

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Lumbar-sacral orthoses (LSO) and thoracic-lumbar-sacral orthoses (TLSO) are rigid or semi-rigid devices, 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. Spinal orthoses are used to immobilize the specified areas of the spine and offer an intimate fit so that they can be typically worn under clothing. (¹ CMS, 2015).

- **Prefabricated orthoses** are manufactured without a specific individual in mind. These include off the shelf (OTS) or custom fitted devices that can be modified to fit an individual; an orthosis that is assembled from prefabricated components is also considered prefabricated.
- **Custom-fabricated orthoses** are individually constructed for a specific individual; basic materials may include plastic, metal, leather, or cloth in the form of sheets, bars, etc. which are cut, bent, molded, and/or sewed to create the orthosis. Prefabricated parts may also be included.

Scoliosis

Back bracing is also prescribed to treat adolescent idiopathic scoliosis to stop the progression of spinal curvature in a growing child/adolescent or to decrease the amount of curvature of the spine. Spinal orthoses are classified as prefabricated, pre-fitted, or custom-fabricated: (^{1,2} Scherl, 2022).

- **Prefabricated orthoses** are manufactured by size from prefabricated materials and not customized.
- **Custom-fitted orthoses** are prefabricated and changes by bending, molding, or trimming it to fit a specific individual.
- **Custom-fabricated orthosis** are made specifically for an individual with materials such as plastic, metals, cloths, or leather. Substantial labor from cutting, bending, molding, and sewing are required to complete the orthosis. A mold is made from an impression of the body part through plaster casting or CAD-CAM (computer aided technology); the impression is used to make the model and then the actual orthosis.

Prefabricated orthoses may be used prior to custom-fitted orthoses. Custom-fitted are generally attempted prior to custom fabricated orthoses. A custom fitted orthosis may be required initially for unstable spinal fractures that are treated nonoperatively. A custom fabricated (or molded orthoses) are generally required for the treatment of scoliosis and kyphosis. Examples of custom fabricated braces are the Boston and Milwaukee braces. (^{1,2} Scherl, 2022).

COVERAGE POLICY

General Criteria

Prefabricated thoracic-lumbar-sacral orthoses (TLSO), lumbar-sacral orthoses (LSO), and lumbar orthoses **are considered medically necessary** when the following criteria is met: (MCG, 2022; ² CMS, 2015)

1. Orthoses are used to:
 - a. Reduce pain by restricting mobility of the trunk; **OR**
 - b. Facilitate healing after an injury to the spine or related soft tissues; **OR**
 - c. Facilitate healing after a surgical procedure on the spine or related soft tissue; **OR**
 - d. Support weak spinal muscles.

AND

2. Orthosis is applicable to the Member's condition; **AND**
3. Brace or other device is rigid or semi-rigid that supports a weak or deformed body part or can restrict or eliminate motion in a diseased or injured body part; **AND**
4. Appropriate support and counterforce are demonstrated; **AND**
5. Brace or device is high quality, prefabricated or custom-fabricated, and can endure use long-term.

Device Specific Criteria

In addition to the General Criteria above, the Member must meet **at least ONE** of the following criteria:

1. **Lumbar Sacral Orthoses (LSO)** may be covered for the treatment of lower back pain when symptoms are emergent. A referral may be indicated for the evaluation and management of **ANY** of the following specialties:
 - a. Behavioral health
 - b. Endocrinology (e.g., metabolic bone disease such as osteoporosis, Paget disease)
 - c. Infectious disease
 - d. Neurology
 - e. Neurosurgery
 - f. Occupational medicine (e.g., need for work restrictions)
 - g. Oncology
 - h. Pain management (e.g., chronic low back pain, prolonged narcotic usage)
 - i. Physical medicine and rehabilitation (physiatry)
 - j. Physical therapy
 - k. Rheumatology
 - l. Surgery – orthopedic spine
2. **Cervical Thoracic Lumbar Sacral Orthoses (CTLSO) or Thoracic-Lumbar-Sacral Orthoses (TLSO)** may be covered for the treatment of scoliosis in children and adolescents when **ALL** of the following are met:
 - a. Idiopathic spinal curve angle between 25 and 60 degrees; **AND**
 - b. Member's spinal growth is not complete as evidenced by a Risser grade of 0-3 and no more than one (1) year post-menarche (females); **OR**
 - c. Idiopathic spinal curve angle greater than 20 degrees; **AND**
 - d. A documented increase in the curve angle is present; **AND**
 - e. Member has at least two (2) years of growth remaining as evidenced by a Risser grade of 0 or 1 and females are pre-menarche.

