

Vertebral Body Stapling and Vertebral Body Tethering for the Treatment of Scoliosis

Policy # 00769

Original Effective Date: 01/10/2022

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers vertebral body stapling for the treatment of scoliosis to be **investigational**.*

Based on review of available data, the Company considers vertebral body tethering for the treatment of scoliosis to be **investigational**.*

Policy Guidelines

This policy does not address conventional posterior spinal fusion surgery for scoliosis in individuals with curve angles measuring 45° or more. Brace treatment for idiopathic scoliosis is usually recommended for juveniles and adolescents with curves above $20^\circ \pm 5^\circ$ Cobb, still growing (Risser 0 to 3), and with demonstrated progression of deformity or elevated risk of worsening, unless otherwise justified in the opinion of a clinician specialized in conservative treatment of spinal deformities. It is recommended not to apply bracing to treat patients with curves below $15^\circ \pm 5^\circ$ Cobb, unless otherwise justified in the opinion of a clinician specialized in conservative treatment of spinal deformities.

Assessments related to decision-making for interventions in adolescent idiopathic scoliosis.

Cobb Angle in Scoliosis

The Cobb angle is the standard radiographic measure (in degrees) used to quantify the magnitude of a spinal curvature in scoliosis in the coronal (frontal) plane. The standard method for measurement uses a full-length, upright (standing) posteroanterior (PA) or anteroposterior (AP) spine radiograph so the curve is assessed under physiologic load. The upper and lower end vertebrae (e.g., T5–T12) used to calculate each Cobb angle are recorded.

A coronal spinal curve is considered scoliosis when the Cobb angle is greater than or equal to 10° on an appropriate radiograph. Curves less than 10° are commonly described as spinal asymmetry

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rather than scoliosis. Because scoliosis is a three-dimensional deformity, other abnormalities may be assessed alongside the Cobb angle, including vertebral rotation, trunk/rib prominence, and coexisting sagittal-plane abnormalities (e.g., kyphosis or lordosis measured using Cobb-type techniques on lateral radiographs).

The classification of abnormalities by Cobb angle magnitude is summarized as:

- **Less than 10°:** Spinal asymmetry (not diagnostic of scoliosis)
- **10–24°:** Mild scoliosis
- **25–40°:** Moderate scoliosis
- **Greater than 40°:** Severe scoliosis

Risser Grading System (Risser Sign).

The Risser grading system (also called the Risser sign) is a radiographic method used to estimate skeletal maturity by assessing the degree of ossification and fusion of the iliac crest apophysis. It is most commonly used in the evaluation and management of adolescent idiopathic scoliosis (AIS) because remaining spinal growth strongly influences the risk of curve progression. This evaluation informs how closely to monitor a curve and whether nonoperative or operative treatment is likely to be beneficial.

A standing AP pelvis radiograph or a full-length standing spine radiograph that includes both iliac crests is used for assessment.

The stage/grade (0–5) that serves as a proxy for remaining growth is summarized as follows:

- **Risser 0–1:** Substantial growth remaining; considered the highest-risk window for AIS progression.
- **Risser 2–3:** Ongoing but decelerating growth; moderate progression risk (risk varies with curve magnitude, age, menarche status, and other maturity markers).
- **Risser 4:** Near maturity (depending on which grading variant is used); typically, lower progression risk than earlier grades, but not necessarily “zero growth remaining.”
- **Risser 5:** Skeletal maturity with fusion of the iliac apophysis; generally low risk of growth-driven progression (large curves may still progress slowly in adulthood).

Sanders Skeletal Maturity Score (SMS)

SMS stages skeletal maturity using a posteroanterior (PA) radiograph of the hand and wrist (commonly the left). The score is assigned by evaluating the appearance and fusion status of epiphyses/physes in the phalanges and metacarpals and the distal radius. SMS is a categorical staging system designed to align with clinically meaningful growth phases, particularly the curve-acceleration period in AIS.

Summary of 8 stages of SMS:

- **Stages 1–2 (prepubertal/early adolescence):** substantial growth remaining; scoliosis progression risk depends heavily on curve size but can increase as the patient approaches Peak Height Velocity (PHV).

