The following information describes the items or documentation necessary for reimbursement from the Centers for Medicare and Medicaid Services, also known as CMS or Medicare. Because Medicare typically has the most stringent insurance requirements, fulfilling these requirements could also strengthen reimbursement claims from other third-party payors.

Ottobock has relied upon the CMS guidance and recommendations set forth in this document’s reference section below.

**Item 1: Documentation from the Ordering Physician**

**Note:** The Physician must evaluate the patient and document both medical necessity and functional capabilities.

- 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. **Note:** 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
  - 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

- **c. Status of current orthosis/component(s) and reason for replacement (if pertinent)**

- **d. Past experience with orthosis/brace and other failed treatments**

e. **Recent physical examination that is relevant to functional deficits**

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

- Weight and height, including any recent weight loss/gain
- Musculoskeletal examination
  - May include but not limited to: presence of deformity, swelling, tenderness, contracture, spasticity, joint laxity/stability
  - Range of motion

f. **Document that patient meets criteria for coverage for the type of AFO/KAFO being ordered**

**For an AFO/KAFO**

- Diagnosis of weakness or deformity of the foot and ankle requiring stabilization, **and**
- If the order is for a KAFO there must be diagnosed knee instability as well, **and**
- Potential to benefit functionally.

**If the AFO/KAFO is custom fabricated**

One of the following reasons must be documented:

- 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 over a model to prevent tissue injury, **or**
- The beneficiary has a healing fracture which lacks normal anatomical integrity or anthropometric proportions.

**If the KAFO includes Stance Control**

- Document the medical need for a stance control orthosis.
- If the stance control orthosis is electronic or microprocessor controlled, document why the patient cannot use a non-electronic/non-microprocessor stance control orthosis.

**g. Recommendation for the new AFO/KAFO and/or components**

- Include rationale for decision
- Brand name not required
**Item 2: Dispensing Prescription**

Requirements:

- The dispensing prescription must comply with state prescribing and/or other applicable laws. It is the practitioner’s responsibility to ensure this compliance.
- For Medicare, the dispensing prescription can either be verbal and documented in the patient’s chart OR written by the ordering physician.
- For Medicare, if the Detailed Written Order is dated prior to delivery, a dispensing prescription is not required; however state laws prevail if more stringent.

Elements that must be included in the dispensing prescription for Medicare:

- Patient’s name
- Start date of order
  - For written order: use the date on the prescription
  - For verbal order: use the date the call was received
- Description of item
- Physician’s printed name and credential
- For written order: Physician’s signature and date
- For verbal order: Printed name of person taking order, signature, date, time

**Item 3: Detailed Written Order**

Requirements:

- The provider may write the detailed order, however the physician must review and sign it.
- The detailed order 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 prescription (see Item 2) in addition to the detailed order.
- If this is your dispensing prescription, it must comply with state prescribing or other applicable laws. It is the provider’s responsibility to ensure this compliance.

All of the following elements must be included in the detailed written order:

- Start date of the order from the dispensing prescription (if applicable)
- Patient’s name on each page
- ICD-9 Diagnosis Code (recommended, not required)
- Side of body, for each item being provided for (recommended, not required)
- Describe the unique features of the basecode and every add-on code that you intend to bill (e.g. narrative description or brand name & model number)
- Physician demographics (printed name, credential, address, phone, NPI)
- Physician’s handwritten signature and date

**Item 4: Documentation in Orthotist's Records**

Requirements:

- Historical documentation of the Current AFO/KAFO orthosis/component(s)
- History of the orthosis/components being replaced
- Description of the labor involved.
- Reason for replacement
  - Item was lost
  - Item was accidentally damaged beyond repair
  - Item was irreparably damaged
  - Patient’s medical condition changed (i.e. item no longer meet’s patient’s needs)

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

b. Functional evaluation of the patient
- Should corroborate physician’s documentation that criteria for coverage has been met [see Item 1(f.)]

c. Recommendation for the type of new orthosis
- Must be based on physician’s recommendation
- Include rationale for your decision
- Include justification for each code that will be billed

d. Chart note for each contact with patient, caregiver, or physicians (in-person visits, telephone calls, consultations, fittings, follow-ups, etc.)
- Each note should include the printed name, credential, and signature of the person who wrote the note, and must be dated.
- Each page should have the patient’s name on it.
**Additional Billing Notes:**

- **KX modifier** is an attestation that the patient meets the criteria outlined in the AFO/KAFO LCD, and the evidence is retained in the supplier’s files, available on request.
- RT/LT modifiers required.
- All codes with same date of service must be on the same claim.
- There should be medical justification in your file for each code billed (including add-on codes).

**Item 5: Proof of Delivery**

**Requirements:**

- The signature date must be the date patient received the orthosis/component(s).
- The signature date must also be the date of service on the claim.
- 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, or other document(s), in compliance with CMS regulations.

- Patient’s name
- 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
  - May use narrative description or brand name & model number
  - Include serial number if available
- 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.
- Date of Signature (handwritten by the signator)
- Recommend signature time (if signed on the same day the prescription is obtained).

**Item 6: Beneficiary Authorization**

**Requirements:**

- This authorization should give you permission to bill and receive payment on behalf of the beneficiary, and exchange medical records in the process.
- A new authorization is required anytime a new orthosis/component(s) is provided. In other words, anytime a 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.