OR

3. **Supportive Back Braces** are considered medically necessary when used to:
 - a. Facilitate healing following after injury to the spine or related soft tissues; **OR**
 - b. Facilitate healing after a surgical procedure on the spine or related soft tissue; **OR**
 - c. Minimize pain by restricting mobility of the trunk; **OR**
 - d. Support weak spinal muscles and/or a deformed spine.

Molina Clinical Policy

Back Braces: Policy No. 067

Last Approval: 2/8/2023

Next Review Due By: February 2024



OR

4. **Custom-Fitted and Custom-Fabricated Back Braces** are considered medically necessary when **ONE** of the following are met:
- Brace is prefabricated and modified to fit a specific individual after failure, contraindication, or intolerance to an unmodified, prefabricated back brace; **OR**
 - Brace is the initial one following surgical stabilization of the spine following traumatic injury; **OR**
 - A custom-fabricated back brace (constructed to fit a specific individual) is required due to a failure, contraindication, or intolerance to a custom-fitted back brace.

OR

5. **Postoperative Back Braces** are considered medically necessary when:
- It is part of the treatment plan and surgical protocol; **AND**
 - Brace will improve Member's condition; **AND**
 - Brace is applied within six (6) weeks following a surgical procedure of the spine or related soft tissue.

OR

6. **Rehabilitation Braces** are considered medically necessary when the above general criteria are met and are applied within six (6) weeks of surgery or injury.

OR

7. **Braces for Congenital Defects or Advanced Neuromuscular Conditions** are considered medically necessary when: the above general criteria are met. For replacement braces, the following must be met:
- Member has outgrown the previous or current brace; **OR**
 - Member's condition has changed, and the previous or current brace cannot be used.

Quantity Level Limits (QLL) for All Back Braces

Molina covers **one (1) back brace every five (5) years** based on the average lifetime of a back brace.

Limitations and Exclusions

- Contraindications to scoliosis bracing include:
 - Skeletal maturity (Risser sign 4 to 5 and ring apophyses fused)
 - Cobb angle $\geq 50^{\circ}$
 - Cobb angle $< 20^{\circ}$
 - Thoracic Lordosis (relative contraindication)
- Spinal orthoses are considered NOT medically necessary due to insufficient evidence for the following (Weinstein et al., 2013; Negrini et al., 2010; Gabos et al., 2004):
 - Management of acute or chronic back pain
 - Management of preoperative or postoperative spinal fusion surgery.
 - Treatment of adult kyphosis.
 - Treatment of spinal burst fractures with or without neurological deficits.
 - The orthotic or requested accessories are used for sports participation, to improve athletic performance, or to prevent injury in an otherwise uninjured body part are not considered necessary for medical treatment.
 - Duplicate orthoses for convenience or orthotics containing convenience or luxury features.
- Completely elastic supports (e.g., athletic supporter, joint supports, non-rigid trusses, etc.) and inflatable lumbar supports as they do not last long-term due to the type of materials used to make the supports.
- Upgrade of spinal orthoses are considered a deluxe Durable Medical Equipment (DME) item and not medically necessary when the primary purpose is to: allow the Member to perform leisure or recreational activities; includes comfort, luxury, or convenience features; or a feature which exceeds that which is considered medically necessary to treat the individual's condition.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Mehta et al. (2022) performed a retrospective review on non-operative management of thoracolumbar spine fractures and the use of thoracolumbar spine orthosis. The benefit of TLSO bracing is controversial due to reports in the medical literature that prolonged brace use may result in diminished lung capacity, skin breakdown, and paraspinal muscular atrophy – no significant difference was found in pain and functional outcomes between patients treated with or without TLSO. Data from an 18-month period and 42 patients were included and outcomes were documented via a questionnaire. Sixty percent of patients stated that they did not receive satisfactory information about the duration of treatment. 43% stated that brace use that the brace affected activities of daily living, and 73% stopped using the brace before indicated (60% of these patients indicated that they would rather be without the brace, if able).

