Vertebral Body Tethering for Scoliosis (for North Carolina Only)

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Instructions for Use

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Application

This Medical Policy only applies to the state of North Carolina.

Coverage Rationale

Vertebral body tethering for the treatment of scoliosis is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0656T	Anterior lumbar or thoracolumbar vertebral body tethering; up to 7 vertebral segments
0657T	Anterior lumbar or thoracolumbar vertebral body tethering; 8 or more vertebral segments
0790T	Revision (e.g., augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed
22836	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments
22837	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments
22838	Revision (e.g., augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed
22899	Unlisted procedure, spine

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Description of Services

Scoliosis is an abnormal lateral and rotational curvature of the spinal column. Adolescent idiopathic scoliosis (AIS) is the most common form of scoliosis. AIS is defined as a lateral curvature of the spine, of unknown cause, with a Cobb angle (a measure of spine curvature) of at least 10°, that occurs in children and adolescents aged 10 to 18 years. AIS is a progressive condition that usually worsens during adolescence and before skeletal maturity. Individuals with spinal curvature greater than 40° at skeletal maturity will likely experience the progression of curvature into adulthood. Severe spinal curvature may be associated with adverse long-term health consequences, including pulmonary disorders, disability, back pain, psychological effects, cosmetic issues, and reduced quality of life (USPSTF, 2018).

Fusionless surgical procedures, such as vertebral body tethering (VBT), are being evaluated as alternatives to spinal fusion or bracing. VBT uses vertebral body screws and other surgical hardware to secure a flexible tensioning cord across the convex side of the spine. When the cord is tensioned, the compressive force is intended to slow growth on the concave side of the spine, but allow continued growth on the convex side. This induced asymmetric growth may help obtain and maintain correction of progressive AIS while preserving spinal motion. Single or dual cords may be used for VBT. VBT is performed under general anesthesia by anterior thoracotomy, thoracoscopic, or mini-open approach. Surgical revision to replace, remove, or add VBT surgical hardware may be required due to the potential for an increased risk of complications, including inadequate correction, overcorrection, and cord breakage. VBT is intended for individuals who are skeletally immature, with a major cobb angle of 30 to 65°, and who have failed and/or are intolerant to bracing.

Clinical Evidence

Currently, there is limited evidence on this vertebral body tethering (VBT). Furthermore, existing studies are limited by the lack of comparison to other interventions, including well-established and safe usual care interventions. Additional studies, with a concurrent comparison group, larger number of total subjects and longer follow-up, are needed to evaluate the safety and efficacy of this procedure, as the evidence is currently insufficient to determine the long-term effects of the technology on health outcomes.

Alasadi et al. (2024) conducted a systematic literature review of VBT for the treatment of adolescent idiopathic scoliosis (AIS) in relation to radiographic and clinical outcomes, complications, and learning curve. The review included 26 studies that reported the minimum 2-year results of 1,366 patients. The mean age ranged between 11.0 and 15.0 years. The mean follow-up was between 20.1 and 64.5 months. Of the total, 19 studies reported thoracic curve measurements. The study results revealed percent correction of the major thoracic curve ranged from 19.7 to 82.0%. Percent correction of the proximal thoracic curve ranged from 23 to 51.0%. Percent correction of compensatory lumbar curvature was between 7.1 and 82.0%. Mean coronal alignment corrected to -0.7 to 1.4 cm. Sixteen studies reported on thoracic kyphosis and lumbar lordosis. Mean thoracic kyphosis corrected to 17.0 to 33.0°. Mean preoperative lumbar lordosis remained relatively stable. Mean sagittal alignment ranged from -8.8 to 1.8 cm. Six studies included patient-reported outcomes measured with the Scoliosis Research Society questionnaire (SRS-22). Mean preoperative and postoperative SRS scores were 3.7 (2.5 to 4.9) and 4.4 (2.4 to 5.0), respectively. The total SRS score improved across all studies with surgery. Pulmonary complications were reported in 7.0% of patients (across the 11 studies that reported pulmonary complications), ranging from 3.3 to 80% of the total patients within each study. Procedure-related complications were reported in 16 of 17 studies that commented on complications. Presumed or confirmed tether breakages were reported in 20.8% of patients (0 to 36%) with a mean follow-up of 32.4 months (20.1 to 64.5 months). Revision surgery was reported in 8.3% of patients, of which 2.4% had reoperations due to tether breakage and 4.9% for overcorrection. Conversion to posterior spinal fusion (PSF), either due to tether breakage or overcorrection, was reported in 2.4% of patients. The authors concluded this systematic literature review illustrates the potential benefits and challenges of treating AIS with VBT and can serve as a basis for the further study and refinement of this technique. Limitations of this systematic literature review include the methodology, which may have affected the quality of the included studies. (Publications by Bernard et al., 2022, Rushton et al., 2021, Yucekul et al., 2021, Miyanji et al., 2020, Newton et al., 2020, Newton et al., 2018, and Samdani et al., 2014, which were previously cited in this policy, are included in this review.)

Tsirikos et al. (2024) performed a systematic review to collect and analyze data from the available literature on minimally invasive surgical techniques for AIS. The systematic review included 43 studies, including 14 for thoracoscopic surgery (ATS), 13 for posterior minimally invasive surgery (PMIS), and 16 for VBT. Of the 16 VBT studies, 12 were case series. Four studies were comparative studies, with two comparing the outcomes of VBT with posterior spinal instrumentation and fusion (PSIF), one study comparing VBT with PSIF and magnetic growing rods, and one study comparing VBT with anterior spinal fusion. The authors concluded the ATS approach is well-established in terms of comparable coronal and sagittal correction to PSF. However, the current use of ATS for instrumented fusion has become less popular due to a steep learning curve, high pulmonary and vascular complication rates, implant failures, and increased non-union rates.

