MASSACHUSETTS

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Medical Policy

Orthotics for Progressive Scoliosis

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Policy Number: 550

BCBSA Reference Number: 2.01.83 (For Plan internal use only)
NCD/LCD: N/A

Related Policies

Vertical Expandable Prosthetic Titanium Rib, #305

Policy[1]

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue[SM] and Medicare PPO Blue[SM] 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 Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	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.

Males and females are equally affected by scoliosis, but curve progression is up to 10 times more common in females than males.[2,] Patients who are overweight or obese have a greater risk of presenting with larger Cobb angles and more advanced skeletal maturity, possibly due to delayed detection.[3,]

Treatment

Treatment of scoliosis currently depends on 3 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® Scoliosis System, are also being evaluated. The SpineCor is composed of a thermoplastic pelvic base with stabilizing and corrective bands across the upper body.

Surgery

Fusionless surgical procedures, such as vertebral body stapling and vertebral body tethering, are being evaluated as alternatives to bracing. Both procedures use orthopedic devices off-label. The goal of these procedures is to reduce the rate of spine growth unilaterally, thus allowing the other side of the spine to "catch up." The mechanism of action is believed to be down-regulation of the growth plate on the convex (outer) side by compression and stimulation of growth on the endplate of the concave side by distraction. In the current stapling procedure, nickel-titanium alloy staples with shape memory are applied to the convex side of the curve. The shape memory allows the prongs to be straight when cooled and clamp down into the bone when the staple returns to body temperature. Anterolateral tethering uses polyethylene ligaments that are attached to the convex side of the vertebral bodies by pedicle screws or staples. The ligament can be tightened to provide greater tension than the staple. The optimum degree of tension is not known. The polyethylene ligaments are more flexible than staples and are predicted to allow more spinal mobility. The goal of a fusionless growth modulating procedure is to reduce the curve and prevent progression, maintain spine mobility following correction, and provide an effective treatment option for patients who are noncompliant or who have a large curve but substantial growth is remaining. Observational data suggest that overweight patients may be at higher risk for scoliosis progression after surgery.[4,]

Research Recommendations

The Scoliosis Research Society provided evidence-based recommendations in 2005,[5,] which were updated in 2015,[6,] for bracing studies to standardize inclusion criteria, methodologies, and outcome measures to facilitate comparison of brace trials. Janicki et al (2007) ,the first study to use the Scoliosis Research Society criteria, concluded that a brace should prevent progression in 70% of patients to be considered effective.[7,] The Scoliosis Research Society evidence review and recommendations may also aid in the evaluation of fusionless surgical treatments for scoliosis progression in children.

The Scoliosis Research Society review of the natural history of scoliosis indicated that skeletally immature patients and patients with larger curves (between 20° and 29°) are significantly more likely to have more than 5° curve progression.[5,] Brace treatment for idiopathic scoliosis is usually recommended for juveniles and adolescents with curves measuring between 25° and 40° who have not completed spinal growth, with maturity defined as Risser grade 4, or at least 2 years after menarche for girls.[8,9,] Bracing may also be recommended for curves greater than 20° in a patient who has a rapidly progressing curve with more than 2 years of growth remaining.

Success from brace treatment is most frequently defined as progression of less than 5° before skeletal maturity, although alternative definitions may include progression of less than 10° before skeletal maturity or preventing the curve from reaching the threshold for surgical intervention. Surgery is usually recommended when the curve magnitude exceeds 45° to 50° (before or at skeletal maturity), although many patients will not undergo surgery at this point. Based on this information, Scoliosis Research Society provided the following recommendations for brace studies on adolescent idiopathic scoliosis:

- "Optimal inclusion criteria for brace studies consist of: age is 10 years or older when the brace is prescribed, Risser [grade] 0-2, curve 25°-40°, and no prior treatment."
- Outcomes of brace effectiveness should include all of the following:
    - "The percentage of patients with 5° or less curve progression and the percentage of patients who have 6° or more progression at skeletal maturity."
        - The number of patients at the start and end of treatment exceeding 10°, 30°, and 50° Cobb angles, as these risk thresholds have potential health consequences in adulthood, such as back pain and curve progression.
        - "A minimum of 2-year follow-up beyond skeletal maturity for each patient who was 'successfully' treated with a brace to determine the percentage who subsequently required or had surgery recommended. The surgical indications must be documented."
    - Clinically significant outcomes such as aesthetics, deformity progression, disability, pain, and quality of life.
- "Skeletal maturity should be considered achieved when <1 cm change in standing height has occurred on measurements made on 2 consecutive visits 6 months apart…. when Risser 4 is present and, in females, when the patient is 2 years after menarche."
- "All patients, regardless of subjective reports of compliance, should be included in the results. This process makes 'intent to treat' analysis possible.... An 'efficacy analysis' … should also be considered."

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 systematic review, a high-quality nonrandomized controlled trial, and 3 retrospective studies. 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. Two retrospective studies with long-term follow-up (mean, 13 to 15 years) has also shown that curvature corrections with bracing were maintained. Another retrospective study demonstrated that nighttime bracing was more effective than a 24-hour brace for avoiding surgery and preventing curve progression, but investigators attributed this finding to likely noncompliance with the 24-hour brace. A systematic review and meta-analysis reported higher success with full-time and nighttime rigid braces compared to soft bracing or observation only. 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. 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 an 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. 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 (n=12) ultimately limited the interpretation of these results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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. 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 that the technology results in an improvement in the net health outcome.

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, a case-control study, and case series. 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 studies with larger sample sizes and longer follow-up are needed to evaluate the safety and efficacy of this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive vertebral body tethering, the evidence includes case series. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Vertebral body tethering has been evaluated for thoracic curves at high risk of progression. Currently, there is very limited evidence on this technique, with published case series on the Dynesys® system reporting 1-year follow-up in 32 patients, 2-year follow-up in 11 patients, 3-year follow-up in 13 patients, and an additional prospective study reporting approximately 2-year follow-up in 21 patients. Available evidence for The Tether™ is limited to a small, single-center, uncontrolled, unpublished retrospective cohort study of 57 pediatric patients. Although reported Cobb angle corrections are promising, serious adverse events occurred, data is lacking on other important health outcomes, and there are important study design limitations including lack of a control group. Additional studies, with a larger number of total subjects and longer follow-up, are needed to evaluate the safety and efficacy of this surgical procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
6/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
5/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
6/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
5/2019	Annual 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. Annual policy review. Policy section clarified; statements otherwise unchanged.

12/2016	Annual policy review. New references added.
10/2015	Annual policy review. New investigational indications described. Clarified coding information. Effective 10/1/2015.
6/2013	Annual policy review. New references added.
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

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Endnotes

[1] Based on expert opinion