da Silveira et al. (2022) conducted a prospective randomized study with the aim of showing the benefit of bracing for adolescents with idiopathic scoliosis. The goal of the study was to confirm short- and long-term effects of using a spinal brace; this includes utilization of an exercise program for the spine, body balance, and plantar load distribution during gait. The study included 45 adolescents who were undergoing conservative treatment; they were evaluated at two stages of intervention. Significant improvement was found in the main scoliotic curvature, with a 12-degree reduction in Cobb angle pre- and post-short-term immediate use of spinal brace and a 5.3-degree correction after six months of spinal brace use in combination with specific exercises (long term). The authors also found that short- and long-term brace use along with an exercise program increased a patient's anteroposterior and mediolateral balance – a reduction in plantar overload on the heel during gait was also found with an effect size between moderate and high.

Hofler and Jones (2020) performed a systematic review to examine the efficacy of spinal orthoses for osteoporotic vertebral fractures. A total of 16 studies were reviewed including five randomized controlled trials (RCTs), six nonrandomized prospective comparative studies, one retrospective case-control study, and four prospective single-arm studies. Four studies resulted in low-quality evidence that bracing was safe (with or without bedrest). Two studies found low quality evidence that bracing improved pain and disability. Four studies found that using a rigid brace was comparable to use of a soft brace or no brace. Two studies found a benefit of kyphoplasty versus bracing alone. The authors concluded that evidence does not exist to demonstrate that a rigid brace is superior to a soft brace or no brace. Of the RCTs, three overlapped with RCTs reviewed by Kweh et al. (2021) which are discussed below. and two demonstrated that the use of spinal orthoses benefited individuals diagnosed with osteoporotic fractures.

Kweh et al. (2021) performed a systematic review utilizing MEDLINE, EMBASE, Google Scholar, and Cochrane Databases. At time of publication, this was the first type of review conducted on the role of spinal orthoses for elderly patients who sustain low energy trauma vertebral fractures. A total of 7 articles were reviewed which included 4 randomized controlled trials and 3 prospective cohort studies. Improvement in pain scores and quality of life were reported with bracing. Benefits were found for the use of spinal orthoses in patients aged 60 years and older who are neurologically intact with osteoporotic compression vertebral fractures – benefits include biomechanical vertebral stability, reduced kyphotic deformity, enhanced postural stability, greater muscular strength, and superior functional.

Scoliosis

The body of literature composed of randomized controlled studies (RCTs), systematic reviews and observational comparative studies support bracing in skeletally immature patients with adolescent scoliosis. Bracing is noted to reduce the risk of curve progression to $\geq 50^\circ$ (the usual threshold for surgery) at skeletal maturity. The efficacy of bracing is directly related to the number of hours per day that the brace is worn. There are limited studies that compare one type of brace to the other. (Gabos et al., 2004; Gepstein et al., 2002). A summary relevant RCTs are below.

A large randomized controlled multicenter study of 242 patients with scoliosis was conducted – 116 were randomly assigned to bracing or observation and 126 chose between bracing and observation. Patients in the bracing group were instructed to wear the brace at least 18 hours per day. The primary outcomes were curve progression to 50

Molina Clinical Policy

Back Braces: Policy No. 067

Last Approval: 2/8/2023

Next Review Due By: February 2024



degrees or more (treatment failure) and skeletal maturity without this degree of curve progression (treatment success). The trial was stopped early owing to the efficacy of bracing. In an analysis that included both the randomized and preference cohorts, the rate of treatment success was 72% after bracing, as compared with 48% after observation (propensity-score–adjusted odds ratio for treatment success, 1.93; 95% confidence interval [CI], 1.08 to 3.46). In the intention-to-treat analysis, the rate of treatment success was 75% among patients randomly assigned to bracing, as compared with 42% among those randomly assigned to observation (odds ratio, 4.11; 95% CI, 1.85 to 9.16). There was a significant positive association between hours of brace wear and rate of treatment success. Bracing significantly decreased the progression of high-risk curves to the threshold for surgery in patients with adolescent idiopathic scoliosis. The benefit increased with longer hours of brace wear. (Rowe et al., 1997).

