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For Durable Medical Equipment (DME) Suppliers and Inventors

Several callers have requested help to obtain a billing code, having been advised this step is required to gain Medicare reimbursement. This is a free self-help guide. I am available to consult if needed.

Medicare claims use two sets of billing codes to describe items and services: HCPCS and CPT. CMS administers HCPCS codes. AMA administers CPT codes. Medicare requires a HCPCS code for DME reimbursement. CPT codes do not apply to DME items.

Medicare posts its general DME requirements for reimbursement here in Section 110.1. Not all DME items qualify. Requirements of commercial plans may differ.

If your DME item is new, your first step is to review the DMEMAC site for a relevant local coverage decision (LCD) and associated Policy Article which govern the category of devices that includes yours. If a relevant LCD exists, confirm your device is congruent to the devices that are covered. If your device is not congruent, consider whether you wish to change it before going to the FDA for market approval. The intended use statement of your item set forth by the FDA must conform to indications and limitations of coverage statement in the LCD.

Your next step will be to gain approval from the FDA to market it in the U.S. If you need an FDA consultant, I can provide referrals. Once you have FDA clearance, you may apply for a HCPCS Level II code for billing of DME to all insurance companies.

You may attempt to secure a HCPCS code and coverage concomitantly. Although you can contact CMS directly for a code, I recommend you request PDAC assign a code to your device. The process is called code verification review. CMS contracts with the PDAC to provide this service. The PDAC has excellent customer service designed to help you. If you need help with your PDAC code verification application, contact the PDAC or me.

If the PDAC verifies your item is described by an existing code, PDAC will add it to its list of products described by that code. Then your item will be covered under the relevant LCD and the payment amount from Medicare will be 80% of that which is allowed for that code. Others are responsible to pay the remaining 20%

If your item is truly new, PDAC will assign to it a miscellaneous code (A.K.A. Not otherwise specified—NOS--/generic/unlisted). You can use the formal PDAC letter of assignment to apply to HCPCS Level II Work Group at CMS for a new specific code that generically describes your

device. Until the Group decides, your supplier may use the NOS code to bill the DMEMACs and other insurers. However, unless your device is covered, the DMEMAC will deny payment.

You may request one of the DMEMACs to cover your device concomitantly with your code application to CMS. If you found a relevant LCD you will ask the DME policy people to reconsider the LCD and add your device to it. Most likely your device will be subject to the same indications and limitations that govern those listed in the LCD. If no LCD governs your device, you may request the DMEMAC create a new LCD.

The coverage process for a new type of DME item requires you prove, with scientific evidence, that your device satisfies Medicare coverage requirements which are set forth starting with Chapter 110 in the Medicare Benefit Policy Manual. Not only must your item fulfill all of the DME requirements for a Medicare benefit, it must be medically necessary to diagnose or treat an illness or injury or repair the function of a deformed body member. Typically, the information you provided to the FDA for its marketing approval is insufficient for Medicare coverage.

If the DMEMAC refuses to cover your device, all is not lost. You may appeal its denial to CMS. I can help you with this step. On the other hand, with your FDA clearance to market, you may prefer to sell your device directly to patients on the retail market. Medicare would not be involved.

Benefit category rules vary between commercial insurance companies and Medicare. Some items may be a benefit of commercial plans but not a benefit of Medicare. Examples include certain nebulizers and disposable insulin pumps. Typically, medical necessity requirements are the same or very similar.

In summary, the steps to gain payment for DME from Medicare and other third-party payers in the U.S include addressing your statement of intended use, applying for a code verification, addressing coverage, and the need for a new code.

Disclaimers. This document does not constitute legal advice. Medicare regulations constantly change, which could make some parts of this document obsolete.