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PMIS is an effective alternative to the standard open PSF. Though, the steep learning curve and longer surgical time with PMIS are potential disadvantages. The current evidence for VBT is limited, but suggests the procedure merits consideration in terms of radiological correction and clinical outcomes. However, VBT has a high complication and reoperation rate. Additionally, the most appropriate indications and long-term outcomes for VBT remain unclear. Limitations of the study noted by the authors include the significant heterogeneity observed in terms of study designs, curve types, correction techniques, management protocols at different centers, and reporting of outcomes. No meta-analysis of the data was performed. Due to the steep learning curve, several PMIS studies have noted an improvement in outcomes after the first 25 cases. However, six out of nine comparative studies included in the systematic review reported outcomes in the first 25 or fewer cases. The majority of VBT studies were case series, lacking a control group. The current literature for VBT lacks good quality clinical trials, including comparative studies of VBT with other growth modulation techniques and PSIF for a more comprehensive analysis of safety and efficacy. (Publications by Bernard et al., 2022, Rushton, et al., 2021, Yucekul et al., 2021, Miyanji et al., 2020, and Newton et al., 2020, which were previously cited in this policy, are included in this review.)

Hayes completed an evolving evidence review of The Tether™ - Vertebral Body Tethering System (Zimmer Biomet Spine, Inc.) for skeletally immature patients with progressive idiopathic scoliosis. Hayes concluded a review of full-text clinical studies suggested minimal support for the use of VBT with The Tether for correcting spinal curvature in skeletally immature patients with progressive idiopathic scoliosis. The review included two retrospective chart reviews (single-arm), and one retrospective chart review (with comparison treatment groups). While these studies consistently reported improvement from baseline in the main spinal curve deformity, high rates of complications were noted. These studies were also limited by a very poor level of quality and retrospective design. Only one study had comparison groups. The other studies compared pretest-posttest placement metrics only. Hayes also concluded a full-text review of one systematic review with a meta-analysis suggested minimal support for use of VBT with The Tether for correcting spinal curvature in skeletally immature patients with progressive idiopathic scoliosis. Most of the studies included in the review were retrospective or case series and did not mention the surgical systems used. Fusion and anterior VBT were found to provide similar curve correction. However, VBT had a much higher incidence of complications. Additionally, Hayes concluded that a review of full-text clinical practice guidelines and position statements, appeared to confer no/unclear support for use of The Tether for correcting spinal curvature in skeletally immature patients with progressive idiopathic scoliosis. Only one position statement specifically referred to The Tether and advocated for payer coverage based on safety and probable benefit. However, this statement was based on expert opinion, without a formal process. Other related position statements recommended more research on VBT to determine longer-term patient benefit. Overall, the recommendations were found to be generally conflicting or inconsistent. Hayes noted that the evidence reported corrections in abnormal spinal angles. However, the comparative evidence was extremely limited for VBT versus standard care, PSF, and alternative treatments, such as growing rods. The potential risks of The Tether need to be weighed against the potential benefits due to a lack of longer-term clinical and safety data beyond 3 years post-index surgery. A Hayes annual review identified ten newly published clinical studies, ten systematic reviews, and one guideline. After a review of the new clinical studies and systematic review abstracts, Hayes concluded the impact was unlikely to change the current minimal level of support on the use of The Tether for correcting spinal curvature in skeletally immature patients with progressive idiopathic scoliosis. Additionally, after a review of clinical practice guideline abstracts, Hayes concluded the impact was no change in the current no/unclear level of support on the use of The Tether for correcting spinal curvature in skeletally immature patients with progressive idiopathic scoliosis (Hayes, 2022; Annual Review: 2024).

Braun et al. (2024) conducted a retrospective review of individuals with AIS consecutively treated with anterior VBT by a single surgeon over a ten year period. The study included 52 individuals with multiple Lenke curve types (33 to 70°) with skeletal maturity spanning Risser -1 to 5. Of the total, 46 of 52 individuals (88%) with 65 curves (35 thoracic and 30 thoracolumbar/lumbar) were satisfactorily treated with anterior VBT. These individuals demonstrated curve correction from 48.6° pre-operatively (range 33 to 70°) at age 15.1 years (range 9.2 to 18.8 years) and skeletal maturity of Risser 2.8 (range -1 to 5) to 23.2° post-operatively (range 0 to 54°) and 24.0° final (range 0 to 49°) at 3.3 years follow-up (range 2 to 10 years). Curve corrections from pre-operatively to post-operatively and pre-operatively to final were both significant ($p < 0.001$). The 0.8° change from post-operatively 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. Axial rotation demonstrated a slight trend toward improvement. Skeletal maturity of Risser 4 or greater was achieved in all but one individual. However, only 68% of 52 patients achieved a good or excellent result after a single surgical intervention. Four of 52 individuals (8%) required additional procedures for tether rupture (3 replacements) or overcorrection (1 removal) to achieve satisfactory treatment status after anterior VBT. Six of 52 individuals (12%) were not satisfactorily treated with anterior VBT. These individuals required fusion for overcorrection (n = 2) or inadequate correction (n = 4). The study authors concluded that the majority of individuals with AIS were satisfactorily treated with anterior VBT over a broad range of curve magnitudes, curve types, and skeletal maturity. Late revision surgery for overcorrection, inadequate correction, or tether rupture was not uncommon. Though, the refinement of indications eliminated the complication of overcorrection after the first ten individuals. Limitations of this study include the retrospective, single-surgeon design.

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Cahill et al. (2024) retrospectively reviewed multicenter registry data to define the incidence of tether breakage for individuals with AIS who underwent thoracic anterior VBT. The study included 208 individuals from 10 centers with right-sided, thoracic curves with at least 2 and up to 3 years of radiographic follow-up. The average age was 12.1 ±1.6 years and median Risser stage 0 (interquartile range 0 to 1). Tether breakage between two vertebrae was defined a priori as any increase in adjacent screw angle > 5° from the minimum, over the follow-up period. The study results revealed that radiographically identified tether breakage occurred in 75 patients (36%). The initial break occurred at or beyond 24 months in 66 patients (88%). A Kaplan-Meier survival analysis estimated the cumulative rate of expected tether breakage was 19% at 24 months, increasing to 50% at 36 months. Twenty-one individuals (28%) with a radiographically identified tether breakage went on to require reoperation. Nine individuals (12%) required conversion to PSF. Individuals with a radiographically identified tether breakage went on to require conversion to PSF more often than those patients without identified tether breakage (12% versus 2%; p = 0.004). The average major coronal curve angle at final follow-up was significantly larger for individuals with tether breakage identified radiographically than those individuals without tether breakage (3° ±12 versus 26° ±12; p = 0.002). The authors concluded the incidence of thoracic anterior VBT tether breakage is high, and is expected to occur in 50% of individuals by 36 months postoperatively. The authors noted that a limitation of the study is the use of radiographs to identify tether breakages. This may lead to the underreporting of true tether breaks. Additionally, the study focused on thoracic curves and did not include lumbar curves in the analysis. The study is also limited by the retrospective design. (This study is included in the Hayes 2022; Annual Review: 2024 evolving evidence review.)

