Item 1: Documentation from the Ordering Physician

Note: The Physician must evaluate the patient and document medical necessity, functional capabilities, type of brace, and if a custom fabricated brace is needed.

- Medicare wants to see chart notes reflecting the need for the care (e.g., treatment plan, history and physical, operative report) from the patient’s medical records (located at the physician’s office, hospital, or nursing home).
- To be on the safe side, Medicare recommends that you collect this information up-front to be sure the physician’s documentation supports your claim.
- Each chart note must be signed by the treating physician, and preferably include the physician’s printed name and credentials. Recommend Attestation/Signature log if printed name is absent or illegible.
- Electronic signature and date is only allowed on electronic documents.
- All supporting documents must be signed and dated by the physician prior to the delivery date.
- Each page/chart note must clearly identify the patient.

The following information must be included in the ordering physician’s medical records:

a. History of the Injury, Illness, or Condition
   - Diagnosis related to medical necessity for the orthosis
   - Diagnosis code
   - Affected side
   - Symptoms
   - Clinical course
   - Therapeutic interventions and results
   - Prognosis

b. Description of nature and extent of functional limitations on a typical day including:
   - Description of activities of daily living and how impacted by deficit(s)
   - Diagnoses causing these symptoms
   - Other comorbidities either relating to ambulatory problems or impacting the use of a new orthosis
   - Ambulatory assistance (cane, walker, wheelchair, caregiver) currently used in addition to the orthosis

- Useful Lifetime for an AFO/KAFO is 5 years.
- To replace an AFO/KAFO before 5 years, there must be a documented reason why the current device is no longer working for the patient, or the device has to be accidentally damaged and irreparable.
- If the problem is due to wear and tear only, an AFO or KAFO < 5 years of age may be repaired, but it may not be replaced.

c. Status of current orthosis/component(s) and reason for replacement (if pertinent)
   - Describe the condition of the AFO/KAFO and whether the device needs to be repaired or replaced.
   - If the patient’s condition has changed, describe why the current orthosis is no longer appropriate. (e.g. weight gain/loss, decreased stability, etc.).
   - If the device was damaged, describe the incident.

d. Describe patient’s past experience with orthoses/braces and other failed treatments.

e. There should be a recent physical examination that is relevant to functional deficits.

- Focus should be on the body systems responsible for the patient’s ambulatory difficulties or that impact the patient’s functional ability.

Include the following:
- Weight and height, including any recent weight loss/gain
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- Musculoskeletal examination with **objective** descriptions; may include, not limited to:
  - Joint laxity (e.g., varus/valgus instability, anterior/posterior drawer test)
  - Presence of deformity, swelling, tenderness, contracture, spasticity
  - Range of Motion

f. Document that patient meets the following criteria for an Ankle Foot Orthosis (AFO)
   - Patient is ambulatory
   - Diagnosis of weakness/deformity of both the foot ankle, and the need for stabilization.
   - Potential to benefit functionally.

g. Additional required for Knee Ankle Foot Orthosis (KAFO)
   Diagnosis of weakness/deformity of the knee, and the need for stabilization.

h. Additional required if device is Custom Fabricated
   - Document one of the following reasons:
     1) The beneficiary could not be fit with a prefabricated AFO, or
     2) The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months), or
     3) There is a need to control the knee, ankle or foot in more than one plane, or
     4) The beneficiary has a documented neurological, circulatory, or orthopedic status that requires custom fabricating over a model to prevent tissue injury, or
     5) The beneficiary has a healing fracture which lacks normal anatomical integrity or anthropometric proportions.

i. Additional required if it is a Stance Control KAFO
   - Document why the patient cannot use a standard KAFO
   - If the Stance Control KAFO is electronic/microprocessor controlled, document why the patient cannot use a non-electronic/microprocessor device.

j. Document your recommendation for the type of AFO/KAFO
   - Include rationale for your decision
   - Brand name of the device is not required

**Item 2: Dispensing Order** (required if item will be dispensed before the DWO is signed)

- The dispensing order must comply with state prescribing and/or other applicable laws. It is the practitioner’s responsibility to ensure this compliance.
- For Medicare, the dispensing order can either be verbal and documented in the patient’s chart OR written by the ordering physician.
- For Medicare, there only needs to be one date on the dispensing order. This will be considered the “start” date.
- The orthosis/component may be delivered upon receipt of a dispensing order; however, a signed Detailed Written Order must be obtained prior to billing.

