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

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Vertebral body stapling and vertebral body tethering for the treatment of scoliosis **are considered experimental, investigational and/or unproven.**

Policy Guidelines

There is no specific code to describe vertebral body stapling, therefore it may be billed using nonspecific 22899.

Description

Scoliosis
Scoliosis is an abnormal lateral and rotational curvature of the vertebral column. Adolescent idiopathic scoliosis is the most common form of idiopathic scoliosis, defined by the U.S.

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

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

Males and females are equally affected by scoliosis, but curve progression is up to 10 times more common in females than males. (2) Patients who are overweight or obese have a greater risk of presenting with larger Cobb angles and more advanced skeletal maturity, possibly due to delayed detection. (3) 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). (4)

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.

<u>Surgery</u>

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. (5)

Regulatory Status

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 by the FDA through the 510(k) process for bone fixation include the OSStaple™ (BioMedical Enterprises) and the reVERTO™ Dynamic Compression Device. FDA product code: JDR. Vertebral body stapling in scoliosis is considered off-label use.

A new 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.

Table 1. Scoliosis 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	8/16/019	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, LLD	4/4/2019	K182943	Off Label Use for Scoliosis support
Geo Staple System	Gramercy Extremity Orthopedics, LLC	1/11/2019	K182212	Off Label Use for 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

Rationale

Medical policies assess the 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, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients 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.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

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 individuals with juvenile or adolescent idiopathic scoliosis at high risk of progression.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with juvenile or adolescent idiopathic scoliosis at high risk of progression.

Interventions

The therapy being considered is VBS.

This is a fusionless surgical procedure intended to replace the use of traditional braces.

Comparators
Comparators of interest include observation conducted by orthopedists and primary care providers in an outpatient clinical setting. Self-treatment includes physical exercise and stretching.

Outcomes
The general outcomes of interest are change in disease status, morbid events, quality of life, and treatment-related morbidity. The existing literature evaluating VBS as a treatment for juvenile or adolescent idiopathic scoliosis at high risk of progression has varying lengths of follow-up, ranging from 2 to 4 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 4 years of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Nonrandomized Comparative Study
In a multicenter study, Cuddihy et al. (2015) reported on a matched comparison of VBS and bracing for immature patients with moderate (25° to 44°) idiopathic scoliosis (see Tables 2 and 3). (6) Forty-two consecutive patients in the VBS group (57 curves) met inclusion criteria, and 52 patients in the bracing group (66 curves) were matched by initial Cobb angle, age at the start of treatment, follow-up of at least 2 years, and sex. The average curve size was 31°, and the average follow-up was 40.8 months in the VBS group and 105 months in the bracing group (maturity). For smaller thoracic curves (25° to34°), there was a nonstatistically significant trend for stapling to be more effective (progression <10°, 81%) compared with bracing (61%; p=.16). For larger thoracic curves (>35°), VBS did not halt curve progression, with a success rate of 18% compared with 50% for bracing. For lumbar curves (25° to 34°), results were comparable for VBS and bracing. There were insufficient numbers of patients with lumbar curves of 35° or greater to compare results.

Observational Studies
Several case series and 1 case-control study evaluating VBS are described below and in Tables 2 and 3.

Cuddihy et al. (2015) compared VBS to bracing in a matched cohort of skeletally immature patients with moderate idiopathic scoliosis. (6) A total of 52 patients (66 curves) were matched

according to age at the start of treatment (10.6 years vs. 11.1 years, respectively) and gender (see Tables 2 and 3). In smaller thoracic curves (25° to 34°) there was a nonsignificant trend toward better results with VBS versus bracing. For those with thoracic curves ≥35°, 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 to11.1 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). (7) 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 to 14.6 years) and scoliotic curves of 25° to 40°. (8) Not all patients could (or would) wear a brace. At a mean follow-up to maturity of 48 months (range, 25 to 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=.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 to 9.7 years) who were considered extremely likely to require fusion (i.e., curves of 30° to 39° in a young child). (9) At an average 3.4-year follow-up (range, 2.2 to 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. (10) 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% to 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. (11) Patients with adolescent idiopathic scoliosis 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 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. (12) 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 to 13 years), with an average follow-up of 3.2 years (range, 2 to 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 2. Summary of Key Observational Study Characteristics for Vertebral Body Stapling