McAviney et al. (2020) performed a systematic review to examine the research on the use of spinal orthoses by adults with idiopathic or degenerative scoliosis. Literature reviewed was published between 1967 and 2018 – a total of 339 adults with all types of scoliosis were included. A search of 10 studies found that patients reported a modest or significant reduction of pain after use of a spinal orthosis. Patients wore the brace from 2 to 23 hours each day; mixed compliance was reported. Evidence shows that orthosis use may have a positive short to medium term influence on pain and function. The authors concluded that additional prospective trials are needed to gain more understanding of the efficacy of bracing in adult scoliosis.

Spinal Burst Fractures

Evidence is insufficient to conclude if spinal orthoses improve outcomes in the management of spinal burst fractures. A multicenter, randomized, nonblinded equivalence trial conducted to determine whether TLSO is equivalent to no orthosis in the treatment of acute AO Type A3 thoracolumbar burst fractures. Forty-seven patients were enrolled into the TLSO group and 49 patients into the NO group. The RMDQ score at 3 months post injury was 6.8 ± 5.4 (standard deviation [SD]) for the TLSO group and 7.7 ± 6.0 (SD) in the NO group. Treating these fractures using early ambulation without a brace avoids the cost and patient deconditioning associated with a brace and complications and costs associated with long-term bed rest if a TLSO or body cast is not available. (Bailey et al., 2013).

A Cochrane review (Weinstein et al., 2013) concluded that the contradictory evidence provided by two small and potentially biased randomized controlled trials is insufficient to conclude whether surgical or non-surgical treatment yields superior pain and functional outcomes for people with thoracolumbar burst fractures without neurological deficit.

Back Pain and Spinal Fusion

Evidence is insufficient to conclude whether spinal orthoses improve outcomes in the management of back pain or for spinal fusion. A Cochrane Review evaluated randomized control trials to determine the effectiveness of lumbar brace supports in the prevention and treatment of non-specific low back pain and concluded that it remains unclear whether lumbar supports are more effective than no or other interventions for treating low-back pain (Gabos et al., 2004).

Dailey et al. (2014) reported on a trial of preoperative bracing prior to lumbar fusion to determine the efficacy of braces; the authors also analyzed the use following lumbar surgery to promote a successful arthrodesis. Lumbar orthoses do not eliminate motion in the lumbar spine hence their efficacy have been questioned. Low back pain may be minimized with the use of lumbar bracing however evidence is low; prophylactic use of braces does not reduce the incidence of low-back pain or decrease the amount of lost productivity in the general working population. While lumbar bracing is effective in select populations, it is not effective for patients with chronic low-back pain. Rigid braces were found to be more effective over soft braces. Data does not exist that demonstrates a benefit of preoperative external bracing following lumbar spinal fusion for low back pain. In addition, bracing does not improve fusion rates or clinical outcomes after instrumented lumbar fusion for degenerative disease.

National and Specialty Organizations

The **North American Spine Society (NASS)** (2020) published the guideline *Diagnosis and Treatment of Low Back Pain*. Based on several randomized control trials, the NASS outlines evidence on the efficacy of lumbosacral and sacroiliac braces to improve pain and function in patients with subacute low back pain.

The NASS (2011) also published the guideline *Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis*. The use of a lumbosacral corset is recommended to increase walking distance and decrease pain in patients with lumbar spinal stenosis as evidence does not show that results are maintained once the brace is removed.

Molina Clinical Policy
Back Braces: Policy No. 067

Last Approval: 2/8/2023
 Next Review Due By: February 2024



Patients with moderate symptoms may benefit from medical / interventional treatment. One study demonstrated that those who did not undergo surgery found the same results as those with no treatment except for pain medication. However, the authors note that the treatment is not clearly defined. Level IV treatment evidence found that decompression provides improvement in pain 50-60% of the time while 20-36% of patients were likely to worsen. Level IV evidence also suggests that medical / interventional management may improve pain relief 33% of the time.

The **American College of Physicians (ACP)** published the guideline *Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain*. The clinical recommendations include the use of lumbar supports / braces as a noninvasive, nonpharmacologic therapy option (Qaseem et al., 2017).

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes – None.

