NOTE: This policy is not effective until August 1, 2025.

Medical Policy Manual Durable Medical Equipment, Policy No. 97

Spinal Orthoses: Thoracic-Lumbar-Sacral (TLSO), Lumbar-Sacral (LSO), and Lumbar

Effective: August 1, 2025

Next Review: March 2026
Last Review: March 2025

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Thoracic-lumbar-sacral (TLSO), lumbar-sacral (LSO), and lumbar (LO) spinal orthoses are back braces used for several purposes, including treatment of spinal deformities, injury, and back pain. This policy addresses the use of spinal orthoses for immobilization or support of the spine.

MEDICAL POLICY CRITERIA

Notes:

- This policy only applies to certain member contracts. Please check the preauthorization website for the member contract to confirm requirements.
- Member contracts for covered equipment and services vary. Member contract language takes precedence over medical policy. Items that are not covered benefits do not necessarily mean the items are not appropriate for the member, but only that the item falls outside of the member benefit contract.

I. The use of a custom-fitted or custom-fabricated thoracic-lumbar-sacral orthosis (TLSO), lumbar-sacral orthosis (LSO), or lumbar orthosis (LO) may be considered **medically necessary** when both of the following criteria (A and B) are met:

   A. One or more of the following are present:

      1. Pain originating from the spine, including but not limited to fracture, joint instability, or hypermobility; or
      2. Spinal injury and/or surgical procedure on the spine or related soft tissues; or
      3. Weak spinal muscles and/or a deformed spine, including but not limited to scoliosis and kyphosis; and

   B. There is clear documentation that the patient's needs cannot be adequately met with a prefabricated spinal orthosis.

II. The use of a custom-fitted or custom-fabricated thoracic-lumbar-sacral orthosis (TLSO), lumbar-sacral orthosis (LSO), or lumbar orthosis (LO) is considered **not medically necessary** if Criterion I. is not met.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

LIST OF INFORMATION NEEDED FOR REVIEW

REQUIRED DOCUMENTATION:

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- Make/model and manufacturer name of equipment/device
- Physician's Order, if applicable
- Medical records and chart notes relevant to the item or equipment requested
- Other documentation as appropriate for the specific item or equipment under review
- Documentation of pain originating from the spine, spinal injury and/or surgical procedure on the spine, and/or spinal deformity
- Documentation that the patient's needs cannot be adequately met with use of a prefabricated or custom-fitted orthosis.

CROSS REFERENCES

1. Durable Medical Equipment, Prosthetic and Orthotic Replacements, Duplicates, Repairs, and Upgrades to Existing Equipment, Durable Medical Equipment, Policy No. 75
2. Powered and Microprocessor-Controlled Knee and Ankle-Foot Prosthesis and Microprocessor-Controlled Ankle-Foot Orthoses, Durable Medical Equipment, Policy No. 81
3. General Medical Necessity Guidance for Durable Medical Equipment, Prosthetic, Orthotics and Supplies (DMEPOS), Durable Medical Equipment, Policy No. 88

BACKGROUND

SPINAL ORTHOSES

For purposes of this policy, the following definitions apply:

Spinal Orthoses

Spinal orthoses have the following characteristics[1]:

- Used to immobilize the specified areas of the spine; and
- Intimate fit and generally designed to be worn under clothing; and
- Not specifically designed for persons in wheelchairs.

A spinal orthosis is designed to control both gross trunk movement and intersegmental vertebral motion in one or more anatomical planes:

- Lateral/flexion (side bending) in the coronal/frontal plane. Control in this plane is achieved through a rigid panel in the mid-axillary line. This panel may be either an integral component of the 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 through a rigid posterior panel.
- Axial rotation (twisting) in the transverse plane. Shoulder straps attached to a posterior panel alone do not provide transverse spinal control.

Prefabricated Orthosis

A prefabricated orthosis is manufactured in quantity for general use rather than for a specific individual. These spinal orthoses may be dispensed without requiring placement or adjustment by a certified orthotist.

Custom-fitted Orthosis.

