
Medical Policy



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. When Centers for Medicare and Medicaid (CMS) coverage rules are not fully developed, this medical policy may be used by BCBSM or BCN Medicare Advantage plans 42 CFR § 422.101 (b)(6). Please reference the appropriate certificate or contract for benefit information. This policy may be updated and is therefore subject to change.

***Current Policy Effective Date: 1/1/26**
(See policy history boxes for previous effective dates)

Title: Interventions for Juvenile and Adolescent Progressive Scoliosis

Description

Orthotic rigid bracing devices are used to slow spinal curve progression and reduce the need for fusion surgery in individuals with juvenile or adolescent idiopathic scoliosis who are at high risk of progression. 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 2 years after menarche for girls. Bracing may also be recommended for curves greater than 20° in an individual who has a rapidly progressing curve with more than 2 years of growth remaining.

Vertebral Body Tethering (VBT) and Vertebral Body Stapling (VBS) are minimally invasive fusionless surgical procedures used to treat scoliosis in growing children by correcting and preventing the progression of spinal curves. VBT uses a flexible cord to guide growth while the spine continues to grow, while VBS employs a series of staples on the convex side of the curve to halt further worsening.

Note: This policy does not address **criteria** for conventional surgery for scoliosis in individuals with curve angles measuring 45° or more.

Medical Policy Statement

Orthotic rigid bracing devices are established for individuals with juvenile and adolescent idiopathic scoliosis when medical criteria are met.

Vertebral body tethering (VBT) is established for juvenile and adolescent idiopathic scoliosis when criteria are met,

Non-rigid bracing devices (e.g., microcomputer-controlled braces, flexible braces, smart braces) for juvenile and adolescent idiopathic scoliosis are experimental and investigational. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

Vertebral Body Stapling (VBS) for juvenile and adolescent idiopathic scoliosis is considered experimental and investigational. There is insufficient evidence to determine that the technology results in an improvement of net health outcomes.

Inclusionary and Exclusionary Guidelines

Inclusions:

1. A rigid brace (cervical-thoracic-lumbar-sacral, thoracic-lumbar-sacral orthosis) for the treatment of scoliosis in juvenile and adolescent individuals at high risk of progression that meets the following criteria:
 - a. Idiopathic spinal curve angle between 25° and 40°; **AND**
 - b. Spinal growth has not been completed (Risser grade 0-3; no more than 1 year after menarche in females).

OR

- a. Idiopathic spinal curve angle greater than 20°; **AND**
 - b. There is a documented increase in the curve angle; **AND**
 - c. At least 2 years of growth remain (Risser grade 0 or 1; premenarche in females).
2. Vertebral Body Tethering (VBT) for juvenile and adolescent scoliosis when **all** the following are present:
 - a. Progressive idiopathic scoliosis
 - b. Thoracic curve 30-65°
 - c. Bending films document flexibility with curve improving to less than 30°
 - d. Skeletal immaturity defined by Risser 0-2 or Sanders less than or equal to 5
 - e. Failure of bracing (progression of greater than 5° despite bracing) or intolerance of bracing
3. Removal or revision of VBT for juvenile and adolescent idiopathic scoliosis for **any** of the following indications:
 - a. Hardware failure (e.g., screw loosening, tether breakage)
 - b. Curve progression
 - c. Over or under correction
 - d. As a part of a spinal fusion procedure
 - e. Local complications related to spinal tether (e.g., infection)

4. Isolated hardware removal for juvenile and adolescent idiopathic scoliosis when **any** of the following are present:
 - a. Hardware loosening, malposition or failure
 - b. Skin or soft tissue compromise or infection
 - c. Intolerable local symptoms that are unresponsive to 6 months of non-operative therapy* when other causes have been ruled out
 - d. Hardware has been identified as the likely cause of pain (e.g., response to hardware block)

*Non-operative treatments must be dated within the past 12 months and include a combination of the following unless the provider documents a contraindication.:

- I. Analgesics or anti-inflammatory medications (e.g., acetaminophen, NSAIDS, corticosteroids), any route
- II. Activity modification/joint conservation techniques (e.g., limiting physical activity or repetitive motion, use of an assistive device, etc.)
- III. Physical therapy, or detailed professionally directed home exercise program

EXCLUSIONS:

1. Non-rigid bracing devices (e.g., microcomputer-controlled braces, flexible braces, smart braces and any other bracing devices that do not meet criteria. This list is not all inclusive).
2. Vertebral Body Tethering (VBT) is contraindicated when **any** of the following are present:
 - a. Skeletal maturity
 - b. Congenital scoliosis
 - c. Chest wall deformity (e.g., pectus excavatum, prior chest wall surgery)
 - d. Spastic or decreased core muscular strength or trunk control
 - e. Patient documented as non-ambulatory at baseline
 - f. Thoracic-hyperkyphosis greater than 40⁰
 - g. Hybrid procedure (e.g., combined spinal fusion and vertebral body tethering)
 - h. Double curve/Double tether
 - i. Osteopenia (T score of less than -1.5)
3. Vertebral Body Stapling

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

22836 22837 22838 0656T 0657T 0790T

Other codes (investigational, not medically necessary, etc.):

22899

Background

Progressive idiopathic scoliosis is an abnormal, side to side spinal curvature where the curve worsens over time, specifically during a child's peak growth spurt. Idiopathic scoliosis is most common, but its cause is often unknown and progressive means that the spinal curvature is not stable. The curvature is at risk for increasing in magnitude if there is no intervention. It is difficult to predict which curves will be progressive. Factors such as age, Cobb angle, gender, and skeletal maturity as assessed during the child's growth spurt.

Scoliosis is a lateral (toward the side) curvature in the normally straight vertical line of the spine. There are many types of scoliosis including:

- Congenital scoliosis: caused by a bone abnormality present at birth
- Neuromuscular scoliosis: a result of abnormal muscles or nerves (e.g., spina bifida, cerebral palsy)
- Degenerative scoliosis: may result from traumatic bone collapse (e.g., previous back surgery, osteoporosis)
- Idiopathic scoliosis: the most common type of scoliosis that has no specific identifiable cause.
- Juvenile scoliosis is considered to be a spinal curvature that affects children between the ages of 3 and 10. The juvenile scoliosis period is intense as it occurs during a time period of heightened growth which increases the risk of curve progression of curvature of 40 degrees or greater.
- Adolescent scoliosis is a common spinal curvature that develops during adolescence between the ages of 10 to 18. It is seen with curves which are greater than 40 degrees.

Curves caused by scoliosis are initially detected on school screening exams, by a child's pediatrician or family doctor, or by a parent. Some clues to scoliosis include uneven shoulders, a prominent shoulder blade, uneven waist, or leaning to one side. The diagnosis of scoliosis and the determination of the type of scoliosis are made by bone exam and an x-ray to evaluate the magnitude of the curve.

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 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° 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; $p=.019$) due to treatment delays.⁴

Treatments for scoliosis include braces or surgery. Bracing is the usual treatment choice for adolescents who have a spinal curve between 25° and 40°, particularly if their bones are still maturing and if they have at least 2 years of growth remaining. The purpose of bracing is to halt progression of the curve. Those who have curves beyond 40° to 50° are often considered for scoliosis surgery, spinal fusion with instrumentation and/or bone grafting. The goal is to make sure the curve does not progress.

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 perpendicularly 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 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 (e.g., 2-year) period.

For severe juvenile and adolescent idiopathic scoliosis treatment, the standard of care is anterior or posterior spinal arthrodesis and fusion. Posterior spinal instrumented fusion (PSIF), which reduces the deformity and fuses the spine to prevent progression is the gold standard surgical procedure for AIS.³⁹ The concern for early PSIF is it will halt remaining spinal growth and reduce the thorax volume, decreasing pulmonary function.³⁶

Growth modulation techniques include vertebral body stapling (VBS) and vertebral body tethering (VBT). Fusionless surgical procedures such as vertebral body stapling and vertebral body tethering are being evaluated as an alternative to bracing. These techniques are minimally invasive, preserve motion, and do not preclude spinal fusion if they are unsuccessful.