Study	Country	Study Design	N[a]	Participants			Minimum FU, y
				Mean Age, y	Curve	Risser Grade	
Murray et al. (2020) (7)	U.S.	Case series	7	9.3	27.3° to 37.9°	NR	6
Cuddihy et al. (2015) (6)	U.S.	Case control	123	11	25° to 44°	0	2
Bumpass et al. (2015) (8)	U.S.	Case series	33	11	25° to 40°	0	2
Theologis et al. (2013) (9)	U.S.	Case series	12	8	30° to 39°	NR	2
Laituri et al. (2012) (10)	U.S.	Case series	7	9	25° to 41°	NR	2
O'Leary et al. (2011) (11)	U.S.	Case series	11	7	68° to 105°	0	1
Betz et al. (2010) (12)	U.S.	Case series	29	9	20° to 45°	0	2

FU: follow-up; NR: not reported; U.S.: United States; y: year.

[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 3. Summary of Key Observational Study Outcomes for Vertebral Body Stapling

Study	Tx	Change in Curve				
		>10° Progressed	Stable	>10° Improved		
Murray et al. (2020) (7)	VBS	2	4	1		
		>10° Progressed	Stable/Improved	p	Progressed ≥50°	Subsequent Fusion
Cuddihy et al. (2015) (6)	VBS	Thoracic curves 25°-34°: (19) Thoracic curves 35°-44°: (82)	Thoracic curves 25°-34°: (81) Thoracic curves 35°-44°: (18) Lumbar curves 25°-34°: (80)	>0.05 for all comparisons of VBS vs brace	NR	NR

		Lumbar curves 25°-34°: (20) Lumbar curves 35°-44°: (40)	Lumbar curves 35°-44°: (60)			
		>10° Progressed	**Stable**	**>10° Corrected**		
Bumpass et al. (2015) (8)	VBS	13 (39)	14 (42)	6 (18)	9 (27)	11 (31)
Theologis et al. (2013) (9)	VBS	0 (0)	5 (42)	7 (58)	0 (0)	0 (0)
Laituri et al. (2012) (10)	VBS	0 (0)	2 (29)	5 (71)	0 (0)	0 (0)
O'Leary et al. (2011) (11)	VBS	3 (27)	6 (55)	2 (18)	0 (0)	8 (73)
		Baseline Curve	**>10° Progressed**	**Stable/Improved**		
Betz et al. (2010) (12)	VBS	<35° ≥35°	4 (22) 6 (75)	14 (78) 2 (25)	1 (6) 6 (75)	NR NR

Values are n (%) unless otherwise indicated.
NR: not reported; Tx: treatment; VBS: vertebral body stapling.

Section Summary: 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.

Vertebral Body Tethering

Clinical Context and Therapy Purpose

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

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

Interventions
The therapy being considered is vertebral body tethering.

This is a fusionless surgical procedure intended to replace the use of traditional braces.

Comparators
Comparators of interest include observation conducted by orthopedists and primary care providers in an outpatient clinical setting. Self-treatment includes physical exercise and stretching.

Outcomes
The general outcomes of interest are change in disease status, morbid events, quality of life, and treatment-related morbidity. The existing literature evaluating vertebral body tethering as a treatment for juvenile or adolescent idiopathic scoliosis at high risk of progression has varying lengths of follow-up, ranging from 1 to 15 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
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. (13) 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. Studies included in this review are listed in Table 4.

Table 4. Studies Included in Systematic Review

Study	Zhu et al. (13) (2022)
Boudissa (2017)	●
Cobet (2017)	●
Ergene (2019)	●
Wong (2019)	●
Alanay (2020)	●
Baroncini (2020)	●
Newton (2020)	●
Baker (2020)	●
Pehlivanoglu (2021)	●
Miyanji (2021)	●
Hoernschemeyer (2020)	●
Buyuk (2021)	●
Pahlivanoglu (2021)	●
Pehlivanoglu (2020)	●
Trobisch (2021)	●
Baroncini (2021)	●
Abdullah (2021)	●
Miyanji (2020)	●
Yucekul (2021)	●
Mathew (2021)	●
Shen (2021)	●
Samdani (2021)	●
Takahashi (2021)	●
Hegde (2021)	●
Mackey (2021)	●

Rushton (2021)	•

Adapted from Zhu et al. (2022) (13).