HCPCS Codes

HCPCS	Description
L0450	Thoracic-lumbar-sacral orthosis (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, prefabricated, off-the-shelf
L0452	Thoracic-lumbar-sacral orthosis (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	Thoracic-lumbar-sacral orthosis (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
L0455	Thoracic-lumbar-sacral orthosis (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, off-the-shelf
L0456	Thoracic-lumbar-sacral orthosis (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
L0457	Thoracic-lumbar-sacral orthosis (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, off-the-shelf
L0458	Thoracic-lumbar-sacral orthosis (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 xiphoid, 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, includes fitting and adjustment
L0460	Thoracic-lumbar-sacral orthosis (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

Molina Clinical Policy
Back Braces: Policy No. 067

Last Approval: 2/8/2023
 Next Review Due By: February 2024



L0462	Thoracic-lumbar-sacral orthosis (TLSO), triplanar control, modular segmented spinal system, three 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, includes fitting and adjustment
L0464	Thoracic-lumbar-sacral orthosis (TLSO), triplanar control, modular segmented spinal system, four rigid plastic shells, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to the sternal notch, soft liner, restricts gross trunk motion in sagittal, coronal, and transverse planes, lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated, includes fitting and adjustment
L0466	Thoracic-lumbar-sacral orthosis (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
L0467	Thoracic-lumbar-sacral orthosis (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, off-the-shelf
L0468	Thoracic-lumbar-sacral orthosis (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
L0469	Thoracic-lumbar-sacral orthosis (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, off-the-shelf
L0470	Thoracic-lumbar-sacral orthosis (TLSO), triplanar control, rigid posterior frame and flexible soft anterior apron with straps, closures and padding extends from sacrococcygeal junction to scapula, lateral strength provided by pelvic, thoracic, and lateral frame pieces, rotational strength provided by subclavicular extensions, restricts gross trunk motion in sagittal, coronal, and transverse planes, provides intracavitary pressure to reduce load on the intervertebral disks, includes fitting and shaping the frame, prefabricated, includes fitting and adjustment
L0472	Thoracic-lumbar-sacral orthosis (TLSO), triplanar control, hyperextension, rigid anterior and lateral frame extends from symphysis pubis to sternal notch with two anterior components (one pubic and one sternal), posterior and lateral pads with straps and closures, limits spinal flexion, restricts gross trunk motion in sagittal, coronal, and transverse planes, includes fitting and shaping the frame, prefabricated, includes fitting and adjustment
L0480	Thoracic-lumbar-sacral orthosis (TLSO), triplanar control, one-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, 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	Thoracic-lumbar-sacral orthosis (TLSO), triplanar control, one-piece rigid plastic shell with interface liner, 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	Thoracic-lumbar-sacral orthosis (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 the sagittal, coronal, and transverse planes, includes a carved plaster or CAD-CAM model, custom fabricated

Molina Clinical Policy
Back Braces: Policy No. 067

Last Approval: 2/8/2023
 Next Review Due By: February 2024



L0486	Thoracic-lumbar-sacral orthosis (TLSO), triplanar control, two-piece rigid plastic shell with interface liner, 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 the sagittal, coronal, and transverse planes, includes a carved plaster or CAD-CAM model, custom fabricated
L0488	Thoracic-lumbar-sacral orthosis (TLSO), triplanar control, one-piece rigid plastic shell with interface liner, 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, prefabricated, includes fitting and adjustment
L0490	Thoracic-lumbar-sacral orthosis (TLSO), sagittal-coronal control, one-piece rigid plastic shell, with overlapping reinforced anterior, with multiple straps and closures, posterior extends from sacrococcygeal junction and terminates at or before the T-9 vertebra, anterior extends from symphysis pubis to xiphoid, anterior opening, restricts gross trunk motion in sagittal and coronal planes, prefabricated, includes fitting and adjustment
L0491	Thoracic-lumbar-sacral orthosis (TLSO), sagittal-coronal 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 xiphoid, soft liner, restricts gross trunk motion in the sagittal and coronal planes, lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated, includes fitting and adjustment
L0492	Thoracic-lumbar-sacral orthosis (TLSO), sagittal-coronal control, modular segmented spinal system, three 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 xiphoid, soft liner, restricts gross trunk motion in the sagittal and coronal planes, lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated, includes fitting and adjustment
L0621	Sacroiliac orthosis (SO), flexible, provides pelvic-sacral support, reduces motion about the sacroiliac joint, includes straps, closures, may include pendulous abdomen design, prefabricated, off-the-shelf
L0622	Sacroiliac orthosis (SO), flexible, provides pelvic-sacral support, reduces motion about the sacroiliac joint, includes straps, closures, may include pendulous abdomen design, custom fabricated
L0623	Sacroiliac orthosis (SO), provides pelvic-sacral support, with rigid or semi-rigid panels over the sacrum and abdomen, reduces motion about the sacroiliac joint, includes straps, closures, may include pendulous abdomen design, prefabricated, off-the-shelf
L0624	Sacroiliac orthosis (SO), provides pelvic-sacral support, with rigid or semi-rigid panels placed over the sacrum and abdomen, reduces motion about the sacroiliac joint, includes straps, closures, may include pendulous abdomen design, custom fabricated
L0625	Lumbar orthosis (LO), flexible, provides lumbar support, 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 pendulous abdomen design, shoulder straps, stays, prefabricated, off-the-shelf
L0626	Lumbar orthosis (LO), 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 (LO), 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
L0628	Lumbar-sacral orthosis (LSO), 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, prefabricated, off-the-shelf
L0629	Lumbar-sacral orthosis (LSO), 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

