Local Coverage Article

Spinal Orthoses: TLSO and LSO - Policy Article

A52500

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Contractor Information
Article Information

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Article Guidance

Article Text

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. “reasonable and necessary”).

In order for a beneficiary’s orthosis to be eligible for reimbursement, the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination (LCD) must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Lumbar-sacral orthoses (LSO) and thoracic-lumbar-sacral orthoses (TLSO) are covered under the Medicare braces benefit (Social Security Act §1861(s)(9)). For coverage under this benefit, the orthosis must be a rigid or semi-rigid device, which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Items that are not sufficiently rigid to be capable of providing the necessary immobilization or support

to the body part for which it is designed do not meet the statutory definition of the braces benefit. Items that do not meet the definition of a brace are statutorily noncovered, no benefit.

Elastic or other fabric support garments (A4467 (BELT, STRAP, SLEEVE, GARMENT, OR COVERING, ANYTYPE)) with or without stays or panels do not meet the statutory definition of a brace because they are not rigid or semi-rigid devices. Code A4467 is denied as noncovered (no Medicare benefit). Refer to the CODING GUIDELINES section below for additional information.

Both “off-the-shelf” (OTS) and custom-fit items are considered prefabricated braces for Medicare coding purposes. 42 CFR §414.402 establishes that correct coding of a spinal orthosis is dependent upon whether there is a need for “minimal self-adjustment” during the final fitting at the time of delivery. (See definitions below in CODING GUIDELINES). If a custom fit code is billed when minimal self-adjustment was provided at the final delivery, or if an OTS code is billed when more than minimal self-adjustments were made at the final delivery, claims will be denied as incorrect coding.

A prefabricated orthosis is one, which is manufactured in quantity without a specific beneficiary in mind. A prefabricated orthosis may be considered an OTS or a custom fitted device that may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific beneficiary. An orthosis that is assembled from prefabricated components is considered prefabricated. It is inherent in the definition of prefabricated that a particular item is complete.
A custom-fabricated orthosis is one, which is individually made for a specific beneficiary starting with basic materials including, but not limited to, plastic, metal, leather, or cloth in the form of sheets, bars, etc. It involves substantial work such as cutting, bending, molding, sewing, etc. It may involve the incorporation of some prefabricated components. It involves more than trimming, bending, or making other modifications to a substantially prefabricated item. Custom-fabricated additions are appropriate only for custom-fabricated base orthotics and should not be billed with prefabricated base orthotics.
A protective body sock (L0984) does not meet the definition of a brace and is noncovered.

There is no separate payment for computer-aided design/computer-aided manufacturing (CAD/CAM) technology when it is used to fabricate an orthosis. Reimbursement is included in the allowance of the codes for custom fabricated orthoses.

Evaluation of the beneficiary, measurement and/or casting, and fitting/adjustments of the orthosis are included in the allowance for the orthosis. There is no separate payment for these services.

Payment for a spinal orthosis is included in the payment to a hospital or SNF if:

1. The orthosis is provided to a beneficiary prior to an inpatient hospital admission or Part A covered SNF stay; and
2. The medical necessity for the orthosis begins during the hospital or SNF stay (e.g., after spinal surgery).

A claim should not be submitted to the DME MAC in this situation.

Payment for a spinal orthosis is also included in the payment to a hospital or a Part A covered SNF stay if:

1. The orthosis is provided to a beneficiary during an inpatient hospital or Part A covered SNF stay prior to the day of discharge; and
2. The beneficiary uses the item for medically necessary inpatient treatment or rehabilitation.

A claim must not be submitted to the DME MAC in this situation.

Payment for a spinal orthosis delivered to a beneficiary in a hospital or a Part A covered SNF stay is eligible for coverage by the DME MAC if:

1. The orthosis is medically necessary for a beneficiary after discharge from a hospital or Part A covered SNF stay; and
2. The orthosis is provided to the beneficiary within two days prior to discharge to home; and
3. The orthosis is not needed for inpatient treatment or rehabilitation but is left in the room for the beneficiary to take home.

REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO Final Rule 1713 (84 Fed. Reg Vol 217)

Final Rule 1713 (84 Fed. Reg Vol 217) requires a face-to-face encounter and a Written Order Prior to Delivery (WOPD) for specified HCPCS codes. CMS and the DME MACs provide a list of the specified codes, which is periodically updated. The required Face-to-Face Encounter and Written Order Prior to Delivery List is available here .

Claims for the specified items subject to Final Rule 1713 (84 Fed. Reg Vol 217) that do not meet the face-to-face encounter and WOPD requirements specified in the LCD-related Standard Documentation Requirements Article (A55426) will be denied as not reasonable and necessary.