Mariscal et al. (2023) performed a systematic review and meta-analysis to analyze the efficacy and safety of anterior VBT for individuals with AIS. The review included 12 studies and 538 individuals (age 11 to 14 years). Most of the studies included individuals in the early stage of skeletal maturity and Lenke 1 curves. Follow-up ranged between 24 and 60 months. The study results revealed significant corrections to the main thoracic [mean deviation (MD) 22.51, 95% (confidence interval {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). There were no statistically significant corrections 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 in 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%). The reoperation rate was 10.1%. The authors concluded that anterior VBT was effective to reduce the curve in the coronal plane and clinical deformity. The maximum correction was achieved at one year. However, the method should be optimized to reduce the rate of complications. Further studies, including more skeletally mature individuals, curve types, and higher curves would allow for a more complete assessment of anterior VBT effectiveness and safety. A limitation of the systematic review and meta-analysis is the low number of studies included in the clinical variables and some of the complications. There is also a risk of bias due to the included case series and cohort studies and absence of control group. (Publications by Bernard et al., 2022, Hegde et al., 2021, Rushton, et al., 2021, Miyanji et al., 2020, Newton et al., 2018, and Samdani et al., 2015, which were previously cited in this policy, are included in this review.) (This study is included in the Hayes 2022; Annual Review: 2024 evolving evidence review.)

Vatkar et al. (2023) performed a systematic review and meta-analysis to evaluate the relevant literature pertaining to the efficacy of anterior VBT with respect to degree of correction of the major curve Cobb angle, complications, and revision rates. The review included nine studies and 196 individuals (mean age 12.08 years) who underwent anterior VBT for correction of AIS. Mean follow-up was 34 months. The study results revealed a significant correction of the main thoracic curve of scoliosis (mean preoperative Cobb angle 48.5°, post-operative Cobb angle at final follow-up 20.1°; p = 0.01). However, the average rates of overcorrection and mechanical complications were observed as 14.34% and 27.53%, respectively. Pulmonary complications, including atelectasis and pleural effusion, were seen in 9.7% of individuals. Tether revision was performed in 7.85% of individuals and revision to PSF in 7.88% of individuals. The primary reason for revision was due to tether breakage. However, not all broken tethers required revision. The authors concluded that the current literature on anterior VBT is largely restricted to retrospective studies without randomization. A prospective, multi-center trial of anterior VBT with strict inclusion criteria and standardized outcome measures was recommended. The authors noted outcome reporting bias as a limitation of the systematic review and meta-analysis. The number of findings reported and the methods of reporting the findings differed across the studies reviewed. (Publications by Miyanji et al., 2020, Newton et al., 2020, and Samdani et al., 2014, which were previously cited in this policy, are included in this review.) (This study is included in the Hayes 2022; Annual Review: 2024 evolving evidence review.)

Courvoisier et al. (2023) reported on a retrospective case series of 85 patients with AIS and a minimum two year follow-up after VBT. The mean age at surgery was 12.5 years (Risser index between 0 and 2). The inclusion criteria included patients with severe curves (> 40° for thoracic scoliosis and > 35° for lumbar scoliosis). The major and compensatory curves were measured pre-operatively, at the 1st standing X-ray, at one year, and then at the last available follow-up.

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Complications were also analyzed. The study results revealed that improvement was observed in the curve magnitude after surgery. Both the main and the secondary curves continued to progress over time. Ninety-five percent of patients reached Risser 3 or more. Both the thoracic kyphosis and lumbar lordosis remained stable over time. However, overcorrection occurred in 11% of cases. Tether breakage was observed in 2% of cases and pulmonary complications in 3% of cases. The authors concluded that VBT is an effective technique for the management of patients with AIS with residual growth potential. Additionally, VBT offers a more subtle and patient-specific surgical treatment for AIS that considers parameters such as flexibility and growth. Limitations of this study, noted by the authors, include its retrospective, uncontrolled nature and the absence of long-term data. Conducting prospective randomized studies in spine surgery is complex, but necessary to compare different treatments.

O'Donnell et al. (2023) conducted a prospective, single-surgeon cohort study to compare post-operative pain and recovery in patients with AIS who underwent anterior VBT or PSIF. The study included nine patients who underwent anterior VBT and 22 patients who underwent PSIF. The mean age was 13.7 years. Post-operative pain and recovery were evaluated with pain scores, pain confidence scores, Patient Reported-Outcomes Measurement Information System (PROMIS®) scores for pain behavior, interference, and mobility, and functional milestones of opiate use, independence in activities of daily living (ADLs), and sleeping. Patients were evaluated at 1 week, 2 weeks, and 6 weeks after surgery. The study results revealed decreased pain scores at 2 and 6 weeks after surgery ($p = 0.004$ and $p = 0.030$, respectively), decreased PROMIS pain behavior at all time points ($p = 0.024$, $p = 0.049$, and $p = 0.001$, respectively), decreased pain interference at 2 and 6 weeks after surgery ($p = 0.012$ and $p = 0.009$, respectively), increased PROMIS mobility scores at all time points ($p = 0.036$, $p = 0.038$, and $p = 0.018$, respectively), and faster time to functional milestones of weaning opiates, independence in ADLs, and sleep at all time points ($p = 0.024$, $p = 0.049$, and $p = 0.001$, respectively). The authors concluded that the early recovery period following anterior VBT for AIS is characterized by less pain, increased mobility, and faster recovery of functional milestones, compared with PSIF. Limitations of this study include the single-surgeon design and small sample size.

