

DOCUMENTATION CHECKLIST

SPINAL ORTHOSES

REQUIRED DOCUMENTATION

Effective April 13, 2022, the L0648 and L0650 must have a Face-to-Face Encounter and Written Order Prior to Delivery (WOPD).

- Standard Written Order (SWO)**
 - Beneficiary's name or Medicare Beneficiary Identifier (MBI)
 - General description of the item - The description can be either a general description (e.g., wheelchair or hospital bed), a HCPCS code, a HCPCS code narrative, or a brand name/model number
 - 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)
 - 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). Quantity to be dispensed, if applicable
 - Order Date
 - Treating Practitioner Name or NPI
 - Treating Practitioner's signature
- The practitioner's signature on the standard written order meets **CMS Signature Requirements**: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf>

Direct Delivery	Shipped/Mail Order Tracking Slip	Shipped/Mail Order Return Post-Paid Delivery Invoice
<ul style="list-style-type: none"> <input type="checkbox"/> Beneficiary's name <input type="checkbox"/> Delivery address <input type="checkbox"/> Quantity delivered <input type="checkbox"/> 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. <input type="checkbox"/> Signature of person accepting delivery <input type="checkbox"/> Relationship to beneficiary <input type="checkbox"/> Delivery date 	<ul style="list-style-type: none"> <input type="checkbox"/> Shipping invoice <ul style="list-style-type: none"> <input type="checkbox"/> Beneficiary's name <input type="checkbox"/> Delivery address <input type="checkbox"/> 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. <input type="checkbox"/> Quantity shipped <input type="checkbox"/> Tracking slip <ul style="list-style-type: none"> <input type="checkbox"/> References each individual package <input type="checkbox"/> Delivery address <input type="checkbox"/> Package I.D. #number <input type="checkbox"/> Date shipped <input type="checkbox"/> Date delivered <input type="checkbox"/> 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) 	<ul style="list-style-type: none"> <input type="checkbox"/> Shipping invoice <ul style="list-style-type: none"> <input type="checkbox"/> Beneficiary's name <input type="checkbox"/> Delivery address <input type="checkbox"/> 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. <input type="checkbox"/> Quantity shipped <input type="checkbox"/> Date shipped <input type="checkbox"/> Signature of person accepting delivery <input type="checkbox"/> Relationship to beneficiary <input type="checkbox"/> Delivery date

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

Medical Records

Effective April 13, 2022 a Face-to-face Encounter is required within six months prior to prescribing the L0648 and L0650.

- The treating practitioner had a face-to-face encounter with a beneficiary within the six (6) months prior to prescribing item.



- The encounter must be used to gather subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.
- The face-to-face encounter must be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, progress notes, treatment plans or other sources of information that may be appropriate). The supporting documentation must include subjective and objective, beneficiary specific information used for diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.
- If the encounter is performed via telehealth, the requirements for telehealth services and payment for telehealth services must be met.
- A supplier must maintain the written order/prescription and the supporting documentation provided by the treating practitioner and make them available to CMS and its agents upon request.
- Prefabricated Orthoses: Off-The-Shelf (OTS) (L0450, L0455, L0457, L0467, L0469, L0621, L0623, L0625, L0628, L0641, L0642, L0643, L0648, L0649, L0650, L0651)**
 - Medical records document the spinal orthosis was ordered for one of the following indications:
 - Reduce pain by restricting mobility of the trunk; or
 - Facilitate healing following an injury to the spine or related soft tissues; or
 - Facilitate healing following a surgical procedure on the spine or related soft tissue; or
 - Support weak spinal muscles and/or a deformed spine.
 - Requires minimal self-adjustment for fitting, at the time of delivery, for appropriate use and does not require expertise in trimming, bending, and molding, assembling, or customizing to fit an individual.
 - This fitting does not require expertise of a certified orthotist or an individual who has specialized training in the provision of orthoses to fit the item to the individual beneficiary.
 - For the L0648 and L0650 Effective April 13, 2022 a Face-to-face Encounter
 - A practitioner visit is required within six months preceding the order.
 - The encounter must be used to gather subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.
 - The face-to-face encounter must be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, progress notes, treatment plans or other sources of information that may be appropriate). The supporting documentation must include subjective and objective, beneficiary specific information used for diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.
 - If the encounter is performed via telehealth, the requirements for telehealth services and payment for telehealth services must be met.
 - A supplier must maintain the written order/prescription and the supporting documentation provided by the treating practitioner and make them available to CMS and its agents upon request.
- Prefabricated Orthoses: Custom Fitted (L0454, L0456, L0458, L0460, L0462, L0464, L0466, L0468, L0470, L0472, L0488, L0490, L0491, L0492, L0626, L0627, L0630, L0631, L0633, L0635, L0637, L0639)**
 - Medical records document the spinal orthosis was ordered for one of the following indications:
 - Reduce pain by restricting mobility of the trunk; or
 - Facilitate healing following an injury to the spine or related soft tissues; or
 - Facilitate healing following a surgical procedure on the spine or related soft tissue; or
 - Support weak spinal muscles and/or a deformed spine



