**Clinical Practice Guideline: Thoracic and Lumbar Orthoses**

**Date of Implementation: December 20, 2012**

**Product: Specialty**

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## GUIDELINES

I. Use of thoraco-lumbar orthoses for the treatment of low back pain are considered not medically necessary as the scientific literature is inconclusive regarding their clinical effectiveness.

II. Lumbar orthoses are considered not medically necessary as they are ineffective in the *prevention* of low back injury and any use is not supported by the available evidence.

III. Lumbar supports, if used in rare circumstances, should only be utilized upon failure of other conservative measures for low back pain and only in the short term as a bridge to active care.

IV. All uses of a thoracic-lumbar-sacral orthosis incorporating pneumatic inflation are considered unproven.

Bracing for scoliosis may be considered as a covered treatment option only when the following criteria are met:

1. A cervical-thoracic-lumbar-sacral or thoracic-lumbar-sacral orthosis is considered medically necessary for the treatment of scoliosis in juvenile and adolescent members at high risk of progression and meets the following criteria:
   - Idiopathic spinal curve angle between 25 and 40 degrees; AND
   - Spinal growth has not been completed (Risser grade 0-3; no more than 1 year after menarche in females).

OR

- Idiopathic spinal curve angle greater than 20 degrees; AND
- There is documented increase in the curve angle; AND
- At least 2 years growth remain (Risser grade 0 or 1; premenarche in females).


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2. Use of an orthosis for the treatment of scoliosis that does not meet the criteria above is considered investigational.

For Medicare recipients, per the Centers for Medicare & Medicaid Services (CMS) Local Coverage Determinations, a spinal orthosis (L0450 - L0651) is covered when it is ordered for one of the following indications by a medical physician:

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

**HCPCS Codes and Descriptions**

| HCPCS Codes | HCPCS Code Description |
|---|---|
| L0450 | 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 | 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 |
| L0455 | 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 | 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 |

| HCPCS Codes | HCPCS Code Description |
|---|---|
| L0457 | 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 | 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 | 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 |
| L0462 | 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 | 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 | 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 |

| HCPCS Codes | HCPCS Code Description |
|---|---|
| L0467 | 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 | 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 | 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 | 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 | 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 | 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 |

| HCPCS Codes | HCPCS Code Description |
|---|---|
| L0482 | 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 | 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 |
| L0486 | 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 | 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 | 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 | 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 |

| HCPCS Codes | HCPCS Code Description |
|---|---|
| L0492 | 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, 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, flexible, provides pelvic-sacral support, reduces motion about the sacroiliac joint, includes straps, closures, may include pendulous abdomen design, custom fabricated |
| L0623 | Sacroiliac orthosis, 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, 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, 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, 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 |

| HCPCS Codes | HCPCS Code Description |
|---|---|
| L0628 | 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, prefabricated, off-the-shelf |
| 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 |
| 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 |

| HCPCS Codes | HCPCS Code Description |
|---|---|
| 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 |
| L0635 | Lumbar-sacral orthosis, 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, 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, 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 |

| HCPCS Codes | HCPCS Code Description |
|---|---|
| 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 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, 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 |
| L0641 | 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, off-the-shelf |
| L0642 | 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, off-the-shelf |
| L0643 | 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, off-the-shelf |
| L0648 | 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, off-the-shelf |

| HCPCS Codes | HCPCS Code Description |
|---|---|
| L0649 | 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, off-the-shelf |
| L0650 | Lumbar-sacral orthosis (LSO), 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, 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 |
| L0970 | TLSO, corset front |
| L0972 | LSO, corset front |
| L0974 | TLSO, full corset |
| L0976 | LSO, full corset |
| L0980 | Peroneal straps, prefabricated, off-the-shelf, pair |
| L0982 | Stocking supporter grips, prefabricated, off-the-shelf, set of four (4) |
| L0984 | Protective body sock, prefabricated, off-the-shelf, each |
| L0999 | Addition to spinal orthosis, not otherwise specified |
| L1000 | Cervical-thoracic-lumbar-sacral orthosis (CTLSO) (Milwaukee), inclusive of furnishing initial orthosis, including model |
| L1001 | Cervical thoracic lumbar sacral orthosis, immobilizer, infant size, prefabricated, includes fitting and adjustment |
| L1005 | Tension based scoliosis orthosis and accessory pads, includes fitting and adjustment |
| L1010 | Addition to cervical-thoracic-lumbar-sacral orthosis (CTLSO) or scoliosis orthosis, axilla sling |
| L1020 | Addition to CTLSO or scoliosis orthosis, kyphosis pad |
| L1025 | Addition to CTLSO or scoliosis orthosis, kyphosis pad, floating |
| L1030 | Addition to CTLSO or scoliosis orthosis, lumbar bolster pad |