Treuheim et al. (2023) conducted a retrospective review to compare minimum 2-year anterior VBT outcomes in skeletally immature patients versus those with minimal remaining skeletal growth. The study included consecutive patients with AIS who were treated with single thoracic anterior VBT. Patients were grouped by their preoperative skeletal maturity, immature (n = 16; Risser 0 to 2) versus mature (n = 19; Risser 3 to 5). The preoperative age was 12.5 (9 to 16) versus 15 (12 to18) years with major Cobb 51° (36 to 69°) and 49° (40 to 69°) for immature and mature, respectively. Outcomes were assessed at the preoperative, first erect, and 2-year timepoints. Median (range) was compared with nonparametric tests ($p < 0.05$). At the first erect timepoint, the study results revealed there was no difference in correction. However, at the 2-year timepoint, the immature group yielded a lower residual curve [15° (-16 to 38°) versus 29° (12 to 42°); $p = 0.008$]. Thoracolumbar/lumbar curves were corrected without group differences. Clinically successful correction (< 35°) [n = 15 (94%) versus n = 15 (79%)] and suspected cord breakages [n = 2 (13%) versus n = 2 (12%)] were similar at the 2-year timepoint. Two overcorrections occurred, both in immature patients. SRS-22 outcomes at the final follow-up were similar between groups. No revision reoperations or conversions to spinal fusion were needed. The authors concluded skeletally immature patients benefit from greater growth-modulated curve correction than mature patients, but at the increased risk of overcorrection. Mature patients maintained clinically significant correction at the latest follow-up. Longer-term follow-up is required to determine durability of outcomes for patients undergoing anterior VBT who have minimal remaining growth at the time of index surgery. Limitations of this study include the retrospective, single-surgeon design.

Welborn et al. (2023) conducted a retrospective review of a prospective, multi-center registry of patients with idiopathic scoliosis with Lenke 1A or 1C curves that underwent selective thoracic anterior VBT. The purpose of the study was to evaluate changes in the thoracic and thoracolumbar/lumbar curves and truncal balance at a minimum of 2 years follow-up. The study included a matched cohort of patients with AIS (Risser 0 to 1; Sanders 2 to 5) with Lenke 1A curves (1A group) (n = 43) or Lenke 1C curves (1C group) (n = 19) treated with selective thoracic anterior VBT. Age at the index procedure was 13.2 years (9.8 to 17.2) in the 1A group and 13.7 years (11.7 to 16.0) in the 1C group. Digital radiographic software was used to assess Cobb angle and coronal alignment on preoperative, postoperative and subsequent follow-up radiographs. Coronal alignment was assessed by measuring the distance from the center sacral vertical line to the midpoint of the lowest instrumented vertebra (LIV), apical vertebra for thoracic and lumbar curves and C7. The study results revealed there was no difference in the thoracic curve measured preoperatively, at first erect, pre-rupture, or at the most recent follow-up. There was also no difference in C7 alignment ($p = 0.057$) or apical thoracic alignment ($p = 0.272$) between the 1A and 1C groups. Thoracolumbar/lumbar curves were smaller in the 1A group at all-time points. However, there was no difference between the percent correction between the two groups thoracic ($p = 0.453$) and thoracolumbar/lumbar curves ($p = 0.105$). The Lenke 1C curves had improved coronal translational alignment of the LIV at the most recent follow-up ($p = 0.0355$). Additionally, the number of patients considered to have successful curve correction (Cobb angle correction of both the thoracic and thoracolumbar/lumbar curves to ≤ 35°) was equivalent between Lenke 1A and Lenke 1C curves ($p = 0.80$). There was no difference in the rate of revision surgery, with one patient in each group treated with fusion surgery ($p = 0.546$). Though, 50% of all patients had an apparent tether rupture with an

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average loss of correction of 5° (range -2 to 34°). The authors concluded Lenke 1C curves demonstrated less absolute correction of the thoracolumbar/lumbar curve at all time points after selective thoracic anterior VBT, but have equivalent percent correction of the thoracic and thoracolumbar/lumbar curves. The two groups had equivalent alignment at C7 and the thoracic curve apex. Lenke 1C curves had better alignment at the LIV at the most recent follow-up. Furthermore, they had an equivalent rate of revision surgery compared to Lenke 1A curves. Selective thoracic anterior VBT is a viable option for selective Lenke 1C curves. However, despite equivalent correction of the thoracic curve, there was less correction of the thoracolumbar/lumbar curve at all-time points. Currently, anterior VBT has a high rate of revision surgery when compared to selective thoracic fusion. Anterior VBT remains in the experimental stage, both from a technical and patient selection standpoint. Judicious patient selection, extensive patient counseling, and vigorous outcomes analysis are essential for the application of anterior VBT. The study has several limitations including the retrospective design and small sample size due to incomplete registry data.

Roser et al. (2023) conducted a systematic review and meta-analysis to determine the expected curve reduction and potential complications for patients with AIS after VBT. The systematic review included 19 studies and 677 patients. Sixteen studies had sufficient data for the meta-analysis. The study results revealed VBT displayed a statistical reduction in Cobb angle from pre-operative to final (minimum 2 years) measurements. The initial mean Cobb angle was 47.8° (CI 95% 42.9 to 52.7°) and decreased to 22.2° (CI 95% 19.9 to 24.5°). The mean difference was -25.8° (CI 95% -28.9 to 22.7°) ($p < 0.01$). The overall complication rate was 23% (CI 95% 14.4 to 31.6%). The most common complication was tether breakage (21.9%) (CI 95% 10.6 to 33.1%). The spinal fusion rate was 7.2% (CI 95% 2.3 to 12.1%). The authors concluded that VBT results in a reduction of AIS at 2 years of follow-up. The overall complication rate was relatively high. However, the consequences of the complications were unknown. Additional 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. It is effective at reducing scoliotic curves and preventing spinal fusion in a majority of patients. Due to the nature of growing adolescents, studies examining the curves with longer follow-up are needed to determine the longitudinal effectiveness of VBT into skeletal maturity. The clinical effect from broken tethers has not yet been quantified. Studies that evaluate the change in major curve Cobb angle after a broken tether would also be beneficial. The systematic review and meta-analysis is limited as a majority of the included studies were retrospective, pre-post studies that lacked randomization or a control group. (Publications by Bernard et al., 2022, Rushton et al., 2021, Yucekul et al., 2021, Miyanji et al., 2020, Newton et al., 2020, Newton et al., 2018, and Samdani et al., 2014, which were previously cited in this policy, are included in this review).

