

# Types of Fabrication

Definitions matter.

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Are the devices advertised to us as custom, truly custom? With the advent of modern manufacturing techniques, the answer may not always be as obvious as one may think. This article will elaborate on this question and how this may affect your reimbursement.

Traditionally, podiatrists have prescribed and/or dispensed types of orthotic devices (foot, ankle foot, and knee ankle foot) for the lower extremity. Each of these can be provided to the patient in one of three categories:

1) **Custom Fabricated:** This type of device is made from raw materials with the intent to fit a single patient. These devices typically require significant skill to produce. The clinician may take a variety of measurements and negative impressions with scans/casts of the body part. This may or may not result in the production of a positive mold of the patient's extremity (thus custom molded device), or the measurements or scan may provide a virtual positive. This can lead to either a custom device being milled by a router or the computer can produce a positive model over which a device is manufactured. The result is a truly custom-made device for a specific patient. With the advent of 3D and 4D printers, other additive rather than subtractive manufacturing techniques are now employed. But custom fabricated devices are not the only category of custom devices available.

2) **Custom Fitted:** This type of device is pre-fabricated in large quantities by manufacturers with no specific patient in mind. They may come in a variety of sizes (e.g., small, medium, large) or in a large variety of SKU with specific parameters in

mind (medial arch height, foot width, length, circumference, or diameter, etc.) With these specific measurements in mind, the practitioner selects one specific device for a patient. The device is then further significantly adjusted or modified to make this device specific for the individual patient for whom it is prescribed. There are many potential modifications then made, including but not limited to adding postings, grinding, heating, additional relief paddings, etc. These

if modern-day devices all neatly fit into these categories.

## Custom-Fabricated Devices

From recent history with therapeutic shoe inserts, we have come to understand that there are two different types of custom fabricated shoe inserts. A custom molded, custom fabricated device is derived from a physical positive model. This can be derived from either a physical or virtual negative impression. But that is only one type

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are all done to significantly alter a device so that by the time the device is dispensed to the patient, it will have undergone significant changes, rendering it unique to fit for one specific patient. A qualifier by Medicare, is that for a device to qualify as custom fitted, these modifications must have been performed by a qualified healthcare provider. That person must be a licensed healthcare provider (DPM, MD/DO, CO, CPO, CPed, etc.).

3) **Off-the-shelf (OTS):** Like custom fitted devices, these pre-fabricated devices are made in huge quantities in a variety of sizes and shapes with no specific patient intended in mind. Any adjustments to these devices are usually minimal, not requiring the skills of a qualified healthcare provider. The minimal self-adjustment can often be done by the patients themselves.

Based on these traditional, tried, and true definitions, one may wonder

of custom fabricated device. Custom milled orthotics also qualify as custom fabricated devices. The manufacturing process with a custom milled device typically includes either a physical negative or body part scan, either of which is used to create a virtual positive. This virtual image of the patient's foot is then used to create an insert. Hence the term custom milled, but nevertheless still custom fabricated. 3D printed devices are currently not considered custom fabricated by Medicare.

Custom fabricated devices in the orthotic/prosthetic world may also involve taking intricate measurements of the patient's anatomy, which are then used to produce a device from raw materials. While this does not meet the definition of a custom molded device, it is, nevertheless, still custom fabricated. Many custom fabricated spinal orthotics (back braces) are

*Continued on page 36*

## *Fabrication (from page 35)*

made using this technique with the patient serving as the model.

Another option for custom fabricated devices are kits with numerous parts, which first must be molded directly onto the patient, with the patient again serving as the anatomical model. The other parts provided are then assembled onto the main structure of the device. These devices may also be considered custom fabricated because many raw materials or designated parts need to be assembled while the device is molding to the patient's extremity.

Custom fabrication often takes time to manufacture and may require prior authorization. Custom fabricated devices cannot be provided on demand to serve an urgent or immediate need.

### **Custom-Fitted and OTS Devices**

Custom fitted and OTS devices can be provided on demand to fit an

urgent need and may not require prior authorization. They usually, but not always, have a lower wholesale cost and can be stocked in the office. Custom fitted devices may require in-office, time-consuming modifications by the clinician, needing the requisite skills to perform these modifications, which would have otherwise been performed by a laboratory providing custom fabricated orthotics.

### **Resolving Confusion**

Last to consider are manufacturers advertising consumer products as custom. This creates confusion for our patients, often requiring us to resolve for the patient the differences between custom vs. non-custom.

To summarize the difference between custom and off-the-shelf (over-the-counter) is to ask these questions:

1) Was the device pre-fabricated, taken out of the package, and dispensed with no modification performed by a healthcare provider? If the

answer is yes, the device is not custom, and it is off-the-shelf/over-the-counter.

2) Was the device made from raw materials using patient measurements, scans casts, etc.?

Then the device is likely custom fabricated.

3) Was the device pre-fabricated with no intended patient in mind, then assembled and/or undergone significant modification by a healthcare practitioner? If so, then it is custom fitted. **PM**



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