A custom-fitted orthosis is a prefabricated device, typically manufactured as a plastic torso shell, that is modified for individual patient use. Modification occurs after appropriate body measurements are taken, must be performed by an appropriately licensed and trained medical professional, and may include:

- Trimming
- Bending
- Molding (with or without heat)
- Other adjustments

An orthosis assembled from prefabricated components is classified as prefabricated, not custom-fitted.

Custom-fabricated or Custom-molded Orthosis

A custom fabricated or custom molded orthosis is individually constructed for a specific patient by a trained medical professional using basic materials such as plastic, metal, leather, or cloth. This process requires substantial custom work, such as vacuum forming, cutting, molding, and sewing. This level of customization involves more extensive modification than trimming, bending, or altering a prefabricated plastic shell.

A molded-to-individual orthosis requires:

- Creation of a patient-specific impression using casting (usually plaster), anthropometric measurements, and/or computerized modeling

- Development of a positive model of the targeted body part using the patient-specific impression
- Use of this positive model to custom fit the orthosis

Lumbar Sacral Orthoses (LSO) and Thoracic Lumbar Sacral Orthoses (TLSO) are considered back braces. Flexible spinal orthoses that are made primarily of nonelastic material (e.g., canvas, cotton or nylon) or that have a rigid posterior panel are considered braces. Elastic support garments (e.g. made of material such as neoprene or spandex) are not considered braces because they are not rigid or semi-rigid orthoses.

Rigid or semi-rigid LSO and TLSO spinal orthoses are designed to restrict the effects of a three-point pressure system. Posterior panels must encompass the paraspinal muscle bodies from one lateral border to another to provide sufficient surface area for the three-point pressure system. The posterior panel provides coverage for the minimum height specified for specific types of spinal orthoses.

For classification as a TLSO, the posterior component of the orthosis must extend from the sacrococcygeal junction to the inferior border of the scapular spine. This measurement excludes any elastic shoulder straps or additional strapping materials. The anterior portion must extend, at minimum, from the symphysis pubis to the xiphoid process. In some cases, clinical requirements may necessitate the anterior portion to extend superiorly to the sternal notch.

REGULATORY STATUS

Most orthotic devices are classified as Class I medical devices by the United States Food and Drug Administration (FDA) and are therefore exempt from premarket notification requirements. Certain specialized orthotic devices may be classified as Class II medical devices and require premarket approval. While many orthotic devices do not require FDA premarket approval, devices must still comply with applicable FDA regulations and quality standards. The majority of TLSO, LSO, and LO orthotic devices are classified as Class I medical devices and do not require FDA premarket approval.

EVIDENCE SUMMARY

Evaluating the effectiveness of TLSO, LSO, LO devices requires comparison between different types of spinal supports, including custom-fabricated, custom-fitted, and prefabricated devices, as well as comparison with no orthotic support. The most informative data come from prospective comparative studies with objective measures that directly address pain reduction, functional mobility, healing outcomes, and health-related quality of life.

Systematic Reviews

Veiskarami (2024) published a systematic review of the effectiveness of spinal orthoses on muscle function and kyphosis angle in elderly subjects with age-related postural hyper-kyphosis, a condition characterized by exaggerated anterior curvature of the thoracic spine that can impair balance and increase fall and fracture risk.[2] The analysis included 18 articles (12 of which were randomized controlled trials [RCTs]) covering 709 individuals. The reviewers reported significant improvements in several areas. There was a significant reduction in kyphosis angle among 148 participants who used spinal orthoses (standard mean difference [SMD]: -3.79, 95% Confidence Interval [CI] -7.02 to -0.56, $p<0.01$). Nearly all studies reported

significant increases in back muscle strength with orthosis use, with particularly notable improvements in long-term follow-up (mean difference [MD]: 84.73; 95% CIs, 23.24 to 146.23; p<0.01). Pain reduction was also substantial and significant (SMD: -1.66; 95% CIs, -2.39 to 0.94; p<0.01). The reviewers concluded that spinal orthoses are an effective treatment for elderly hyper-kyphosis but that the evidence is limited by a small number of heterogeneous studies.