If a supplier delivers an item prior to receipt of a WOPD, it will be denied as not reasonable and necessary. If the WOPD is not obtained prior to delivery, payment will not be made for that item even if a WOPD is subsequently obtained by the supplier. If a similar item is subsequently provided by an unrelated supplier who has obtained a WOPD, it will be eligible for coverage.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

MODIFIERS

CG Modifier

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. (Refer to the Coding Guidelines section below for instructions on the use of code A4467 for elastic spinal garments.)

When providing orthoses 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

For prefabricated orthoses, there is no physical difference between orthoses coded as custom fitted versus those coded as OTS. The differentiating factor for proper coding (refer to the definitions in the

CODING GUIDELINES section below) is the need for “minimal self-adjustment” at the time of fitting by the beneficiary, caretaker for the beneficiary, or supplier. This minimal self-adjustment does not require the services of a certified orthotist or an individual who has specialized training. Items requiring minimal self-adjustment are coded as OTS orthoses. For example, adjustment of straps and closures, bending or trimming for final fit or comfort (not all-inclusive) fall into this category.

Fabrication of an orthosis using CAD/CAM or similar technology without the creation of a positive model with minimal self-adjustment at delivery is considered as OTS.

Items requiring more than minimal self-adjustment by a qualified practitioner are coded as custom fitted (L0454, L0456, L0458, L0460, L0462, L0464, L0466, L0468, L0470, L0472, L0488, L0490, L0491, L0492, L0626, L0627, L0630, L0631, L0633, L0635, L0637 and L0639). 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. This information must be available upon request.

For custom fabricated orthoses (L0452, L0480, L0482, L0484, L0486, L0622, L0624, L0629, L0632, L0634, L0636, L0638 and L0640), there must be detailed documentation in the treating practitioner’s records to support the medical necessity of custom fabricated rather than a prefabricated orthosis as described in the Coverage Indications, Limitations and/or Medical Necessity section of the related LCD. This information will be corroborated by the functional evaluation in the orthotist’s or prosthetist’s records. This information must be available upon request.

CODING GUIDELINES

Off-the-shelf (OTS) orthotics are:

- Items that are prefabricated.
- They may or may not be supplied as a kit that requires some assembly. Assembly of the item and/or installation of add-on components and/or the use of some basic materials in preparation of the item does not change classification from OTS to custom fitted.
- OTS items require minimal self-adjustment for fitting at the time of delivery for appropriate use and do 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.

The term “minimal self-adjustment” is defined at 42 CFR §414.402 as an adjustment the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and that does not require the services of a certified orthotist (that is, an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training. For example, adjustment of straps and closures, bending or trimming for final fit or comfort (not all-inclusive) fall into this category. See “more than minimal self-adjustment” definition below for additional information.

Use of CAD/CAM or similar technology to create an orthosis without a positive model of the patient may be considered as OTS if the final fitting upon delivery to the patient requires minimal self-adjustment not requiring expertise as described in this section.

Custom fitted orthotics are:

- Devices that are prefabricated.
- They may or may not be supplied as a kit that requires some assembly. Assembly of the item and/or installation of add-on components and/or the use of some basic materials in preparation of the item does not change classification from OTS to custom fitted.

- Classification as custom fitted requires more than minimal self-adjustment at the time of delivery in order to provide an individualized fit, i.e., the item must be trimmed, bent, molded (with or without heat), or otherwise modified resulting in alterations beyond minimal self-adjustment.
- This fitting at delivery does require expertise of a certified orthotist or an individual who has specialized training in the provision of the orthosis to fit the item to the individual beneficiary.

In contrast to “minimal self-adjustment,” “more than minimal self-adjustment” is defined as changes made to achieve an individualized fit during the final fitting at the time of delivery of the item that requires the 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. 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.

In most cases for prefabricated orthoses, the correct coding of the orthosis is dictated by actions that take place at the time of fitting to the beneficiary, either custom-fit (requiring expertise) or OTS (requiring minimal self-adjustment). However, for certain types of orthoses, the HCPCS code narrative that best describes the product does not make a distinction between prefabricated orthoses that are provided as custom-fit or OTS. These code narratives are correct and must be used for Medicare billing, without regard to how the product is provided to the beneficiary at the final delivery.

There are products that may be either fit by the beneficiary or require custom fitting at the time of final delivery where there are parallel sets of HCPCS codes that describe identical types of items. The codes are only differentiated based upon the nature of the final fitting performed at the time of delivery. The alternative HCPCS code types are:

- HCPCS codes which describe “PREFABRICATED, OFF-THE-SHELF” must be used when minimal self-adjustment is the extent of the fitting performed at delivery.
- HCPCS codes which describe “PREFABRICATED ITEM THAT HAS BEEN TRIMMED, BENT, MOLDED, ASSEMBLED, OR OTHERWISE CUSTOMIZED TO FIT A SPECIFIC PATIENT BY AN INDIVIDUAL WITH EXPERTISE” must be used when more than minimal self-adjustment is necessary at delivery.