| HCPCS Codes | HCPCS Code Description |
|---|---|
| L1040 | Addition to CTLSO or scoliosis orthosis, lumbar or lumbar rib pad |
| L1050 | Addition to CTLSO or scoliosis orthosis, sternal pad |
| L1060 | Addition to CTLSO or scoliosis orthosis, thoracic pad |
| L1070 | Addition to CTLSO or scoliosis orthosis, trapezius sling |
| L1080 | Addition to CTLSO or scoliosis orthosis, outrigger |
| L1085 | Addition to CTLSO or scoliosis orthosis, outrigger, bilateral with vertical extensions |
| L1090 | Addition to CTLSO or scoliosis orthosis, lumbar sling |
| L1100 | Addition to CTLSO or scoliosis orthosis, ring flange, plastic or leather |
| L1110 | Addition to CTLSO or scoliosis orthosis, ring flange, plastic or leather, molded to patient model |
| L1120 | Addition to CTLSO, scoliosis orthosis, cover for upright, each |
| L1200 | Thoracic-lumbar-sacral-orthosis (TLSO), inclusive of furnishing initial orthosis only |
| L1210 | Addition to TLSO, (low profile), lateral thoracic extension |
| L1220 | Addition to TLSO, (low profile), anterior thoracic extension |
| L1230 | Addition to TLSO, (low profile), Milwaukee type superstructure |
| L1240 | Addition to TLSO, (low profile), lumbar derotation pad |
| L1250 | Addition to TLSO, (low profile), anterior ASIS pad |
| L1260 | Addition to TLSO, (low profile), anterior thoracic derotation pad |
| L1270 | Addition to TLSO, (low profile), abdominal pad |
| L1280 | Addition to TLSO, (low profile), rib gusset (elastic), each |
| L1290 | Addition to TLSO, (low profile), lateral trochanteric pad |
| L1300 | Other scoliosis procedure, body jacket molded to patient model |
| L1310 | Other scoliosis procedure, post-operative body jacket |
| L1499 | Spinal orthosis, not otherwise specified |
| L4000 | Replace girdle for spinal orthosis (CTLSO or SO) |
| L4002 | Replacement strap, any orthosis, includes all components, any length, any type |

## INTRODUCTION

Low back pain (LBP) is a major health problem in the United States with an estimate of 70-85% of the population suffering from this condition at some point in their life. Most patients recover quickly and 80-90% recover within three months. The group of patients who do not recover within three months become a significant cost to the healthcare system and make up a large proportion of time lost at work (Asche et al., 2007).


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Lumbar supports are used in the management of low back pain and as a method to prevent low back pain. They have been recommended for reducing pain, limiting spinal motion, reducing mechanical load, and correcting deformity. Spinal orthoses for the mid and lower back include thoracic orthoses (TO), thoracic-lumbar-sacral orthoses (TLSO), lumbar-sacral orthoses (LSO), and lumbar orthoses (LO).

Spinal orthoses may be flexible, rigid, or semi-rigid. Flexible orthoses are generally used for muscle support to reduce low back pain. They are used in cases of spinal instability or arthritic conditions. Rigid orthoses are used post-fracture or postoperatively for spinal immobilization. They are also used in the treatment of scoliosis. Orthoses may be prefabricated or custom-fabricated.

## REVIEW OF THE LITERATURE

### Lumbar Supports and Pain Reduction

A Cochrane Review by van Duijvenbode et al. (2008) assessed the effects of lumbar supports for prevention and treatment of non-specific low back pain. Looking at the high quality randomized controlled trials (RCTs), they concluded that there was moderate evidence that lumbar supports were not more effective than training of lifting techniques, or no intervention, in preventing low back pain. The outcomes measured back pain and sick leave due to back pain. There was limited evidence that lumbar supports plus back school reduced the number of workdays lost from back injury, but not in preventing incidence of pain.