Vertebral body stapling (VBS) for juvenile and adolescent scoliosis is a minimally invasive surgical technique in which special malleable metal staples are attached to adjacent vertebral bodies that make up the bend of the curve. These nickel-titanium alloy staples are cooled and while in an open position, are placed on the appropriate vertebral segments. As the staples are warmed by the body, they clamp down, so they are unable to dislodge. The staples are supposed to keep the curve from progressing by slowing the growth on the convex (protruding) side of the curve while allowing the spine's own natural growth on the concave (recessed) side.

Vertebral body tethering (VBT) is a minimally invasive technique in which pedicle screws are placed into the front of the vertebral bodies and attached to a flexible cable at the bend of the curve. The cable is tightened, which may provide some immediate correction of the curve as well as possible continued improvement as the spine grows. A single tethering device has

been approved by the US Food and Drug Administration (FDA) for the correction of juvenile and adolescent idiopathic scoliosis that has not responded to conservative treatment options (e.g., bracing).

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. The relevant outcomes are change in disease status, morbid events, QOL, and treatment-related morbidity. Bracing has been considered the only option to prevent curved 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 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 RCT. The relevant outcomes are change in disease status, morbid events, QOL, 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 non-rigid or flexible brace, the evidence includes a randomized and a nonrandomized comparative study. The relevant outcomes are change in disease status, morbid events, QOL, 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 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 (VBT), most published studies are retrospective or prospective case series with small populations, demonstrating varying clinical outcomes. Early reports of a correction in Cobb angle from published reports on the Dynesys system are promising, but little is known about longer-term outcomes with this procedure. In Braun's retrospective study (2024), adolescent idiopathic scoliosis (AIS) was satisfactorily treated with anterior vertebral tethering (AVT) in the majority of patients over a broad range of curve

magnitudes, curve types, and skeletal maturity. Seventy-four individuals with AIS treated with AVT, including 52 patients (47 were female, 5 were male) had sufficient 2-year follow-up for inclusion; 46 of these 52 patients (88 %) with 65 curves (35 T, 30 TL/L) were satisfactorily treated with AVT demonstrating curve correction. A meta-analysis by Zhu et al (2022), 26 studies representing 1045 subjects (mean age range, 11.1 to 14.9 years) were treated with vertebral body tethering. Studies indicated that the Cobb angle of the major curve was significantly corrected from 40.0° to 59.0° at baseline to 15.9° to 38.0° immediately post-surgery and 10° to 38° at final follow-up. This led to overall success rate of 73% (95% CI, 68.31% to 78.05%). Some studies comparing VBT to posterior spinal fusion found that complication and reoperation rates were significantly higher in patients undergoing VBT (Roser, et al., 2023; Zhu, et al., 2022).^{36, 30} Most commonly reported complications were tether breakages, pulmonary complications, and overcorrections. Larger, controlled studies are needed to verify these findings. 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 vertebral body stapling, the evidence includes a comparative cohort study and case series. The relevant outcomes are change in disease status, morbid events, QOL, 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. 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 that the technology results in an improvement in the net health outcome.

Additional clinical input was sought from consultative providers in September 2025, which included orthopedic surgeons, about the use of vertebral body tethering and vertebral body stapling as a treatment modality for individuals who had adolescent idiopathic scoliosis. A thorough review of the medical literature for both procedures was completed. The recommendation received proposed that individuals who met criteria may benefit from vertebral body tethering, a minimally invasive procedure. This intervention was recommended to prevent spinal curve progression and as alternative to reducing the need for spinal fusion surgery in individuals with juvenile or adolescent idiopathic scoliosis. The clinical input received for vertebral stapling included no medical evidence in support of this treatment for juvenile and adolescent idiopathic scoliosis.

Rationale

Evidence reviews assess clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms. The following is a summary of the key literature to date.

Conventional Rigid Braces

Clinical Context and Therapy Purpose

The purpose of a conventional rigid brace is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as observation, in patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

Review of Evidence

24-Hour Brace

Nonrandomized Comparative Study

Weinstein et al (2013) reported results from the National Institutes of Health–sponsored multicenter Bracing in Adolescent Idiopathic Scoliosis Trial (BrAIST, NCT00448448) that compared bracing versus watchful waiting.⁸ Patients were enrolled who met current criteria for bracing: skeletally immature (Risser grade 0-2); premenarchal or postmenarchal by no more than 1 year; primary angle between 20° and 40°; curve apex caudal to T7, as well as no previous surgical or orthotic treatment for AIS. Due to difficulty recruiting into the randomized trial, the final study included both a randomized (n=116) and a preference cohort (n=126). The primary outcomes were curve progression to 50° or more (treatment failure) or skeletal maturity without this degree of progression (treatment success). The trial began in 2007 with an estimated 500 patients but was stopped early by the data safety and monitoring board due to the efficacy of bracing found in interim analysis. The rate of treatment success was 72% after bracing compared with 48% after observation, with a propensity score–adjusted odds ratio for treatment success of 1.93. Intention-to-treat analysis of the randomized cohort showed that the number needed to treat to prevent one case of curve progression warranting surgery was 3.0. Hours of brace wear, measured with a temperature sensor embedded in the brace, was significantly correlated with the rate of treatment success. The effectiveness of brace wear of less than 6 hours per day was similar to observation (41%), while success rates of 90% to 93% were found in patients who wore a brace for at least 12.9 hours per day.

Retrospective Study

Aulisa et al (2021) conducted a nested cohort study of 163 patients with adolescent idiopathic scoliosis who received progressive action short bracing.³³ Outcomes were compared between patients with Cobb angles less than 30° and more than 30° after 10 years of follow-up. The mean age at brace removal was 13.46 years. The mean pre-brace Cobb angle in the first group was 37.26°, which decreased to 22.98° after brace weaning, then increased to 25.07° at 10 years. In the second group, the mean pre-brace Cobb angle was 24.4°, which decreased to 8.69° after brace weaning, then increased to 9.98° at 10 years. There was no significant difference in the mean progression of curve magnitude between groups at 10 years follow-up.

Aulisa et al (2017) investigated whether scoliotic curve correction was maintained long-term in patients with AIS who were treated with the rigid brace.⁹ From a database of patients treated with a rigid brace, 93 patients who had completed treatment at least 10 years prior agreed to participate and underwent a follow-up examination. Participants had a mean age of 32.6 years and had been treated with the brace for a mean 5.3 years. Mean follow-up was 15 years of post-treatment. The mean pre-brace Cobb angle was 32°, which was reduced to 19° following brace removal. At short-term follow-up (5 years), the mean Cobb angle was 21°; at long-term follow-up, the angle had increased to 22°. The change in Cobb angle from brace

removal to long-term follow-up was not statistically significant. Subgroup analyses on patients with pre-brace Cobb angles of 30° or less compared with pre-brace Cobb angles greater than 30°, showed no significant difference in angle increase at long-term follow-up. Tables 2 and 3 summarize the key characteristics and results of these trials.

Table 2. Summary of Key Nonrandomized Trials Characteristics

Study	Study Type	Country	Date	Participants	Treatment (1)	Treatment (2)	Follow Up
Weinstein et al (2013)	Multicenter, with a randomized and nonrandomized cohort	United States, Canada	2007-2011	Adolescents with idiopathic scoliosis (n=242)	Rigid thoracolumbosacral orthosis	Control	Average 22 months
Aulisa et al (2021)	Nonrandomized controlled cohort nested in a prospective database	Italy	1980-2018	Patients who had completed brace treatment at least 10 years prior (n=163)	Progressive action short brace		Mean 13.41 years post-treatment
Aulisa et al (2017)	Retrospective	Italy	1980-2016	Patients who had completed treatment with a rigid brace at least 10 years prior (n=93)	Lyon or progressive action short brace		Mean 15 years post-treatment

Table 3. Summary of Key Nonrandomized Trials Results

Study	Rate of Treatment Success	Average PedsQL scores	Pre-brace Mean Cobb Angle (degrees)	Post-brace Mean Cobb Angle (degrees)	Mean Cobb Angle at 10 Year Follow-up (degrees)
Weinstein et al (2013)					
Bracing	72%	82			
Control	48%	81.9			
OR	1.93				
p-value		.97			
Aulisa et al (2021)¹²,					
Cobb angle >30° group			37.26 (+/- 7.5)	22.98 (+/- 9.7)	25.07 (+/- 11.2)
Cobb angle <30° group			24.40 (+/- 2.6)	8.69 (+/- 7.3)	9.98 (+/- 7.8)
Aulisa et al (2017)			32.17 (+/- 9.4)	19.39 (+/- 10.8)	22.12 (+/- 12.11)

OR: odds ratio; PedsQL: Pediatric Quality of Life Inventory (score range, 0-100).