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- **Stages 3–4 (early puberty and around PHV):** highest-risk window for rapid curve progression (curve-acceleration phase); management decisions aim to ensure appropriate treatment is in place before or during this period.
- **Stage 5 (late PHV / early deceleration):** growth continues but begins slowing; risk of progression persists, especially for larger curves.
- **Stages 6–7 (decelerating growth / approaching maturity):** less remaining growth; progression risk typically declines but does not become zero, particularly for larger curves.
- **Stage 8 (skeletal maturity):** minimal remaining growth; in AIS, progression risk decreases, although larger curves (especially Greater than or equal to $\sim 50^\circ$) may still progress after maturity.

Traditional pelvic maturity measures such as the Risser sign can be less granular during the early-to-mid pubertal period when AIS progression risk is greatest. SMS provides multiple stages during the time when some patients would still be classified as “Risser 0,” which can improve risk stratification and support more tailored follow-up and treatment timing.

Scoliosis Research Society-22 (SRS-22 / SRS-22r) Score.

The Scoliosis Research Society-22 (SRS-22) is a disease-specific patient-reported outcome measure (PROM) designed to assess health-related quality of life (HRQoL) in scoliosis and spinal deformity populations. The current recommended version is the SRS-22r (refined) which has been validated for ages greater than or equal to 10 years.

The SRS-22 score measures 5 domains—pain, function/activity, self-image/appearance, mental health each with 5 items in the domain, and satisfaction with management with 2 items. Items are scored on a 1 (worst) –5 (best) Likert scale; domain scores are typically the mean of items in that domain. Higher scores indicate better HRQoL (less pain, better function, better self-image/mental health, greater satisfaction).

The score is commonly used to quantify baseline burden, compare interventions (e.g., bracing vs surgery; different surgical techniques), and evaluate change over time in clinical studies and registries.

Background/Overview

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.” 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

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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. 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. A retrospective review of 341 patients with adolescent idiopathic scoliosis who underwent surgery at a single tertiary pediatric hospital between 2013 and 2018 found that the major curve magnitude at presentation was significantly higher in patients with public compared to private insurance (50.0° versus 45.1°; $p=.0040$ and in Black compared to White patients (51.8° versus 47.0°; $p=.042$). Additionally, the odds of having an initial major curve magnitude $<40^\circ$ within the range of nonoperative treatment were 67% lower among Black patients with public insurance compared to Black patients with private insurance (odds ratio [OR], 0.33; 95% CI, 0.13 to 0.83; $p=.019$).

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.

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Surgery

Fusionless surgical procedures, such as vertebral body stapling and vertebral body tethering, are being evaluated as alternatives to bracing. 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.

Vertebral Body Tethering Procedure Summary

Vertebral Body Tethering (VBT) is a technique for scoliosis correction in selected adolescent idiopathic scoliosis patients.

Vertebral body tethering is performed under general anesthesia with an operating time of 4-6 hours. Double-lumen intubation confirmed by bronchoscopy establishes single-lung insufflation and the patient is positioned lateral decubitus with the curve convexity upward. A 12-mm thoroscopic portal is placed, carbon dioxide insufflation facilitates lung deflation, and the spinal pleura is opened to expose the lateral vertebral bodies while preserving disc spaces. A total of 3-5 portals may be used to introduce instrumentation.

Using biplanar fluoroscopy, bicortical tether anchors are placed sequentially from caudal to cephalad levels on the convex side, with motor evoked potentials obtained at each level. The tether is introduced through the caudal portal, secured proximally, and sequentially tensioned across anchors, with maximal tension at the curve apex and decreasing tension toward the ends. Radiographs confirm correction. A chest tube is typically placed to re-inflate the lung and may be retained depending on patient status.

Post operative hospitalization is anticipated to be 3-5 days with resumption of baseline activity by 12 weeks. Serial radiographic follow-up continues until skeletal maturity or identification of a clinical concern.

Anterior vertebral tethering is associated with complications that may arise from both the surgical approach and the implanted device. Approach-related complications include pulmonary events such as pneumonia, pneumothorax, and hemothorax. In addition, the anterior approach places adjacent anatomical structures at risk, including major vascular structures, visceral organs including the heart,

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lungs, liver, kidneys, spleen, and bowel; and neurologic structures such as the spinal cord and spinal nerve roots.

