

POLICY TITLE	INTERVENTIONS FOR PROGRESSIVE SCOLIOSIS
POLICY NUMBER	MP- 1.120

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I. POLICY

A cervical-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**.

Vertebral body stapling and vertebral body tethering for the treatment of scoliosis is considered **investigational**.

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

Policy Guidelines

This policy does not address conventional surgery for scoliosis in patients with curve angles measuring 45 degrees or more. Brace treatment for idiopathic scoliosis is usually recommended for juveniles and adolescents with curves measuring between 25 and 40 degrees who have not completed spinal growth, with maturity defined as Risser 4, or 2 years post-menarche for girls. Bracing may also be recommended for curves greater than 20 degrees in a patient who has a rapidly progressing curve with more than 2 years of growth remaining.

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- A rigid cervical-thoracic-lumbar-sacral orthosis is primarily prescribed for patients with thoracic apices above T7 for control of upper thoracic sagittal deformities and for other spinal deformities not amenable to treatment with lower-profile designs.
- A low profile, rigid thoracic-lumbar-sacral orthosis worn full-time (18-23 hours per day) through skeletal maturity is used for most idiopathic curve patterns with a thoracic curve apex at or below T7 (the majority of idiopathic curves).
- Night time bracing systems are more effective in patients with isolated flexible thoracolumbar and lumbar curves than in double curves; they may also be indicated in patients who are noncompliant with a full-time wear program, patients in whom other types of orthotic management had failed, and patients nearing skeletal maturity who may not require full-time wear.

Cross-reference:

MP-1.136 Vertical Expandable Prosthetic Titanium Rib

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO- Refer to FEP Medical Policy Manual MP-2.01.83 Interventions for Progressive Scoliosis. The FEP Medical Policy manual can be found at: <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

III. DESCRIPTION/BACKGROUND

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SCOLIOSIS

Scoliosis is an abnormal lateral and rotational curvature of the vertebral column. Adolescent idiopathic scoliosis (AIS) 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

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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 AIS 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 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, are also being evaluated. The SpineCor is composed of a thermoplastic pelvic base with stabilizing and corrective bands across the upper body.

Surgery

Fusion less 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

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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.

Research Recommendations

The Scoliosis Research Society (SRS) provided evidence-based recommendations in 2005,² updated in 2015,³ for bracing studies to standardize inclusion criteria, methodologies, and outcome measures to facilitate comparison of brace trials. Janicki et al (2007) reported the first study to use the SRS criteria concluded that a brace should prevent progression in 70% of patients to be considered effective.⁴ The SRS evidence review and recommendations may also aid in the evaluation of fusionless surgical treatments for scoliosis progression in children.

The SRS 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.² 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.^{5,6} 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, SRS provided the following recommendations for brace studies on AIS:

“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:

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“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.”

REGULATORY STATUS

Some braces used for the treatment of scoliosis are considered class I devices by the U.S. Food and Drug Administration (FDA) and are exempt from 510(k) requirements (examples include the Boston scoliosis brace [Boston Orthotics & Prosthetics, Avon, MA] and the SpineCor® Scoliosis System).

Staples, using a shape memory nickel-titanium alloy, have been cleared for marketing by FDA through the 510(k) process for various bone fixation indications. For example, nitinol staples (Sofamor Danek, Memphis, TN) are indicated for fixation with spinal systems. Other memory shape staples cleared for marketing by FDA through the 510(k) process for bone fixation include the OSStaple™ (BioMedical Enterprises, San Antonio, TX) and the reVERTO™ Dynamic Compression Device. FDA product code: JDR. Vertebral body stapling in scoliosis is considered off-label use

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IV. RATIONALE

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SUMMARY OF EVIDENCE

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 RCT. 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 RCT. 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. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. One RCT evaluating a flexible brace did not show equivalent outcomes compared with conventional brace designs. Another study has suggested that 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 VBS, the evidence includes a comparative cohort 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

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interventions for preventing curve progression in juvenile and adolescent idiopathic scoliosis. VBS 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.

For individuals who have juvenile or adolescent idiopathic scoliosis at high risk of progression who receive VBT, the evidence includes case series. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. VBT has been evaluated for thoracic curves at high risk of progression. Currently, there is very limited evidence on this technique, with case series reporting 1-year follow-up in 32 patients and 2-year follow-up in 11 patients. 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 the effects of the technology on health outcomes.

V. DEFINITIONS

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510 (K) refers to a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

RISSEY SIGN is defined by the amount of calcification present in the iliac apophysis and measures remaining spinal growth by progressive anterolateral to posteromedial ossification. 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, e.g., 2-year, period.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization.

