



MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Medical Policy Orthotics for Progressive Scoliosis

Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)
- [Endnotes](#)

Policy Number: 550

BCBSA Reference Number: 2.01.83

NCD/LCD: N/A

Related Policies

Vertical Expandable Prosthetic Titanium Rib, #[305](#)

Policy¹

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

A rigid cervical-thoracic-lumbar-sacral or thoracic-lumbar-sacral orthosis may be considered **MEDICALLY NECESSARY** for the treatment of scoliosis in juvenile and adolescent patients at high-risk of progression which meets the following criteria:

- Idiopathic spinal curve angle between 25° and 40°; AND
- Spinal growth has not been completed (Risser grade 0-3; no more than 1 year post menarche in females)

OR

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

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

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .

Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO BlueSM	Prior authorization is not required .
Medicare PPO BlueSM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
L1000	Cervical-thoracic-lumbar-sacral orthotic (CTLSO) (Milwaukee), inclusive of furnishing initial orthotic, including model
L1001	Cervical-thoracic-lumbar-sacral orthotic (CTLSO), immobilizer, infant size, prefabricated, includes fitting and adjustment
L1200	Thoracic-lumbar-sacral orthotic (TLSO), inclusive of furnishing initial orthotic only
L1300	Other scoliosis procedure, body jacket molded to patient model
L1310	Other scoliosis procedure, postoperative body jacket

Description

Scoliosis

Scoliosis is an abnormal lateral and rotational curvature of the vertebral column. Adolescent idiopathic scoliosis is the most common form of idiopathic scoliosis, defined by the U.S. Preventive Services Task Force as "a lateral curvature of the spine with onset at ≥ 10 years of age, no underlying etiology, and risk for progression during puberty."¹ Progression of the curvature during periods of rapid growth can result in deformity, accompanied by cardiopulmonary complications. Diagnosis is made clinically and radiographically. The curve is measured by the Cobb angle, which is the angle formed between intersecting lines drawn perpendicular to the top of the vertebrae of the curve and the bottom vertebrae of the curve. Patients with adolescent idiopathic scoliosis are also assessed for skeletal maturity, using the Risser sign, which describes the level of ossification of the iliac apophysis.

The Risser sign measures remaining spinal growth by progressive anterolateral to posteromedial ossification. Risser sign ranges from 0 (no ossification) to 5 (full bony fusion of the apophysis). Immature patients will have 0% to 25% ossification (Risser grade 0 or 1), while 100% ossification (Risser grade 5) indicates maturity with no spinal growth remaining. Children may progress from a Risser grade 1 to grade 5 over a brief (eg, 2-year), period.

Treatment

Treatment of scoliosis currently depends on three factors: the cause of the condition (idiopathic, congenital, secondary), the severity of the condition (degrees of the curve), and the growth of the patient remaining at the time of presentation. Children who have vertebral curves measuring between 25° and 40° with at least 2 years of growth remaining are considered to be at high-risk of curve progression. Genetic markers to evaluate the risk of progression are also being evaluated. Because severe deformity may lead to compromised respiratory function and is associated with back pain in adulthood, surgical intervention with spinal fusion is typically recommended for curves that progress to 45° or more.

Bracing

Bracing is used to reduce the need for spinal fusion by slowing or preventing further progression of the curve during rapid growth. Commonly used brace designs include the Milwaukee, Wilmington, Boston, Charleston, and Providence orthoses. The longest clinical experience is with the Milwaukee cervical-thoracic-lumbar-sacral orthosis. Thoracic-lumbar-sacral orthoses, such as the Wilmington and Boston braces, are intended to improve tolerability and compliance for extended (>18-hour) wear and are composed of lighter weight plastics with a low profile (underarm) design. The design of the nighttime Charleston and Providence braces is based on the theory that increased corrective forces will reduce the needed wear time (ie, daytime), thereby lessening social anxiety and improving compliance. The smart brace consists of a standard rigid brace with a microcomputer system, a force transducer, and an air-bladder control system to control the interface pressure. Braces that are more flexible than thoracic-lumbar-sacral orthoses or nighttime braces, such as the SpineCor, are also being evaluated. The SpineCor is composed of a thermoplastic pelvic base with stabilizing and corrective bands across the upper body.

Summary

Orthotic bracing attempts to slow spinal curve progression and reduce the need for fusion surgery in patients with juvenile or adolescent idiopathic scoliosis who are at high-risk of progression. Vertebral body stapling and vertebral body tethering, both fusionless surgical procedures, have been evaluated to determine whether the procedures could be used as alternatives to traditional orthotic bracing. This review does not address patients who are not at high-risk of progression or conventional fusion surgery for scoliosis, such as patients with Cobb angles measuring 45° or more.