Molina Clinical Policy
Back Braces: Policy No. 067

Last Approval: 2/8/2023
 Next Review Due By: February 2024



L0630	Lumbar-sacral orthosis (LSO), 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 (LSO), 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
L0632	Lumbar-sacral orthosis (LSO), 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 (LSO), 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 (LSO), 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
L0635	Lumbar-sacral orthosis (LSO), sagittal-coronal control, lumbar flexion, rigid posterior frame/panel(s), lateral articulating design to flex the lumbar spine, 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, anterior panel, pendulous abdomen design, prefabricated, includes fitting and adjustment
L0636	Lumbar-sacral orthosis (LSO), 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 (LSO), 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 (LSO), 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 (LSO), sagittal-coronal control, rigid shell(s)/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, anterior extends from symphysis pubis to xyphoid, produces intracavitary pressure to reduce load on the 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 (LSO), sagittal-coronal control, rigid shell(s)/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, anterior extends from symphysis pubis to xyphoid, produces intracavitary pressure to reduce load on the 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

Molina Clinical Policy
Back Braces: Policy No. 067

Last Approval: 2/8/2023
 Next Review Due By: February 2024



L0641	Lumbar orthosis (LO), 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, off-the-shelf
L0642	Lumbar orthosis (LO), 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, off-the-shelf
L0643	Lumbar-sacral orthosis (LSO), 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, off-the-shelf
L0648	Lumbar-sacral orthosis (LSO), 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, off-the-shelf
L0649	Lumbar-sacral orthosis (LSO), 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, off-the-shelf
L0650	Lumbar-sacral orthosis, sagittal-coronal control, with rigid anterior and 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, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L0651	Lumbar-sacral orthosis (LSO), sagittal-coronal control, rigid shell(s)/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, anterior extends from symphysis pubis to xyphoid, produces intracavitary pressure to reduce load on the intervertebral discs, overall strength is provided by overlapping rigid material and stabilizing closures, includes straps, closures, may include soft interface, pendulous abdomen design, prefabricated, off-the-shelf
L1000	Cervical-thoracic-lumbar-sacral orthosis (CTLSO) (Milwaukee), inclusive of furnishing initial orthotic, including model
L1499	Spinal orthosis not otherwise specified

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

2/8/2023	Policy reviewed, updated criteria in Coverage Policy section to include TLSO, CTLSO, and LSO as well as other types of back braces; updated Overview, Summary of Medical Evidence and Reference sections.
4/13/2022	Policy reviewed; no changes to criteria; updated Summary of Medical Evidence and Reference sections.
6/19/2019, 4/23/2020, 4/5/2021	Policy reviewed, no changes to criteria; added descriptions for each HCPCS code on 6/15/2021.
3/8/2018	Policy reviewed, no changes to criteria.

REFERENCES

- Government Agency**
- Centers for Medicare and Medicaid Services (CMS). Local coverage article. Spinal orthoses: TLSO and LSO – policy article (A52500). Available from [CMS](#). Effective Date October 1, 2015. Accessed December 19, 2022.
 - Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Local coverage determination (LCD) – spinal orthoses: TLSO and LSO (L33790). Available from [CMS](#). Effective Date October 1, 2015. Accessed December 19, 2022.