Nighttime Braces

Systematic Review

Costa et al (2021) conducted a systematic review and meta-analysis to compare different bracing methods in patients with adolescent idiopathic scoliosis, including full-time and nighttime wear of rigid braces and soft braces.²⁷ Thirty-three studies were included, approximately 25 of which were conducted in patients at high risk of progression (e.g., Cobb angle between 25° and 40°, Risser grade 0-2). All but one of the 32 studies used rigid braces, 2 studies used nighttime braces, and 2 studies used part-time braces. The meta-analysis was limited to 16 studies with a medium or low risk of bias that defined progression as $\leq 5^\circ$. Success with full-time rigid bracing was 73.2% (95% CI, 60.9% to 85.5%), with nighttime rigid bracing was 78.7% (95% CI, 72.4% to 85%), with soft bracing was 62.4% (95% CI, 55.1% to 69.6%), and with observation only was 50% (95% CI, 44% to 56%).

Randomized Controlled Trial

In a Randomized Control Trial conducted by Charalampidis et al (2024), this study compared nighttime bracing plus physical activity or scoliosis-specific exercise plus physical activity to physical activity alone in individuals with moderate-grade adolescent idiopathic scoliosis.⁴⁰ The trial included 135 children or adolescents (mean age, 12.7 years; standard deviation [SD], 1.5; 82% female) with adolescent idiopathic scoliosis. Forty-five individuals were added to each group. The patients randomized to the nighttime brace group were instructed to wear the brace for 8 hours nightly. Adjustment of the brace throughout the study was conducted as needed by an orthotist. The primary outcome was treatment success, defined as curve progression of 6° or less by skeletal maturity. Following the completion of the primary outcome, all patients were followed for up to 2 years. Treatment success was seen in 34 of 45 patients (76%) in the nighttime brace group and in 24 of 45 patients (53%) in the physical activity alone group (odds ratio [OR], 2.7; 95% CI, 1.1 to 6.6). The number needed to treat to prevent curve progression with nighttime bracing was 4.5 (95% CI, 2.4 to 33.5). The mean (SD) time in the study was 22.8 (12.9) months in the nighttime brace group and 16.2 (10.5) months in the physical activity only group. In the nighttime brace group, 16 adverse events were reported in 12 patients. For those who experienced treatment failure, 6 patients in the nighttime brace group were transitioned to full-time bracing and 4 were treated surgically compared to 14 patients in the physical activity group transitioned to full-time bracing and 6 treated surgically. At the 2-year follow-up, 9 patients in each of the 3 groups underwent surgery. Tables 5 and 6 describe the key characteristics and results.

Table 5. Summary of Key RCT Characteristics

Trial	Countries	Sites	Dates	Participants	Interventions		
					Active 1	Active 2	Comparator
Charalampidis et al (2024); CONTRAIS	Sweden	6	2013-2018	Children and adolescents aged 9 to 17 years with an AIS primary curve Cobb angle of 25° to 40°, apex T7 or caudal, and skeletal immaturity	Physical activity + nighttime bracing (n=45)	Physical activity + scoliosis-specific exercise (n=45)	Physical activity alone (n=45)

AIS: adolescent idiopathic scoliosis; CONTRAIS: Conservative Treatment for Adolescent Idiopathic Scoliosis; RCT: randomized controlled trial.

Table 6. Summary of Key RCT Results

Study	Treatment Success ^a n (%)
Charalampidis et al (2024); CONTRAIS	n=90 ^b
Physical activity + nighttime bracing	34/45 (76%)
Physical activity alone	24/45 (53%)
OR (95% CI)	2.7 (1.1 to 6.6)
NNT (95% CI)	4.5 (2.4 to 33.5)
RRR (95% CI)	48% (4% to 71%)

CI: confidence interval; CONTRAIS: Conservative Treatment for Adolescent Idiopathic Scoliosis; NNT: number needed to treat; OR: odds ratio; RCT: randomized controlled trial; RRR: relative risk reduction.

^a Defined as curve progression of 6° or less

^b Total N was 135, but comparison of scoliosis-specific exercise to physical activity is not relevant to this review and was omitted from Table 6.

The purpose of the study limitations tables (see Tables 7 and 8) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides conclusions on the sufficiency of evidence supporting the position statement.

Table 7. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Charalampidis et al (2024); CONTRAIS		5. Compliance with the treatment plan did not include objective measures	5. Compliance with the treatment plan did not include objective measures	7. Option to transition to a full-time brace after treatment failure may have contributed to no difference in surgical rates among the 3 groups at 2-year follow-up	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5. Other.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Retrospective Trial

Using the new SRS criteria, Janicki et al (2007) reported outcomes from a database of patients with AIS who had used a thoracic-lumbar-sacral orthosis (TLSO) or a nighttime orthosis.⁴ Retrospective analysis identified 160 patients treated orthotically for idiopathic scoliosis between 1992 and 2004. Patients with incomplete follow-up were phoned and asked to return if needed. From the cohort of 160 patients, 83 met the SRS inclusion criteria and had complete data. Due to poor outcomes with TLSO, which the investigators suspected were predominantly due to a lack of compliance, practice had been changed from using a TLSO to recommending a nighttime orthosis. Thus, the 48 patients treated with TLSO and 35 treated with nighttime orthosis were not concurrent. For patients with an initial curve between 25° and 40° and treated with TLSO, 85% progressed greater than 5°, 56% progressed to greater than 45°, and 79% progressed to surgery. With the nighttime orthosis, 69% progressed to greater than 5°, 45%

progressed to greater than 45°, and 60% progressed to surgery. Thus, only 21% in the TLSO group and 40% in the nighttime orthosis group were considered to have had successful orthotic management. Subgroup analysis showed little benefit of either brace type in patients with an initial curve between 36° and 40°, with 86% of the TLSO group and 91% of the nighttime orthosis group progressing to surgery.

Section Summary: Conventional Orthotic Rigid Brace

The highest quality study on bracing is a sizable National Institutes of Health-sponsored trial from 2013, which had both randomized and observational arms comparing standard rigid bracing with watchful waiting. This trial was stopped after interim analysis because of a significant benefit of bracing for the prevention of progression and need for spinal fusion. A study with long-term follow-up (mean 15 years; range, 10-35 years) demonstrated that curve corrections from rigid bracing were stable. A randomized controlled trial demonstrated that nighttime bracing was more effective than a 24-hour brace for preventing curve progression, avoiding surgery. Investigators attributed this finding to likely noncompliance with the 24-hour brace. Compared to physical activity alone, a nighttime brace resulted in higher rates of treatment success in an RCT. A systematic review and meta-analysis reported higher success with full-time and nighttime rigid braces compared to soft bracing or observation only. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Microcomputer Controlled Braces (Smart Brace)

Clinical Context and Therapy Purpose

The purpose of a microcomputer-controlled brace is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as observation, in patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

Review of Evidence

Randomized Controlled Trial

Lou et al (2012) published a pilot RCT that compared a microcomputer-controlled brace (smart brace) with a standard rigid brace in 12 patients with scoliosis.¹⁰ Patients were randomized to wear the smart brace for 1 year followed by 1 year with a standard brace or to wear the standard brace for 2 years. Both groups were followed for 3 years after treatment. Compliance with the microcomputer-controlled brace in the first year of bracing (2 years of total bracing) was similar in the two groups. The smart brace was associated with greater pad pressure and improved outcomes. None of the patients in the smart brace group had a significant change in their curves (a Cobb angle change <5°), whereas 2 of 6 patients in the standard TLSO group had a significant change in Cobb angle (7° and 20°) over the 3 years of the study.