Sánchez-Pinto-Pinto (2022) published a systematic review of the effectiveness of spinal orthoses in treating adverse effects associated with osteoporotic hyperkyphosis.[3] The analysis included four RCTs, all with a low risk of bias according to the revised Cochrane risk-of-bias tool. The studies included 326 women with osteoporosis, ranging in age from 51 to 93 years. The review examined multiple outcome measures, including quality-of-life variables (such as back pain), functional variables (including back extensor strength), and osteoporotic-related variables (such as lumbar spine bone mineral density). The findings demonstrated that wearing a dynamic hyperextension orthosis for at least two hours daily over a six-month period improved functionality, mobility, back extensor strength, respiratory function, and reductions in thoracic kyphosis angle.

Kweh (2021) published a systematic review of spinal orthoses in elderly patients with osteoporotic vertebral fractures caused by low energy trauma.[4] Seven studies were included: four RCTs and three prospective cohort studies. Five studies reported improved spinal column stability with either rigid or semi-rigid orthoses, while one study reported equivocal results. Biomechanical benefits translated into functional improvements, specifically in postural stability and reduced body sway. Additionally, patients reported subjective improvements in pain scores and quality of life while using braces. The reviewers concluded that spinal orthoses provide multiple benefits for patients aged 60 years and older with osteoporotic compression vertebral fractures including improved biomechanical vertebral stability, reduced kyphotic deformity, enhanced postural stability, greater muscular strength, and superior functional outcomes.

Hofler (2020) published a systematic review of the efficacy of spinal orthoses for treatment of osteoporotic vertebral fractures.[5] The review analyzed 16 studies, including five RCTs, six nonrandomized prospective comparative studies, one retrospective case-control study, and four prospective single-arm studies. Four studies, primarily consisting of single-arm and nonrandomized studies, provided low-quality evidence supporting the safety of bracing, with or without bedrest. Low-quality evidence from two studies suggested that bracing improved pain and disability outcomes. Four studies, including two high-quality RCTs, demonstrated that rigid braces were not superior to soft braces or no bracing at all. Additionally, two RCTs provided low-quality evidence supporting the superiority of bracing over no brace, while one nonrandomized study suggested that dynamic braces were more effective than rigid orthoses. The reviewers concluded that there is limited evidence supporting the safety of spinal orthoses for treating osteoporotic compression fractures and for the use of rigid braces over soft braces.

McAviney (2020) published a systematic review which assessed the use of spinal orthoses by adults with idiopathic or degenerative scoliosis.[6] Ten studies were included, four case reports and six cohort studies. No randomized or other controlled trials were identified by the reviewers. Among studies which assessed pain, all reported either modest or significant pain reduction after use of a spinal orthosis. The inclusion of multiple brace designs in this study limits the ability to make comparisons across studies.

Section Summary

Evidence for TLSO, LSO, and LO devices consists of several systematic reviews, RCTs, and nonrandomized studies. Multiple systematic reviews reported improved health outcomes for patients with spinal deformities such as scoliosis or kyphosis, osteoporotic vertebral fractures, and back pain. Limited evidence supports the superiority of rigid versus soft back orthoses, and the optimal duration of orthotic use remains unclear.

PRACTICE GUIDELINE SUMMARY

North American Spine Society (NASS)

A 2011 NASS evidence-based guideline for the diagnosis and treatment of degenerative lumbar spinal stenosis stated, “The use of a lumbosacral corset is suggested to increase walking distance and decrease pain in patients with lumbar spinal stenosis. There is no evidence that results are sustained once the brace is removed.” This recommendation was graded Level B (fair evidence).[7]

A 2021 NASS evidence-based guideline on the diagnosis and treatment of low back pain stated that, “There is conflicting evidence that bracing results in improvements in pain and function in patients with subacute low back pain.” This recommendation was graded Level I (insufficient or conflicting evidence not allowing a recommendation for or against intervention).[8]