Further, the Cochrane Review noted that there was conflicting evidence as to whether lumbar supports (are effective) in treating patients with low back pain. With return to work and functional status as the outcomes, there was some evidence of efficacy for the lumbar supports.

Bigos et al. (2009) did a systematic review of controlled trials to evaluate the effectiveness of various interventions in preventing low back pain (LBP). They found four (4) trials involving lumbar supports that met their inclusion criteria and none of them reduced the incidence or severity of LBP compared with controls.

Jensen et al. (2012) compared rest versus exercise as a treatment for patients with low back pain (LBP) and Modic changes (pathological changes in the vertebrae). The resting group also used a flexible lumbar belt and were instructed to use it up to four (4) hours per day. Outcomes included pain scales and sick leave, as well as the Back Depression Inventory. At the end of the ten (10) week trial, data was collected on eighty-seven (87) of the one hundred (100) patients. There was no statistically significant difference in any of the outcomes.

A good quality systematic review on lumbar supports for low back pain consisting of 8 trials determined that evidence was insufficient to determine the effects of a lumbar support for either acute or chronic LBP. Therefore, lumbar supports should only be utilized upon failure of other conservative measures for mechanical LBP.

- For acute or subacute low back pain, there was insufficient evidence to determine effects of lumbar supports versus no lumbar supports or an inactive treatment, due to methodological shortcomings and inconsistent results. (Chou et al., 2016)
- For chronic low back pain, there was insufficient evidence to determine effects of lumbar supports versus no lumbar supports, due to methodological shortcomings and inconsistent results. (Chou et al., 2016)
- For acute or subacute low back pain, no differences existed between a lumbar support plus an education program versus an education program alone in pain or function after 1 year. (Chou et al., 2016)
- For chronic low back pain, no difference was found between a lumbar support plus exercise (muscle strengthening) versus exercise alone in short-term (8 weeks) or long-term (6 months) pain or function. (Chou et al., 2016)
- There were no clear differences between lumbar supports versus other active treatments in pain or function. (Chou et al., 2016)

According to the National Institute of Care and Excellence (NICE) guidelines (2017), belts or corsets for managing low back pain with or without sciatica should not be offered. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline from the American College of Physicians (2017) states that low-quality evidence showed no difference in pain or function between lumbar supports added to an educational program compared with an educational program alone or other active interventions in patients with acute or subacute low back pain.

Gignoux et al. (2020) noted that clinical practice guidelines for non-specific low back pain do not recommend the use of non-rigid lumbar supports (NRLSs) despite the publication of several positive randomized controlled studies. Given this, they conducted a systematic review with meta-analysis to assess the efficacy of NRLSs in the treatment and prevention of non-specific low back pain. Of the 1581 records retrieved, only 4 full-text articles were included, with 777 patients: 378 in the NRLS group, and 348 in the control group. NRLSs conferred greater amelioration of disability (effect size -0.54, 95% CI -0.90; -0.17) and pain (-0.29, -0.46; -0.12) than standard management. Insufficient data prevented a comparison of the efficiency for acute, subacute and recurrent low back pain as well as meta-regression of responder phenotypes (sociodemographic and other patient characteristics). Authors concluded that despite the lack of support in guidelines, they demonstrated the overall efficacy of NRLSs for both disability and pain. However, further studies are needed to assess which patients can benefit the most from lumbar supports based on patient phenotype and the characteristics of low back pain. Lurati (2020) evaluates the evidence for use of lumbar supports for prevention or treatment of low back pain. She summarizes that exercise continues to have the best evidence for prevention and treatment of low back pain, however in an occupation such as nursing and based on their case study, a lumbar belt could be used for certain activities to increase comfort.

