The following information describes the 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 payers.

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**

- The Physician must evaluate the patient and document medical necessity, functional capabilities, type of brace, 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 or 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 and 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 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)

   - Useful Lifetime for a spinal orthosis is no less than 5 years. To replace a spinal orthosis before 5 years, there must be a documented reason why the current device is no longer meeting the patient’s functional needs, or the device has to be accidentally damaged and irreparable. For normal wear and tear, the device must be repaired.
   - Describe the condition of the orthosis 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.
d. Past experience with orthosis/brace and other failed treatments

e. Recent physical examination that is relevant to patient’s functional deficits

- Focus should be on the body systems responsible for or that impact the patient’s functional ability.
  - Weight and height, including any recent weight loss/gain
  - Musculoskeletal examination with objective descriptions. May include (if appropriate), not limited to:
    - Posture
    - Presence of abnormality, deformity, swelling, or tenderness
    - Range of Motion
    - Palpation
    - Neurological

f. Document that patient meets one of the following criteria for a spinal orthosis:

1. To reduce pain by restricting mobility of the trunk; or
2. To facilitate healing following an injury to the spine or related soft tissues; or
3. To facilitate healing following a surgical procedure on the spine or related soft tissue; or
4. To support weak spinal muscles and/or a deformed spine.

g. Additional required if the orthosis will be Custom Fabricated

- Detailed a reason why a prefabricated device could not be fit (e.g. underlying deformity or body somatotype which would preclude the use of a prefabricated brace).

h. Document your recommendation for the type of spinal orthosis

- Include rationale for your decision.
- Include statement that patient has the potential to benefit functionally from this device.
- Brand name of the device is not required

Item 2: Dispensing Order

- The dispensing order is only required if the item will be delivered to the patient prior to obtaining the Detailed Written Order (DWO).
- The dispensing order/DWO 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 the “start” date.
- The item 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 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 (DWO)

- The provider may write the detailed order; however, the physician must review and sign it.
- For Medicare, two dates are required on a provider generated DWO (Start date and the physician’s signature date)
- The detailed order must be signed & dated by the ordering physician prior to submitting the claim.
- If the item 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 (DWO):
- Start date
  - Use the start date from the dispensing order if you have one.
  - Otherwise use the date the DWO is prepared.
- Patient’s name on each page
- Describe the unique features of the base code and every add-on code that you intend to bill
  - Include a narrative description of each item
  - Include brand name and model number for items 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, the physician should 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 of a spinal orthosis 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 spinal orthosis (if applicable):
  - History of the orthosis/components being replaced
  - Reason for replacement
    - Item was lost
    - Item was accidentally damaged beyond repair
    - Patient’s medical condition changed (i.e. item no longer meets patient’s functional needs)
    - Item is worn and useful lifetime has been exceeded

b. Functional evaluation of the patient:
  - Should corroborate physician’s documentation that criteria for coverage has been met (see Items 1-f through 1-g)
  - Should support the need for custom fabrication over prefabrication (if applicable)

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. Fitting Notes

Custom Fabricated Orthosis, NEW document the following:

- Brace was individually made for the patient using a positive model
- Impression Method used to make Positive Model: Based on clinically derived and rectified castings, tracings, measurements, and/or other images (such as X-rays) of the body part.
- Materials Used: 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.

Prefabricated Custom-Fitted Orthosis, note that fitting requires expertise of certified orthotist. 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.

Examples (not all inclusive)

- Waist to hip ratio or disparity
- Obesity
- Short stature /torso
- Hyper/hypo-lordosis
- Pendulous abdomen
- Multi-vertebral level injury/surgery
- Accommodate post-surgical dressings
- Scoliosis
- Spinal Deformity
- Compromised cognitive/physical ability
- Hyper-kyphosis

Prefabricated Off-the-Shelf Orthosis

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.)

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.

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.
- Revised: A signature date is no longer required; however, if there is one on the form, it will be the official 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.

Elements to be included on the delivery slip:

- Delivery Date
- Patient’s name
- Address where item is delivered (your office, patient’s home, SNF, etc.)
- The quantity delivered
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- 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/serial number for components ordered from manufacturer.
    Recommended description style:
    “Ottobock 50R139 Cyber Max LSO, lateral control L1-S1”
  - Contact Ottobock Reimbursement for assistance if needed.
- 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:

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

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.

References:
Joint DME MAC publication. Local Coverage Determination Spinal Orthoses;
Joint DME MAC Local Coverage Article: Spinal Orthoses - Policy Article.
Joint DME MAC Local Coverage Article: Standard Documentation Requirements for all Claims Submitted to DME MACs.