International Scientific Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT)

A 2018 evidence-based guideline on orthopaedic and rehabilitation treatment of idiopathic scoliosis stated, “The use of brace is recommended in patients with evolutive idiopathic scoliosis above 25° during growth; in these cases, physiotherapy scoliosis-specific exercises (PSSE) alone (without bracing) should not be performed unless prescribed by physicians expert in scoliosis.”[9] Nighttime rigid bracing for 8 to 12 hours per day, part-time rigid bracing mainly while outside of or school or in bed for 12 to 20 hours per day, or full time rigid bracing for 20 to 24 hours per day are recommended depending on specific patient needs and factors.

American College of Physicians (ACP)

The ACP evidence-based guideline for Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain stated that the evidence is insufficient to compare lumbar support with no lumbar support due to low-quality evidence which showed no difference between a lumbar support plus exercise versus exercise along for back pain at eight weeks or six months.[10]

SUMMARY

Prefabricated thoracic-lumbar-sacral (TLSO), lumbar-sacral (LSO), and lumbar spinal orthoses (LO) improve health outcomes by providing support and restricting movement of the spine to reduce pain, allow proper healing after spinal injuries or surgery, and provide needed support for spinal muscle weakness or spinal deformities. Therefore, these spinal orthoses may be considered medically necessary when policy criteria are met.

When policy criteria are not met, there is insufficient evidence to show that prefabricated thoracic-lumbar-sacral (TLSO), lumbar-sacral (LSO), and lumbar spinal orthoses (LO) improve health outcomes. Therefore, these devices are considered not medically necessary when policy criteria are not met.

Custom-fitted and custom-fabricated thoracic-lumbar-sacral (TLSO), lumbar-sacral (LSO), and lumbar spinal orthoses (LO) may provide improved fit and function compared to prefabricated devices for individuals who cannot use prefabricated spinal orthoses due to body shape, deformity, or documented failure of or contraindication to prefabricated orthoses. Therefore, custom-fitted and custom-fabricated spinal orthoses (TLSO, LSO, and LO) may be considered medically necessary when policy criteria are met.

When policy criteria for custom-fitted or custom-fabricated fabricated thoracic-lumbar-sacral (TLSO), lumbar-sacral (LSO), and lumbar spinal orthoses (LO) are not met, there is insufficient evidence to show that custom-fitted or custom-fabricated spinal orthoses (TLSO, LSO, and LO) improve health outcomes compared to prefabricated devices. Therefore, these custom devices are considered not medically necessary when policy criteria are not met.

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CODES

Codes	Number	Description
CPT	None	
HCPCS	L0452	TLSO, flexible, provides trunk support, upper thoracic region, produces intracavitary pressure to reduce load on the intervertebral disks with rigid stays or panel(s), includes shoulder straps and closures, custom fabricated
	L0454	TLSO flexible, provides trunk support, extends from sacrococcygeal junction to above T-9 vertebra, restricts gross trunk motion in the sagittal plane, produces intracavitary pressure to reduce load on the intervertebral disks with rigid stays or panel(s), includes shoulder straps and closures, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
	L0456	TLSO, flexible, provides trunk support, thoracic region, rigid posterior panel and soft anterior apron, extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, restricts gross trunk motion in the sagittal plane, produces intracavitary pressure to reduce load on the intervertebral disks, includes straps and closures, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
	L0460	TLSO, triplanar control, modular segmented spinal system, two rigid plastic shells, posterior extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, anterior extends from the symphysis pubis to the sternal notch, soft liner, restricts gross trunk motion in the sagittal, coronal, and transverse planes, lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated item that has been trimmed, bent, molded, assembled or otherwise customized to fit a specific patient by an individual with expertise
	L0466	TLSO, sagittal control, rigid posterior frame and flexible soft anterior apron with straps, closures and padding, restricts gross trunk motion in sagittal plane, produces intracavitary pressure to reduce load on intervertebral disks, prefabricated item that has been trimmed, bent, molded, assembled or otherwise customized to fit a specific patient by an individual with expertise
	L0468	TLSO, sagittal-coronal control, rigid posterior frame and flexible soft anterior apron with straps, closures and padding, extends from sacrococcygeal junction over scapulae, lateral strength provided by pelvic, thoracic, and lateral frame pieces, restricts gross trunk motion in sagittal and coronal planes, produces intracavitary pressure to reduce load on intervertebral disks, prefabricated item that has been trimmed, bent, molded, assembled or otherwise customized to fit a specific patient by an individual with expertise
	L0480	TLSO, triplanar control, one piece rigid plastic shell without interface liner, with multiple straps and closures, posterior extends from sacrococcygeal junction