FLEXIBLE BRACES

Clinical Context and Therapy Purpose

The purpose of a flexible brace is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as observation, in patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

Randomized Controlled Trial

Wong et al reported a prospective study of clinical efficacy and acceptance of rigid or flexible spinal bracing in 43 patients with moderate adolescent scoliosis in 2008. Follow-up to a mean of 45.1 months after skeletal maturity was reported in 2013.¹¹ Female patients with a Cobb angle between 20° and 30°, apical vertebra below T5, age between 10 and 14 years, and Risser sign of 2 or less were randomized to the flexible SpineCor orthosis or a rigid underarm brace. The subjects were requested to wear the brace 23 hours a day, with 1 hour for bathing and physical exercises. Follow-up visits took place after the first month of intervention and then every 3 months. Acceptance of the brace was measured with a 16-question visual analog scale assessing pain, skin irritation, and daily activities. If the curve progressed more than 5° more than SpineCor brace, patients were required to switch to a rigid brace. At the end of a 45-month study period, a significantly higher percentage of the subjects (35.0%) in the flexible brace group showed curve progression of more than 5° compared with 5.6% of subjects in the rigid brace group ($p < .05$). One patient in each group required surgery due to rapid curve progression. Patients' acceptance of the two orthoses was similar. Although the rigid brace caused significantly more problems with heat (85% vs. 27%, respectively), as well as difficulties with donning and doffing, the patients using the elastic braces had difficulties with toileting. Follow-up for a mean of 45 months (range, 24-77 months) after the brace was worn showed a rate of progression of 1.5 after the post-maturity, with no additional patients proceeding to surgery.

Nonrandomized Comparative Study

Plewka et al (2013) reported the efficacy of the SpineCor brace ($n=45$) compared with physical therapy and observation ($n=45$) in children and adolescents with scoliosis.^{12,13} The control group comprised children who qualified for brace treatment but whose parents did not agree to treatment or in whom the treatment was not possible because of social reasons. Baseline measures of the two groups were similar with an average age of about 12 years (range, 7-16). After 2 years of treatment, the patients treated with the SpineCor brace showed significant improvements in clinical parameters. There was no significant difference in measurements between baseline and follow-up in control patients. Stabilization or improvement of the angle was observed in 78% of the SpineCor-treated patients (45% stabilized and 33% improved) compared with 53% of the control group (53% stabilized, none improved). Compliance with brace wear was good, with 95% of the patients reporting regular brace wear.

Vertebral Body Stapling

Clinical Context and Therapy Purpose

The purpose of vertebral body stapling (VBS) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as observation, in patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

Review of Evidence

Observational Studies

Several case services evaluating VBS are described below and in Tables 4 and 5.

Cuddihy et al (2015) compared VBS to bracing in a matched cohort of skeletally immature patients with moderate idiopathic scoliosis.¹⁸ A total of 52 patients (66 curves) were matched according to age at the start of treatment (10.6 years v s. 11.1 years, respectively) and gender (see Tables 4 and 5). In smaller thoracic curves (25° to 34°) there was a nonsignificant trend toward better results with VBS versus bracing. For those with thoracic curves $\geq 35^\circ$, VBS was

not found to be effective, and for lumbar curves 25° to 35°, results appear to be similar for both VBS and bracing.

Murray et al (2020) described VBS in 7 patients with a mean age of 9.3 years (range, 7.8 to 11.1 years) and an average preoperative Cobb angle of 30° (standard deviation [SD], 6°); the mean follow-up was 83 months (range, 72 to 95 months).²⁹ At the first postoperative visit and most recent follow-up visit, the average Cobb angle was 20° (SD, 7°) and 37° (SD, 22°), respectively. One patient showed improvement of greater than 10° from preoperative to final postoperative Cobb angle, 4 patients showed no change in their curve, and 2 showed progression of their curves by greater than 10° compared with preoperative imaging.

Bumpass et al (2015) described VBS in 31 consecutive patients with a mean age of 10.5 years (range, 7.0-14.6 years) and scoliotic curves of 25° to 40°.¹⁴ Not all patients could (or would) wear a brace. At a mean follow-up to maturity of 48 months (range, 25-79 months), curves less than 35° had a control rate (<10° progression) of 75% while curves with a Cobb angle of at least 35° had a control rate of 22% (p=0.01). The overall control rate was 61%, with 11 (31%) patients requiring subsequent fusion and 2 (6%) overcorrections.

Theologis et al (2013) described VBS in 12 children younger than 10 years old (range, 6.3-9.7 years) who were considered extremely likely to require fusion (i.e., curves of 30° to 39° in a young child).¹⁵ At an average 3.4-year follow-up (range, 2.2-5.4 years), curves had decreased by a mean of 10° (range, -3° to 20°). All curves in this high-risk population were successfully treated, with either no change (within 10°) or improvement in the curve (>10°).

Laituri et al (2012) retrospectively reviewed 7 children ages 8 to 11 years old who had undergone VBS and had at least 2 years of follow-up.¹⁶ All children either had curve progression, despite bracing, or were unable to wear a brace. Before stapling, the mean angle was 34.1°. The mean percentage correction was 36% (range, 16.2%-56%). None of the children had curve progression or required postoperative bracing or spinal fusion.

O'Leary et al (2011) reported that VBS in young children with large Cobb angles was ineffective.¹⁷ Patients with AIS were not included in this report. Diagnoses included myelodysplasia, congenital scoliosis, juvenile and infantile idiopathic scoliosis, Marfan syndrome, paralytic scoliosis, and neuromuscular scoliosis. At an average 22-month follow-up, curves averaged 69°, and 8 of 11 patients had undergone or were scheduled to undergo further spinal surgery for curve progression. It is unknown whether the young age at surgery, the severe preoperative curve, or the nature of the underlying scoliosis contributed to the high failure rate.

Betz et al (2010) reported on 29 patients with juvenile or adolescent idiopathic scoliosis (from a database of 93 patients) who met the study inclusion criteria.¹⁹ Selected were patients with idiopathic scoliosis, a coronal curve magnitude of 20° to 45°, Risser grade 0 or 1, and staples with tines proportional to staple size (beginning in 2002). The average age at the time of stapling was 9.4 years (range, 4-13 years), with an average follow-up of 3.2 years (range 2-5.3 years). For thoracic curves greater than 35° at baseline, 75% progressed to greater than 50° (the threshold for recommending spinal fusion). For thoracic curves less than 35° at baseline, 6% of patients progressed to greater than 50° (the threshold for surgery).

Table 8. Summary of Key Observational Study Characteristics for VBS

Study	Country	Study Design	n ^a	Participants			Minimum FU, y
				<i>Mean Age, y</i>	<i>Curve</i>	<i>Risser Grade</i>	
Murray et al (2020) ²⁹	U.S.	Case series	7	9.3	27.3° to 37.9°	NR	6
Cuddihy et al (2015) ¹⁸	U.S.	Case control	123	11	25° to 44°	0	2
Bumpass et al (2015) ¹⁴	U.S.	Case series	33	11	25° to 40°	0	2
Theologis et al (2013) ¹⁵	U.S.	Case series	12	8	30° to 39°	NR	2
Laituri et al (2012) ¹⁶	U.S.	Case series	7	9	25° to 41°	NR	2
O'Leary et al (2011) ¹⁷	U.S.	Case series	11	7	68° to 105°	0	1
Betz et al (2010) ¹⁹	U.S.	Case series	29	9	20° to 45°	0	2

FU: follow-up; NR: not reported; VBS: vertebral body stapling.

