

Subject: Back Braces	Original Effective Date: 5/21/09
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DISCLAIMER

This Molina Clinical Review (MCR) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Review (MCR) document and provide the directive for all Medicare members.¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Spinal orthoses also known as thoracic lumbar sacral orthoses (TLSO) are designed to limit the motion of the spine to promote the healing process and minimize discomfort following trauma, injury or fracture, or postoperative fusions. 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, prefitted, or custom-fabricated:

- A *prefabricated orthosis* is manufactured by size from prefabricated materials and is not made specifically for an individual patient.
- A *custom-fitted orthosis* is a prefabricated orthosis that has been changed by bending, molding or trimming to fit a specific patient.
- A *custom-fabricated orthosis* is 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 taking an impression of the body part through plaster casting, or CAD-CAM (computer aided technology). The impression is used to make the model. The actual orthosis is then made from the model.

Prefabricated orthoses may be used prior to custom-fitted orthoses. Custom-fitted are generally attempted prior to a 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.

RECOMMENDATION ²⁻²⁰

- ☐ Scoliosis spinal orthoses are considered medically necessary when all of the following criteria are met:
[ALL]

- Diagnosis of juvenile or adolescent scoliosis; and
- Skeletal immaturity defined as Risser sign grade 0-1-2; and
- Radiographic evidence of a Cobb angle over 30°;

OR

- Radiographic evidence of a Cobb angle between 20° and 30° that has increased by $\geq 5^\circ$ within a six to eight month period during observation

Note: Radiographic evidence of Cobb angles over 50° with skeletal immaturity require an Orthopedic Surgeon evaluation

- ☐ Kyphosis spinal orthoses are considered medically necessary when all of the following criteria are met:
[ALL]

- Diagnosis of Scheuermann kyphosis (juvenile kyphosis); and
- Skeletally immaturity defined as Risser sign grade 0-1-2; and
- Radiographic evidence that kyphosis exceeds 60 degrees

- ☐ The following are **contraindications** to scoliosis bracing:
 - Skeletal maturity (Risser sign 4 to 5 and ring apophyses fused)
 - Cobb angle $\geq 50^{\circ}$
 - Cobb angle $< 20^{\circ}$
 - Thoracic Lordosis (relative contraindication)

- ☐ A spinal orthoses is **considered NOT medically necessary** due to insufficient evidence for the following:
 - Management of acute or chronic back pain¹⁶
 - Management of preoperative or postoperative spinal fusion surgery¹⁷
 - Treatment of adult kyphosis
 - Treatment of spinal burst fractures with or without neurological deficits¹⁴⁻¹⁵
 - 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

SUMMARY OF MEDICAL EVIDENCE

Scoliosis

The body of literature composed of randomised controlled studies, systematic reviews and observational comparative studies support bracing in skeletally immature patients with adolescent scoliosis.⁴⁻¹² 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.⁸⁻⁹ A summary of the most relevant RCT is outlined 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 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 ($P < 0.001$). 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.⁷

Spinal Burst Fractures ¹⁴⁻¹⁵

The evidence is insufficient to conclude whether spinal orthoses improve outcomes in the management of spinal burst fractures. A multicentre, randomized, nonblinded equivalence trial conducted to determine whether TLSO is equivalent to no orthosis (NO) 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. ¹⁴ A Cochrane review (2013) concluded that the contradictory evidence provided by two small and potentially biased randomised 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. ¹⁵

Back Pain and Spinal Fusion

The 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. ¹⁶ A trial of preoperative bracing prior to lumbar fusion is not recommended because no correlation between response to bracing and fusion outcome was observed. Brace therapy as an adjunct to or substitute for lumbar fusion is not recommended. ¹⁷

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
	N/A

HCPCS	Description
L0452, L0480, L0482, L0484, L0486	Orthotic devices, spinal [custom fabricated]
L1000 - L1499	Orthotic devices - scoliosis procedures

ICD-10	Description: [For dates of service on or after 10/01/2015]
M40- M40.299	Kyphosis
M41.1- M41.129	Juvenile and adolescent scoliosis

RESOURCE REFERENCES

Government Agency

- Centers for Medicare and Medicaid Services. National Coverage Determinations (NCDs). Accessed at: <https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>

Hayes

2. Hayes, Inc. Hayes Search and Summary. Lumbar-Sacral Orthoses for Scoliosis. Lansdale, PA: Hayes, Inc.; February, 2009. [archived]
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Peer Reviewed Publications

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6. Gabos PG, Bojescul JA, Bowen JR, et al. Long-term follow-up of female patients with idiopathic scoliosis treated with the Wilmington orthosis. J Bone Joint Surg Am. 2004; 86-A(9):1891-1899.
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14. Bailey CS1, Urquhart JC1, Dvorak MF2 et al. Orthosis versus no orthosis for the treatment of thoracolumbar burst fractures without neurologic injury: a multicenter prospective randomized equivalence trial. Spine J. 2013 Oct 31. pii: S1529-9430(13)01612-4.
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16. van Duijvenbode I, Jellema P, van Poppel M, van Tulder MW' Lumbar supports for prevention and treatment of low back pain. Cochrane Database of Systematic reviews 2008, Issue 2. Art No.: CD001823. DOI: 10.1002/14651858.CD001823.pub3.

Professional Society Guidelines

17. Dailey AT1, Ghogawala Z, Choudhri TF 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
18. Negrini et al. 2016 SOSORT guidelines: orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth. Scoliosis and Spinal Disorders (2018) 13:3

Other Resources

19. UpToDate: Scherl S. [website]. Waltham, MA: Walters Kluwer Health; 2021. Treatment and Prognosis of adolescent idiopathic scoliosis.
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21. Wheelless' Textbook of Orthopaedics. Scheuermann's Kyphosis. [Website]. Updated 2021. Accessed at: http://www.wheellesonline.com/ortho/scheuermanns_kyphosis

REVISION/REVIEW HISTORY:

3/8/18 Policy reviewed, no changes to criteria.

6/19/19, 4/23/20 & 4/5/21: Policy reviewed, no changes to criteria.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Review (MCR) document and provide the directive for all Medicare members.

No CMS National Coverage Determination (NCD) is available for lumbar-sacral orthoses for scoliosis or other indications. Local coverage determinations are available for Spinal Orthoses: TLSO and LSO. ¹