Clinical Policy Title: Spinal orthoses (back braces)

Clinical Policy Number: 14.02.13

Effective Date:	**October 1, 2017**
Initial Review Date:	August 17, 2017
Most Recent Review Date:	August 30, 2018
Next Review Date:	September 2019

Policy contains:

- Back braces.
- Lumbar sacral orthoses.
- Spinal orthoses.
- Thoracolumbar orthoses.

Related policies:

None.

ABOUT THIS POLICY: *AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.*

Coverage policy

AmeriHealth Caritas considers the use of spinal orthoses, specifically thoracolumbosacral orthoses , lumbo-sacral orthoses, or lumbar orthoses, to be medically necessary when any of the following conditions are met:

- To facilitate healing after an injury to the spine or related soft tissue.
- To facilitate healing after a surgical procedure on the spine or related soft tissue.
- To reduce pain by restricting mobility of the trunk for members with six months or less of pain.
- To support weak spinal muscles and/or deformed spine with a neurological deficit.
- To treat spinal deformities including (but not limited to) scoliosis and kyphosis (CMS, 2015).

For adolescents with scoliosis and still in growth phase, spinal orthoses should only be used with a Cobb angle (measurement of the largest tilt of spinal bones in each curve) of 25° to 40°.

Limitations:

All other uses of spinal orthoses are considered investigational or experimental, and thus are not medically necessary. The efficacy of using non-customized, off-the-shelf braces has not been proven, and is therefore considered not medically necessary.

Alternative covered services:

None.

Background

A spinal orthosis, also known as a back brace, is a device to hold the spine in place, prevent progression of disease, and reduce the need for spinal fusion surgery. Spinal orthoses are classified as thoracolumbosacral orthoses, lumbar sacral orthoses, or lumbar orthoses (MedicineNet, 2018). While each model has a unique construction, back braces are often stiff, tight, plastic devices that extend from the thoracic vertebrae to the base of the spine, and hold both the front and back of the body in place.

Spinal orthoses offer a non-surgical alternative to achieve spinal stability, for conditions such as spinal fracture, scoliosis, injuries, and other conditions. They are frequently used following spinal surgery (MedicineNet, 2016). In addition to promoting spinal stability, spinal orthoses can also reduce pain and prevent or heal injuries.

Back braces have been used for nearly a century, starting with correcting casts such as the turnbuckle cast and localizer casts for scoliosis. The Milwaukee brace, developed in 1946 and since widely used, is a molded pelvic girdle made of leather and metal that increases rigidity. Later models included the Wilmington, Boston, Charleston, Providence, and SpineCor braces, all of which are still in use. The latter is guided by software, and is worn 20 hours a day through skeletal maturity (Fassyoux, 2010).

Concerns with back braces vary, but often include patient non-compliance, lack of flexibility, discomfort, and limits to bending, twisting, reaching, and other basic movements, as well as the inability for wearers to engage in athletics. Patients with back braces are often children or adolescents, particularly when conditions such as scoliosis are present. About 3 percent of children develop adolescent idiopathic scoliosis (Stokes, 2013).

A panel of experts recommended against back bracing as a prognostic tool prior to spinal fusion, as no correlation between bracing and fusion outcome has been observed (Dailey, 2014). The American Association of Orthopedic Surgeons did not recommend for or against bracing for osteoporotic spinal compression fractures (AAOS, 2010). However, the association also noted that the most compelling evidence for use of spinal orthoses was to treat traumatic spinal injury (Agabegi, 2010). Another association recommendation for the use of back braces was for spinal trauma, correction of deformity, chronic neck and back pain, and postoperative bracing (Anderson, 2013).

A team of experts concluded no evidence exists to recommend any particular brace over another to treat adolescent idiopathic scoliosis (Sanders, 2012). The Scoliosis Research Society recommends that back braces be considered in adolescents who are still growing, and with a curvature between 25° and 40° (SRS, 2011).

Searches

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality's National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on July 2, 2018. Search terms were: "lumbar orthosis," "lumbar sacral orthosis," "spinal orthosis," "thoracolumbar orthosis," and "Boston brace."

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

Systematic reviews have addressed spinal orthosis for various conditions:

- **Fractures**. An early attempt found no systematic reviews or randomized controlled trials for bracing in patients with thoracolumbar fractures; seven retrospective studies showed no significant benefits of bracing (Giele, 2009). A review of 12 studies (n = 626) found no evidence that orthoses improved vertebral deformity, and rigid orthoses had the highest complication rates (Newman, 2016). A review of 62 studies assessing patients with and without back braces after surgery for thoracolumbar fractures showed significantly worse outcomes for the brace group in a) higher loss of surgical kyphotic reduction (4.79° versus 3.77°; $p < .001$); b) overall complication rate (16.3 percent versus 11.9 percent; $p < .01$); but c) a lower pseudoarthrosis rate (2.4 percent versus 6 percent; $p < .001$) (Skoch, 2016).