^a Number of patients in all studies, except for Bumpass et al (2015) and Cuddihy et al (2015), where N is the number of curves.

Table 9. Summary of Key Observational Study Outcomes for VBS

Study	Tx	Change in Curve				
		>10° Progressed	Stable	>10° Improved		
Murray et al (2020) ²⁹	VBS	2	4	1		
		>10° Progressed	Stable/Improved	p	Progressed ≥50°	Subsequent Fusion
Cuddihy et al (2015) ¹⁸	VBS	Thoracic curves 25°-34°: (19) Thoracic curves 35°-44°: (82) Lumbar curves 25°-34°: (20) Lumbar curves 35°-44°: (40)	Thoracic curves 25° to 34°: (81) Thoracic curves 35° to 44°: (18) Lumbar curves 25° to 34°: (80) Lumbar curves 35° to 44°: (60)	>.05 for all comparisons of VBS vs. brace	NR	NR
	Brace	Thoracic curves 25°-34°: (39) Thoracic curves 35°-44°: (50) Lumbar curves 25°-34°: (19) Lumbar curves 35°-44°: (100)	Thoracic curves 25° to 34°: (61) Thoracic curves 35° to 44°: (50) Lumbar curves 25° to 34°: (81) Lumbar curves 35° to 44°: (0)			
		>10° Progressed	Stable	>10° Corrected		

Bumpass et al (2015) ¹⁴	VBS	13 (39)	14 (42)	6 (18)	9 (27)	11 (31)
Theologis et al (2013) ¹⁵	VBS	0 (0)	5 (42)	7 (58)	0 (0)	0 (0)
Laituri et al (2012) ¹⁶	VBS	0 (0)	2 (29)	5 (71)	0 (0)	0 (0)
O'Leary et al (2011) ¹⁷	VBS	3 (27)	6 (55)	2 (18)	0 (0)	8 (73)
		Baseline Curve	>10° Progressed	Stable/Improved		
Betz et al (2010) ¹⁹	VBS	<35° ≥35°	4 (22) 6 (75)	14 (78) 2 (25)	1 (6) 6 (75)	NR

Values are n (%) unless otherwise indicated.

NR: not reported; Tx: treatment; VBS: vertebral body stapling.

Vertebral Body Tethering

Clinical Context and Therapy Purpose

The purpose of vertebral body tethering (VBT) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as observation, in patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

Review of Evidence

In a retrospective study, Hoernschemeyer et al (2020) reported post-operative radiographic and clinical outcomes for patients treated with VBT.⁴¹ This clinical and radiographic review of 31 consecutive patients included an analysis of pre-operative, peri-operative, and post-operative details, including the Lenke classification; Cobb angle measurements of the proximal thoracic, main thoracic, and lumbar curves; the sagittal profile; and skeletal maturity. Successful outcomes were defined by a residual curve of less than or equal to 30° in skeletally mature patients who did not undergo a PSF. Of the 31 patients treated, 29 met the inclusion criteria, and 2 were lost to follow-up. The mean patient age (and SD) at the time of the surgical procedure was 12.7 ± 1.5 years (range of 10.2 to 16.7 years), with most patients classified as Risser grade 0 or 1 (52 %) and Sanders stage 3 (32 %). A mean of 7.2 ± 1.4 vertebral levels were instrumented, with a minimum pre-operative Cobb angle of 42°. At the latest follow-up, 27 patients had reached skeletal maturity (Sanders stage of greater than or equal to 7) and 20 patients exhibited a curve magnitude less than or equal to 30°, for a success rate of 74 %. A suspected broken tether occurred at greater than or equal to 1 level in 14 patients (48 %); 2 patients underwent PSF and 4 had tether revision. The overall revision rate was 21% (6 of 29). The authors concluded that the findings of this study showed the success and revision rates as well as the impact of a suspected broken tether on the procedural success of VBT. Despite this patient population being slightly more mature at the time of the surgical procedure compared with previous studies, these investigators had a higher success rate and a lower revision rate. A PSF was avoided in 93 % of patients, indicating that VBT may be a reliable therapeutic option for adolescent scoliosis in skeletally immature individuals.

Meza et al (2022) critically analyzed the study by Hoernschemeyer et al (2020) that assessed the clinical and radiographic outcomes of VBT in the treatment of adolescent scoliosis.⁴² The authors demonstrated successful treatment in 74 % of patients, based on radiographic outcomes and avoidance of subsequent posterior spinal fusion. Nearly 25 % of patients require revision surgery. Almost 50 % suffered a broken tether, although the effects of such complications were not fully understood. The study provided valuable information for determining which patients are reasonable candidates for VBT and emphasized several

questions surrounding this novel technology that remain unanswered. Meza et al discussed the study's strengths and weaknesses, suggesting potential directions for future research, and examined the potential indications for VBT.

Systematic Reviews

In a systematic review of 19 studies and meta-analysis of 16 of these, Roser et al (2023) identified VBT as an emerging surgical procedure intending to correct and reduce spinal curves in skeletally immature individuals and prevent progression with one surgery, whilst preventing a posterior spinal instrumentation fusion (PSIF).³⁶ They examined the expected curve reduction and potential complications for adolescent patients after VBT. The mean patient age was 12.2 years, and 84.8% were female. The median Risser score was 0, and the median Sanders score was 3. Studies met the inclusion criteria if they evaluated the treatment of adolescent idiopathic scoliosis (AIS) in skeletally immature patients with a main thoracic curve; performed anterior VBT; reported the pre- and post-operative major curve Cobb angle; and had a minimum two-year follow-up. Studies were excluded if they solely investigated non-idiopathic scoliosis; performed finite element analysis; used non-human models; were a review article, conference abstract, or case report; or only detailed surgical technique. The primary outcome measure was the change in the Cobb angle of the major curvature of the spine. Other outcome measures included surgical details and surgical complications. The mean follow-up of 34.1 months. Most studies used a thoracoscopic approach and the Zimmer Biomet tether. The mean number of vertebral levels treated was 7.6, the mean surgical time was 223 minutes, the mean intra-operative blood loss was 144 ml, and the mean hospital inpatient stay was 4.9 days. The initial mean Cobb angle was 47.8° (confidence interval [CI] 95% 42.9–52.7°) and decreased to 22.2° (CI 95% 19.9–24.5°), with a mean difference of –25.8° (CI 95% – 28.9–22.7) ($p < .01$). One study included crossed the line of null effect. The overall complication rate was 23% (CI 95% 14.4–31.6%). The mean rate of tether breakage was 21.9% (CI 95% 10.6–33.1%), overcorrection was 11.4% (CI 95% 5.7–17.2%), reoperation was 11.4% (CI 95% 6.2–16.7%), spinal fusion rate was 7.2% (CI 95% 2.3–12.1%), and postoperative pulmonary complications was 6.7% (CI 95% 4–9.5%). Overall complication rate was relatively high although the consequences of the complications are unknown. Further research is required to explore the reasons behind the complication rate and determine the optimal timing for the procedure. VBT remains a promising new procedure that is effective at reducing scoliotic curves and preventing spinal fusion in the majority of patients.

Zhu et al (2022) published a systematic review and meta-analysis of 26 studies representing 1045 subjects (mean age range, 11.1 to 14.9 years) treated with vertebral body tethering (VBT) for scoliosis, finding that the Cobb angle of the major curve was significantly corrected from 40.0° to 59.0° at baseline to 15.9° to 38.0° immediately post-surgery and 10° to 38° at final follow-up.³⁰ The overall clinical success rate was 73.02% (95% CI, 68.31% to 78.05%). The pooled overall unplanned reoperation rate after VBT was 8.66% (95% CI, 5.53% to 13.31%; 23 studies). The top 3 reinterventions were conversion to posterior spinal fusion (3.51%; 95% CI, 2.45% to 5.01%), tether removal (2.3%; 95% CI, 1.47% to 3.58%), and tether replacement (1.09%; 95% CI, 0.57% to 2.08%). The overall complication incidence rate was 36.8% (95% CI, 23.9% to 49.7%; 24 studies). Most common complications included curve progression with tether breakage (16.79%; 95% CI, 7.43% to 26.15%), pulmonary complications (6%; 95% CI, 4.66% to 7.68%), and overcorrections (4.55%; 95% CI, 3.4% to 6.06%). A subgroup analysis of patients with more than 36 months follow-up time indicated that these patients had increased clinical success (73.88% vs. 65.93%), unplanned reoperation (15.8% vs. 4.55%), and complication rates (52.17% vs. 23.79%) compared to those with less than 36 months follow-up, respectively. Thus, based on the increased

reoperation and complication rates observed with longer follow-up, the authors concluded that further improvements to the implant and refinement of patient selection criteria are warranted and should be assessed in the context of high-quality randomized controlled trials. Study demographics and outcomes based on race, ethnicity, and sex were not reported, potentially limiting the generalizability of these findings.