Codes	Number	Description
		and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, anterior or posterior opening, restricts gross trunk motion in sagittal, coronal, and transverse planes, includes a carved plaster or CAD-CAM model, custom fabricated
	L0482	TLSO, triplanar control, one piece rigid plastic shell with interface liner, with multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, anterior or posterior opening, restricts gross trunk motion in sagittal, coronal, and transverse planes, includes a carved plaster or CAD-CAM model, custom fabricated
	L0484	TLSO, triplanar control, two piece rigid plastic shell without interface liner, with multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, lateral strength is enhanced by overlapping plastic, restricts gross trunk motion in sagittal, coronal, and transverse planes, includes a carved plaster or CAD-CAM model, custom fabricated
	L0486	TLSO, triplanar control, two piece rigid plastic shell with interface liner, with multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, lateral strength is enhanced by overlapping plastic, restricts gross trunk motion in sagittal, coronal, and transverse planes, includes a carved plaster or CAD-CAM model, custom fabricated
	L0626	Lumbar orthosis, sagittal control, with rigid posterior panel(s), posterior extends from L-1 to below L-5 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled or otherwise customized to fit a specific patient by an individual with expertise
	L0627	Lumbar orthosis, sagittal control, with rigid anterior and posterior panels, posterior extends from L-1 to below L-5 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled or otherwise customized to fit a specific patient by an individual with expertise
	L0629	Lumbar-sacral orthosis, flexible, provides lumbo-sacral support, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include stays, shoulder straps, pendulous abdomen design, custom fabricated
	L0630	Lumbar-sacral orthosis, sagittal control, with rigid posterior panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
	L0631	Lumbar-sacral orthosis, sagittal control, with rigid anterior and posterior panels, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise

Codes	Number	Description
	L0632	Lumbar-sacral orthosis, sagittal control, with rigid anterior and posterior panels, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, custom fabricated
	L0633	Lumbar-sacral orthosis, sagittal-coronal control, with rigid posterior frame/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
	L0634	Lumbar-sacral orthosis, sagittal-coronal control, with rigid posterior frame/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panel(s), produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, custom fabricated
	L0636	Lumbar-sacral orthosis, sagittal-coronal control, lumbar flexion, rigid posterior frame/panels, lateral articulating design to flex the lumbar spine, posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, anterior panel, pendulous abdomen design, custom fabricated
	L0637	Lumbar-sacral orthosis, sagittal-coronal control, with rigid anterior and posterior frame/panels, posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
	L0638	Lumbar-sacral orthosis, sagittal-coronal control, with rigid anterior and posterior frame/panels, posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, custom fabricated
	L0639	Lumbar-sacral orthosis, sagittal-coronal control, rigid shell(s)/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, anterior extends from symphysis pubis to xiphoid, produces intracavitary pressure to reduce load on intervertebral discs, overall strength is provided by overlapping rigid material and stabilizing closures, includes straps, closures, may include soft interface, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
	L0640	Lumbar-sacral orthosis, sagittal-coronal control, rigid shell(s)/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, anterior extends from symphysis pubis to xiphoid, produces intracavitary pressure to reduce load on intervertebral discs, overall strength is provided by overlapping rigid material and stabilizing closures, includes straps, closures, may include soft interface, pendulous abdomen design, custom fabricated

Date of Origin: *March 2025*