A review of 45 studies of persons with thoracolumbar fractures found no difference in functional outcomes after conservative management (including orthoses) compared to surgery, and found that no single conservative treatment was superior to others (Bakhsheshian, 2014). An analysis of nine studies on external supports (spinal brace, orthosis, postural tape) for osteoporotic vertebral fracture revealed no consistent findings in impairments, activities, and participation (Goodwin, 2016). A review of five randomized controlled trials on treatments for osteoporotic vertebral compression fractures included two studies that found significantly increased medium-term pain relief and disability reduction from orthoses (Rzewuska, 2015). Another review of persons with subacute vertebral fractures found the Spinomed brace to be superior to soft braces or thoracolumbosacral orthoses (Jin, 2016).

- **Spinal stenosis**. A review of 11 studies (n = 918) of persons with lumbar spinal stenosis who underwent surgery after failing to respond to conservative therapy (including orthosis) after three to six months had improved pain, disability, and quality of life, but not walking, and this improvement continued for two to four years after surgery (Kovacs, 2011). A Cochrane study of symptomatic stenosis reviewed five trials, including one of surgery versus orthosis and exercise, but could not differentiate between pain outcomes for surgery and conservative treatments (Zaina, 2016).

- **Scoliosis**. An early systematic review that assessed efficacy of orthoses for adolescent idiopathic scoliosis documented a prospective multi-center study, a long-term prospective controlled study, and a meta-analysis to support bracing (Weiss, 2008). Two studies (n = 329) of girls with adolescent idiopathic scoliosis showed braces improved curve progression better than observation or electric stimulation, and that rigid braces performed better than elastic ones (Negrini, 2010). In a review of seven studies (five randomized controlled trials) of adolescent idiopathic scoliosis, two studies showed that bracing did not change quality of life during treatment, and did not change quality of life, back pain, and psychological and cosmetic issues over 16 years, but did prevent curve progression (Negrini, 2016). A review of 10 studies found adolescent idiopathic scoliosis patients wearing a brace versus no brace reduced walking speed and cadence, but increased stride length and reduced gait load asymmetry (Daryabor, 2017).

- **Spinal cord injury**. Articles have been published on use of orthoses for spinal cord injuries. One review of 20 studies (many were single cases) indicated that medical linkage orthoses increased independence and cosmesis and reciprocating gait orthoses improved gait parameters, energy expenditure, and stability, compared to traditional orthoses (Ahmadi Boni, 2015).

- **Trunk motor performance**. A review of eight studies assessed effects of prolonged (one to six months) use of lumbosacral orthosis on motor performance. The most common measures were maximum strength of trunk flexors/extensors and endurance/fatigability of trunk extensors. No negative effects were noted, but quality of evidence was weak (Takasaki, 2017).

Spinal orthoses are often used prior to fusion surgery, if they fail to generate improvements, for certain conditions. A review found that no clinical tests, or experience with thoracolumbosacral orthoses, can accurately predict the outcome of fusion surgery for chronic lower back pain (Willems, 2013).

Long-term studies have been conducted on thoracolumbosacral orthosis patients. One followed 272 juvenile or adolescent scoliosis patients who had used a Boston brace; average time since the brace was removed was 25 years. The major curve of the spine was 33.2^{o} at pre-brace, 28.3^{o} at weaning, and 32.5^{o} at latest follow-up, leading authors to describe results as "satisfactory" (Lange, 2011). A total of 77 adolescent scoliosis patients were tracked for 25 years after their Boston braces were removed, showing no difference in mean curve magnitude between those who wore braces for 18 hours versus 23 hours a day (Pellios, 2016).

SpineCor, the most recently developed of the major braces, was compared to rigid braces in a study of 38 female subjects ages 10 – 14 with adolescent idiopathic scoliosis. Rigid braces were superior, as curve progression in the SpineCor group was significantly higher (Guo, 2014).

A systematic review of 35 studies failed to uncover evidence that long-term use of lumbosacral orthoses in persons with low back pain resulted in trunk muscle weakness (Azadinia, 2017).

Policy updates:

In July 2018, two professional society guidelines/other and two peer-reviewed references were added to this policy, and one professional society guideline/other was removed.