Elements that must be included in the dispensing prescription for Medicare:
- Patient’s name
- Date of the order (For written order, this is the date on the prescription; For verbal order this is date the call was received)
- Description of each item being dispensed (brand name not required)
- Printed name of signatory (for written order, the physician’s printed name can be circled; for verbal order handprint the name of person taking the order)
- Signature (written order needs physician’s signature; verbal order needs signature of person taking the order)
Item 3: Detailed Written Order (DWO)

- The provider may write the DWO; however, the physician must review and sign it.
- For Medicare, two dates are required on a supplier generated DWO (Start date and physician’s signature date)
- The DWO must be signed & dated by the ordering physician prior to submitting the claim.
- If the orthosis/component(s) has already been delivered, you must also have a dispensing order (see Item 2) in addition to the DWO.
- If this is also your dispensing order, it must comply with state prescribing or other applicable laws. It is the provider’s responsibility to ensure this compliance.
- Signature/date stamps are not allowed.

a. The following elements must be included in the DWO:
   - Start date (from the dispensing order if applicable, otherwise use the date the DWO is prepared).
   - Patient’s name on each page
   - Side of body, for each item being provided for (highly recommended, not required)
   - Describe the unique features of the base code and every add-on code that you intend to bill
     - Use a narrative description
     - Include information such as manufacturer, brand name & model number, etc. for components ordered from manufacturer.
   - Physician demographics (printed name, credential, address, phone, NPI)
   - Physician’s handwritten signature and date

Note: If this is the only order and the orthosis will be delivered same day, we recommend having the physician include the time of signature to prove that the order was signed prior to delivery.

b. For items provided on a periodic basis (e.g. liners), DWO must also include:
   - Items to be dispensed
   - Quantity to be dispensed
   - Frequency of use
   - Number of refills

Note: Item can only be replaced if worn (and the wear is documented).

Item 4: Documentation in Orthotist’s Records

- Medical records must support that the device is still medically necessary
- Useful lifetime of an AFO/KAFO is 5 years
- Medicare expects that a lost/damaged item would be reported to some authority (e.g. police, homeowners insurance, etc.) and requires that a copy of that report be available. If patient did not report the accident/loss, you will need a signed statement from the patient describing the incident.

a. Historical documentation of the Current AFO/KAFO orthosis/component(s)
   - History of the all prior orthoses/components, including those being replaced
   - Reason for replacement
     - Item was lost
     - Item was accidentally damaged beyond repair
     - Patient’s medical condition changed (i.e. item no longer meet’s patient’s needs)

b. Functional evaluation of the patient
   - Should corroborate physician’s documentation (see 1.f. through 1.j.) that criteria for coverage has been met
   - Should support the need for custom fabrication over prefabrication (if applicable)
c. Recommendation for the type and brand of new orthosis
   - Must be based on physician’s recommendation (see Item 1.g.)
   - Include rationale for your decision
   - Include justification for each code that will be billed

d. NEW: For a custom fabricated orthosis, document the following:
   - Brace was individually made for the patient
   - Positive Model: Based on clinically derived and rectified castings, tracings, measurements, and/or other images (such as X-rays) of the body part.
   - Materials: 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.
   - Labor & Fitting: Substantial work such as vacuum forming, cutting, bending, molding, sewing, drilling, and finishing prior to fitting on the beneficiary.

e. Fitting Notes
   - If billing a prefabricated off-the-shelf code, there should still be a note in your chart (e.g. adjusted straps/closures, bent, trimmed for final fit or comfort, no adjustment needed, etc.)
   - If billing a custom-fitted code, there must be documentation demonstrating that substantial modification was provided at the time of delivery in order to provide an individualized fit, i.e., the item must have been trimmed, bent, molded (with or without heat), or otherwise modified resulting in alterations beyond minimal self-adjustment.

f. There should be a chart note for each contact with patient, caregiver, or physicians (in-person visits, telephone calls, consultations, fittings, follow-ups, etc.)
   - Each note should be dated and include the printed name, credential, and signature of the person who wrote the note.
   - Each page should have the patient’s name on it.