Bizzoca et al. (2022) summarized the evidence regarding the safety and effectiveness of anterior VBT in the management of idiopathic scoliosis (IS) in skeletally immature patients. (14) A total of 7 clinical trials recruiting 163 patients were included in the review; 5 of the 7 studies were classified as high quality, while the remaining 2 studies were classified as moderate quality. A total of 151 of 163 AVBT procedures were performed in the thoracic spine, and the remaining 12 tethering in the lumbar spine. Only 117 of 163 (71.8 %) patients had a non-progressive curve at skeletal maturity; 23 of 163 (14.11 %) patients required unplanned revision surgery within the follow-up period. Conversion to posterior spinal fusion (PSF) was performed in 18 of 163 (11 %) patients. The authors concluded that anterior VBT is a promising growth-friendly technique for treatment of IS in growing patients, but pointed out that it has moderate success and peri-operative complications, revision and conversion to PSF. They went on to state that future level-I studies, with long-term follow-up, are needed to define the limits and potentials of this emerging surgical technique.

Mariscal et al. (2023) analyzed the efficacy and safety of anterior vertebral body tethering in patients with adolescent idiopathic scoliosis. (15) A literature search was performed, and the following data analyzed: baseline characteristics, efficacy measures (corrections of the main thoracic curve, proximal thoracic curve, and thoracolumbar curve, thoracic kyphosis, lumbosacral lordosis, rib hump, lumbar prominence and SRS-22 scores, and complications. Analyses were performed with Cochrane's Review Manager version 5.4. Twelve studies met the inclusion criteria. Significant corrections of the main thoracic (mean difference [MD] 22.51, 95% CI 12.93 to 32.09) proximal thoracic (MD 10.14°, 95% CI 7.25° to 13.02°), and thoracolumbar curve (MD 12.16, 95% CI 9.14 to 15.18) were found. No statistically significant corrections were observed on the sagittal plane assessed by thoracic kyphosis (MD - 0.60°, 95% CI - 2.45 to 1.26; participants = 622; studies = 4; I2 = 36%) and lumbosacral lordosis (MD 0.19°, 95% CI - 2.16° to 2.54°). Significant corrections were identified for rib hump (MD 5.26°, 95% CI 4.19° to 6.32°) and lumbar prominence (MD 1.20°, 95% CI 0.27° to 2.13°) at final follow-up. Significant improvements of total SRS-22 score (MD - 0.96, 95% CI - 1.10 to - 0.83) were achieved at final follow-up. The most common complication was overcorrection (8.0%) and tether breakage (5.9%), with a reoperation rate of 10.1%. Authors concluded that anterior vertebral body tethering is effective to reduce the curve in the coronal plane and clinical deformity. Maximum correction is achieved at one year. However, further studies with longer follow-up periods should be developed to assess the loss of anterior vertebral body tethering correction.

In a systematic review and meta-analysis, Roser et al. examined the expected curve reduction and potential complications for adolescent patients after VBT. (16) Records were screened against pre-defined inclusion and exclusion criteria. Data sources were prospective and retrospective studies. Demographics, mean differences in Cobb angle, surgical details and complication rates were recorded. Meta-analysis was conducted using a random-effects model. This systematic review included 19 studies, and the meta-analysis included 16 of these. VBT displayed a statistically significant reduction in Cobb angle from pre-operative to final

(minimum of 2 years) measurements. The initial mean Cobb angle was 47.8° (95% CI: 42.9 to 52.7°) and decreased to 22.2° (95% CI: 19.9 to 24.5°). The mean difference was - 25.8° (95% CI: -28.9 to 22.7) ($p < 0.01$). The overall complication rate was 23 % (95% CI: 14.4 % to 31.6%), the most common complication was tether breakage 21.9% (95 % CI: 10.6% to 33.1%). The spinal fusion rate was 7.2% (95% CI: 2.3% to 12.1%). The reviewers concluded that VBT resulted in a significant reduction of adolescent idiopathic scoliosis at 2 years of follow-up. Overall complication rate was relatively high although the consequences of the complications were unknown. Further research is needed to examine the reasons behind the complication rate, the long-term effects of VBT, and to determine the optimal timing for the procedure.

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. (17) 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.

