

Custom Fabricated Durable Medical Equipment (DME)

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Introduction

Custom fabricated durable medical equipment (DME) is addressed by this guideline.

Criteria

Custom fabricated DME is indicated when basic coverage criteria have been met, the condition requiring the device is anticipated to be permanent or of long-standing duration, and **any** of the following:

- The individual has a medical condition that necessitates the creation of a **custom made device**.
- The individual is unable to be fitted with a standard pre-made device.
- The individual has failed a trial with a standard pre-made device.

Definitions

A **custom fabricated item** is made for a specific individual based on clinically derived castings, tracings, molds, or images of the body part. Custom fabrication may be appropriate when specific fit issues are unable to be addressed by adjusting a prefabricated item (e.g., cutting, bending, adding extra straps). Custom fabricated additions are appropriate only for custom fabricated orthoses and should not be billed with prefabricated orthoses.

A **molded-to-individual-model** is a particular type of custom fabricated device in which either: an impression (usually by means of a plaster or fiberglass cast) of the specific body part is made directly on the individual, and this impression is then used to make a positive model of the body part from which the final product is crafted; or a digital image of the individual's body part is made using computer-aided design/computer-aided manufacturing (CAD/CAM) systems software. This technology includes specialized probes/digitizers and scanners that create a computerized positive model, and then direct milling equipment to carve a positive model. The device is then individually fabricated and molded over the positive model.

A **positive model** is an exact replica of the actual body part for which the custom fabricated device is being constructed. Fabrication of a device using molding, CAD/CAM, or similar technology without the creation of a positive model is considered to be a prefabricated device.

References

1. Social Security Act of 1935, 42 U.S.C. 1395x § 1861(n) (2024). https://www.ssa.gov/OP_Home/ssact/title18/1861.htm
2. Centers for Medicare & Medicaid Services (CMS). Public Health Act - Title 42, Chapter IV, Subchapter B, Part 414, Subpart D, § 414.202 (42 CFR 414.202). 2024 ed1990. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-414/subpart-D/section-414.202>
3. Medicare Local Coverage Article (LCA): Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426) <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55426&ver=110&bc=0>
4. Centers for Medicare & Medicaid Services (CMS). Public Health Act - Title 42, Chapter IV, Subchapter B, Part 410, Subpart B, § 410.10 (42 CFR 410.10). 2024 ed1990. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-410/subpart-B/section-410.10>
5. Medicare National Coverage Determination (NCD): Durable Medical Equipment Reference List (280.1) <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=190&ncdver=3&bc=0>
6. Centers for Medicare & Medicaid Services (CMS). Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services, Section 110.2 - Repairs, Maintenance, Replacement, and Delivery (2015). <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>
7. Teel J, Wang JY, Loschiavo M. Durable medical equipment: a streamlined approach. *Fam Pract Manag.* 2021;28(2):15-20
8. White NT, Delitto A, Manal TJ, Miller S. The American Physical Therapy Association's top five choosing wisely recommendations. *Phys Ther.* 2015;95(1):9-24. doi:10.2522/ptj.20140287
9. Centers for Medicare & Medicaid Services, Medicare Learning Network. DMEPOS Quality Standards (MLN905709). Updated 2023. Accessed 19 August, 2024. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html>
10. Titus L, Guilbault L, Mortenson B, et al. Wheeled Mobility and Seating Equipment Following Spinal Cord Injury. In: Eng J, Teasell R, Miller W, et al., eds. *Spinal Cord Injury Rehabilitation Evidence*. 7.0 ed. 2019. <https://docslib.org/doc/6424031/wheeled-mobility-and-seating-equipment-following-spinal-cord-injury>
11. Medicare Local Coverage Determination (LCD): Ankle-Foot/Knee-Ankle-Foot Orthosis (L33686)/LCA (A52457) <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33686>
12. Johnston TE, Keller S, Denzer-Weiler C, Brown L. A clinical practice guideline for the use of ankle-foot orthoses and functional electrical stimulation post-stroke. *J Neurol Phys Ther.* 2021;45(2):112-196. doi:10.1097/NPT.0000000000000347
13. Medicare Local Coverage Determination (LCD): Spinal Orthoses: TLSO and LSO (L33790) / LCA (A52500). <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33790>
14. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int.* 2022;33(10):2049-2102. doi:10.1007/s00198-021-05900-y