of irreparable loss and damage include one-time events leading to the destruction or loss of a device (e.g., fire, theft, car runs over a device). These must be documented in the chart, and having the patient obtain a police report is strongly advised. In addition to the specific HCPCS codes and usual modifiers (e.g., KX, RT), the RA modifier must be included. This will indicate to the DME MAC that the device is being replaced due to irreparable loss or damage.

2) Significant change in the beneficiary's condition such as a substantial change in the patient's weight or diagnosis making the current device inappropriate. Examples of the latter include a patient wearing an AFO with a flexible hinge who now requires a dorsiflexion assist or solid AFO.

Replacement of a complete orthosis or component of an orthosis due to loss is covered if the device is still reasonable and necessary.

3) For a custom CROW boot (L4631), a change in the Charcot deformity making the current device inappropriate. In any case, where one is claiming a change in the patient's clinical condition, it is important to document why the current device is inappropriate (or dangerous) for the patient to wear.

4) Night splints for plantar fasciitis (L4396/L4397) include a soft tissue interface which is not separately covered at the time of the initial dispensing. These devices have a five-year expected useful lifetime. However, a replacement interface (L4392) is covered as long as the beneficiary continues to meet indications and other coverage rules for the splint. Coverage of a replacement interface is limited to a maximum of one (1) per six months. Additional interfaces will be denied as not reasonable or necessary.

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5) Surgical dressings: are a benefit with unique provisions based on the type of dressing(s) dispensed. The frequency of each type of surgical dressing (Hydrogel, Alginate, etc.) is specifically stipulated in the Surgical Dressing LCD. The frequency (units dispensed) is based on the amount of drainage and do not allow for more than a 30-day supply at a time. The inherent expectation is that patients will need fewer dressings as healing progresses and with each prescription renewal.

The frequency of each type of surgical dressing (Hydrogel, Alginate, etc.) is specifically stipulated in the Surgical Dressing LCD.

Summary

DMEPOS are subject to different global periods stipulated in the LCD and MUE. Each HCPCS device belongs to a family of devices covered under the jurisdiction of a specific DME MAC LCD. Coverage qualifications and unique frequency allowances are specified within each LCD. One should not automatically assume that devices covered by the DME MAC have the same frequency. This is no different than surgical procedures which also have specified global periods specified either in LCD or CPT. Since each family of devices has unique circumstances and since these devices are often expensive and labor intensive to produce, it is important to confirm that your patient is entitled to a new device (based on both clinical and other parameters). Subscribing to your DME MAC web-based provider portal is the best way to ensure compliance within the aforementioned requirements. **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.