Samdani et al. (2014, 2015) published 2 retrospective reviews on the off-label use of the Dynesys system for anterior vertebral body tethering for idiopathic scoliosis. (18, 19) They reported pursuing vertebral body tethering at their children's hospital due to lack of success with VBS for thoracic curves greater than 35°. At the time of these reports, 32 patients had a minimum of 1-year follow-up, (19) and 11 consecutive patients had a 2-year follow-up. (18) The mean age at surgery was 12 years, and all patients were skeletally immature. Three patients also had VBS for their lumbar curves. For the 11 patients with 2-year follow-up, on average, 7.8 levels (range, 7 to 9 levels) 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 required that tension be reduced after 2 years due to overcorrection.

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. (20) 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). (21) 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. (22) 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 had 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. Sagital 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. (23) 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.

In a retrospective review, Braun et al. (2024) analyzed their first 74 adolescent idiopathic scoliosis patients treated with VBT between 2010 and 2020. (24) Multiple Lenke curve types 33° to 70° were treated with skeletal maturity spanning Risser -1 to 5. Of 74 consecutive adolescent idiopathic scoliosis patients treated with VBT, 52 patients (47 female, 5 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 VBT 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 ($p < 0.001$). 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 VBT. An additional 6 of the 52 patients (12%), however, were not satisfactorily treated with VBT, requiring fusion for over-correction (n=2) or inadequate correction (n=4). Researchers concluded that in this study, adolescent idiopathic scoliosis was satisfactorily treated with VBT 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. Authors went on to state that additional study is needed to further improve the safety and effectiveness of this new procedure.

There is a growing body of evidence, consisting mainly of retrospective and prospective case series, in the peer reviewed published scientific literature evaluating the safety and efficacy of vertebral body tethering as a treatment of adolescent idiopathic scoliosis. (25-34) Although some results are promising, appropriate patient selection criteria have not been clearly established. Additionally, most of the studies have reported on relatively small sample populations with a short follow-up duration.

Section Summary: Vertebral Body Tethering

There is limited published evidence on vertebral body tethering. Available evidence for The Tether is limited. Although reported Cobb angle corrections are promising, serious adverse events occurred, data are lacking on other important health outcomes, and there are important study design limitations, including lack of a control group. Additional early reports of a correction in Cobb angle from published reports on the Dynesys system are also 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.

Most commonly reported complications were tether breakages, pulmonary complications, and overcorrections. Although a number of retrospective and prospective case series have been recently published, the studies were limited by small sample sizes, short follow-up duration, and questions around appropriate patient selection criteria. Larger, controlled studies are needed to verify these preliminary findings.

UpToDate
In an UpToDate article on adolescent idiopathic scoliosis management and prognosis (2024), it was noted that in observational studies, vertebral body tethering has been associated with progressive correction and appears to be safe, although overcorrection is a concern, and few long-term results are available. (35)

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 systematic reviews, and meta-analyses 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. Currently, there is very limited evidence on this technique, with published observational studies with the REFLECT device, The Tether, and on off-label use of the Dynesys system. 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. Most commonly reported complications were tether breakages, pulmonary complications, and overcorrections. Although reported Cobb angle corrections are promising, serious adverse events occurred, data are lacking on other important health outcomes, and there are important study design limitations including lack of a control group. Additional studies, with a larger number of total subjects and longer follow-up, are needed to evaluate the safety and efficacy of this surgical procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements
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. (2) VBS and vertebral body tethering are not addressed on the Academy'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 in (last reviewed, July 2023). (36) 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. 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. (37) 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 three 3 main categories (observation, bracing, surgery) and is based on the risk of curve progression. (38) 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 35º, 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/Pediatric Orthopaedic Society of North America

A joint Scoliosis Research Society/Pediatric Orthopaedic Society of North America position statement (2020) on payor coverage for anterior fusionless scoliosis technologies for immature patients with idiopathic scoliosis drew the following conclusions after a review of scientific evidence on anterior vertebral growth modulation (39):

- "...payors should provide coverage for any FDA approved devices under FDA stated clinical indications and requirements (limited to surgeons with active IRB approval) at the same level as traditional spinal instrumentation/fusion and growing rod procedures for management of skeletally immature patients (Risser ≤ 2 or Sanders ≤ 5) with idiopathic scoliosis (as defined above, 30 to 65 degrees Cobb angle)."
- "For those patients who meet criteria for use of The Tether™ or other similarly FDA approved growth modulation systems, the decision for fusion versus growth modulation is

best made between the patient, guardians, and treating physician - accounting for individual needs, values, and perspectives."

