United Healthcare Community Plan

Vertebral Body Tethering for Scoliosis (for Tennessee Only)

Policy Number: CS170TN.I
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➲ Instructions for Use

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Related Policies
None

Application

This Medical Policy applies to Medicaid and CoverKids in the state of Tennessee.

Coverage Rationale

Vertebral body tethering (VBT) surgery may be medically necessary for idiopathic scoliosis when all the following criteria are met:

- The individual meets **all** the following clinical criteria:
  - There is physician documentation to establish failed conservative management (e.g., bracing, observation, or physical therapy) prior to the initial procedure with curvature progression to at least 45 degrees; and
  - The Cobb Angle of the major coronal curve is 45 to 65 degrees for the single curve planned for surgery and none of the spinal curves present are greater than 65 degrees; and
  - Skeletal immaturity is defined by the Sanders Maturity Score of 2 to 5; and
  - The Cobb Angle decreases in magnitude to 30 degrees or less on bending films; and
  - Osseous structure is dimensionally adequate to accommodate screw fixation; and
  - The VBT instrumentation does not extend above T4 or below L4

  and
- The facility where the surgical procedure will be performed has **all** the following:
  - An established, on-site surgical pediatric scoliosis program; and
  - Inpatient pediatric physical therapy is available for post-operative training; and
  - Intraoperative advanced imaging capability; and
  - A pediatric anesthesiologist on staff; and
  - A pediatric intensive care unit

  and
- The surgery will be performed by the pediatric orthopedic spine surgeon with experience in scoliosis and surgical procedures such as VBT and who has determined that the procedure is appropriate for the individual; and
- The pediatric orthopedic spine surgeon is listed as an investigator on a prospective research study being performed at the pediatric spine center that has an approved Institutional Review Board protocol that is actively recruiting participants for VBT utilizing The Tether™ Vertebral Body Tethering System, which has FDA approval under a Humanitarian Device Exemption and for which the member is a study cohort candidate; and

- The individual and family have engaged in a Shared Decision-Making conversation with the pediatric orthopedic spine surgeon

Revision surgery for VBT may be medically necessary when one or more of the following are present:
- Tether breakage or other hardware failure; or
- Under- or over-correction of curves; or
- Removal of tether and/or anchor screws for surgical complication (e.g., impingement on vital organs, infection, intractable pain)

VBT surgery is not medically necessary when the above criteria are not met.

Refer to the U.S. Food and Drug Administration (FDA) section for information regarding FDA labeling and Humanitarian Device Exemption for VBT.

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the services requested.

The patient's medical record must contain documentation that fully supports the medical necessity for the requested services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request.

Definitions

Cobb Angle: An objective, standard method to quantify the scoliosis angle based on measurements calculated from radiographs. The Cobb Angle method is preferred for its better reproducibility, easier application, and suitability for measuring more severe spinal curvature. The Scoliosis Research Society has adopted the Cobb Angle as a standard method for quantifying scoliosis deformities, and it remains the most commonly used method for assessing the curvature of the spine to date (Jin et al., 2022).

Lenke Classification System: An instrument used in adolescent idiopathic scoliosis that categorizes scoliosis based on the curve type (1-6), with a sagittal thoracic modifier (-, N, or +), and a lumbar spine modifier (A, B, C) to help surgeons determine which vertebral levels are appropriate for an arthrodesis. Curve types are based on vertebral location while the lumbar modifiers are used to describe the relationship between the central sacral vertical line and the lumbar curve apex, and the sagittal modifier describes the thoracic kyphosis (Slattery and Verma, 2018).

Institutional Review Board (IRB): An independent ethics committee responsible for reviewing, approving, and monitoring clinical research involving human participants. IRBs ensure that research complies with ethical principles and federal regulations, protecting study participants' rights, safety, and welfare [U.S. FDA and the Office for Human Research Protections (OHRP, February 2025)].

Sanders Skeletal Maturity Staging System: A method used to evaluate skeletal maturity through x-rays of the hand and wrist to assess ossification of the epiphyses of the wrist and hand bones. The staging system consists of eight levels with level 1 (slow growth in early adolescence) through level 8 indicating full skeletal maturity (Lenz et al., 2021).

Shared Decision-Making: A collaborative process in which a provider/clinician and a patient (including caregivers and family) work together to make healthcare decisions about what is best for the patient. The optimal decision considers evidence-based information about available options, the provider’s experience and knowledge, and the values, goals, preferences, and circumstances of the patient. This includes comparing the benefits, harms, and risks of each option and discussing what matters most to the patient (Agency for Healthcare Research and Quality, 2023).

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 curvatures 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. VBT uses vertebral body screws and other surgical hardware to secure flexible tensioning cords across the convex side of the spine. When the cords are 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 flexibility. 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 to address complications, including inadequate correction, overcorrection, or cord breakage.