Siu et al. (2023) conducted a retrospective cohort study to compare individuals with AIS who underwent either anterior VBT or instrumented PSF. The study included 23 individuals who underwent anterior VBT and 24 matched individuals who underwent instrumented PSF. Inclusion criteria were based on the anterior VBT group, and included primary thoracic idiopathic scoliosis, Risser ≤ 1, curve magnitude 40 to 70°, age 9 to 15 years, no prior spine surgery, index surgery between 2014 and 2019, and a minimum 2-year follow-up. Individuals undergoing anterior VBT and PSF were similar in age (12 ±1 years versus 13 ±1 years; $p = 0.132$) and average follow-up time (3.8 ±1.6 years versus 3.3 ±1.4 years; $p = 0.210$). The study results revealed that estimated blood loss (498 ±290 mL versus 120 ±47 mL; $p < 0.001$) and procedure duration (419 ±95 minutes versus 331 ±83 minutes; $p = 0.001$) were significantly greater in the instrumented PSF group compared with the anterior VBT group. The length of stay was lower in the anterior VBT group compared with the PSF group (4 ±1 days versus 5 ±2 days; $p = 0.04$). The PSF group had significantly greater total postoperative opiate morphine equivalent use compared with the anterior VBT group (2.2 ±1.9 mg/kg versus 5.6 ±3.4 mg/kg; $p < 0.001$). Preoperative radiographic parameters were similar between both groups, with a major thoracic curve at 51° ±10 for the anterior VBT group and 54° ±9 for the instrumented PSF group ($p = 0.214$). At the most recent follow-up, individuals in the instrumented PSF group had greater curve reduction to a mean major thoracic curve of 11° ±7 (79%) compared with 19° ±10 (63%) in the anterior VBT group ($p = 0.002$). Nine individuals (39%) required revision surgery following anterior VBT, compared with 4 individuals (17%) following instrumented PSF ($p = 0.09$). The authors concluded that in a select cohort of individuals, anterior VBT offers decreased surgical time, blood loss, length of stay, and postoperative opiate usage compared with instrumented PSF. While instrumented PSF resulted in greater deformity correction at the 2-year follow-up, the majority of individuals who underwent anterior VBT had ≤ 35° major curves and avoided fusion. While there is optimism for anterior VBT as a treatment option for select individuals with AIS, long-term complications are still being understood, and the risk for revision surgeries remains high. The study is limited by the retrospective design and small sample size.

Zhu et al. (2022) conducted a systematic review and single-arm meta-analysis to evaluate VBT efficacy and safety for treating scoliosis. Twenty-six studies involving 1,045 patients were included in the meta-analysis. The correction rate of major curve immediately post-operation was 46.6% ±13.8 (16 to 69%). The correction rate of major curve at final follow-up was 53.2% ±17.9 (16 to 79%). The single-arm meta-analysis results of all included studies showed that VBT was effective in general. The overall clinical success rate was 73.02% (95% CI 68.31 to 78.05%). The pooled overall unplanned reoperation rate was 8.66% (95% CI 5.53 to 13.31%). The overall incidence rate of complications was 36.8% (95% CI

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23.9 to 49.7%). The subgroup analysis, based on follow-up time, indicated that patients with follow-up time > 36 months had increased clinical success rate, unplanned reoperation rate, and incidence rate of complications compared with those with < 36 months follow-up time. The preliminary results showed that after 36 months of follow-up, only 7.17% (95% CI 4.81 to 10.55%) of patients required PSF surgery and nearly 93% of patients avoided spinal fusion surgeries. The authors concluded that the evidence from at least 3-year follow-up in different countries indicated that VBT is an effective surgical approach for treating scoliosis, with 73.88% of patients achieving clinical success. About one in seven patients (15.8%) required unplanned reoperations, but only 7.17% required PSF. About half (52.17%) of the patients experienced complications. However, due to the limitation of the study number and quality, the conclusion may be biased and requires verification by further studies with longer follow-up times. (Publications by Hegde et al., 2021, Rushton et al., 2021, Yucekul et al., 2021, and, Newton et al., 2020, which were previously cited in this policy, are included in this review). (This study is included in the Hayes 2022; Annual Review: 2024 evolving evidence review.)

Raitio et al. (2022) performed a systematic review to describe the indications and surgical technique of VBT and to critically evaluate the results and complications. The review included 23 studies on 843 individuals (mean age 12.7 years) who underwent VBT. These individuals were followed for a minimum of 2 years. The study results revealed the mean pre-operative main thoracic curve corrected from 49° to 23° in first postoperative imaging. VBT provided sustainable median-term results. The reported curves averaged 23° after a minimum of two-year follow-up. Kyphosis was unchanged at 23°. There were limited studies on the correction of lumbar and double curves using VBT. Two studies showed that a single lumbar tether seemed to have a relatively high cord breakage of up to 50% within two years. Limited evidence suggested that using a double tether with double screws could reduce the risk of cord breakage to 16% during the first year. Another study reported an initial 64% correction of thoracic and 69% of lumbar curves with additional growth modulation resulting in 80% and 82% correction at 2-year follow-up, respectively. However, the complication rate for VBT was 18%. Fifteen percent of individuals who underwent VBT required reoperations for pulmonary or tether-related issues (10%). Though, less than 5% required conversion to spinal fusion. The authors concluded that while the reported median-term results of VBT appear promising, long-term results of this technique are currently lacking. Limitations of this systematic review include the lack of RCTs or prospective follow-up studies comparing the outcomes of anterior VBT and segmental pedicle screw instrumentation. (The Publications by Bernard et al., 2022, Hegde et al., 2021, Rushton et al., 2021, Yucekul et al., 2021, and Newton et al., 2020, which were previously cited in this policy, are included in this review). (This study is included in the Hayes 2022; Annual Review: 2024 evolving evidence review.)

A systematic review performed by Bizzoca et al. (2022) summarized the current evidence about the efficacy and safety of anterior VBT in the management of idiopathic scoliosis in skeletally immature patients. Seven clinical trials recruiting 163 patients were included in the review. Based on the study design and the depicted flaws, five studies were classified as high quality and two studies were classified as moderate quality. A total of 151 of 163 anterior VBT 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 nonprogressive curve at skeletal maturity. A postoperative complication rate of 17.8% was observed. Complications were also observed in patients that achieved a successful outcome at skeletal maturity. Postoperative complications included pulmonary complications (n = 12; 7.4%), including atelectasis (n = 5; 3.07%), pneumonia (n = 2; 1.23 %), pneumothorax (n = 4; 2.45%) and chylothorax (n = 1; 0.6%). All these complications were successfully managed conservatively. Twenty-three of 163 (14.11%) patients required unplanned revision surgery within the follow-up period. Conversion to PSF was performed in 18 of 163 (11%) patients. The authors concluded that anterior VBT is a promising growth-friendly technique for the treatment of idiopathic scoliosis in growing patients. However, anterior VBT has moderate success, as well as perioperative complications, revision, and conversion to PSF. The authors noted that the main study limitation was the low level of evidence of the included studies. Further research with RCTs is needed to validate these findings. (The publications by Newton et al., 2020 and Samdani et al., 2014, which were previously cited in this policy, are included in this review.)