Molina Clinical Policy

Back Braces: Policy No. 067

Last Approval: 2/8/2023

Next Review Due By: February 2024



Evidence Based Reviews and Publications

1. Dane Street Peer Review. Policy reviewed on February 7, 2023 by a practicing, board-certified physician in the Orthopedic Surgery.
2. MCG. Ambulatory care: Durable medical equipment, prosthetics – orthotics, and supplies (DMEPOS) – musculoskeletal conditions – lumbar, lumbosacral, and thoracolumbosacral orthoses (A-0880), 26th ed. Available from [MCG](#). Updated August 31, 2022. Accessed December 19, 2022. Registration and login required.
3. ¹Scherl SA, Hasley BP. Adolescent idiopathic scoliosis: Clinical features, evaluation, and diagnosis. Available from [UpToDate](#). Updated August 10, 2022. Accessed December 20, 2022. Registration and login required.
4. ²Scherl SA. Adolescent idiopathic scoliosis: Management and prognosis. Available from [UpToDate](#). Updated July 21, 2022. Accessed December 20, 2022. Registration and login required.

Peer Reviewed Publications

1. Bailey CS, Urquhart JC, Dvorak MF, Nadeau M, Boyd MC, Thomas KA, et al. Orthosis versus no orthosis for the treatment of thoracolumbar burst fractures without neurologic injury: A multicenter prospective randomized equivalence trial. *Spine J*. 2014 Nov 1;14(11):2557-64. doi: 10.1016/j.spinee.2013.10.017. PMID: 24184649.
2. Dailey AT, Ghogawala Z, Choudhri TF, Watters WC, Resnick DK, Sharan A, et al. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 14: Brace therapy as an adjunct to or substitute for lumbar fusion. *J Neurosurg Spine*. 2014 Jul;21(1):91-101. doi: 10.3171/2014.4.SPINE14282. PMID: 24980591.
3. da Silveira GE, Andrade RM, Guilhermino GG, Schmidt AV, Neves LM, Ribeiro AP. The effects of short- and long-term spinal brace use with and without exercise on spine, balance, and gait in adolescents with idiopathic scoliosis. *Medicina (Kaunas)*. 2022 Jul 29;58(8):1024. doi: 10.3390/medicina58081024. PMID: 36013490 PMCID: PMC9413676.
4. Gabos PG, Bojescul JA, Bowen JR, Keeler K, Rich L. Long-term follow-up of female patients with idiopathic scoliosis treated with the Wilmington orthosis. *J Bone Joint Surg Am*. 2004 Sep;86(9):1891-9. doi: 10.2106/00004623-200409000-00006. PMID: 15342750.
5. Gepstein R, Leitner Y, Zohar E, Angel I, Shabat S, Pekarsky I, et al. Effectiveness of the Charleston bending brace in the treatment of single-curve idiopathic scoliosis. *J Pediatr Orthop*. Jan-Feb 2002;22(1):84-7. PMID: 11744860.
6. Hoffer RC, Jones GA. Bracing for acute and subacute osteoporotic compression fractures: A systematic review of the literature. *World Neurosurg*. 2020; 141: e453-e460. doi: 10.1016/j.wneu.2020.05.199. PMID: 32474094.
7. Kweh BTS, Lee HQ, Tan T, Rutges J, Marion T, Tew KS, et al. The role of spinal orthoses in osteoporotic vertebral fractures of the elderly population (age 60 years or older): Systematic review. *Global Spine J*. 2021 Jul;11(6):975-987. doi: 10.1177/2192568220948036. PMID: 32990034 PMCID: PMC8258809.
8. McAviney J, Mee J, Fazalbhoy A, Plessis JD, Brown BT. A systematic literature review of spinal brace/orthosis treatment for adults with scoliosis between 1967 and 2018: Clinical outcomes and harms data. *BMC Musculoskelet Disord*. 2020; 21(1):87. doi: 10.1186/s12891-020-3095-x. PMID: 32035480. PMCID: PMC7007692.
9. Mehta S, Yusuf BS, Chiew D, Rathore S, Reddy NR, Nair D, et al. Thoracolumbar sacral orthosis for spinal fractures: What's the evidence and do patients use them? *Cureus*. 2022 Nov 5;14(11):e31117. doi: 10.7759/cureus.31117. PMID: 36475169; PMCID: PMC9720085.
10. Negrini S, Minozzi S, Bettany-Saltikov J, Chockalingam N, Grivas TB, Kotwicki T, et al. Braces for idiopathic scoliosis in adolescents. *Cochrane Database Syst Rev*. 2015 Jun 18;(6):CD006850. doi: 10.1002/14651858.CD006850.pub3. PMID: 26086959.
11. Rowe DE, Bernstein SM, Riddic MF, Adler F, Emans JB, Gardner-Bonneau D. A meta-analysis of the efficacy of non-operative treatments for idiopathic scoliosis. *J Bone Joint Surg Am*. 1997; 79(5):664-674. PMID: 9160938.
12. Weinstein SL, Dolan LA, Wright JG, Dobbs MB. Effects of bracing in adolescents with idiopathic scoliosis. *N Engl J Med*. 2013 Oct 17;369(16):1512-21. doi: 10.1056/NEJMoa1307337. PMID: 24047455. PMCID: PMC3913566.

