Documentation Requirements for Knee Orthosis
Revision effective March 4, 2016

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.1-13

Item 1: Documentation from the Ordering Physician

- REVISED: The Physician must evaluate the patient and document medical necessity, functional capabilities, type of and if a custom 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
   - 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
   - Describe the condition of the current knee brace 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.
   - If the device needs repair, there needs to be a statement of continued medical need.

c. Past experience with orthosis/brace and other failed treatments.

d. 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.
   - Weight and height, including any recent weight loss/gain
   - 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
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e. **REVISED:** Document whether the patient meets criteria for Custom Fabricated, rather than Prefabricated (if pertinent).
   - Custom-Fabricated “over patient model”
     Following are examples (not all inclusive) of when a prefabricated brace might not fit.
     - Deformity of the leg or knee;
     - Size of thigh and calf;
     - Minimal muscle mass upon which to suspend an orthosis.

f. Document your recommendation for the type of knee orthosis and/or components
   - Include rationale for your decision (based on the information above).
   - Include statement that patient has the potential to benefit functionally from this device.
   - Brand name of the device is not required

**Item 2: Dispensing Orders**

- 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.
- **NEW:** For Medicare, there only needs to be one date on the dispensing order. This will be 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
- **REVISED:** Date of order (For written order, this is the date on the prescription; For verbal order this is date the call was received)
- Description of item (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**

- The provider may write the detailed order; however, the physician must review and sign it.
- **NEW:** For Medicare, two dates are required on a provider generated DWO (Start date from the dispensing order and physician’s signature date)
- 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 order (see Item 2) in addition to the detailed order.
- 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.

The following elements must be included in the detailed written order:
- **NEW:** Start date from the dispensing order
- Patient’s name on each page
- ICD-10 Diagnosis Codes (recommended, not required)
- Side of body, for each item being provided
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- 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 brand name & model number for components ordered from the manufacturer. Example: Ottobock 50K205 post-op prefab knee brace dbl upright with ROM 0°-120°, locks from 0°-45°
- Physician demographics (printed name, credential, address, phone, NPI) & handwritten signature and date

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

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

- Medical records must support that the device is still medically necessary
- Useful lifetime is:
  - 1 yr. L1810, L1812, L1820, L1830
  - 2 yrs. L1831, L1832, L1833
- Medicare does not cover irreparable wear during useful lifetime
- 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.
- 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)

b. Functional evaluation of the patient
   - should corroborate physician’s documentation that criteria for coverage has been met (see Items 1-f through 1-f)

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

d. **REVISED:** Fitting Notes
   - For custom fitted it must be documented that substantial modification for fitting 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.
   - If a prefabricated device is not substantially modified as described above, then it needs to be billed with an off-the-shelf (OTS) code. If there is not an OTS code to describe the product, a miscellaneous code must be used.

e. 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 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.

a. Historical documentation of the Current orthosis/component(s)
   - History of the orthosis/components being replaced
   - Detailed description of the labor involved (casting, molding, modification, time, tools used, materials used/modified)
Item 5: Proof of Delivery

- **NEW:** A signature date is no longer required; however, if there is one on the form, it must match the delivery date. Supplier may pre-fill the signature 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
- **NEW:** 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 brand name & model/serial number for components ordered from manufacturer. Example: Ottobock 50K205 post-op prefab knee bracedbl upright with ROM 0°-120°, locks from 0°-45°
  - **NEW:** Effective 3/4/16 – Long version HCPCS descriptions may be used.
  - Contact Ottobock Reimbursement for assistance with this.
- 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).

Item 6: Beneficiary Authorization

- A new authorization is required anytime a new orthosis/component(s) is provided.
  - In other words, a new authorization is required 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.
- 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_____________
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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 the criteria outlined in the Knee Brace LCD, 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.
- RT/LT modifiers required.
- K0902 and L1845 must be PDAC approved.