Item 5: Proof of Delivery (POD)

- There must be a “delivery date” on the POD, which is also the date of service on the claim.
- The patient’s signature date is no longer required; however, if there is one on the form, Medicare will consider it to be the “delivery date.”
- If the patient or designee’s signature is illegible, recommend handwriting name beneath.
- If the Detailed Written Order is signed on same day as the delivery and it is the only order, both documents will need to indicate the time of the signature.

The following elements should be included on the delivery slip.
   - Patient’s name
   - Address where item is delivered (your office, patient’s home, SNF, etc.)
   - The quantity delivered
   - Right and/or left side for each item
- Sufficiently detailed description to identify the item(s) being delivered. This should support the codes you bill
   - Use a narrative description
   - Include information such as manufacturer, brand name & model number, serial number, etc., for components ordered from a manufacturer.
- Effective 3/4/16 - long version HCPCS descriptions may be used if it sufficiently describes the item.

- Signature and Printed Name of the patient or designee
  - If designee signs: Include the designee’s relationship to the patient and the reason why patient could not sign.
  - Designee cannot have any financial connection to the provider.

Recommend signature time (if signed on the same day the prescription is obtained).
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Item 6: Beneficiary Authorization

- A new authorization is required anytime a new orthosis/component(s) is provided / or new HCPCS code is billed.
  - To be on the safe side, the authorization can be combined with the Proof of Delivery. That way you will always have a current signature.
- This authorization should give you:
  - Permission to submit claims on behalf of beneficiary.
  - Permission to pay you directly (assigns the benefits to the provider).
  - Release to authorize the provider to obtain confidential medical information about the beneficiary in order to process the claim.

Example of an Authorization:

Name of Beneficiary         HICN
I authorize (supplier)_______ to submit claims to Medicare on my behalf. I request that payment of authorized Medicare benefits be made either to me or on my behalf to (supplier)________________________ for any services furnished me by that supplier.
I authorize any holder of medical information about me to release to (supplier) ________________ and/or the Centers for Medicare & Medicaid Services and its agents any information needed to determine these benefits or the benefits payable for related services.
Signature________________________
Date______________________________

Item 7: Advanced Beneficiary Notice (ABN) if required

- **NOTE:** Medicare does not allow “blanket” ABN’s to be issued. In other words one cannot give an ABN to every patient, in anticipation that Medicare might deny. ABNs are to be used on a case-by-case basis when there is a clear indication that the device will be denied as not medically necessary/not reasonable and necessary.

Examples of when an ABN might be used:
- Patient does not meet criteria for coverage as stated in LCD
- Physician clearly has not provided sufficient documentation to meet Medicare’s documentation requirements and there is a high probability that the claim will be denied as not medically necessary.

Additional Billing Notes:

- All codes with same date of service must be on the same claim.
- KX modifier is an attestation that the patient meets Medicare criteria and the evidence is retained in the provider’s files (available on request). If criteria are not met a GA/GZ modifier must be used. Claim lines without KX, GA, or GZ modifier will be denied as missing information.
- Use RA modifier if item is replaced due to loss or irreparable damage.
- RT/LT modifiers are required.
- Only use a miscellaneous code (L2999) when there is not an existing code. Include a narrative description Manufacturer, Product name and number, Supplier Price List (PL) amount, and HCPCS code of related item (if applicable).
- When billing for a custom fabricated orthosis, include a narrative description (e.g. describe item, what makes it unique, breakdown of charges - material and labor used in the fabrication) /manufacturer quote okay.

References:

Joint DME MAC publication. Local Coverage Determination (LCD):Ankle-Foot/Knee-Ankle-Foot Orthosis;
Joint DME MAC Local Coverage Article: Ankle-Foot/Knee-Ankle-Foot Orthoses - Policy Article.