Observational Studies

As noted in the Regulatory section above, on 6/4/2019, the U.S. Food and Drug Administration (FDA) granted a Humanitarian Device Exemption to a new vertebral body tethering device called The Tether (Zimmer Biomet Spine, HDE #H190005, product code QHP). Available evidence for The Tether includes only 1 small retrospective cohort study of 57 pediatric patients that is yet unpublished and is only summarized in the FDA's Humanitarian Device Exemption Summary of Safety and Probable Benefit report.²⁰ In this study, pediatric patients who failed brace treatment (e.g., greater than 5° of progression and/or intolerance to brace wear) received vertebral body tethering with Dynesys vertebral body screws, which are similar to those of the marketed version of The Tether, but that have a slightly higher screw profile. Study participants were 86.4% female, with a mean age of 12.4 years. At baseline, mean Cobb angles were 30° to 44° in 75.4% of participants and 45° to 65° in 24.6% of participants. After 2 years, among the 44 subjects with 24-month data (out of the original 57), 43 met the probable benefit success criteria of achievement of a Cobb angle of 40° or less. Overall, the mean Cobb angles improved from 40.4° to 14.3° (+65%). Although assessment of quality of life at the last follow-up visits were described as "positive" based on the Pediatric Quality of Life Inventory, the clinical importance of this data is unclear as no baseline assessments were completed for comparison. A total of 8 participants had serious adverse events (14%), including overcorrection of the instrumented curve (8.8%), definite cord break (1.8%), development of a new curve (1.8%), and spondylolisthesis (1.8%). Other common adverse events were back pain (24.6%), overcorrection of the instrumented curve (21.1%), nausea/vomiting (21.1%), and extremity pain (21.1%). A total of 8 patients (6%) required surgical revision due to adverse events.

In 2014 and 2015, Samdani et al published 2 retrospective reviews on the off-label use of the Zimmer Dynesys for anterior vertebral body tethering for idiopathic scoliosis.^{21,22} The authors reported that they pursued vertebral body tethering at their institution due to lack of success with vertebral body stapling for thoracic curves greater than 35°. At the time of these reports, 32 patients had a minimum of 1-year follow-up, 20 and 11 consecutive patients had 2-year follow-up.²² The mean age at surgery was 12 years, and all patients were skeletally immature. Three patients also had vertebral body stapling of their lumbar curves. For the 11 patients with 2-year follow-up, an average of 7.8 levels (range, 7-9) were tethered. Thoracic Cobb angle averaged 44.3° preoperatively, was corrected to 20.3° after surgery, and improved to 13.5° at 2 years. The lumbar curve improved from 25.1° preoperatively to 7.2° at 2 years. Two patients require that tension be reduced after 2 years due to overcorrection. Samdani et al from a children's hospital and Zimmer Biomet are conducting a phase 2 safety and efficacy study for FDA approval of the procedure.

Pehlivanoglu et al (2021) conducted a prospective cohort study of 13 skeletally immature patients (mean age, 11.8 years) who underwent vertebral body tethering with the Dynesys system for adolescent idiopathic scoliosis with double curves.³¹ At baseline, the mean thoracic/thoracolumbar and lumbar curve magnitudes were 48.2° and 45.3°, respectively. An average of 11.8 levels of tethering were undertaken. Postoperatively, mean thoracic/thoracolumbar curve magnitudes were 14.3° to 17.3°. At the last follow-up (mean,

36.4 months), the mean thoracic/thoracolumbar curve magnitudes were 8.2° to 9.7°. No major complications were reported.

Meyers et al (2022) performed a retrospective review of adolescent scoliosis patients (N=49; 74% female) treated with VBT via the Dynesys system after reaching peak height velocity (Risser stage 3-5).³² Mean patient age was 15 ± 1.9 years with mean follow-up duration 32.5 ± 9.1 months. In patients with thoracic major curvatures (n=24), the Cobb angle improved from 51.1 ± 6.9° to 27.2 ± 8.1° (47.7% correction; p<.01). In those with thoracolumbar major curves, curvature improved from 37.2 ± 10.7° to 18.8 ± 9.4° (49.5% correction; p<.01). Improvements in major curve inclinometer measurements and SRS-22 domains improved significantly (p≤.05), except for the SRS-22 activity domain. Overall, 37/49 (76%) of patients were deemed clinically successful with residual major curves ≤30°. At final follow-up, 2 major complications were reported. At 3.1 years after VBT, 1 patient required posterior fusion of the thoracic curve due to curve progression and revision of the thoracolumbar tether due to tether breakage. A second patient developed late onset superior mesenteric artery syndrome (SMAS) 1 year postoperatively which required Ladd's derotation surgery. Overall, 20 (41%) patients experienced tether breakage. However, only 4 of 19 (21%) patients with broken tethers failed to meet criteria for clinical success which was comparable to the 7 of 29 (24%) patients with intact tethers. Thus, treatment success in subjects with limited remaining skeletal growth was feasible. While treatment success was not impacted by age or Risser stage, patients with treatment failures reported slightly larger major Cobb angles at baseline.

Baroncini et al 2022 reported a retrospective, 2-center cohort study in 86 patients in Europe who underwent VBT with the REFLECT system.³⁴ The majority of patients were female (84%) with a mean age of 13.2 years. Nearly half of patients (42%) were Risser stage 0. At 2-year follow-up, Cobb angles at the thoracic level decreased from 52.4 ± 13.9° to 28.5 ± 13.6° at the thoracic level and from 47.6 ± 14.3° to 26.6 ± 12.7° at the lumbar level. Six patients had postoperative complications including 5 recurrent pleural effusions and one case of psoas irritation. Sagittal alignment parameters were also analyzed, and the findings indicated increased thoracic kyphosis and maintenance of lumbar lordosis. No other clinical outcomes were reported.

Hegde et al 2023 reported another retrospective analysis of the REFLECT system in 75 patients from a single center in India.³⁵ The mean age of patients was 14.96 years and 94% were female. At a mean follow-up of approximately 2 years, Cobb angles at the thoracic level decreased from 52 ± 7.74° to 16.92 ± 5.06° and mean thoracolumbar/lumbar Cobb angles decreased from 51.45 ± 11.26° to 14.24 ± 4.85°. The SRS-22 (revised) score was 78.0 ± 3.2 preoperatively and 92.5 ± 3.1 postoperatively.