Implant-related complications primarily involve mechanical and fixation issues. These include rupture of the tether as well as malposition or loosening of the anchoring components, which may compromise device stability and intended biomechanical correction including producing treatment limiting overcorrection.

While VBT had originally been developed for adolescent idiopathic scoliosis, some studies have explored its use in selected patients with non-idiopathic scoliosis and early-onset scoliosis. Non-idiopathic patients may also carry higher infection and pulmonary complication risks, making the less invasive nature of VBT particularly appealing due to reduced pain and earlier mobilization. The VBT procedure has also demonstrated improved curve correction, fewer implant-related complications, and fewer unplanned surgeries compared to other procedures, while preserving spinal mobility and soft tissues until definitive fusion.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Some braces used to treat 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] and the SpineCor Scoliosis System). This classification does not require submission of clinical data regarding efficacy but only notification of FDA prior to marketing.

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

Several of the FDA cleared devices are described in Table 1.

A vertebral body tethering device (The Tether^{TM‡}; Zimmer Biomet Spine) received an FDA Humanitarian Device Exemption (HDE) (H190005, product code QHP) on 6/4/2019. The FDA HDE states that this device is indicated for "skeletally immature patients that require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, with a major Cobb angle of 30 to 65 degrees whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. Patients should have failed bracing and/or be intolerant to brace wear." The REFLECT^{TM‡} Scoliosis Correction System (Globus Medical), another vertebral tethering system, was granted HDE by the FDA on 5/15/2023 and intended for use in the same population as The Tether.

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Table 1. Scoliosis Bracing and Stapling Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Coronet Soft Tissue Fixation System	CoNexTions Medical	3/4/2020	K200028	Off Label Use for Scoliosis support
Superelastic Staple	Neosteo	2/28/2020	K192447	Off Label Use for Scoliosis support
Mactafix CI Fixation Button With Continuous Loop	Medacta International SA	2/10/2020	K193165	Off Label Use for Scoliosis support
Motoband Cp Implant System	CrossRoads Extremity Systems, LLC	1/10/2020	K193452	Off Label Use for Scoliosis support
Trimax Implant System	CrossRoads Extremity Systems, LLC	8/16/2019	K190772	Off Label Use for Scoliosis support
Colink Plating System, Fracture and Correction System, Rts Implant System, Neospan Compression Staple System	In2Bones USA, LLC	8/8/2019	K190385	Off Label Use for Scoliosis support
Trimed Nitinol Staple System	TriMed, Inc.	7/1/2019	K190166	Off Label Use for Scoliosis support
Vertex Nitinol Staple System	Nvision Biomedical Technologies, LLC	4/4/2019	K182943	Off Label Use for Scoliosis support
Geo Staple System	Gramercy Extremity	1/11/2019	K182212	Off Label Use for

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	Orthopedics LLC			Scoliosis support
DynaClip™ Bone Staple	MedShape Inc.	11/5/2018	K181781	Off Label Use for Scoliosis support
DynaBridge	Fusion Orthopedics LLC	10/15/2018	K181815	Off Label Use for Scoliosis support
MotoCLIP/HiMAX Step Staple Implant System	CrossRoads Extremity Systems LLC	8/9/2018	K181866	Off Label Use for Scoliosis support
DePuy Synthes Static Staples	Synthes (USA) Products LLC	7/24/2018	K180544	Off Label Use for Scoliosis support
MotoCLIP/HiMAX Implant System	CrossRoads Extremity Systems LLC	6/29/2018	K181410	Off Label Use for Scoliosis support
Clench Compression Staple	F & A Foundation LLC d.b.a. Reign Medical	4/6/2018	K173775	Off Label Use for Scoliosis support
Orbitum Bone Staple Implant X and VI	Orthovestments LLC	2/23/2018	K173693	Off Label Use for Scoliosis support
ExoToe Staple	ExoToe LLC	1/11/2018	K172205	Off Label Use for Scoliosis support
ToggleLoc System	Biomet Inc.	1/5/2018	K173278	Off Label Use for Scoliosis support

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Description

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.

