DOCUMENTATION CHECKLIST

JURISDICTIONS B & C

Ankle-Foot/Knee-Ankle-Foot Orthosis

REQUIRED DOCUMENTATION

☐ **Standard Written Order (SWO)/Written Order Prior to Delivery (WOPD)**

NOTE: Some codes may require a Face-to-Face (F2F) Encounter and WOPD. See the required F2F and WOPD List at: https://www.cms.gov/files/document/required-face-face-encounter-written-order-prior-delivery-list.pdf

- ○ Beneficiary's name or Medicare Beneficiary Identifier (MBI)
- ○ Order Date
- ○ General description of the item
  - ☐ The description can be either a general description (e.g., ankle orthoses), a HCPCS code, a HCPCS code narrative, or a brand name/model number
  - ☐ For equipment – In addition to the description of the base item, the SWO may include all concurrently ordered options, accessories or additional features that are separately billed or require an upgraded code (List each separately).
  - ☐ For supplies – In addition to the description of the base item, the DMEPOS order/prescription may include all concurrently ordered supplies that are separately billed (list each separately)
- ○ Quantity to be dispensed, if applicable
- ○ Treating Practitioner Name or NPI
- ○ Treating Practitioner's signature
  - ☐ Practitioner's signature on the written order meets CMS Signature Requirements 100-08 Program Integrity Manual (PIM), Chapter 3, Section 3.3.2.4
- ○ Standard Written Order was obtained prior to submitting the claim to Medicare or prior to delivering the item

  Refer to the WOPD lookup tool under **Online Resources (below) to determine when a WOPD is required*
- ○ Any changes or corrections have been initialed/signed and dated by the ordering practitioner

☐ **Delivery Documentation**

Direct Delivery	Shipped/Mail Order Tracking Slip	Shipped/Mail Order Return Post-Paid Delivery Invoice
☐ Beneficiary's name ☐ Delivery address ☐ Quantity delivered ☐ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ☐ Delivery date ☐ Signature of person accepting delivery ☐ Relationship to beneficiary	☐ Shipping invoice ○ Beneficiary's name ○ Delivery address ○ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ○ Quantity shipped ☐ Tracking slip ○ References each individual package ○ Delivery address ○ Package I.D. #number ○ Date shipped ○ Date delivered ☐ A common reference number (package ID #, PO #, etc.) links the invoice and tracking slip (may be handwritten on one or both forms by the supplier)	☐ Shipping invoice ○ Beneficiary's name ○ Delivery address ○ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ○ Quantity shipped ○ Date shipped ○ Signature of person accepting delivery ○ Relationship to beneficiary ○ Delivery date

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Ankle-Foot/Knee-Ankle-Foot Orthosis

NOTE: Custom Fitted and Custom Fabricated items require fitting at the time of delivery (cannot be shipped to the Beneficiary)

Medical Records

AFOs NOT USED DURING AMBULATION:

An L4396 or L4397 (Static or dynamic positioning ankle-foot orthosis) is covered if either all of criteria 1–4 or criterion 5 is met:

1. Plantar flexion contracture of the ankle (refer to the Group 1 Codes in the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses) with dorsiflexion on passive range of motion testing of at least 10 degrees (i.e., a nonfixed contracture); and
2. Reasonable expectation of the ability to correct the contracture; and
3. Contracture is interfering or expected to interfere significantly with the beneficiary's functional abilities; and
4. Used as a component of a therapy program which includes active stretching of the involved muscles and/or tendons.
   - When an L4396 or L4397 is used for the treatment of a plantar flexion contracture, the pre-treatment passive range of motion must be measured with a goniometer and documented in the medical record.
   - Documentation of an appropriate stretching program carried out by professional staff (in a nursing facility) or caregiver (at home).

OR

5. The beneficiary has plantar fasciitis (refer to the Group 1 Codes in the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses).

AFOs AND KAFOs USED DURING AMBULATION:

Ankle-foot orthoses (AFO) described by codes L1900, L1902, L1904, L1906, L1907, L1910, L1920, L1930, L1932, L1933, L1940, L1945, L1950, L1951, L1952, L1960, L1970, L1971, L1980, L1990, L2106, L2108, L2112, L2114, L2116, L4350, L4360, L4361, L4386, L4387 and L4631

- ☐ Medical records document an ambulatory beneficiary with weakness or deformity of the foot and ankle, who also
- ☐ Require stabilization for medical reasons, and
- ☐ Have the potential to benefit functionally.

Knee-ankle-foot orthoses (KAFO) described by codes L2000, L2005, L2010, L2020, L2030, L2034, L2035, L2036, L2037, L2038, L2126, L2128, L2132, L2134, L2136, and L4370

- ☐ Medical records document the above for an ambulatory beneficiary and additional knee stability is required.