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Members and providers should consult the member’s benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered when used to report vertebral body stapling or tethering for the treatment of scoliosis:

CPT Codes®							
22899							

Current Procedural Terminology (CPT) copyrighted by American Medical Association. All Rights Reserved.

HCPCS Code	Description
L1001	Cervical-thoracic-lumbar-sacral orthotic (CTLSO), immobilizer, infant size, prefabricated, includes fitting and adjustment

Covered when medically necessary:

HCPCS Code	Description
L0700	Cervical-thoracic-lumbar-sacral orthotic (CTLSO), anterior-posterior-lateral control, molded to patient model, (Minerva type)
L0710	Cervical-thoracic-lumbar-sacral orthotic (CTLSO), anterior-posterior-lateral-control, molded to patient model, with interface material, (Minerva type)
L1000	Cervical-thoracic-lumbar-sacral orthotic (CTLSO) (Milwaukee), inclusive of furnishing initial orthotic, including model
L1005	Tension based scoliosis orthotic and accessory pads, includes fitting and adjustment

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HCPCS Code	Description
L1010	Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, axilla sling
L1020	Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, kyphosis pad
L1025	Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, kyphosis pad, floating
L1030	Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, lumbar bolster pad
L1040	Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, lumbar or lumbar rib pad
L1050	Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, sternal pad
L1060	Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, thoracic pad
L1070	Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, trapezius sling
L1080	Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, outrigger
L1085	Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, outrigger, bilateral with vertical extensions
L1090	Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, lumbar sling
L1100	Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, ring flange, plastic or leather
L1110	Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, ring flange, plastic or leather, molded to patient model
L1120	Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO), scoliosis orthotic, cover for upright, each
L1200	Thoracic-lumbar-sacral orthotic (TLSO), inclusive of furnishing initial orthotic only
L1210	Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), lateral thoracic extension
L1220	Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), anterior thoracic extension
L1230	Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), Milwaukee type superstructure
L1240	Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), lumbar derotation pad
L1250	Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), anterior ASIS pad
L1260	Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), anterior thoracic derotation pad
L1270	Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), abdominal pad
L1280	Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), rib gusset (elastic), each

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HCPCS Code	Description
L1290	Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), lateral trochanteric pad
L1300	Other scoliosis procedure, body jacket molded to patient model
L1310	Other scoliosis procedure, postoperative body jacket
L1499	Spinal orthotic, not otherwise specified

ICD-10-CM Diagnosis Codes	Description
M41.112	Juvenile idiopathic scoliosis; Juvenile idiopathic scoliosis, cervical region
M41.113	Juvenile idiopathic scoliosis; cervicothoracic region
M41.114	Juvenile idiopathic scoliosis; thoracic region
M41.115	Juvenile idiopathic scoliosis; thoracolumbar region
M41.116	Juvenile idiopathic scoliosis; lumbar region
M41.117	Juvenile idiopathic scoliosis; lumbosacral region
M41.119	Juvenile idiopathic scoliosis, site unspecified
M41.122	Adolescent idiopathic scoliosis, cervical region
M41.123	Adolescent idiopathic scoliosis, cervicothoracic region
M41.124	Adolescent idiopathic scoliosis, thoracic region
M41.125	Adolescent idiopathic scoliosis, thoracolumbar region
M41.126	Adolescent idiopathic scoliosis, lumbar region
M41.127	Adolescent idiopathic scoliosis, lumbosacral region
M41.129	Adolescent idiopathic scoliosis, site unspecified
Q67.5	Congenital deformity of spine

IX. REFERENCES

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29. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.01.83, Interventions for Progressive Scoliosis April 2018.*

X. POLICY HISTORY

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MP-1.120	CAC 11/30/2010 New Policy, Adopt BCBSA
	CAC 11/22/11 Consensus.
	CAC 10/30/12 Minor revision. Statement regarding the use of the vertical expandable titanium rib was removed from the policy and is now found in MP-1.136 Vertical Expandable Prosthetic Titanium Rib. References updated. FEP variation revised. Codes reviewed 9/24/12
	CAC 11/26/13 Consensus review. No changes to the policy statements. References updated. Rationale added.
	CAC 11/25/14 Consensus review. References and rationale updated. No changes to the policy statements. Updated the ICD 10 codes. Coding Reviewed and verified CLBJ
	CAC 11/24/15 Minor revision. Vertebral body tethering added as investigational. Background, references, and rationale updated. Coding reviewed/updated.
	CAC 9/27/16 Consensus review. No change to the policy statement. References updated. Variations reformatted. Coding reviewed.
	CAC 11/28/17 Consensus review. No change to policy statement. References and rationale updated. Coding reviewed.
	7/23/18 Consensus review. No changes to the policy statements. Background and references updated. Rationale revised.
	10/26/18 Admin coding review. Diagnosis updated.

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