

• ORTHOTICS CHART | JURISDICTION B •

OFF-THE-SHELF

- Prefabricated
- May or may not be supplied as a kit that requires some assembly.
- Requires *minimal* self-adjustment for fitting at the time of delivery. This may be done by the beneficiary or the supplier.
- Does **NOT** require expertise in trimming, bending, molding, assembling, or customizing to fit an individual.
- Does **NOT** require the expertise of a certified orthotist or an individual who has specialized training in the provision of orthoses to fit the item to the beneficiary.
- Use of CAD/CAM or similar technology to create an orthosis *without a positive model* of the patient may be considered off-the-shelf if the final fitting upon delivery to the beneficiary requires **minimal** self-adjustment.

Refer to the applicable Policy Articles for additional information: <http://www.cgsmedicare.com/jb/coverage/lcdinfo.html>

The DMEPOS Quality Standards are located at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html>

CUSTOM-FIT

- Prefabricated
- May or may not be supplied as a kit that requires some assembly.
- Requires *more than* minimal self-adjustment at the time of delivery.
- The item must be trimmed, bent, molded, or otherwise modified for individualized fit, resulting in alterations beyond minimal self-adjustment.
- Fitting at delivery **REQUIRES** the expertise of a certified orthotist or an individual who has specialized training in the provision of orthosis to fit the item to the beneficiary.
- Use of CAD/CAM or similar technology to create an orthosis *without a positive model* of the patient may be considered as custom fitted if the final fitting upon delivery to the patient requires **more than minimal** self-adjustment requiring expertise.
- In addition to the "reasonable and necessary" criteria documentation must be sufficiently detailed to include, but is not limited to, a detailed description of the modifications necessary at the time of fitting the orthosis to the beneficiary. This information must be available upon request.

CUSTOM-FABRICATED

- ▶ Made for a **specific beneficiary**.
- ▶ Positive model, exact replica of a body part
- ▶ Involves *substantial work* such as vacuum forming, cutting, bending, molding, sewing, etc.
- ▶ **Requires more than trimming, bending, or making other modifications to a prefabricated item.**

Two categories for billing:

- ▶ Orthoses that are custom fabricated by a manufacturer/central fabrication facility and then sent to someone other than the beneficiary. See specific LCDs and Policy Articles for codes.
- ▶ Orthoses that are custom fabricated from raw materials and are dispensed directly to the beneficiary by the entity that fabricated the orthosis. These items do not have to be listed on the PDAC website in order to be billed using a custom code. However, the supplier must provide a list of the materials that were used and a description of the custom fabrication process on request.
- ▶ In addition to the "reasonable and necessary" criteria there must be detailed documentation in the treating practitioner's records to support the medical necessity of custom fabricated rather than a prefabricated orthosis as described in the Coverage Indications, Limitations and/or Medical Necessity section of the related LCD. This information will be corroborated by the functional evaluation in the orthotist's or prosthetist's records. This information must be available upon request.