Custom-Fabricated AFOs and KAFOs are covered for ambulatory beneficiaries when the basic coverage criteria above and one of the following criteria are met:

- ☐ The beneficiary could not be fit with a prefabricated AFO; or
- ☐ The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months); or
- ☐ There is a need to control the knee, ankle, or foot in more than one plane: or
- ☐ The beneficiary has a documented neurological, circulatory, or orthopedic status that requires custom fabricating to prevent tissue injury; or
- ☐ The beneficiary has a healing fracture which lacks normal anatomical integrity or anthropometric proportions.

REMINDERS

- A Written Order Prior to Delivery (WOPD) and Face-to-Face (F2F) Encounter is required for specific HCPCS in the Ankle-Foot/Knee-Ankle-Foot Orthoses LCD. **Refer to the lookup tool **(below)**.*

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Ankle-Foot/Knee-Ankle-Foot Orthosis

- Prior Authorization is required for specific HCPCS in the Ankle-Foot/Knee-Ankle-Foot Orthoses LCD. **Refer to the lookup tool **(below)**.*
- Newly enrolled DMEPOS suppliers and those undergoing 100% change of ownership are under Probationary Prior Authorization (PPA) effective October 15, 2026, for specific codes.
  - JB: https://www.cgsmedicare.com/jb/pa/probationary-prior-authorization.html
  - JC: https://www.cgsmedicare.com/jc/pa/probationary-prior-authorization.html

Custom-Fabricated Orthoses

There must be documentation in the supplier's records to support the medical necessity of that type of device rather than a prefabricated orthosis.

- ☐ Provide the product that is specified by the treating practitioner
- ☐ The treating practitioner's medical record justifies the need for the type of product (i.e., prefabricated versus custom fabricated)
- ☐ Bill for the HCPCS code that accurately reflects both the type of orthosis and the appropriate level of fitting
- ☐ Detailed documentation in the supplier's record that justifies the code selected

Custom-fabricated additions are appropriate only for custom-fabricated base orthotics and should not be billed with prefabricated base orthotics.

Additions will be denied as not reasonable and necessary if either the base orthosis is not reasonable and necessary, or the specific addition is not reasonable and necessary.

Prefabricated Orthoses

There is no physical difference between orthoses coded as custom fitted versus those coded as OTS.

The differentiating factor for proper coding is the need for "minimal self-adjustment" at the time of fitting by the beneficiary, caretaker for the beneficiary, or supplier.

This minimal self-adjustment does not require the services of a certified orthotist or an individual who has specialized training. Items requiring minimal self-adjustment are coded as OTS orthoses. For example, adjustment of straps and closures, bending or trimming for final fit or comfort (not all-inclusive) fall into this category.

Custom Fitted Orthoses

Are coded as custom fitted and require more than minimal self-adjustment by a qualified practitioner:

- Documentation must be sufficiently detailed to include, but is not limited to, a detailed description of why the modifications are necessary and what modifications were performed at the time of fitting the orthosis to the beneficiary.

ONLINE RESOURCES

- **Local Coverage Determination (LCD) and Policy Articles (PAs)**
  - JB: https://www.cgsmedicare.com/jb/coverage/lcdinfo.html
  - JC: https://www.cgsmedicare.com/jc/coverage/LCDinfo.html
- **Definitions Used for Off-the-Shelf versus Custom Fitted Prefabricated Orthotics (Braces) – Correct Coding**
  - JB: https://www.cgsmedicare.com/jb/pubs/news/2021/03/cope20993.html
  - JC: https://www.cgsmedicare.com/jc/pubs/news/2021/03/cope20993.html
- **DME MAC Supplier Manual**
  - JB: https://www.cgsmedicare.com/jb/pubs/index.html
  - JC: https://www.cgsmedicare.com/jc/pubs/index.html
- **Orthoses Required Prior Authorization**
  - JB: https://www.cgsmedicare.com/jb/mr/orth_prior_auth.html
  - JC: https://www.cgsmedicare.com/jc/mr/orth_prior_auth.html

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- **WOPD Code Lookup—***Check this link to see if you must have a FTF and WOPD prior to delivering the item to the beneficiary*
  - JB: https://www.cgsmedicare.com/medicare_dynamic/jb/wopd/wopd.aspx
  - JC: https://www.cgsmedicare.com/medicare_dynamic/jc/wopd/wopd.aspx
- **Prior Authorization Lookup Tool—***Check this link to see if you must submit a prior authorization for the item you are providing*
  - JB: https://www.cgsmedicare.com/medicare_dynamic/jb/pa/pa.aspx
  - JC: https://www.cgsmedicare.com/medicare_dynamic/jc/pa/pa.aspx
- **DMEPOS Quality Standards**
  https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html

NOTE: It is expected that the beneficiary's medical records will reflect the need for the care provided. These records are not routinely submitted to the DME MAC but must be available upon request. Therefore, while it is not a requirement, it is a recommendation that suppliers obtain and review the appropriate medical records and maintain a copy in the beneficiary's file.

DISCLAIMER

This document was prepared as an educational tool and is not intended to grant rights or impose obligations. This checklist may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either written law or regulations. Suppliers are encouraged to consult the DME MAC Supplier Manual and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.

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