- "The SRS and POSNA do not support the use or reimbursement for anterior nonfusion instrumentation in skeletally mature individuals for the management of scoliosis or other spinal deformities."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and/or unpublished trials that might influence this policy are listed in Table 5.

Table 5. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
NCT05830825	The Tether™ - Vertebral Body Tethering System Post-Market Clinical Follow-Up Study in UK	100	Dec 2031
NCT04992845[a]	Fusionless Treatment of Idiopathic Scoliosis With the SCOLI-TETHER System During The Growth Period	51	May 2025
NCT02897453[a]	Retrospective Review With Prospective Surveillance of Safety and Efficacy in a Clinical Series of Spinal Tethering Patients	56	Oct 2022 (unknown status)
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
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

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	22836, 22837, 22838, 22899, 0656T, 0657T, 0790T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

1. U.S. Preventive Services Task Force (USPSTF). Final Recommendation Statement: Adolescent Idiopathic Scoliosis: Screening. 2018; Available at <https://www.uspreventiveservicestaskforce.org> (accessed February 8, 2024).
2. American Academy of Orthopaedic Surgeons (AAOS). Idiopathic Scoliosis in Children and Adolescents. April 2021; Available at <https://orthoinfo.aaos.org> (accessed February 8, 2024).
3. Margalit A, McKean G, Constantine A, et al. Body Mass Hides the Curve: Thoracic Scoliometer Readings Vary by Body Mass Index Value. J Pediatr Orthop. Jun 2017; 37(4):e255-e260. PMID 27861214
4. Heffernan MJ, Younis M, Song B, et al. Disparities in Pediatric Scoliosis: The Impact of Race and Insurance Type on Access to Nonoperative Treatment for Adolescent Idiopathic Scoliosis. J Pediatr Orthop. Sep 01 2022; 42(8):427-431. PMID 35856501
5. Mishreky A, Parent S, Miyanji F, et al. Body mass index affects outcomes after vertebral body tethering surgery. Spine Deform. May 2022; 10(3):563-571. PMID 35013996
6. Cuddihy L, Danielsson AJ, Cahill PJ, et al. Vertebral Body Stapling versus Bracing for Patients with High-Risk Moderate Idiopathic Scoliosis. Biomed Res Int. 2015; 2015:438452. PMID 26618169
7. 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
8. 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-E1314. PMID 26655807
9. 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° to 39°. Spine (Phila Pa 1976). Dec 01 2013; 38(25):E1583-E1588. PMID 23963018
10. Laituri CA, Schwend RM, Holcomb GW. 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
11. O'leary PT, Sturm PF, Hammerberg KW, et al. Convex hemiepiphysiodesis: the limits of vertebral stapling. Spine (Phila Pa 1976). Sep 01 2011; 36(19):1579-1583. PMID 21681138
12. Betz RR, Ranade A, Samdani AF, et al. Vertebral body stapling: a fusionless treatment option for a growing child with moderate idiopathic scoliosis. Spine (Phila Pa 1976). Jan 15 2010; 35(2):169-176. PMID 20081512

13. 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
14. Bizzoca D, Piazzolla A, Moretti L, et al. Anterior vertebral body tethering for idiopathic scoliosis in growing children: A systematic review. World J Orthop. May 18 2022; 13(5):481-493. PMID 35633741
15. Mariscal G, Morales J, Perez, S, et al. Meta-analysis on the efficacy and safety of anterior vertebral body tethering in adolescent idiopathic scoliosis. Eur Spine J. Jan 2023; 32(1):140-148. PMID 36443510
16. Roser MJ, Askin GN, Labrom RD, et al. Vertebral body tethering for idiopathic scoliosis: a systematic review and meta-analysis. Spine Deform. Nov 2023; 11(6):1297-1307. PMID 37432604
17. U.S. Food and Drug Administration (FDA). SUMMARY OF SAFETY AND PROBABLE BENEFIT (SSPB): The Tether Vertebral Body Tethering System. 2019; Available at <https://www.accessdata.fda.gov> (accessed February 8, 2024).
18. 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
19. 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
20. 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
21. 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):3161. PMID 35683548
22. Baroncini A, Courvoisier A, Berjano P, et al. The effects of vertebral body tethering on sagittal parameters: evaluations from a 2-years follow-up. Eur Spine J. Apr 2022; 31(4):1060-1066. PMID 34910244
23. 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
24. Braun JT, Federico SC, Lawlor DM, et al. Anterior vertebral tethering for adolescent idiopathic scoliosis: our initial ten year clinical experience. Spine Deform. Sep 2024; 12(5):1355-1367. PMID 38796815
25. Miyanji F, Pawelek J, Nasto LA, et al. Safety and efficacy of anterior vertebral body tethering in the treatment of idiopathic scoliosis. Bone Joint J. Dec 2020; 102-B(12):1703-1708. PMID 33249889
26. Hoernschemeyer DG, Boeyer ME, Robertson MD, 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. PMID 32618924