Meyers et al. (2022) performed a retrospective study to evaluate the clinical outcomes of VBT at 2 to 5 years when applied to adolescents after peak height velocity. The study included 49 consecutive patients with AIS treated by a single surgeon, a minimum 2-year follow-up, and Risser 3 to 5. Mean age at the time of VBT was 15.0 ±1.9 years with mean follow-up of 32.5 ±9.1 months. The study results revealed, for thoracic major curvatures, thoracic curvature improved from 51.1° ±6.9 to 27.2° ±8.1 ($p < 0.01$) and thoracolumbar from 37.2° ±10.7 to 19.2° ±6.8 ($p < 0.01$). For thoracolumbar major curvatures, thoracic improved from 37.2° ±10.7 to 18.8° ±9.4 ($p < 0.01$) and thoracolumbar from 49.0° ±6.4 to 20.1° ±8.5 ($p < 0.01$). Major curve inclinometer measurements and SRS-22 domains, except activity, improved significantly ($p \leq 0.05$). At the latest follow-up, one patient (2%) required fusion of the thoracic curve and revision of the thoracolumbar tether due to curve progression in the previously un-instrumented thoracic curve and tether breakage in the thoracolumbar. Twenty patients (41%) experienced tether breakage. VBT in AIS patients with limited remaining skeletal growth resulted in satisfactory clinical outcomes at the latest follow-up. The authors concluded that VBT in patients with AIS and limited remaining skeletal growth resulted in satisfactory clinical outcomes at the latest follow-up. Limitations of this study, noted by the authors, included the lack of Sanders staging, as it is the most reported skeletal maturity indicator

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spanning the period prior to the adolescent growth spurt through skeletal maturity. Numbers were also not sufficient to stratify outcomes based on Risser stage 3, 4, or 5. Future study is required to better elucidate predictors of clinical success in VBT for skeletally mature patients. In addition, the sub-analysis was limited due to the sample size of those who were unsuccessful. However, best results were seen in smaller and more flexible curves. (This study is included in the review by Alasadi et al., 2024 and in the Hayes 2022; Annual Review: 2024 evolving evidence review.)

Mathew et al. (2022) performed a prospective study with a matched retrospective comparison group to evaluate and report comparative outcomes at 2-years for VBT and PSF. The study prospectively enrolled 26 skeletally immature (Sanders ≤ 4; Risser ≤ 2) individuals between the ages of 10 to 16 years who underwent VBT. These individuals were matched 1:1 by age, gender, Risser, and major curve magnitude with individuals who underwent PSF from an institutional registry. At a minimum 2-year follow-up, surgical results and radiographic outcomes were reviewed. The study results revealed that operative time, anesthesia time, blood loss, and length of stay were significantly lower in the VBT group compared to the PSF group ($p < 0.001$, $p = 0.003$, $p < 0.001$, and $p < 0.001$, respectively). The major curve at 2 years was corrected by 46% in the VBT group versus 66% in the PSF group ($p = 0.0004$). Success following VBT, defined as no fusion surgery and Cobb angle < 35° at the 2-year follow-up, was seen in 20 individuals in the VBT group (77%) ($p = 0.0003$). This finding correlated with a mean Cobb angle of < 35° on 3-month imaging. Twelve individuals in the VBT group (46%) showed curve improvement over time. Those individuals had a significantly lower mean Cobb angle on the 3-month radiograph than non-modulators (23° versus 31°, $p = 0.014$). Cord breakage at 2 years occurred in five individuals (19%). Three individuals in the VBT group developed complications (two pleural effusion and one overcorrection needing return to operating room). Growth continued at T1-T12 (mean 13 mm) and over the instrumented levels (mean 10 mm) following VBT, compared to no growth over instrumented segments in the PSF group ($p = 0.011$ and $p = 0.0001$, respectively). The authors concluded that in Sanders stages 3 and 4, for individuals treated in the U.S., a Cobb angle < 35° on 3-month imaging was associated with success at the 2-year follow-up. Curve correction was superior in the PSF group, with 96% of individuals achieving curve correction to < 35° versus 77% of the VBT group. Three individuals developed complications in both the VBT and PSF groups. Additional data are needed for VBT regarding long-term durability and functional outcomes. Limitations of the study include the small sample size, single-site design, and retrospective comparison group.

ECRI completed a clinical evidence assessment of The Tether that focused on the safety and effectiveness of the device for treating skeletally immature individuals with AIS and how it compared with spinal fusion surgery. Three studies were assessed, a single-center, retrospective cohort study with a prospective follow-up, described in a U.S. Food and Drug Administration (FDA) Summary of Safety and Probable Benefit document (n = 57), and two single-center, prospective cohort studies (n = 21 and n = 13, respectively). ECRI concluded the evidence for The Tether was inconclusive. The Tether appeared to be safe, reduced spinal curvature, and maintained curvature correction at up to a 3-year follow-up. However, the available studies provided no data on how well the device worked, compared with spinal fusion surgery. None of the three studies reported on spine correction and function at skeletal maturity. Only one of the three studies reported on changes in functional scores and quality of life (QOL) from baseline. The available studies were at risk of bias due to evidence limitations that included small sample size, retrospective design, single-center focus, short-term follow-up, and/or lack of control groups. Larger, multicenter studies that follow individuals with AIS until skeletal maturity are needed to validate the available studies and compare The Tether with spinal fusion surgery (ECRI, 2021).