References:

1. CGS. Local Coverage Determination (LCD): Knee Orthosis
2. CGS. Local Coverage Article: Knee Orthoses - Policy Article
4. NGS. LCD for Knee Orthoses
5. NGS. Local Coverage Article: Knee Orthoses – Policy Article
6. NGS. Supplier Manual. Chapter 10. Advance Beneficiary Notice of Noncoverage
8. NHIC. Local Coverage Determination (LCD) for Knee Orthosis
9. NHIC. Local Coverage Article for Knee Orthoses - Policy Article
11. Noridian. Local Coverage Determination (LCD) for Knee Orthosis.
## Documentation Checklist for Knee Orthosis (attach to chart)

**Revision effective January 1, 2016**

### From Physician Records

**History of Condition**
- Diagnosis,
- Affected Side,
- Clinical course,
- Therapeutic interventions and results
- Prognosis

**Functional Limitations**
- ADLs and how impacted by deficit(s)
- Diagnoses causing these symptoms
- Other co-morbidities
- Ambulatory assistance

**Status/condition of Current Orthosis**
- Reason for replacement (condition changed, irreparable damage, worn and useful lifetime expired)
- If repair is needed: statement of continued medical need

**Past Experience with orthosis/brace and other failed treatments**

**Physical examination**
- Weight and height, weight loss/gain
- Presence of Deformity
- Document swelling, tenderness, contractures, or spasticity, joint laxity/stability, range of motion (ROM)

**Document that Patient Meets Criteria for Coverage**
- L1810, L1812, L1820: weakness/deformity
- L1831, L1836: flexion/extension contracture
- L1832, L1833, L1834, L1843, L1844, L1845, L1846, K0901, K0902: Knee instability (objective description) & group 4 diagnosis
- L1840 internal ligamentous disruption & group 4 diagnosis
- L1850, L1860 ambulatory & knee instability due to hyperextension & group 5 diagnosis

**If Custom fabricated over patient model (L1840, L1844, L1846, or L1860), one of the following reasons why a prefabricated brace could not be fit must be documented:**
- Deformity of leg or knee
- Size of thigh and calf
- Minimal muscle mass upon which to suspend orthosis
- Other reason

**Recommendation for type of orthosis**
- Include rationale for decision (based on information above)
- Include statement that patient will benefit functionally from the device.
- Brand name not required
- Patient clearly identified on each page

### Dispensing Order (requirements)

- Patient’s name
- Date of order (for written order use date of RX; for verbal order use date of telephone call) (Dated prior to delivery)
- Description of item (brand name not required)
- Printed name of signatory (for physician printed name could 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)
- May be handwritten or electronic

### Detailed Written Order

- Start date of the order from the dispensing order
- ICD-10 Diagnosis Code (recommended, not required)
- Side of body, for each item being provided
- Sufficiently detailed description to identify the item(s) to be provided (e.g. narrative description, including brand name, model number for purchased components)

**Patient’s name on each page**

**Physician signature and date requirements**
- Signed and dated prior to billing
- Handwritten signature and signature date
- Printed name, credential, address, phone, NPI

**Compliance with State Law**

**Orthotist Records**
- History of orthosis being replaced, description of labor, and reason for replacement if pertinent (loss, damage, significant change). Must still be medically necessary.
- Functional evaluation (must corroborate physician’s documentation)
- Recommendation for new orthosis: type/brand and fit (custom/custom fit/OTS), rationale - based on physician order
- Describe modifications (trim, bend, mold, assemble, etc.)
- Chart note for each visit
- Patient name on each page
- Orthotist’s printed name, signature & date on each note (suggest signature log)

### Proof of Delivery

- Patient Name
- Address where item is delivered
- Quantity
- Affected side for each item
- Sufficiently detailed description to identify the item(s) delivered (e.g. narrative description, including brand name, model & serial number for purchased components)
- Handwritten signature
- Printed name of patient/designee & relationship

### Beneficiary Authorization

- Signed by patient prior to delivery

**Advance Beneficiary Notice (ABN) (if required)**
- Signed by patient prior to delivery

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