Vertebral Body Stapling

Evidence on the use of VBS for patients with idiopathic scoliosis consists of a nonrandomized comparative study, a case-control study, and several small case series. Results from the nonrandomized comparative study and case-control study have indicated that VBS might slow curve progression in children with thoracic curves less than 35° and is at least as effective as bracing, but VBS appears to be less effective than bracing in patients with Cobb angles of 35° or more. Results from these studies are considered preliminary because few patients have been followed to skeletal maturity. Studies from other centers are consistent with results from those of the inventor of the procedure. Complications can include broken staples, staple dislodgement, curve overcorrection, congenital diaphragmatic hernia rupture, contralateral pleural effusion, pneumothoraces, and superior mesenteric artery syndrome. Investigators have commented that their approach is almost always to recommend bracing first and offer stapling only if the child or adolescent has difficulty wearing the brace. Notably, for patients with thoracic curves of 35° or greater, Cuddihy et al (2015) now perform vertebral body tethering (see next section) instead of VBS.

Vertebral Body Tethering

There is limited, high-quality, published evidence supporting VBT. A 2025 systematic review found that while VBT offers meaningful perioperative and recovery advantages and comparable short-term patient-reported outcomes in selected skeletally immature patients, it results in less consistent radiographic correction and substantially higher revision rates than PSF. A 2022 systematic review and meta-analysis of 26 studies reported meaningful Cobb angle correction but also substantial safety concerns, with a 74 percent clinical success rate, a 52 percent overall complication rate, and a 16 percent unplanned reoperation rate among patients with more than 36 months of follow-up. Evidence for the FDA-authorized Tether device remains sparse and is based primarily on a small, single-center, uncontrolled retrospective cohort of 57 patients summarized in the Humanitarian Device Exemption report, which showed promising radiographic correction. Additional observational studies of the Dynesys system demonstrate short-term Cobb angle improvements but provide limited insight into long-term durability, with tether breakage and revision surgery occurring

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in a significant portion of patients. Published data for the REFLECT system are similarly limited to observational cohorts with short follow-up and minimal reporting on patient-centered outcomes. Although early radiographic results across devices appear favorable, the overall evidence base remains constrained by small samples, lack of control groups, heterogeneous populations, short duration of follow-up, and high complication and reoperation rates. Larger controlled studies with long-term follow-up are needed to validate clinical benefits, clarify safety, and determine appropriate patient selection.

Summary of Evidence

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 observational studies and a systematic review and meta-analysis of these studies. 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. A 2025 systematic review found that while VBT offers meaningful perioperative and recovery advantages and comparable short-term patient-reported outcomes in selected skeletally immature patients, it results in less consistent radiographic correction and substantially higher revision rates than posterior spinal fusion. A 2022 systematic review and meta-analysis of 26 studies reported meaningful Cobb angle correction but also substantial safety concerns, with a 74 percent clinical success rate, a 52 percent overall complication rate, and a 16 percent unplanned reoperation rate among patients with more than 36 months of follow-up. Evidence for the FDA-authorized The Tether device is based primarily on a single-center, uncontrolled retrospective cohort of 57 patients. Additional observational studies of the Dynesys system (foundation for The Tether device) demonstrate short-term Cobb angle improvements but provide limited insight into long-term durability, with tether breakage and revision surgery occurring in a significant portion of patients. Published data for the REFLECT system are similarly limited to observational cohorts with short follow-up and minimal reporting on patient-centered outcomes. Controlled studies with long-term follow-up are needed to validate clinical benefits, clarify safety, and determine appropriate patient selection. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Orthopaedic Surgeons

Information updated on the American Academy of Orthopaedic Surgeons' OrthoInfo website indicates that the type of treatment required for idiopathic scoliosis in children and adolescents depends on the kind and degree of the curve, child's age, and the number of remaining growth years until the child reaches skeletal maturity.

- Observation is appropriate when the curve is mild ($<25^{\circ}$) or if the child is near skeletal maturity.
- The goal of bracing is to prevent scoliotic curves from worsening. Bracing can be effective if the child is still growing and has a "spinal curve between 25° and 45° ".
- Surgery may be recommended if the curve is "greater than 45° - 50° " or if bracing did not stop the curve from reaching this point. An implant made up of rods, hooks, screws, and/or wires is used to straighten the spine.