Baroncini et al. (2021) performed a retrospective review to analyze the feasibility of correcting double-curve scoliosis using VBT. The study included the first 25 pediatric patients treated by the authors with a bilateral anterior thoracic approach and instrumentation of the spine. The average patient age was 14.5 years (Risser 0 to 4; Sanders 1 to 7). Due to a lack of complete perioperative data and variations in postoperative care, the authors performed an analysis of 30-day complication rates and sub-analysis for a potentially confounding learning curve by comparison of the first 12 patients versus the last 13 patients with a T test ($p < 0.05$). Of the 25 patients treated, one intraoperative complication occurred when VBT had to be abandoned on the opposite side due to the unexpected presence of pleural scarring that would not allow pulmonary deflation. During the 30-day interval, four postoperative complications were noted (16%). Two patients had recurrent pleural effusions, one patient was diagnosed with pneumonia, and one patient, following a 24-hour international flight, had a pulmonary embolism without cardiopulmonary consequences. Another patient developed a pleural effusion at 6-weeks post-surgery outside of the 30-day interval. Patients whose symptoms began after discharge (n = 4) required hospitalization. Those with recurrent pleural effusions required invasive treatment including reinsertion of a chest tube (n = 2), and explorative thoracoscopy with reinsertion of a chest tube (n = 1). When comparing the first 12 patients with the next 13 patients, the authors observed a reduction of intubation time (first 12 patients = 453 minutes, next 13 patients = 397 minutes; $p = 0.02$), surgical time (first 12 patients = 328 minutes, next 13 patients = 280 minutes; $p = 0.03$), and blood loss (first 12 patients = 480 mL, next 13 patients = 197 mL; $p = 0.03$). All patients who received autologous or heterologous blood transfusions were within the early phase of the authors' learning curve. The length of inpatient stay was also decreased (first 12 patients = 10.3 days, next 13 patients = 8.1 days; $p = 0.01$). The authors concluded that the study added important information to the orthopedic literature showing that VBT is feasible and does

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not require staging. However, complication rates are high. Additional research is required to understand root causes of the reported complications. The study is limited by its retrospective observations and small sample size. Further research with RCTs is needed before the clinical usefulness of VBT is proven.

Hayes completed an evolving evidence review of VBT for progressive pediatric and AIS. The review included two retrospective cohort studies with a control group, one retrospective cohort study without a control group, five retrospective pretest-posttest studies, and two retrospective case series. Hayes concluded that a review of full-text clinical studies suggested minimal support for using VBT for the treatment of idiopathic scoliosis in skeletally immature patients. While these studies consistently reported improvement from baseline in the main spinal curve deformity, high rates of broken tethers and revision surgery were noted. These studies were also determined to be of poor or very poor quality. Only two studies had comparison groups. Comparative findings were not consistent between studies. One study reported greater spinal curve correction among patients treated with PSF compared with VBT, and one study favored VBT over PSF for lumbar range of motion and flexibility. A majority of studies compared pre- and postplacement metrics only. No systematic reviews were identified. Additionally, a review of full-text clinical practice guidelines and position statements appeared to confer unclear support of VBT for the treatment of skeletally immature patients with idiopathic scoliosis. The position statements identified were primarily expert opinions and/or lacking a formal evidence evaluation process. Most position statements indicated additional research on VBT is required to determine whether it is associated with patient benefit. However, the recommendations were generally inconsistent. Hayes concluded that VBT appears to confer benefits for some patients. However, the currently available evidence is of low quality and limited to small observational studies. Additional evidence is needed to evaluate the comparative efficacy and safety and to guide patient selection (Hayes, 2021).

Meyers et al. (2021) conducted a retrospective analysis of 90-day complication rates in patients with AIS who underwent anterior VBT by a single surgeon. The study included 184 consecutive patients. The mean age at surgery was 15.0 ±2.4 years. The mean pre-operative Cobb angle was 54.3° ±10.5. There were 22 (12.0%) patients who had a rib resection and the mean number of ribs resected was 2.5 ±1.2. Mean operative time was 186.5 ±60.3 minutes and mean estimated blood loss was 167.2 ±105.0 mL. No patient received an allogenic blood transfusion. Patients received either a thoracic tether [n = 71 (38.6%)], thoracolumbar tether [n = 45 (24.5%)], or both [n = 68 (37.0%)]. Of these, 121 (65.8%) patients had single-corded tethers while 63 (34.2%) had double-corded tethers on at least one curve. No patient required allogenic blood transfusion. Six patients experienced major complications (3.3%), and six patients had minor complications (3.3%). Major complications included chylothoraces (n = 3), hemothoraces (n = 2), and lumbar radiculopathy secondary to screw placement requiring re-operation (n = 1). Rib resection was associated with a greater major complication rate than cases with no rib resection (13.6% versus 1.9%, respectively). Minor complications included respiratory distress requiring supplementary oxygen (n = 1), superficial wound infection (n = 1), prolonged nausea (n = 2), and Raynaud phenomenon (n = 1). The all-complication rate was 6.5%. The authors concluded that anterior VBT demonstrated some success. For select candidates, anterior VBT may be an appropriate treatment. However, complications may be more pulmonary in nature than those seen with PSF. Surgeons who perform anterior VBT should be cautious when using rib resection to optimize screw trajectory, as this was strongly associated with major complications. The findings of this study are limited by the retrospective, single-surgeon design, and small number.

Pehlivanoglu et al. (2021) conducted a retrospective cohort study comparing the clinical and functional outcomes of VBT and PSF in skeletally immature patients with AIS. The study included 43 patients divided into two separate treatment groups, VBT (n = 21) and PSF (n = 22). Patients in both groups had an age of 9 to 14 years, Risser ≤ 2, and Sanders ≤ 4. The mean follow-up duration for both groups was 39.4 months. The study results revealed the VBT group had main thoracic–thoracolumbar curves with an average pre-operative major curve magnitude of 48.2°, which was corrected to 9.1° at the last follow-up visit ($p < 0.001$). The PSF group had main thoracic–thoracolumbar curves with an average pre-operative major curve magnitude of 48.8°, which was corrected to 9.7° at the last follow-up visit ($p < 0.001$). The average lumbar range of motion (ROM) in flexion, extension, lateral bending, and rotation was significantly superior in the VBT Group ($p < 0.001$). The average lumbar anterior and lateral bending flexibility was significantly superior in the VBT Group ($p < 0.001$ and $p = 0.003$, respectively). The average flexor and extensor trunk endurance was significantly higher in the VBT group ($p < 0.001$). The average motor strength of the trunk extensor and anterior–lateral–oblique flexor muscles was significantly superior in the VBT group ($p = 0.003$). The average total SRS-22 score was significantly superior in the VBT group ($p < 0.001$). Average Short Form Health Survey (SF-36) scores were also significantly superior in the VBT group ($p < 0.001$ for the mental component summary and $p < 0.001$ for the physical component summary). The authors concluded that in skeletally immature patients with AIS, VBT yielded significantly superior lumbar ROM, lumbar anterior and lateral flexibility, trunk flexor–extensor endurance, and trunk motor strength as compared to patients who underwent PSF. SRS-22 and SF-36 scores also showed VBT provided better life quality and patient satisfaction than PSF. Spinal motion could be preserved and complications of fusion could be avoided with VBT. Limitations of the study include the single-center, retrospective design, small sample size, and lack of safety outcomes analysis. (This study is included in the review by Tsirikos et al., 2024, the review by Mariscal et al., 2023, and the Hayes 2021 evolving evidence review.)