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive a conventional rigid brace, the evidence includes a high-quality randomized controlled trial. The relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Bracing has been considered the only option to prevent curve progression in juvenile or adolescent idiopathic scoliosis. The highest quality study on bracing is a sizable 2013 National Institutes of Health-sponsored trial that, using both randomized and observational arms, compared bracing with watchful waiting. This trial was stopped after interim analysis because of a significant benefit of bracing for the prevention of spinal fusion. Based on several factors (evidence of efficacy, lack of alternative treatment options, professional society recommendations, potential to prevent the need for a more invasive procedure), bracing with a conventional rigid brace is considered an option for the treatment of scoliosis in patients with a high-risk of curve progression. A study with long-term follow-up (mean, 15 years) has also shown that curvature corrections with bracing were maintained. Curves have a high-risk of progression when they measure 25° or more, and spinal growth has not been completed, or when a 20° curve is progressively worsening and at least 2 years of growth remain. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive a microcomputer-controlled brace, the evidence includes a pilot randomized controlled trial. The relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. A pilot randomized trial using a microcomputer-controlled brace reported improved outcomes compared with the use of a standard rigid brace; however, the low number of individuals included in the trial ultimately limited the interpretation of these results. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive a flexible brace, the evidence includes a randomized and a nonrandomized comparative study. The relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. One randomized controlled trial evaluating a flexible brace did not show equivalent outcomes compared with conventional brace designs. Another study has suggested the flexible brace might improve outcomes compared with no treatment, but this study had design flaws, which interfered with drawing significant conclusions from the study. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive vertebral body stapling, the evidence includes a comparative cohort study and case series. The relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. There is a small body of published evidence on surgical interventions for preventing curve progression in juvenile and adolescent idiopathic scoliosis. Vertebral body stapling with memory shape staples may control some thoracic curves between 20° and 35° but it is less effective than bracing for larger curves. The evidence is composed primarily from a center that developed the technique, along with a few case series from other institutions. Additional study with larger sample sizes and longer follow-up is needed to evaluate the safety and efficacy of this procedure. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
6/2020	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
5/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
6/2018	Investigational statement on vertebral body stapling and vertebral body tethering removed; title changed. Effective 6/1/2018. BCBSA National medical policy review. Policy section clarified; statements otherwise unchanged.
12/2016	New references added from BCBSA National medical policy.
10/2015	BCBSA National medical policy review. New investigational indications described. Clarified coding information. Effective 10/1/2015.
6/2013	New references from BCBSA National medical policy.
5/1/12	New policy describing ongoing coverage and non-coverage.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

References

1. U.S. Preventive Services Task Force. Final Recommendation Statement: Adolescent Idiopathic Scoliosis: Screening. 2018; <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/adolescent-idiopathic-scoliosis-screening1>. Accessed March 9, 2020.
2. Richards BS, Bernstein RM, D'Amato CR, et al. Standardization of criteria for adolescent idiopathic scoliosis brace studies: SRS Committee on Bracing and Nonoperative Management. *Spine (Phila Pa 1976)*. Sep 15 2005;30(18):2068-2075; discussion 2076-2067. PMID 16166897
3. Negrini S, Hresko TM, O'Brien JP, et al. Recommendations for research studies on treatment of idiopathic scoliosis: Consensus 2014 between SOSORT and SRS non-operative management committee. *Scoliosis*. Mar 2015;10:8. PMID 25780381
4. Janicki JA, Poe-Kochert C, Armstrong DG, et al. A comparison of the thoracolumbosacral orthoses and providence orthosis in the treatment of adolescent idiopathic scoliosis: results using the new SRS inclusion and assessment criteria for bracing studies. *J Pediatr Orthop*. Jun 2007;27(4):369-374. PMID 17513954
5. Faysoux RS, Cho RH, Herman MJ. A history of bracing for idiopathic scoliosis in North America. *Clin Orthop Relat Res*. Mar 2010;468(3):654-664. PMID 19462214
6. Schiller JR, Thakur NA, Ebersson CP. Brace management in adolescent idiopathic scoliosis. *Clin Orthop Relat Res*. Mar 2010;468(3):670-678. PMID 19484317