Annaswamy et al. (2021) evaluated the effect of back bracing to treat patients with chronic low back pain. This was a prospective, unblinded, randomized controlled trial of 61 adults with uncomplicated chronic low back pain (>12 wks) and imaging findings of degenerative spondylosis, to assess the effectiveness of a semirigid back brace. All study participants received back school instruction. The treatment group also received a lumbar orthosis and was instructed to wear it as needed for symptom relief. At baseline, 6 wks, 12 wks, and 6 mos after intervention, we collected: Numerical Rating Scale to measure pain intensity, Pain Disability Questionnaire, Patient-Reported Outcome Measurement Information System, and EuroQol 5-Dimension (EQ-5D) to measure patient-reported function and quality of life. An interim analysis at the halfway point in enrollment (61 of 120 planned participants) revealed the Pain Disability Questionnaire, Patient-Reported Outcome Measurement Information System, and EQ-5D scores in the treatment group to be worse than in the control group, but no significant group differences in Numerical Rating Scale scores. Authors halted the study because continuation was unlikely to produce significant changes to the results. Authors concluded that in patients with uncomplicated chronic low back pain, a back brace when combined with education and exercise instruction did not provide any pain relief compared with education and exercise instruction alone.

**Lumbar Supports and Spinal Motion**

Kurd et al. (2007) looked at outcomes of patients with symptomatic isthmic spondylosis treated with a custom fit thoracic-lumbar-sacral orthoses (TLSO) and activity cessation for three (3) months. The TLSO was worn continuously for three months. The goal of the support is to limit motion and have an anti-lordotic effect. At the end of three months, 95% of patients achieved excellent results defined as all pretreatment symptoms being relieved. It is not clear how much limitation of movement the TLSO provided or if it just reinforced the cessation of activity.

Giele et al. (2009) evaluated the effectiveness of bracing in patients with thoracolumbar fractures. The goals of bracing are to prevent failure of bone repair, facilitate immobilization, and provide correct posture. These orthoses are designed to prevent rotation and flexion of the spine. The studies included involved patients with thoracolumbar compression fractures from T10-L5. Most of these fractures were at T12 and L1. The compression of the vertebrae at admission ranged from 11-25%. From the seven (7) retrospective studies included, there was no evidence for the effectiveness of bracing for thoracolumbar fractures.

Jegede et al. (2011) evaluated the effects of three (3) different lumbar orthoses on the range of motion (ROM) of the lumbar spine during fifteen (15) activities of daily living (ADLs).

Ten (10) asymptomatic subjects with a mean age of twenty-six (26) years were measured. They were measured without a brace, while wearing a corset, a semi-rigid lumbar-sacral orthoses (LSO), and a rigid custom-molded LSO. Range of motion was measured with an electrogoniometer. Although significant differences were seen in full ROM with the braces of varying rigidity, there were no significant differences in functional ROM between rigid LSOs, and minimal difference between values for the corset and the rigid LSOs. Functional ROM for eleven (11) of the fifteen (15) activities was less than allowed by each brace. The ADLs that showed a significant difference all involve flexion of the hips and lumbar spine. The authors conclude that bracing serves as a proprioceptive guide that lets patients restrict their own motion.

Zarghooni et al. (2013) assessed the effectiveness and complications of orthotic treatment of acute and chronic disease of the cervical and lumbar spine. They selected three relevant systematic reviews and four controlled trials. Very few controlled trials have studied the efficacy of orthotic treatment compared to other conservative treatments and surgery. They concluded that no definitive evidence was found to support the use of orthoses after surgery and in lumbar radiculopathy. Orthoses were not recommended for nonspecific low back pain.

**Lumbar Belts and Lifting and Muscle Activity**

Zink et al. (2001) examined the effects of muscle activity and joint kinematics while using a weight belt. Electromyography (EMG) activity was measured in fourteen (14) healthy men during the squat exercise. The authors found there was no difference in muscle activity, but the speed of the movement was significantly faster. Escamilla et al. (2002) examined two (2) different deadlift conditions, with and without a belt, and compared EMG activity. Compared with the no belt condition, the belt condition produced significantly greater activity in the rectus abdominis, and less activity in the external obliques. Kingma et al. (2006) evaluated spinal compression forces in weightlifting with and without a belt. Spinal compression was calculated using EMG, kinematics, and ground reaction forces. The belt reduced compression forces by 10%, but only when inhaling before the lift. Walsh et al. (2007) evaluated the use of a belt during the squat exercise. Forty-eight (48) asymptomatic athletes were measured using a three-dimensional (3D) motion analysis system. The use of the support belt did not significantly alter spinal motion during the lift. The authors noted that many of the athletes felt that the belt provided additional support during the lift compared to the no belt condition.