Case Series

In the retrospective study by Braun et al (2024) stated that anterior vertebral tethering (AVT) is a minimally invasive alternative to fusion surgery for adolescent idiopathic scoliosis (AIS) that offers the potential for definitive scoliosis treatment with the possibility of preservation of the growth, motion, function and overall health of the spine.³⁷ This study represented the authors' first 10 years using AVT for the treatment of AIS. These researchers analyzed their first 74 AIS patients treated with AVT between 2010 and 2020. Multiple Lenke curve types 33° to 70° were treated with skeletal maturity spanning Risser -1 to 5. Of 74 consecutive AIS patients treated with AVT, 52 patients (47 were female, 5 were male) had sufficient 2-year follow-up for inclusion; 46 of these 52 patients (88 %) with 65 curves (35 T, 30 TL/L) were satisfactorily treated with AVT demonstrating curve correction from 48.6° pre-op (range of 33°-70°) at age

15.1 years (range of 9.2 to 18.8 years) and skeletal maturity of Risser 2.8 (range of -1 to 5) to 23.2° post-op (range of 0° to 54°) and 24.0° final (range of 0° to 49°) at 3.3 years follow-up (range of 2 to 10 years). Curve corrections from pre-op to post-op and pre-op to final were both significant ($p < .001$). The 0.8° change from post-op to final was not significant; but did represent good control of scoliosis correction over time. Thoracic kyphosis and lumbar lordosis were maintained in a normal range throughout while axial rotation showed a slight trend toward improvement. Skeletal maturity of Risser 4 or greater was achieved in all but 1 patient; 4 of the 52 patients (8 %) required additional procedures for tether rupture (3 replacements) or over-correction (1 removal) to achieve satisfactory treatment status after AVT. An additional 6 of the 52 patients (12 %), however, were not satisfactorily treated with AVT, requiring fusion for over-correction ($n = 2$) or inadequate correction ($n = 4$). The authors concluded that in this study, AIS was satisfactorily treated with AVT in the majority of patients over a broad range of curve magnitudes, curve types, and skeletal maturity. Although late revision surgery for over-correction, inadequate correction, or tether rupture was not uncommon, the complication of over-correction was eliminated after the first 10 patients by a refinement of indications. Moreover, these researchers stated that additional study is needed to further improve the safety and effectiveness of this new procedure.

Eaker et al (2024) reviewed a single surgeon retrospective analysis of a total of 37 consecutive patients, age 14.1 ± 1.6 years, 86.5% F, who were skeletally immature patients (Risser ≤ 4) with AIS, Lenke 5/6 curvature, and a minimum 2-year follow-up (FU).⁴³ Overall, 27 patients (73%) had Lenke 5 and 10 (27%) had Lenke 6 curvatures. Instrumentation of the TL curve alone was performed in 59.5%, and thoracic (T) and TL in 40.5% of patients. VBT for AIS holds the most promise for treatment of the lumbar spine. Data provides support for the use of VBT for the treatment of major thoracolumbar curvatures. At 2–6 years follow-up, we found a clinical success rate of 89% (Major Cobb $< 35^\circ$; all Cobb $< 35^\circ$) with a complication rate of 10.8%. Although tether breakage and loss of correction have been observed, breakage while associated with a segmental loss of correction does not necessarily require re-operation or result in a lack of clinical success (major curve $< 35^\circ$).

Section Summary: Vertebral Body Tethering

Most published studies are retrospective or prospective case series with small populations, demonstrating varying clinical outcomes. Early reports of a correction in Cobb angle from published reports on the Dynesys system are promising, but little is known about longer-term outcomes with this procedure. Published data for the REFLECT VBT are limited to observational studies, and data are lacking on important health outcomes. A meta-analysis of vertebral body tethering studies with more than 36 months follow-up reported a 74% clinical success rate, a 52% complication rate, and a 16% unplanned reoperation rate. In the largest single surgeon retrospective study, patients with thoracolumbar major curvature treated with VBT experienced a high rate of clinically successful outcomes with maintenance of lumbar lordosis and relatively low complication rates at the latest follow-up. In review with our orthopedic consultative providers of clinical evidence, there was mutual support in the use of tethering for adolescent idiopathic scoliosis that could prevent the potential need for surgical intervention.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT)

The guidelines from the Society on Scoliosis Orthopaedic and Rehabilitation Treatment (2016) included recommendations on the following conservative treatments for idiopathic scoliosis²³: assessment, bracing, physiotherapy, physiotherapeutic scoliosis-specific exercises and other 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 (VBS) or vertebral body tethering (VBT). 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.

Scoliosis Research Society (SRS)

SRS states that the treatment of scoliosis falls into three main categories (observation, bracing, surgery) and is based on the risk of curve progression.²⁵ In general, curves progress in two 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, 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 0 and 1 are growing rapidly, while patients who are 4 and 5 have stopped growing.

- Observation is generally for patients whose curves are $<25^\circ$ who are still growing, or for curves $<50^\circ$ in patients who have completed their growth.
- Bracing is for patients with curves that measure between 25° and 40° during their growth phase. The goal of the brace is to prevent the curve from getting bigger.
- Surgical treatment is used for patients whose curves are $>45^\circ$ while still growing or $>50^\circ$ when growth has stopped. The goal surgical treatment is 2-fold; first, to prevent curve progression and, second, to obtain some curve correction. Implants are used to correct the spine and hold the spine in the corrected position until the spine segments, which have been operated on, are fused as one bone.

- Alternative treatments to prevent curve progression or prevent further curve progression, such as chiropractic medicine, physical therapy, yoga, etc., have not demonstrated any scientific value in the treatment of scoliosis.

VBS was not addressed on the Society's website.

American Academy of Orthopaedic Surgeons (AAOS)

Information updated on the AAOS Info 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.²⁴

- Observation is appropriate when the curve is mild (<25°) 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 curvature between 25° and 45°.
- Surgery may be recommended if the curve is >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.

VBS and VBT 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 (NIAMS) has an educational website page on scoliosis in children and adolescents (last reviewed, December 2019).²⁷ 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 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 vertebral body tethering.

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.³⁶ 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 of its efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research."

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (USPSTF) published recommendations for idiopathic scoliosis screening in 2004.²⁵ USPSTF recommends against the routine screening of

asymptomatic adolescents for idiopathic scoliosis (grade: D recommendation). In 2018, USPSTF updated their recommendation to state that there is insufficient evidence to assess screening of adolescents for idiopathic scoliosis (grade I recommendation).²⁷ 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° 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.”

Ongoing and Unpublished Clinical Trials

Some ongoing trials that might influence this policy are listed in Table 10.

Table 10. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05830825	The Tether™ - Vertebral Body Tethering System Post-Market Clinical Follow-Up Study in UK	100	Dec 2031
NCT05001568	Validation of a New Optimized Nighttime Providence Brace for Personalized Treatment of Adolescent Idiopathic Scoliosis	58	Jan 2025
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
NCT04296903 ^a	Post-approval Registry Study to Evaluate the Continued Safety and Probable Benefit of the MID-C System for 5 Years Post-Implantation in Adolescent Idiopathic Scoliosis (AIS)	200	May 2028
NCT04116723	Trial of Personalized 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 2026
NCT04590807	Posterior Spinal Fusion with Pedicle Screws vs. Anterior Vertebral Body Tethering in Adolescent Idiopathic Scoliosis	70	Dec 2025
NCT04505579 ^a	The Tether™ - 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
Unpublished			
NCT04889339	Validation of a New Generation of Orthopedic Brace for Treating Adolescent Idiopathic Scoliosis by Using Growth Modulation	58	Jan 2024
NCT04992845a	Fusionless Treatment of Idiopathic Scoliosis With the SCOLI-TETHER System During the Growth Period	51	May 2025 (terminated)

NCT02897453a	Retrospective Review with Prospective Surveillance of Safety and Efficacy in a Clinical Series of Spinal Tethering Patients	56	Oct 2022 (unknown)
--------------	---	----	--------------------

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

Regulatory Status

Staples, using a shape memory nickel-titanium alloy, have 510(k) clearance from the FDA for a variety of indications for bone fixation. For example, nitinol staples (Sofamor Danek, Memphis, TN) are indicated for fixation with spinal systems. Other memory shape staples that have 510(k) clearance for bone fixation include the OSStaple™ and the reVERTO™. Vertebral body stapling in scoliosis is considered off-label use. FDA product code: JDR.

A vertebral body tethering device (The Tether; 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™ 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.

Government Regulations

National:

There is no national coverage determination (NCD)

Local:

There is no local coverage determination (LCD)

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Growing Rods for Scoliosis (e.g., MAGEC Spinal Bracing and Distraction System)
- Vertical Expandable Prosthetic Titanium Rib

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>.