27. Hegde SK, Venkatesan M, Akbari KK, et al. Efficacy of Anterior Vertebral Body Tethering in Skeletally Mature Children with Adolescent Idiopathic Scoliosis: A Preliminary Report. Int J Spine Surg. Oct 2021; 15(5):995-1003. PMID 34551922
28. Baroncini A, Rodriguez L, Verma K, et al. Feasibility of Single-Staged Bilateral Anterior Scoliosis Correction in Growing Patients. Global Spine J. Jan 2021; 11(1):76-80. PMID 32875858
29. Siu JW, Wu HH, Saggi S, et al. Perioperative Outcomes of Open Anterior Vertebral Body Tethering and Instrumented Posterior Spinal Fusion for Skeletally Immature Patients With Idiopathic Scoliosis. J Pediatr Orthop. Mar 2023; 43(3):143-150. PMID 36746139
30. Pahys JM, Samdani AF, Swang SW, et al. Trunk Range of Motion and Patient Outcomes After Anterior Vertebral Body Tethering Versus Posterior Spinal Fusion: Comparison Using Computerized 3D Motion Capture Technology. J Bone Joint Surg Am. Sep 2022; 104(17):1563-1572. PMID 35766407
31. Mathew SE, Milbrandt TA, Larson AN. Measurable Lumbar Motion Remains 1 Year After Vertebral Body Tethering. J Pediatr Orthop. Sep 2022; 42(8):e861-e867. PMID 35878415
32. Bernard J, Bishop T, Herzog J, et al. Dual modality of vertebral body tethering: anterior scoliosis correction versus growth modulation with mean follow-up of five years. Bone Jt Open. Feb 2022; 3(2):123-129. PMID 35119295
33. Newton PO, Parent S, Miyanji F, et al. Anterior Vertebral Body Tethering Compared with Posterior Spinal Fusion for Major Thoracic Curves: A Retrospective Comparison by the Harms Study Group. J Bone Joint Surg Am. Dec 2022: 104(24):2170-2177. PMID 37010479
34. Shankar D, Eaker L, von Treuheim TDP, et al. Anterior vertebral body tethering for idiopathic scoliosis: how well does the tether hold up? Spine Deform. Jul 2022; 10(4):799-809. PMID 35258844
35. Scherl SA and BP Hasley. Adolescent idiopathic scoliosis: Management and prognosis. UpToDate, Phillips WA (Ed), Waltham, MA. This topic last updated: Nov 27 2024. Available at: <https://www.uptodate.com> (accessed December 13, 2024).
36. National Institute of Arthritis and Musculoskeletal and Skin Diseases. Questions and Answers about Scoliosis in Children and Adolescents. December 2023; Available at <https://www.niams.nih.gov> (accessed February 8, 2024).
37. 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; Available at <https://www.nice.org.uk> (accessed February 8, 2024).
38. Scoliosis Research Society (SRS). Adolescent Idiopathic Scoliosis. n.d.; Available at <https://www.srs.org> (accessed February 7, 2024).
39. Scoliosis Research Society (SRS)/Pediatric Orthopaedic Society of North America (POSNA). Joint SRS/POSNA Position Statement on Payor Coverage for Anterior Fusionless Scoliosis Technologies for Immature Patients with Idiopathic Scoliosis. April 2020; Available at <https://posna.org> (accessed February 8, 2024).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

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A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
02/01/2025	Document updated with literature review. Coverage unchanged. Added references 14, 16, and 22-24; some updated and others removed.
02/01/2024	Document updated with literature review. Coverage unchanged. Added/updated the following references: 2-6, 14, 20, 21-33, and 37.
07/15/2022	Reviewed. No changes.
07/01/2021	New medical document. Vertebral body stapling and vertebral body tethering for the treatment of scoliosis are considered experimental, investigational and/or unproven.