Azadinia et al. (2020) aimed to evaluate available evidence in literature to determine whether lumbosacral orthoses (LSO) results in trunk muscle weakness or atrophy in a systematic review. Prospective studies published in peer-reviewed journals, with full text available in English, investigating the effect of lumbar orthosis on trunk muscle activity, muscle thickness, strength or endurance, spinal force, and intra-abdominal pressure in healthy subjects or in patients with low back pain, were included. Thirty-five studies fulfilled the eligibility criteria. Most studies investigating the effect of lumbar orthosis on electromyographic activity (EMG) of trunk muscles demonstrated a decrease or no change in the EMG parameters. A few studies reported increased muscle activity. Lumbosacral orthosis was found to have no effect on muscle strength in some studies, whereas other studies demonstrated increased muscle strength. Only one study, which included ultrasound assessment of trunk muscle stabilizers, suggested reduced thickness of the abdominal muscles and reduced cross-sectional area of the multifidus muscles. Out of eight studies that investigated spinal compression load, the load was reduced in four studies and unchanged in three studies. One study showed that only elastic belts reduced compression force compared to leather and fabric belts and ascribed this reduction to the elastic property of the lumbar support. Authors concluded that this review showed that the changes in outcome measures associated with muscle work demands were inconsistent in their relation to the use of lumbar supports. This review did not find conclusive scientific evidence to suggest that orthosis results in trunk muscle weakness.

Ludvig et al. (2019) noted that lumbar belts have been shown to increase lumbar stiffness, but it is unclear if this is associated with trunk muscle co-contraction, which would increase the compression on the spine. It has been hypothesized that lumbar belts increase lumbar stiffness by increasing intra-abdominal pressure, which would increase spinal stability without increasing the compressive load on the spine. Given this hypothesis, Ludvig et al. (2019) measured trunk muscle activity and lumbar stiffness and damping in healthy and low-back pain subjects during three conditions: no lumbar belt; wearing an extensible lumbar belt; wearing a non-extensible lumbar belt. Muscle activity was measured while subjects performed controlled forward and backward 20° trunk sways. Lumbar stiffness and damping were measured by applying random continuous perturbation to the chest. Findings noted the following: External oblique activity was decreased when wearing either lumbar belt during all phases of movement, while rectus abdominis and iliocostalis activity were decreased during the phase of movement where the muscles were maximally active while wearing either belt. Trunk stiffness was greatly increased by wearing either belt. There were no consistent differences in either lumbar stiffness or muscle activity between the two belts. Wearing a lumbar belt had little to no effect on damping. There were no group differences in any of the measures between healthy and low-back pain populations. Authors interpreted these findings as consistent with the hypothesis that lumbar belts can increase spinal stability by increasing intra-abdominal pressure, without any increase in the compressive load on the spine. The findings can also be generalized, for the first time, to subjects with low-back pain. Further research is needed to confirm findings.

## Bracing and Scoliosis

Rigo et al. (2006) developed and distributed a questionnaire on braces for scoliosis to specialists interested in the conservative treatment of adolescent idiopathic scoliosis (AIS). There was not an agreement on the type of the brace that should be used or on pad placement, but there was agreement on the importance of the three-point system mechanism.

Schiller et al. (2010) did a review of the history of AIS and other factors, as well as the types of braces available for treatment. One challenge was the definition of "success" in treating the scoliotic patient. The majority of the literature defines success as a progression of less than five (5) degrees. Some authors use a curve progression of ten (10) degrees, and others use a total curve value of forty-five (45) degrees. Many studies are compromised by poor compliance of the patients as braces need to be worn eighteen to twenty-three (18-23) hours per day. There is no prospective, randomized study to determine the effectiveness of bracing.

Aulisa et al. (2012) reviewed the progressive action short brace (PASB) for scoliosis. The results of a case series of 110 patients were presented. The average decrease in rotation was from 15.8 degrees to 8.3 degrees. They had similar success for lateral flexion. The methodology of their study was weak. Data was extracted from their database, and they only included patients who were fully compliant; they did not describe the criteria for compliance.