Spinal orthoses (L0450, L0452, L0454, L0455, L0456, L0457, L0458, L0460, L0462, L0464, L0466, L0467, L0468, L0469, L0470, L0472, L0480, L0482, L0484, L0486, L0488, L0490, L0491, L0492, L0621, L0622, L0623, L0624, L0625, L0626, L0627, L0628, L0629, L0630, L0631, L0632, L0633, L0634, L0635, L0636, L0637, L0638, L0639, L0640, L0641, L0642, L0643, L0648, L0649, L0650, L0651) have the following characteristics:

1. Used to immobilize the specified areas of the spine
2. Intimate fit and generally designed to be worn under clothing
3. Not specifically designed for beneficiaries in wheelchairs

In addition to (1) and (2), the body jacket type orthoses (L0458, L0460, L0462, L0464, L0480, L0482, L0484, L0486, L0488, L0490, L0491, L0492, L0639, L0640, L0651) are characterized by a rigid plastic shell that encircles the trunk with overlapping edges and stabilizing closures and provides a high degree of immobility. The entire circumference of the plastic shell must be the same rigid material.

A rigid or semi rigid orthotic device eliminates or restricts motion in the planes being controlled by an orthosis.

A spinal orthosis is designed to control gross movement of the trunk and intersegmental motion of the vertebrae in one or more planes of motion:

- Lateral/flexion (side bending) in the coronal/frontal plane. Control of this plane is achieved by a rigid panel in the mid-axillary line, which is either an integral part of a posterior or anterior panel, or a separate panel.
- Anterior flexion (forward bending) or posterior extension (backward bending) in the sagittal plane. Control of this plane is achieved by a rigid posterior panel
- Axial rotation (twisting) viewed in the transverse plane. Straps over the shoulders attaching to a posterior panel alone do not provide transverse spinal control.

The purpose of a rigid or semi-rigid LSO and TLSO spinal orthosis is to restrict the effect of the forces within a three-point pressure system. The posterior panel must encompass the paraspinal muscle bodies from one lateral border to another in order to provide sufficient surface area to enhance the three-point pressure system. The posterior panel must provide coverage to meet the minimum height requirements as described in the individual HCPCS codes. Spinal Orthoses that do not meet the Medicare definition of a brace should be coded as A9270.

For an item to be classified as a TLSO the posterior portion of the brace must extend from the sacrococcygeal junction to just inferior to the scapular spine. This excludes elastic or equal shoulder straps or other strapping methods. The anterior portion of the orthosis must at a minimum extend from the symphysis pubis to the xiphoid. Some TLSOs may require the anterior portion of the orthosis to extend up to the sternal notch.

Maternity support garments, which are products that are designed to provide support for the abdomen during pregnancy, do not meet the definition of a brace. These products are coded using A9270 (NON-COVERED ITEM OR SERVICE). L-codes for orthoses must not be used for these items.

Elastic and Similar Stretchable Materials

For items where the HCPCS code specifies “elastic” or other similar terminology for stretchable material, use the code that is most applicable to the item. A NOC (Not Otherwise Classified) or miscellaneous HCPCS code must not be used instead of the specific code. Refer to the long code narrative and any relevant coding guideline for the criteria applicable for each HCPCS code.

For items where the HCPCS code does not specify elastic or other similar terminology for stretchable material, the following guidelines apply:

- Items that are primarily constructed of elastic or other stretchable materials (e.g. support items made of material such as neoprene or spandex (elastane, Lycra®) (not all-inclusive)) must be coded as A4467 (BELT, STRAP, SLEEVE, GARMENT, OR COVERING, ANYTYPE).
- Items that are primarily constructed of elastic or other stretchable materials (e.g. support items made of material such as neoprene or spandex (elastane, Lycra®]) (not all-inclusive)) that contain stays and/or panels must be coded as A4467 (BELT, STRAP, SLEEVE, GARMENT, OR COVERING, ANYTYPE).
- Items that are primarily constructed of inelastic material (e.g., canvas, cotton or nylon (not all-inclusive)) that are incapable of providing the necessary immobilization or support to the body part for which it is designed must be coded using A4467 (BELT, STRAP, SLEEVE, GARMENT, OR COVERING, ANYTYPE).
- Items that are primarily of constructed inelastic material (e.g., canvas, cotton or nylon (not all-inclusive)) that are incapable of providing the necessary immobilization or support to the body part for which it is designed and that have stays and/or panels capable of providing the required immobilization or support to the body part for which it is designed, must be coded using A4467 (BELT, STRAP, SLEEVE, GARMENT, OR COVERING, ANYTYPE).
- Items that are primarily constructed of inelastic material (e.g., canvas, cotton or nylon (not all-inclusive)) capable of providing the necessary immobilization or support to the body part for which it is designed must be coded using the applicable specific HCPCS code for the type of product. A NOC (Not Otherwise Classified) or miscellaneous HCPCS code must not be used