- Orthosis requires more than minimal self-adjustment for fitting at the time of delivery in order to provide an individualized fit
 - Item must be trimmed, bent, molded (with or without heat), or otherwise modified resulting in alterations beyond minimal self-adjustment; and
 - This fitting at delivery requires expertise of a certified orthotist or an individual who has specialized training in the provision of orthotics in compliance with all applicable Federal and State licensure and regulatory requirements.
 - Documentation must be sufficiently detailed to include, but is not limited to, a detailed description of the modifications necessary at the time of fitting the orthosis to the beneficiary
- Custom Fabricated Orthoses (L0452, L0480, L0482, L0484, L0486, L0622, L0629, L0632, L0634, L0636, L0638, L0640)
- Medical records document the spinal orthosis was ordered for one of the following indications:
 - Reduce pain by restricting mobility of the trunk; or
 - Facilitate healing following an injury to the spine or related soft tissues; or
 - Facilitate healing following a surgical procedure on the spine or related soft tissue; or
 - Support weak spinal muscles and/or a deformed spine
 - Detailed documentation in the treating practitioner's records to support the medical necessity of custom fabricated rather than a prefabricated orthosis
 - This information is corroborated by the functional evaluation in the orthotist's or prosthetist's records.
 - Impression of the specific body part was made, and this impression was used to make a positive model of the body part; or
 - Detailed measurements were taken of the beneficiary's torso and used to modify a positive model to make it conform to the beneficiary's body shape and dimensions; or
 - Digital image of the beneficiary's torso was made using CAD-CAM technology which directed the carving of a positive model; and
 - Orthosis was then individually fabricated and molded over the positive model of the beneficiary

REMINDERS

- The CG modifier must be added to code L0450, L0454, L0455, L0621, L0625, or L0628 only if it is one made primarily of nonelastic material (e.g., canvas, cotton or nylon) or having a rigid posterior panel.
 - When providing these items suppliers must:
 - » Provide the product that is specified by the treating practitioner
 - » Be sure that the treating practitioner's medical record justifies the need for the type of product (i.e., Prefabricated versus Custom Fabricated)
 - » Only bill for the HCPCS code that accurately reflects both the type of orthosis and the appropriate level of fitting
 - » Have detailed documentation in the supplier's record that justifies the code selected.
- A certified orthotist is defined as an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification.
 - When providing custom fabricated orthoses (L0452, L0480, L0482, L0484, L0486, L0622, L0624, L0629, L0632, L0634, L0636, L0638 and L0640), the suppliers must:
 - Provide the product that is specified by the treating practitioner
 - Be sure that the treating practitioner's medical record justifies the need for the type of product (i.e., Prefabricated versus Custom Fabricated)
 - Only bill for the HCPCS code that accurately reflects both the type of orthosis and the appropriate level of fitting



- Have detailed documentation in supplier's records that justifies the code selected
- A WOPD and F2F encounter are required for the **L0648** and **L0650** as of April 13, 2022
- Prior Authorization is required for L0648 and L0650
 - Phase 1 - Effective April 13, 2022, in New York, Illinois, Florida, California
 - Phase 2 - Effective July 12, 2022, in Maryland, Pennsylvania, New Jersey, Michigan, Ohio, Kentucky, Texas, North Carolina, Georgia, Missouri, Arizona, Washington
 - Phase 3 - Effective October 10, 2022, Nationwide all remaining states and territories not included in Phase 1 or Phase 2

ONLINE RESOURCES

- **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
- **Spinal Orthoses: TLSO and LSO Local Coverage Determination (LCD) and Policy Article**
 - **JB:** <https://www.cgsmedicare.com/jb/coverage/lcdinfo.html>
 - **JC:** <https://www.cgsmedicare.com/jc/coverage/LCDinfo.html>
- **DME MAC Supplier Manual**
 - **JB:** <https://www.cgsmedicare.com/jb/pubs/supman/index.html>
 - **JC:** <https://www.cgsmedicare.com/jc/pubs/supman/index.html>
- **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.