Weinstein et al. (2013) conducted a multicenter study that included patients with typical indications for bracing due to their age, skeletal immaturity, and degree of scoliosis. Of 242 patients included in the analysis, 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 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. Based on analysis, the rate of treatment success was 72% after bracing, as compared with 48% after observation. 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. There was a significant positive association between hours of brace wear and rate of treatment success. According to authors, 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.

Negrini et al. (2015) authored a Cochrane Review on bracing for idiopathic scoliosis in adolescents. They evaluated the efficacy of bracing for adolescents with scoliosis vs. no treatment or other treatments on quality of life, disability, pulmonary disorders, progression of curve and psychological issues. They included seven studies (662 participants). The authors determined that due to the important clinical differences among the studies, it was not possible to perform a meta-analysis. Two low quality studies showed that bracing did not change quality of life during treatment, back pain, and psychological and cosmetic issues in the long term (16 years). All included papers consistently showed that bracing prevented curve progression (secondary outcome). However, given the low quality of evidence, confidence in the findings is limited and further research is needed. The high rate of failure of RCTs demonstrates the significant difficulties in performing RCTs in a field where parents reject randomization of their children. This will challenge the ability to perform higher quality research in the future.

The U.S. Preventive Services Task Force (USPSTF) (2018) has published conclusions for scoliosis treatments: "The USPSTF found inadequate evidence on treatment with exercise and surgery. It found adequate evidence that treatment with bracing may slow curvature progression in adolescents with mild or moderate curvature severity (Cobb angle <40° to 50°); however, evidence on the association between reduction in spinal curvature in adolescence and long-term health outcomes in adulthood is inadequate. The USPSTF found inadequate evidence on the harms of treatment."

Schoutens et al. (2020) evaluated the effectiveness of nonsurgical treatments in symptomatic adult degenerative scoliosis (ADS) in a systematic review. Six studies were included. Of these, four focused specifically on injections, bracing, or yoga; two involved multiple treatments. Two single-group retrospective cohort studies lent support for bracing to slow curve progression. Evidence for bracing was rated as very low quality. Authors concluded that the quantity and quality of the evidence regarding bracing was insufficient to advise for or against the use of bracing to improve outcomes in symptomatic ADS.

Costa et al. (2021) investigated whether there is a difference in effectiveness between brace types/concepts. All studies on brace treatment for AIS were searched for in PubMed and EMBASE up to January 2021. Articles that did not report on maturity of the study population were excluded. Critical appraisal was performed using the Methodological Index for Non-Randomized Studies tool (MINORS). Brace concepts were distinguished in prescribed wearing time and rigidity of the brace: full-time, part-time, and night-time, rigid braces and soft braces. In the meta-analysis, success was defined as ≤5° curve progression during follow-up. Of the 33 selected studies, 11 papers showed high risk of bias. The rigid full-time brace had on average a success rate of 73.2% (95% CI 61-86%), night-time of 78.7% (72-85%), soft braces of 62.4% (55-70%), observation only of 50% (44-56%). There was insufficient evidence on part-time wear for the meta-analysis. The majority of brace studies have significant risk of bias. No significant difference in outcome between the night-time or full-time concepts could be identified. Soft braces have a lower success rate compared to rigid braces. Bracing for scoliosis in Risser 0-2 and 0-3 stage of maturation appeared most effective.

Dufvenberg et al. (2021) aimed to explore patient adherence and secondary outcomes during the first 6 months in an ongoing randomised controlled trial of three treatment interventions. Interventions consisted of physical activity combined with either hypercorrective Boston brace night shift (NB), scoliosis-specific exercise (SSE), or physical activity alone (PA). Measures at baseline and 6 months included angle of trunk rotation (ATR), Cobb angle, International Physical Activity Questionnaire short form (IPAQ-SF), pictorial Spinal Appearance Questionnaire (pSAQ), Scoliosis Research Society (SRS-22r), EuroQol 5-Dimensions Youth (EQ-5D-Y) and Visual Analogue Scale (EQ-VAS). Patient adherence, motivation, and capability in performing the intervention were reported at 6 months. The study included 135 patients (111 females) with AIS and >1-year estimated remaining growth, mean age 12.7 (1.4) years, and mean Cobb angle 31 (±5.3). At 6 months, the proportion of patients in the groups reporting high to very high adherence ranged between 72 and 95%, while motivation ranged between 65 and 92%, with the highest proportion seen in the NB group. IPAQ-SF displayed significant between group main effects regarding moderate activity, with a medium-sized increase favouring the SSE group compared to NB. From baseline to 6 months, ATR showed significant between group medium-sized main effects favouring the NB group compared to PA, but not reaching a clinically relevant level. In conclusion, patients reported high adherence and motivation to treatment, especially in the NB group. Patients in the SSE and PA groups increased their physical activity levels without other clinically relevant differences between groups in other clinical measures or patient-reported outcomes. The results suggest that the prescribed treatments are viable first-step options during the first 6 months.