Summary of clinical evidence:

Citation	Content, Methods, Recommendations
Daryabor (2017) Effects of spinal orthoses on gait + energy consumption of persons with scoliosis	**Key points:** • Systematic review — 10 studies of adolescent idiopathic scoliosis subjects treated with orthoses versus able-bodied participants. • Scoliosis group walked slower with decreases in 1) hip/pelvic movement, 2) hip mediolated forces, 3) ground reaction force asymmetry, 4) excess energy cost. • With an orthosis, pelvis and hip frontal plane motion decrease, hip and pelvis movement symmetry increase, and ankle/foot kinematics don't change. • Wearing orthoses for scoliosis reduces walking speed and cadence, reduces gait load asymmetry, and increases stride length.
Skoch (2016) Bracing after surgery for thoracolumbar fractures	**Key points:** • Systematic review of 62 studies of patients with and without back braces after surgery for thoracolumbar fractures; median wear time was 13.3 weeks. • No significant differences in pain and return-to-work time between groups. • The group with braces had significantly worse outcomes in a) higher loss of surgical kyphotic reduction (4.79° versus 3.77°; $p < .001$); b) overall complication rate (16.3%

Citation	Content, Methods, Recommendations
	versus 11.9%; p < .01but not in); c) a lower pseudoarthrosis rate (2.4% versus 6.0%; p < .001).
Lange (2011) Long-term results after Boston brace treatment for adolescent idiopathic scoliosis	**Key points:** • Review of 272 patients with juvenile or adolescent idiopathic scoliosis, an average of 24.7 years after Boston brace treatment. • Most (92%) were women; average age at follow-up was 40.4 years. • Average major curve of the spine was 33.2° at pre-brace, 28.3° at weaning, and 32.5° at last follow-up — considered "satisfactory." • Work status was 76 % full time and 10 % part time. • 87% had delivered a baby; 50% had pain in pregnancy.
Kovac (2011) Surgery vs. conservative therapy for lateral spinal stenosis	**Key points:** • Systematic review of 11 studies representing five randomized controlled trials. • Review included 918 patients whose conservative treatment of three to six months failed; orthosis was one of the treatments. • In all the studies, surgery showed better results for pain, disability, and quality of life, although not for walking ability. • Advantage for surgery was observed at three to six months after surgery, and remained for two to four years (although advantage declined over time).

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Professional society guidelines/other:

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Peer-reviewed references:

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CMS National Coverage Determinations (NCDs):

No NCDs identified as of the writing of this policy.

Local Coverage Determinations (LCDs):

L33790 Spinal Orthoses. Effective date October 1, 2015. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33790&ver=15&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=spinal+orthoses&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAA&. Accessed July 2, 2018.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

CPT Code	Description	Comments
N/A	N/A	

ICD-10 Code	Description	Comments
M00.00 - M99.	Diseases of the musculoskeletal system and connective tissue	
S33.0xx+ - S33.39x+	Dislocation of joints of lumbar spine and pelvis [code also any associated open wound of lower back and pelvis]	
S33.4xx+ - S33.9xx+	Sprain of ligaments of lumbar spine and pelvis	
S39.011+ - S39.013+	Strain of muscle, fascia and tendon of abdomen, lower back and pelvis	
A18.01	Tuberculosis of spine	
M40.00 -M41.9	Kyphosis, lordosis and scoliosis	
M43.8x1 - M43.9	Other and unspecified deforming dorsopathies	
M96.2 - M96.5	Postprocedural kyphosis, lordosis and scoliosis	
M99.10 - M99.15	Subluxation complex (vertebral)	
M99.20 - M99.79	Biomechanical lesions: stenosis of neural canal and intervertebral foramina	
M99.83 - M99.84	Other biomechanical lesions of lumbar and sacral region	
Q04.9 - Q07.9	Congenital malformations of the nervous system	
Q67.5 - Q76.0 - Q76.49	Congenital malformations of spine	
S14.0xx+ - S14.9xx+	Injury of nerves and spinal cord at neck level [code also any associated fracture of cervical vertebra]	
S22.000+ - S22.089+	Fracture of thoracic spine	
S32.000+ - S32.2xx+	Fracture of lumbar spine	

HCPCS Level II Code	Description	Comments
L0450	TLSO, flexible, prefabricated, off-the-shelf	
L0452	TLSO, flexible, custom fabricated	
L0454	TLSO flexible,	
L0455	TLSO, flexible, prefabricated, off-the-shelf	
L0456	TLSO, flexible	