Vertebral body tethering (VBT) and vertebral body stapling (VBS) are not addressed on the Society's website.

National Institute of Arthritis and Musculoskeletal and Skin Diseases

The National Institute of Arthritis and Musculoskeletal and Skin Diseases has an educational website page on scoliosis in children and adolescents (last reviewed, July 2023). When treatment is needed, an orthopedic spine specialist should suggest the best treatment for each patient based on the patient's age, how much more he or she is likely to grow, the degree and pattern of the curve, and the type of scoliosis.

- Observation may be advised if "the curve is mild" and "the child's skeleton is still growing."
- Doctors may advise "If the curve is moderate" and the "child or teen is still growing...using a brace to keep the curve from getting any worse."
- Surgery may be advised if the "child or teen is still growing and the scoliosis continues to progress."

The Institute also stated that regular exercise helps children remain physically fit and helps strengthen muscles.

The educational page does not address VBS or VBT.

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National Institute for Health and Care Excellence

In 2022, the National Institute for Health and Care Excellence (NICE) published an interventional procedures guidance on vertebral body tethering for idiopathic scoliosis in children and young people. Recommendations stated that "evidence on the safety of vertebral body tethering for idiopathic scoliosis in children and young people is limited but raises concerns of serious complications. Evidence on its efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research."

Scoliosis Research Society

The Scoliosis Research Society has indicated that the treatment of adolescent idiopathic scoliosis falls into 3 main categories (observation, bracing, surgery) and is based on the risk of curve progression. In general, adolescent idiopathic scoliosis curves progress in 2 ways: first, during the rapid growth period of the patient and, second, into adulthood if the curves are relatively large. Because scoliosis gets larger during rapid growth, the potential for growth is evaluated taking into consideration the patient's age, the status of whether females have had their first menstrual period, as well as radiographic parameters. The Risser grading system rates a child's skeletal maturity on a scale of 0 to 5. Patients who are Risser grade 0 and 1 are growing rapidly, while patients who are 4 and 5 have stopped growing. The Society made the following recommendations:

- Observation is "recommended for patients whose curves are less than 25° or 30° who are still growing, or people who have stopped growing and have curves that aren't changing or causing problems."
- Bracing is "recommended for curves larger than 25°, but smaller than 45° to 50° in someone who is still growing."
- Surgical treatment is "recommended for people with curves usually greater than 45° or 50° and/or who are at high risk of continued worsening even after they are finished growing."
- Statements on VBS and tethers include, "This technique can be used in children who are still growing, have a progressive curvature that measures less than 35°, and who are able to tolerate open or endoscopic exposure of the spine. By placing special vertebral body staples or tethers on the convex side of the curve, growth is inhibited on that side. The idea is that the scoliosis may then correct through more growth on the concave side of the curve."

Scoliosis Research Society

In 2023, the Scoliosis Research Society released a position statement on VBT in idiopathic pediatric spinal deformity. [[Scoliosis Research Society \(SRS\). Vertebral body t... ments](#)]. They stated that "VBT may be an effective treatment modality in some pediatric patients with idiopathic scoliosis. The decision regarding choice of treatment should be made in close dialogue with patients and families, especially underlining that the current scientific results do not show a significant, clinically relevant difference in outcome compared to posterior spinal fusion (PSF), and an increased risk of revision surgery should be expected if VBT is chosen."

Society on Scoliosis Orthopaedic and Rehabilitation Treatment

The guidelines from the Society on Scoliosis Orthopaedic and Rehabilitation Treatment (2016) included recommendations on the following conservative treatments for idiopathic scoliosis: assessment, bracing, physiotherapy, physiotherapeutic scoliosis-specific exercises and other

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conservative treatments for idiopathic scoliosis, exercises, special inpatient rehabilitation, and bracing (nighttime rigid bracing, soft bracing, part-time rigid bracing, full-time bracing). The guidelines did not address vertebral body stapling or vertebral body tethering. Treatment decisions should be individualized based on the probability of progression, curve magnitude, skeletal maturity, patient age, and sexual maturity. The following is a summary of the 20 recommendations in the guidelines specific to bracing:

- Bracing is recommended to treat adolescent, juvenile, and infantile idiopathic scoliosis “as the first step in an attempt to avoid or at least postpone surgery to a more appropriate age.”
- “It is recommended not to apply bracing to treat patients with curves below $15^{\circ} \pm 5^{\circ}$ Cobb, still growing (Risser 0 to 3), and with demonstrated progression of deformity or elevated risk of worsening, unless otherwise justified in the opinion of a clinician specialized in conservative treatment of spinal deformities.”
- “It is recommended that each treating team provide the brace that they know best, which means the brace they are more experienced and with perceived outcomes. This is due to the actual knowledge; there is no brace that can be recommended over the others.”
- Braces should be “worn full time or no less than 18 hours per day at the beginning of treatment ...” and “in proportion with the severity of deformity, the age of the patient, the stage, aim and overall results of treatment, and the achievable compliance.”
- “[B]racing is applied by a well-trained therapeutic team, including a physician, an orthotist, and a therapist, according to ... (prescription, construction, ... correction, follow-up)....”
- Braces should be “specifically designed for the type of the curve to be treated”: to treat frontal, horizontal, and sagittal planes; not to restrict respiratory function; to be least invasive; to ensure patient compliance.

U.S. Preventive Services Task Force Recommendations

The U.S. Preventative Services Task Force (USPSTF) has published recommendations for idiopathic scoliosis screening. The USPSTF (2004) recommended against the routine screening of asymptomatic adolescents for idiopathic scoliosis (grade D recommendation). The USPSTF (2018) updated their recommendation to state that there is insufficient evidence to assess screening of adolescents for idiopathic scoliosis (grade I recommendation). Review conclusions for scoliosis treatments are listed below:

“The USPSTF found inadequate evidence on treatment with exercise and surgery. It found adequate evidence that treatment with bracing may slow curvature progression in adolescents with mild or moderate curvature severity (Cobb angle $<40^{\circ}$ to 50°); however, evidence on the association between reduction in spinal curvature in adolescence and long-term health outcomes in adulthood is inadequate. The USPSTF found inadequate evidence on the harms of treatment.”

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT05830825 ^a	The Tether ^{TM‡} - Vertebral Body Tethering System Post-Market Clinical Follow-Up Study in UK	100	Dec 2033
NCT04805437	3D Designed Boston Brace Versus Standard Boston Brace in Halting Progression in Idiopathic Scoliosis: a Randomized Controlled Trial (PRISCOPRO)	170	Apr 2037
NCT01761305	CONTRAIS: CONservative TReatment for Adolescent Idiopathic Scoliosis. A Randomised Controlled Trial	135	Dec 2030
NCT04116723	Trial of Flexible Bracing Treatment of Adolescents Idiopathic Scoliosis	100	Dec 2025
NCT03506334	Prospective Pilot Study of Anterior Vertebral Body Tethering Using Zimmer Biomet Tether System or Dynesys System Components to Treat Pediatric Scoliosis	80	May 2025
NCT04505579 ^a	The Tether ^{TM‡} - Vertebral Body Tethering System Post Approval Study	200	Dec 2027
NCT04914507	A Prospective Analysis of Long-Term Clinical Outcomes and 3D Spine Growth in Anterior Vertebral Body Tethering	106	Sep 2029

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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12/02/2021	Medical Policy Committee review
12/08/2021	Medical Policy Implementation Committee approval. New policy.
12/01/2022	Medical Policy Committee review
12/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/01/2023	Medical Policy Committee review
06/14/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/13/2023	Coding update
06/06/2024	Medical Policy Committee review
06/12/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/05/2025	Medical Policy Committee review
06/11/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/04/2026	Medical Policy Committee review
06/10/2026	Medical Policy Implementation Committee review.
08/20/2026	Medical Quality Management Committee approval. Separated vertebral body stapling and vertebral body tethering for the treatment of scoliosis into two investigational statements. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0656T, 0657T, 0790T, 22836, 22837, 22838, 22899
HCPCS	No codes
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.