The Authorization should include the following:

- Permission to pay you directly (assigns the benefits to the provider).
- Authorization to submit claims on behalf of beneficiary.
- Release to authorize the provider to obtain confidential medical information about the beneficiary in order to process the claim.

**Example of an Authorization:**

<table>
<thead>
<tr>
<th>Name of Beneficiary</th>
<th>HICN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 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 (if required)**

Examples of when an ABN might be used:

- Patient does not meet criteria for coverage as stated in LCD
- Physician has not provided sufficient documentation to meet Medicare's documentation requirements and the claim may be denied as not medically necessary
### Documentation Checklist – AFOs and KAFOs

#### From Physician Records

| History of Condition          |  |
|------------------------------|  |
| ☐ Diagnosis related to medical necessity for the orthosis |  |
| ☐ Affected side               |  |
| ☐ Clinical course             |  |
| ☐ Therapeutic interventions and results |  |
| ☐ Prognosis                   |  |

| Functional Limitations        |  |
|------------------------------|  |
| ☐ ADLs and how impacted by deficit(s) |  |
| ☐ Diagnoses causing these symptoms |  |
| ☐ Other comorbidities         |  |
| ☐ Ambulatory assistance       |  |

| Status/condition of Current Orthosis |  |
|--------------------------------------|  |
| ☐ Past Experience with orthosis/brace and other failed treatments |  |

| Physical Exam                   |  |
|---------------------------------|  |
| ☐ Weight and height, weight loss/gain |  |
| ☐ Presence of deformity         |  |
| ☐ Document swelling, tenderness, contractures or spasticity, joint laxity/stability, ROM |  |

Documented that patient meets Criteria for Coverage

For AFO/KAFO all three must be documented:

- ☐ Weakness or deformity of the foot and ankle, AND
- ☐ Stabilization required of foot and ankle for medical reason; for KAFO patient requires additional knee stability, AND

Potential to benefit functionally from an AFO/KAFO

If Custom, one of the following must be documented:

- ☐ Permanent condition > 6 months
- ☐ Patient could not fit prefabricated AFO/KAFO
- ☐ Need to control the knee, ankle, or foot in more than one plane

Documented neurological, circulatory, or orthopedic status requires custom fab over a model to prevent tissue injury

- ☐ Healing fracture lacking normal anatomical integrity or anthropometric proportions

If Custom Stance Control:

- ☐ Medical need for a stance control orthosis
- ☐ Reason why patient cannot use a non-electronic stance control orthosis

Recommendation for new orthosis/component/s

- ☐ Include rationale for decision
- ☐ Brand name not required

Patient Clearly Identified on each page

| Signature and Date Requirements |  |
|---------------------------------|  |
| ☐ Physician signature and date on each chart note! |  |
| ☐ Notes are dated prior to delivery |  |
| ☐ May be handwritten or electronic |  |
| ☐ Each chart note includes printed name of physician or signature attestation attached |  |

#### Dispensing Prescription (if required)

| Patient’s name                  |  |
|---------------------------------|  |
| ☐ Start date of order (for written order use date of Rx; for verbal order use date of the telephone call) |  |
| ☐ Description of item (brand name not required) |  |
| ☐ Physician’s printed name and credentials |  |
| ☐ Signature (written order needs physician’s signature & date; verbal order needs printed name of person taking order, signature, date, time) |  |
| ☐ Dispensing prescription must be dated prior to delivery |  |
| ☐ May be handwritten or electronic |  |

#### Detailed Written Order

| Patient's Name on each page |  |
|-----------------------------|  |
| ☐ Start date of the order from the dispensing prescription (if applicable) |  |
| ☐ ICD-9 Diagnosis Code (not required, but recommended) |  |
| ☐ Side of body, for each item being provided for (not required, but recommended) |  |
| ☐ Description of each item provided, including base code and features described by add-on codes |  |

#### Orthotist’s Records

| History of Current Orthosis |  |
|-----------------------------|  |
| ☐ History of orthosis being replaced |  |
| ☐ Description of the labor involved |  |
| ☐ Reason for replacement |  |
| ☐ Functional evaluation (must corroborate physician’s documentation) |  |
| ☐ Recommendation for type of new orthosis (must be based on physician’s recommendation) |  |
| ☐ Rationale for your decision |  |
| ☐ Justification for each code that will be billed |  |

| Patient Name on Each Page |  |
|--------------------------|  |
| ☐ Chart Note for Each Visit |  |

| Prosthetist’s printed name, signature, and date on each note |  |
|-------------------------------------------------------------|  |

#### Proof of Delivery

| Patient’s name |  |
|----------------|  |
| ☐ Quantity |  |
| ☐ Affected side for each item |  |
| ☐ Sufficiently detailed description to identify the item(s) being delivered and the codes that will be billed (e.g., brand name, serial number, narrative description) |  |
| ☐ Signature and printed name of the patient or designee |  |
| ☐ Designee’s relationship |  |
| ☐ Handwritten signature & date |  |

#### Beneficiary Authorization

| ABN (if required) |  |
|-------------------|  |
| ☐ Signed by patient |  |