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Shin et al. (2021) conducted a systematic review and meta-analysis comparing post-operative outcomes between patients with AIS undergoing PSF and anterior VBT. The primary objective was to compare complication and reoperation rates at available follow-up times. Secondary objectives included comparing mid-term SRS-22 scores, and coronal and sagittal-plane Cobb angle corrections. The study included 10 anterior VBT studies (211 patients) and 14 PSF studies (1,069 patients). The average age was 12.4 years for patients undergoing anterior VBT and 14.2 for PSF. Mean preoperative Risser scores were 0.4 for patients undergoing anterior VBT and 1.4 for PSF patients. The average follow-up for the anterior VBT studies was 33.7 months (range 14.4 to 49.5 months) and 46.9 months (range 21.2 to 86.4 months) for the PSF studies. A single-arm, random-effects meta-analysis was performed. The study results revealed pooled complication rates were 26% for anterior VBT versus 2% for PSF. Reoperation rates were 14.1% for anterior VBT versus 0.6% for PSF. The pooled reoperation rate among studies with follow-up times of ≥ 36 months was 24.7% for anterior VBT versus 1.8% for PSF. However, deformity correction, clinical outcomes, and mid-term SRS-22 scores were similar. The authors concluded that the study showed greater rates of complications and reoperations with anterior VBT compared with PSF. Reoperation rates were greater in anterior VBT studies with longer follow-up (≥ 36 months). Deformity correction, clinical outcomes, and mid-term SRS-22 scores were similar. Clinicians should consider anterior VBT with caution, despite its potential as a fusionless treatment for AIS. Patients should be counseled about the higher complication and reoperation rates and clinicians should employ a shared decision-making model. Longer-term, randomized, prospective studies are needed to compare anterior VBT and PSF outcomes. This meta-analysis is limited by the quality of the included studies. Nearly all of the anterior VBT studies were case series. (Publications by Newton et al., 2018, Sandami et al., 2015, and Samdani et al., 2014, which were previously cited in this policy, are included in this review.)

Clinical Practice Guidelines

British Scoliosis Society (BSS)

BSS published a position statement on VBT for scoliosis that notes there are no long-term results for this procedure. Though, early results in the U.S. and U.K. are promising. BSS recommended that VBT should be introduced in a controlled and responsible manner. BSS urged the National Institute for Health and Care Excellence to review VBT and for the National Health Service in England to develop a policy for introduction. Furthermore, the introduction of non-fusion instrumentation for scoliosis should be done in a small number of centers committed to careful patient selection and informed consent. These centers should use the British Spine Registry to monitor the results of VBT and any complications for many years before making a decision regarding wider adoption (BSS, 2016).

National Institute for Health and Care Excellence (NICE)

NICE interventional procedures guidance regarding VBT for idiopathic scoliosis in children and young people states that the evidence is limited, but raises concerns of serious complications. Additionally, the evidence on VBT efficacy is inadequate in quality and quantity. Therefore, VBT should only be used in the context of research. VBT research should include RCTs or analysis of registry data. Additionally, VBT should only be performed in specialist centers by spinal surgeons with specific training in anterior spinal surgery (NICE, 2022).

Pediatric Orthopaedic Society of North America (POSNA) and Scoliosis Research Society (SRS)

A joint position statement by POSNA and SRS on payor coverage for anterior fusionless scoliosis technologies for immature patients with idiopathic scoliosis states centers and surgeons across the U.S., Canada, and outside North America have reproduced clinical results demonstrating acceptable safety and efficacy of anterior VBT in skeletally immature patients. Payors should provide coverage for any FDA approved devices under the 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 the management of skeletally immature patients (Risser ≤ 2 or Sanders ≤ 5) with idiopathic scoliosis (30 to 65° 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, while accounting for the risks (including higher rate of reoperation), motion preserving benefits, individual needs, values, and perspectives. However, POSNA and SRS do not support the use or reimbursement for anterior non-fusion instrumentation in skeletally mature individuals for the management of scoliosis or other spinal deformities. There are no published scientific reports to support the use of VBT or other non-fusion anterior instrumentation in treating scoliosis in skeletally mature individuals (POSNA and SRS, 2020).

Scoliosis Research Society (SRS)

A position statement from SRS on VBT in idiopathic pediatric spinal deformity concludes that this treatment may be effective for some patients. However, the choice of treatment should involve a detailed discussion with the patient and their family. That discussion should include that the current scientific evidence for VBT does not show a significant,

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clinically relevant difference in outcomes compared to PSF. Additionally, an increased risk of revision surgery should be expected if VBT is chosen (SRS, 2023).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The Tether™ - Vertebral Body Tethering System (Zimmer Biomet Spine, Inc.) received FDA humanitarian device exemption (HDE) on August 16, 2019. The Tether 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° 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. Additional information (using product code QHP) is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm. (Accessed August 12, 2024)

The REFLECT™ Scoliosis Correction System (Globus Medical, Inc.) received FDA HDE on May 15, 2023. REFLECT is indicated for skeletally immature patients who require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, who have a major cobb angle of 30 to 65° and who have failed bracing and/or are intolerant to bracing. Additional information (using product code QHP) is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm. (Accessed August 12, 2024)

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Policy History/Revision Information

Date	Summary of Changes
11/01/2025	• Created state-specific policy version for the state of North Carolina (no change to coverage guidelines)
03/01/2025	**Applicable Codes** • Added CPT codes 0790T and 22838 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version CS170.I

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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