instead of the specific code. Refer to the long code narrative and any relevant coding guideline for the criteria applicable for each HCPCS code.

- Items that are primarily of constructed inelastic material (e.g., canvas, cotton or nylon (not all-inclusive)) capable of providing the necessary immobilization or support to the body part for which it is designed and that have stays and/or panels capable of providing the required immobilization or support to the body part for which it is designed, must be coded using the applicable specific HCPCS code for the type of product. A NOC (Not Otherwise Classified) or miscellaneous HCPCS code must not be used instead of the specific code. Refer to the long code narrative and relevant coding guideline for the criteria applicable for each HCPCS code.
- Items that are not capable of providing the necessary immobilization or support to the body part for which it is designed (regardless of materials) must be coded using A9270 (NONCOVERED ITEM OR SERVICE).

Codes L0450, L0454, L0455, L0621, L0625, and L0628 may only be used for orthoses that are made primarily of nonelastic material (e.g., canvas, cotton or nylon).

A custom fabricated orthosis is one which is individually made for a specific beneficiary (no other beneficiary would be able to use this orthosis) starting with basic materials including, but not limited to, plastic, metal, leather, or cloth in the form of sheets, bars, etc. It involves substantial work such as vacuum forming, cutting, bending, molding, sewing, etc. It requires more than trimming, bending, or making other modifications to a prefabricated item. A molded-to-beneficiary-model orthosis is a particular type of custom fabricated orthosis in which either:

1. An impression of the specific body part is made (usually by means of a plaster or fiberglass cast) and this impression is then used to make a positive model (usually of plaster) of the body part; or
2. Detailed measurements are taken of the beneficiary's torso and are used to modify a positive model (which has been selected from a large library of models) to make it conform to the beneficiary's body shape and dimensions; or
3. A digital image of the beneficiary's torso is made using computer (CAD/CAM) software which then directs the carving of a positive model.

The orthosis is then individually fabricated and molded over the positive model of the beneficiary.

CODING VERIFICATION REVIEW

The only products which may be billed using the following list of HCPCS codes are those for which a written coding verification review (CVR) has been made by the Pricing, Data Analysis, and Coding (PDAC) contractor and subsequently published on the Product Classification List (PCL). Information concerning the documentation that must be submitted to the PDAC for a CVR can be found on the PDAC web site or by contacting the PDAC. A PCL with products which have received a coding verification can be found on the PDAC web site. The effective date of the CVR is included for each code.

Effective for claims with dates of service on or after July 1, 2010:
L0450, L0454, L0456, L0458, L0460, L0462, L0464, L0466, L0468, L0470, L0472, L0488, L0490, L0491, L0492, L0625, L0626, L0627, L0628, L0630, L0631, L0633, L0635, L0637, L0639

Effective for claims with dates of service on or after January 1, 2014:
L0455, L0457, L0467, L0469, L0641, L0642, L0643, L0648, L0649, L0650, L0651

There are two categories of custom fabricated spinal orthoses (codes L0452, L0480, L0482, L0484, L0486, L0629, L0632, L0634, L0636, L0638, and L0640):

- Orthoses that are custom fabricated by a manufacturer/central fabrication facility and then sent to someone other than the beneficiary. Effective for claims with dates of service on or after July 1, 2010, these items may be billed using one of these codes only if they are listed in the Product Classification List on the PDAC web site.
- Orthoses that are custom fabricated from raw materials and are dispensed directly to the beneficiary by the entity that fabricated the orthosis. These items do not have to be listed on the PDAC web site in order to be billed using a custom fabricated spinal orthosis code.

However, the supplier must provide a list of the materials that were used and a description of the custom fabrication process on request.

If a product is billed to Medicare using a HCPCS code that requires written coding verification review, but the product is not on the PCL for that particular HCPCS code, then the claim line will be denied as incorrect coding.

Suppliers should contact the PDAC Contractor for guidance on the correct coding of these items.

Associated Documents

Related Local Coverage Documents

Articles

A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

LCDs

L33790 - Spinal Orthoses: TLSO and LSO