National and Specialty Organizations

1. North American Spine Society (NASS). Evidence-based clinical guidelines for multidisciplinary spine care: Diagnosis and treatment of degenerative lumbar spinal stenosis. Available from [NASS](#). Updated 2011. Accessed December 20, 2022.
2. North American Spine Society (NASS). Evidence-based clinical guidelines for multidisciplinary spine care: Diagnosis and treatment of low back pain. Available from [NASS](#). Updated 2020. Accessed December 20, 2022.
3. Qaseem A, Wilt TJ, McLean RM, Forcica MA, Forcica MA, Clinical Guidelines Committee of the American College of Physicians, Denberg TD, et al. Noninvasive treatments for acute, subacute, and chronic low back pain: A clinical practice guideline from the American College of Physicians. *Ann Intern Med*. 2017 Apr 4;166(7):514-530. doi: 10.7326/M16-2367. PMID: 28192789.

Other Peer Reviewed and National Organization Publications (used in the development of this policy)

1. Abdoud M, Chen X, Kong X, Wu T. Surgical versus non-surgical treatment for thoracolumbar burst fractures without neurological deficit. *Cochrane Database Syst Rev*. 2013 Jun 6;6:CD005079. doi: 10.1002/14651858.CD005079.pub3. PMID: 23740669.
2. Howard A, Wright JG, Hedden D. A comparative study of TLSO, Charleston, and Milwaukee braces for idiopathic scoliosis. *Spine (Phila Pa 1976)*. 1998 Nov 15;23(22):2404-11. doi: 10.1097/00007632-199811150-00009. PMID: 9836354.
3. Katz DE, Richards BS, Browne RH, Herring JA. A comparison between the Boston brace and the Charleston bending brace in adolescent idiopathic scoliosis. *Spine (Phila Pa 1976)*. 1997 Jun 15;22(12):1302-12. doi: 10.1097/00007632-199706150-00005. PMID: 9201832.
4. Negrini S, Donzelli S, Gabriele Aulisa A, Czaprowski D, Schreiber S, de Mauroy JC, et al. 2016 SOSORT guidelines: Orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth. *Scoliosis Spinal Disord*. 2018 Jan 10;13:3. doi: 10.1186/s13013-017-0145-8. PMID: 29435499. PMCID: PMC5795289.
5. Shindle MK, Khanna AJ, Bhatnagar R, Sponseller PD. Adolescent idiopathic scoliosis: Modern management guidelines. *J Surg Orthop Adv*. 2006; 15(1):43-52. PMID: 16603112.
6. Trivedi JM, Thomson JD. Results of Charleston bracing in skeletally immature patients with idiopathic scoliosis. *J Pediatr Orthop*. May-Jun 2001;21(3):277-80. PMID: 11371804.
7. van Duijvenbode I, Jellema P, van Poppel M, van Tulder MW. Lumbar supports for prevention and treatment of low back pain. *Cochrane Database Syst Rev*. 2008 Apr 16;2008(2):CD001823. doi: 10.1002/14651858.CD001823.pub3. PMID: 18425875. PMCID: PMC7046130.
8. Wheelless Online. Textbook of orthopaedics: Scheuermann's Kyphosis. Available from [Wheelless](#). Accessed December 20, 2022.