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. Fayssoux 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, Eberson 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- 5. PMID 18496349
12. 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
13. 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
14. 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
15. 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
16. 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

17. 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
18. U.S. Food and Drug Administration (FDA). SUMMARY OF SAFETY AND PROBABLE BENEFIT (SSPB): The Tether Vertebral Body Tethering System. 2019; https://www.accessdata.fda.gov/cdrh_docs/pdf19/H190005b.pdf
19. 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
20. 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
21. 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
22. 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
23. Negrini S, Donzelli S, Aulisa AG, et al. 2016 SOSORT guidelines: orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth. *Scoliosis Spinal Disord*. 2018 Jan 10;13:3. PMID: 29435499
24. American Academy of Orthopaedic Surgeons (AAOS). Idiopathic Scoliosis in Children and Adolescents. *OrthoInfo* 2015; <http://orthoinfo.aaos.org/topic.cfm?topic=A00353>. Accessed February 12, 2018. No longer available.
25. Idiopathic Scoliosis in Adolescents: Screening: US Preventive Services Task Force Recommendation Statement. June 15, 2004.
26. Blue Cross Blue Shield Association. Interventions for Progressive Scoliosis. Medical Policy Reference Manual, Policy MPRM 2.01.83. Published 5/13/10. Last review date April 2025.
27. Grossman DC, Curry SJ, Owens DK, et al. Screening for Adolescent Idiopathic Scoliosis: US Preventive Services Task Force Recommendation Statement. *JAMA*. Jan 09, 2018; 319(2): 165-172. PMID 29318284
28. Costa L, Schlosser TPC, Jimale H, et al. The Effectiveness of Different Concepts of Bracing in Adolescent in Adolescent idiopathic Scoliosis (AIS): A Systematic Review and Meta-Analysis. *J Clin Med*. May 15, 2021; 10(10). PMID 34063540
29. Murray E, Tung R, Sherman A, et al. Continued vertebral body growth in patients with juvenile idiopathic scoliosis following vertebral body stapling. *Spine Deform*. Apr 2020; 8(2): 221-226. PMID 32026438
30. Zhu F, Qiu X, Liu S, et al. Minimum 3-year experience with vertebral body tethering for treating scoliosis: A systematic review and single-arm meta-analysis. *J Orthop Surg (Hong Kong)*. 2022; 30(3):10225536221137753. PMID 36420934
31. Pehlivanoglu T, Oltulu I, Erdag Y, et al. Double-sided vertebral body tethering of double adolescent idiopathic scoliosis curves: radiographic outcomes of the first 13 patients with 2 years of follow-up. *Eur Spine J*. Jul 2021; 30(7): 1896-1904. PMID 33611658
32. Meyers J, Eaker L, Zhang J, et al. Vertebral Body Tethering in 49 Adolescent Patients after Peak Height Velocity for the Treatment of Idiopathic Scoliosis: 2-5 Year Follow-Up. *J Clin Med*. Jun 02, 2022; 11(11). PMID 35683548
33. Aulisa AG, Toniolo RM, Falciglia F, et al. Long-term results after brace treatment with Progressive Action Short Brace in adolescent idiopathic scoliosis. *Eur J Phys Rehabil Med*. Jun 2021; 57(3): 406-413. PMID 32990686

34. Baroncini A, Courvoisier A, Berjano P, et al. The effects of vertebral body tethering on sagittal parameters: evaluations from a 2-year follow-up. *Eur Spine J.* Apr 2022; 31(4): 1060-1066. PMID 34910244
35. Hegde S, Badikillaya V, Kanade U, et al. Are We Looking at a Paradigm Shift in the Management of Adolescent Idiopathic Scoliosis? Comprehensive Retrospective Analysis of 75 Patients of Nonfusion Anterior Scoliosis Correction with 2-5-Year Follow-up: A Single Center Experience. *Asian Spine J.* Jun 2023; 17(3): 529-537. PMID 37211667
36. Roser MJ, Askin GN, Labrom RD, Zahir SF, Izatt M, Little JP. Vertebral body tethering for idiopathic scoliosis: a systematic review and meta-analysis. *Spine Deform.* 2023 Nov; 11(6):1297-1307.
37. Braun JT, Ogilvie JW, Akyuz E, et al: Fusionless scoliosis correction using a shape memory alloy staple in the anterior thoracic spine of the immature goat. *Spine.* 2004;29:1980-1989.
38. National Institute for Health and Care Excellence (NICE). Interventional procedures guidance: Vertebral body tethering for idiopathic scoliosis in children and young people [IPG728]. June 29, 2022; <https://www.nice.org.uk/guidance/ipg728>. Accessed September 2025.
39. Vatkar A, Najjar E, et al. Vertebral body tethering in adolescent idiopathic scoliosis with more than 2 years of follow-up systematic review and meta-analysis. *European Spinal J.* June 2023. 32: 3047-3057.
40. Charalampidis A, Diarbakerli E, Dufvenberg M, et al. Nighttime bracing or exercise in moderate grade adolescent idiopathic scoliosis: a randomized clinical trial. *JAMA.* Jan 2024; 7(1): e2352492.
41. Hoernschemeyer DG, Boeyer ME, Robertson ME, et al. Anterior vertebral body tethering for adolescent scoliosis with growth remaining: a retrospective review of 2-to-5-year postoperative results. *J Bone Joint Surg AM.* Jul 2020; 102(13): 1169-1176.
42. Meza BC, Samuel AM, Albert TJ. The role of vertebral body tethering in treating skeletally immature scoliosis. *HSS J.* Feb 2022. 18(1): 171-174.
43. Eaker L, Mucollari O, Maza N, Lonner B. Vertebral body tethering for thoracolumbar curvatures in adolescent idiopathic scoliosis: radiographic and clinical outcomes at 2–6-year follow-up. *J Clin Med.* Oct 2024; 13(21): 6330.
44. Braun JT, Federico SC, Lawlor DM, et al. Anterior vertebral tethering for adolescent idiopathic scoliosis: our initial ten-year clinical experience. *Spine Deformity.* May 2024; 12: 1355-1367.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 2025, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/17	10/11/16	10/11/16	Joint policy established
1/1/18	10/19/17	10/19/17	Updated rationale section, added references 16 and 17. No change in policy status.
1/1/19	10/16/18	10/16/18	Routine policy maintenance, deleted MDHHS section. No change in policy status.
1/1/20	10/15/19		Rationale reformatted, reference #9 added, reference #26 removed. No change in policy status.
1/1/21	10/20/20		Routine policy maintenance. No change in policy status.
1/1/22	10/19/21		Routine policy maintenance. No change in policy status. Per code update information: 7/1/21: new codes to added: 0656T and 0657T
1/1/23	10/18/22		Routine policy maintenance. No change in policy status. (ky)
1/1/24	10/17/23		Routine policy maintenance. No change in policy status. Vendor: TP policy #1020 Surgery for spinal deformity. (ky)
5/1/24	2/20/24		This policy is coming early as code update – informational to add codes 22836, 22837, 22838, and 0790T eff 1/1/24 per code update as E/I. Codes 0656T and 0657T are revised eff 1/1/24 to clarify their use for vertebral body tethering limited to the lumbar or thoracolumbar spine. This policy will go back to its original date of October 2024 JUMP. Vendor: TP (ky)
1/1/25	10/15/24		Routine maintenance Vendor: TurningPoint (TP) Policy number: OR-1020.24 Spinal for Spinal Deformity (ky)

1/1/26	11/3/25		Status change for VBT from E/I to EST. Rationale updated with new references. Title changed to Interventions for Juvenile and Adolescent Idiopathic Progressive Scoliosis. Codes 22836-22838, 0656T, 0657T and 0790T moved to established. Vendor managed: TurningPoint (TP) Policy number: OR-1020.25 (ds)
--------	---------	--	---

Next Review Date: 4th Qtr. 2026

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: INTERVENTIONS FOR JUVENILE AND ADOLESCENT IDIOPATHIC PROGRESSIVE
SCOLIOSIS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered with criteria
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.