

***Proposed* Definitions of  
Custom Fabricated and Therapeutic Inserts  
DMEPOS Quality Standards**

1. **Custom Fabricated:** A custom fabricated item is one that is individually made for a specific patient. No other patient would be able to use this item. A custom fabricated item is a device which is fabricated based on clinically derived and rectified castings, tracings, measurements, and/or other images (such as x-rays) of the body part. The fabrication may involve using calculations, templates and components. This process requires the use of basic materials including, but not limited to plastic, metal, leather or cloth in the form of uncut or unshaped sheets, bars, or other basic forms and involves substantial work such as vacuum forming, cutting, bending, molding, sewing, drilling and finishing prior to fitting on the patient.
  - a. Molded-to-Patient-Model: A particular type of custom fabricated device in which one of the following techniques is used:
    - i. An impression (usually by means of a plaster or fiberglass cast) of the specific body part is made directly on the patient, and this impression is then used to make a positive model of the body part from which the final product is crafted; or
    - ii. A digital image of the patient'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 of the patient.
    - iii. *For inserts used with therapeutic shoes for diabetes, a digital image of the patient's body part is made using 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 beneficiary-specific insert.*
  - b. Positive Model of the Patient is created by one of the following:
    - i. Molded-to-patient-model is a negative impression taken of the patient's body member and a positive model rectification is constructed;
    - ii. CAD-CAM system, by use of digitizers, transmits surface contour data to software that the practitioner uses to rectify or modify the model on the computer screen. The data depicting the modified shape is electronically transmitted to a commercial milling machine that carves the rectified model; or
    - iii. Direct formed model is one in which the patient serves as the positive model. The device is constructed over the model of the patient and is then fabricated to the patient. The completed custom fabrication is checked and all necessary adjustments are made; or
    - iv. *For inserts used with therapeutic shoes for diabetes, a CAD-CAM system, by use of digitizers, transmits surface contour data to software that the practitioner uses to rectify or modify the model on the computer*

*screen. The data depicting the rectified model is electronically transmitted to a commercial milling machine that carves the patient-specific insert.*

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10. **Therapeutic Shoes and Inserts:** Includes depth or custom-molded shoes along with inserts for individuals with diabetes (Refer to Section 140 of Chapter 15 of the Medicare Benefit Policy Manual).

**a. Custom-Molded Shoes:**

- Are constructed over a positive model of the patient's foot;
- Are made from leather or other suitable material of equal quality;
- Have removable inserts that can be altered or replaced as the patient's condition warrants; and
- Have some form of shoe closure.

**b. Depth Shoes:**

- Have a full length, heel-to-toe filler that, when removed, provides a minimum of 3/16 inch of additional depth used to accommodate custom-molded or customized inserts;
- Are made from leather or other suitable material of equal quality;
- Have some form of shoe closure; and
- Are available in full and half sizes with a minimum of three widths so that the sole is graded to the size and width of the upper portions of the shoes according to the American standard last sizing schedule or its equivalent. (The American standard last sizing schedule is the numerical shoe sizing system used for shoes sold in the United States.)

**c. Inserts:**

- *Are total contact, multiple density, removable inlays;*
- *Are directly molded to the patient's foot or a model of the patient's foot or directly carved from a patient-specific, rectified electronic model; and*
- *Are made of a suitable material with regard to the patient's condition.*