Guy et al. (2022) biomechanically analyzed and compared various passive correction features of braces, designed by several centers with diverse practices, for 3D correction of adolescent idiopathic scoliosis. A wide variety of brace designs exist, but their biomechanical effectiveness is not clearly understood. Many studies have reported brace treatment correction potential with various degrees of control, making the objective comparison of correction mechanisms difficult. A Finite Element Model (FEM) simulating the immediate in-brace corrective effects has been developed and allows to comprehensively assess the biomechanics of different brace designs. For this study, expert clinical teams (one orthotist and one orthopedist) from 6 centers in 5 countries participated in the study. For six scoliosis cases with different curve types respecting SRS criteria, the teams designed two braces according to their treatment protocol. FEM simulations were performed to compute immediate in-brace 3D correction and skin-to-brace pressures. All braces were randomized and labelled according to twenty-one design features derived from SOSORT proposed descriptors, including positioning of pressure points, orientation of push vectors, and sagittal design. Simulated in-brace 3D corrections were compared for each design feature class using ANOVAs and linear regressions (significance $p < 0.05$). Seventy-two braces were tested, with significant variety in the design approaches. Pressure points at the apical vertebra level corrected the main thoracic curve better than more caudal locations. Braces with ventral support flattened the lumbar lordosis. Lateral and ventral skin-to-brace pressures were correlated with changes in thoracolumbar/lumbar Cobb and lumbar lordosis. Upper straps positioned above T10 corrected the main thoracic Cobb better than those placed lower.

Duarte et al. (2022) tested the hypothesis that anterior vertebral body growth modulation (AVBGM) achieves 3D deformity correction after 2-year follow-up while brace treatment limits curve progression for moderate idiopathic scoliosis (30-50°). For idiopathic scoliosis, bracing and AVBGM have overlapping indications in skeletally immature patients with moderate scoliosis curve angles, creating a grey zone in clinical practice between them. The relative 3D deformity control performance over a 2-year period between these fusionless treatments is still uncertain. A retrospective review of a prospective idiopathic scoliosis patients database, recruited between 2013 and 2018 was performed. Inclusion criteria were skeletally immature patients (Risser 0-2), with Cobb angles between 30-50° and a 2-year follow-up after bracing or AVBGM. 3D radiological parameters and Health Related Quality of Life (HRQoL) scores were evaluated. 39 patients (12.7 ± 1.3 y.o.) with Cobb angles ≥30° treated with brace and 41 patients (11.8 ± 1.2 y.o.) with presenting Cobb angles ≤50° who received AVBGM were reviewed. The statistical analysis of 3D deformity measurements showed that at 2-year follow-up, only the 3D spine length and both sides apical vertebral heights changed significantly with brace treatment. While AVBGM treatment achieved statistically significant correction differences in thoracic and lumbar Cobb angles, TrueKyphosis, 3D spine length and selective left apical vertebra height ($p < 0.05$). 35% of brace patients had a curve progression of >5° at final follow-up while it was 0% for AVBGM. HRQoL assessment showed no statistically significant differences between pre and post SRS total scores for each group ($p > 0.05$). Authors concluded that even though these 2 cohorts are not fully comparable, bracing seems to control progression for a significant portion of patients with moderate scoliosis curves, while AVBGM significantly corrected and maintained 3D deformity parameters at 2-year follow-up.

## PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education training and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services.

It is best practice for the practitioner to appropriately render services to a patient only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and expert training, it would be best practice to refer the patient to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

Depending on the practitioner's scope of practice, training, and experience, a member's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is prudent for the practitioner to refer the member for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* policy for information.

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