7. Wall EJ, Reynolds JE, Jain VV, et al. Spine growth modulation in early adolescent idiopathic scoliosis: two-year results of prospective US FDA IDE pilot clinical safety study of titanium clip-screw implant. *Spine Deform.* Sep 2017;5(5):314-324. PMID 28882349
8. Weinstein SL, Dolan LA, Wright JG, et al. Effects of bracing in adolescents with idiopathic scoliosis. *N Engl J Med.* Oct 17 2013;369(16):1512-1521. PMID 24047455
9. Aulisa AG, Guzzanti V, Falciglia F, et al. Curve progression after long-term brace treatment in adolescent idiopathic scoliosis: comparative results between over and under 30 Cobb degrees - SOSORT 2017 award winner. *Scoliosis Spinal Disord.* Oct 30 2017;12:36. PMID 29094108
10. Lou E, Hill D, Raso J, et al. Smart brace versus standard rigid brace for the treatment of scoliosis: a pilot study. *Stud Health Technol Inform.* Jun 2012;176:338-341. PMID 22744524
11. Wong MS, Cheng JC, Lam TP, et al. The effect of rigid versus flexible spinal orthosis on the clinical efficacy and acceptance of the patients with adolescent idiopathic scoliosis. *Spine (Phila Pa 1976).* May 20 2008;33(12):1360-1365. PMID 18496349
12. Guo J, Lam TP, Wong MS, et al. A prospective randomized controlled study on the treatment outcome of SpineCor brace versus rigid brace for adolescent idiopathic scoliosis with follow-up according to the SRS standardized criteria. *Eur Spine J.* Dec 2014;23(12):2650-2657. PMID 24378629
13. Plewka B, Sibinski M, Synder M, et al. Clinical assessment of the efficacy of SpineCor brace in the correction of postural deformities in the course of idiopathic scoliosis. *Pol Orthop Traumatol.* Mar 26 2013;78:85-89. PMID 23535882
14. Plewka B, Sibinski M, Synder M, et al. Radiological evaluation of treatment with SpineCor brace in children with idiopathic spinal scoliosis. *Ortop Traumatol Rehabil.* Jun 28 2013;15(3):227-234. PMID 23897999
15. Cuddihy L, Danielsson AJ, Cahill PJ, et al. Vertebral body stapling versus bracing for patients with high-risk moderate idiopathic scoliosis. *Biomed Res Int.* Dec 2015;2015:438452. PMID 26618169
16. Bumpass DB, Fuhrhop SK, Schootman M, et al. Vertebral body stapling for moderate juvenile and early adolescent idiopathic scoliosis: cautions and patient selection criteria. *Spine (Phila Pa 1976).* Dec 2015;40(24):E1305-1314. PMID 26655807
17. Theologis AA, Cahill P, Auriemma M, et al. Vertebral body stapling in children younger than 10 years with idiopathic scoliosis with curve magnitude of 30 degrees to 39 degrees. *Spine (Phila Pa 1976).* Dec 1 2013;38(25):E1583-1588. PMID 23963018
18. Laituri CA, Schwend RM, Holcomb GW, 3rd. Thoracoscopic vertebral body stapling for treatment of scoliosis in young children. *J Laparoendosc Adv Surg Tech A.* Oct 2012;22(8):830-833. PMID 23039706
19. O'Leary P T, Sturm PF, Hammerberg KW, et al. Convex hemiepiphysiodesis: the limits of vertebral stapling. *Spine (Phila Pa 1976).* Sep 1 2011;36(19):1579-1583. PMID 21681138
20. Betz RR, Ranade A, Samdani AF, et al. Vertebral body stapling: a fusionless treatment option for a growing child with moderate idiopathic scoliosis. *Spine.* Jan 15 2010;35(2):169-176. PMID 20081512
21. U.S. Food and Drug Administration. SUMMARY OF SAFETY AND PROBABLE BENEFIT (SSPB): The Tether Vertebral Body Tethering System. 2019; https://www.accessdata.fda.gov/cdrh_docs/pdf19/H190005b.pdf. Accessed March 6, 2020.
22. Courvoisier A, Eid A, Bourgeois E, et al. Growth tethering devices for idiopathic scoliosis. *Expert Rev Med Devices.* Jul 2015;12(4):449-456. PMID 26027921
23. Samdani AF, Ames RJ, Kimball JS, et al. Anterior vertebral body tethering for idiopathic scoliosis: two-year results. *Spine (Phila Pa 1976).* Sep 15 2014;39(20):1688-1693. PMID 24921854
24. Samdani AF, Ames RJ, Kimball JS, et al. Anterior vertebral body tethering for immature adolescent idiopathic scoliosis: one-year results on the first 32 patients. *Eur Spine J.* Jul 2015;24(7):1533-1539. PMID 25510515
25. Negrini S, Donzelli S, Aulisa AG, et al. 2016 SOSORT guidelines: orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth. *Scoliosis Spinal Disord.* 2018; 13: 3. PMID 29435499
26. Scoliosis Research Society (SRS). Adolescent Idiopathic Scoliosis. n.d.; <http://www.srs.org/professionals/online-education-and-resources/conditions-and-treatments/adolescent-idiopathic-scoliosis>. Accessed March 9, 2020.
27. American Academy of Orthopaedic Surgeons (AAOS). Idiopathic Scoliosis in Children and Adolescents. *OrthoInfo* 2015; <https://orthoinfo.aaos.org/en/diseases--conditions/idiopathic-scoliosis-in-children-and-adolescents>. Accessed March 9, 2020.

28. National Institute of Arthritis and Musculoskeletal and Skin Diseases. Questions and Answers about Scoliosis in Children and Adolescents. 2015; <https://www.niams.nih.gov/health-topics/scoliosis>. Accessed March 9, 2020.
29. Force USPST, Grossman DC, Curry SJ, et al. Screening for Adolescent Idiopathic Scoliosis: US Preventive Services Task Force Recommendation Statement. JAMA. Jan 9 2018;319(2):165-172. PMID 29318284

Endnotes

¹ Based on MPRM 2.01.83 and expert opinion