

Custom Fabricated Durable Medical Equipment (DME)

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Introduction

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

Health Equity Consideration

Health equity is the highest level of health for all individuals; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which individuals are born, grow, live, work, and age. Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include the following: safe housing, transportation, and neighborhoods; racism, discrimination, and violence; education, job opportunities, and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

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.

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