Clinical Evidence

Scientific evidence for medical and surgical techniques in pediatric idiopathic scoliosis management has been evolving over recent years. Vertebral body tethering (VBT) is an example of a technique that may improve quality of life for selected children with progressive idiopathic scoliosis, by preserving spinal flexibility and allowing growth of the spine. This care is emerging as standard of care for a small number of patients meeting narrow clinical criteria. Idiopathic scoliosis, once it has progressed to 40-45 degrees, has a known progression of at least one degree per year with resultant severe curves (Weinstein and Ponseti, 1983). Complications such as ventilatory insufficiency, which are secondary to disease progression, can be mitigated with effective treatment (Raitio et al., 2022). The process of gathering evidence of intervention efficacy and effectiveness in these cases, overseen by an IRB approved clinical trial, is expected to generate knowledge on the surgical techniques, optimal patient selection, and innovations thereby advancing insight and the management of scoliosis (NIH, 2022; Natterson-Horowitz et al., 2023). Prominent guidelines support use of VBT in the controlled setting of clinical research, following careful patient selection, and when performed by spinal surgeons with specific, advanced training in anterior spinal surgery (British Scoliosis Society, 2016; NICE, 2022).

Bauer et al. (2025) conducted a multi-center, multi-surgeon, prospective study to compare thoracic curve correction after lumbar posterior spinal fusion (PSF) vs. lumbar anterior VBT for adolescent idiopathic scoliosis (AIS). Patients with Lenke 5 + 6 lumbar scoliosis who underwent VBT and at least two years' follow-up were compared to matched lumbar PSF patients. Groups were compared for major lumbar (L) and compensatory thoracic (T) curve correction, coronal/sagittal balance, and complications. Twenty-four VBT and 24 PSF patients were matched 1:1 for skeletal maturity and curve flexibility. There were no significant differences between VBT and PSF for average pre-operative or two-year postoperative major L or compensatory T curves. Average final L curve correction was 50% VBT and 60% PSF (p = 0.08); average T curve correction was 17% VBT and 20% PSF (p = 0.18). Compared to preoperative flexibility radiographs, the final post-op thoracic curves were 6° (VBT) and 5° (PSF) larger. PSF had better coronal balance by average of 17 mm (p < 0.0001). There were seven (24%) reoperations in the VBT group: two overcorrections relaxed, two T adding-on (extended to T by PSF-1, VBT-1), one broken tether converted to PSF. There was one (4%) reoperation in the PSF group (10-year post-op extension). The authors concluded that compensatory thoracic correction was achieved to a similar degree for lumbar VBT and PSF patients. There was little change in thoracic curve magnitude over time, and, on average, the correction did not reach the pre-operative flexibility curve measurement. There was better coronal balance by PSF, and a higher rate of re-operation in VBT patients. Limitations of this study include the lack of Sanders skeletal maturation staging score and limited sample size of the number of patients in the cohort that fit the inclusion criteria for two-year follow-up for lumbar VBT, as this is a newer procedure with limited patients available for two-year follow-up. The authors stated as more lumbar tethers are performed, this study can help guide expectations for correction amount of both lumbar and thoracic curves.

Stamiris et al. (2025) conducted a meta-analysis of VBT and posterior spinal fusion (PSF) to compare rates of curve correction, spinal alignment, trunk mobility, patient-reported outcomes, perioperative parameters, and complications. The analysis included 17 published studies (16 retrospective and one prospective RCT) with a total of 1549 patients, with 761 who underwent VBT and 788 who underwent PSF. The authors reported that significant lower postoperative major curves were noted in the PSF group in the eight studies that reported the major curve angle at the final follow-up while the three studies that reported outcomes on minor curve at the last follow-up showed that patients in the PSF group had lower postoperative minor curve in comparison to the VBT group. The authors also reported that, in the nine studies that reported major Cobb correction from baseline at last follow-up, those in the PSF group showed greater improvement. In a subgroup analysis of seven studies that reported percentage change from baseline and of five studies that reported absolute change from baseline, the authors reported that both outcomes remained significant in favor of PSF. Shoulder height difference was reported in four studies at final follow-up and was determined by the authors to show that the VBT group had lower post-operative shoulder asymmetry compared to the PSF group while coronal balance was reported at final follow-up in four studies to be better in the PSF group, although substantial heterogeneity was observed. Patient reported outcomes were reported in three studies and was found to show that those who underwent VBT achieved better scores in pain, satisfaction, and general function according to the authors. Trunk motion, lumbar flexion, side bending, and axial rotation were reported in three studies. According to the authors, pooled data showed greater lumbar flexion in the VBT group, whereas lumbar side bending and axial rotation were similar between both groups. The authors reported that their pooled analysis showed no difference between groups for length of stay (seven studies); however, estimated blood loss (seven studies) was significantly lower in the VBT group as was the operation time (eight studies), and the instrumented levels (nine studies). Complication rates were reported in eight studies at final follow-up and the analysis by the authors showed that the VBT group had a significantly higher complication rate compared to the PSF group as was the revision rate (10 studies). This meta-analysis had several limitations, including the retrospective design of all but one of the studies, the follow-up duration was limited to two years for most of the studies, the limited number of studies available for some of the outcomes analyzed and the heterogeneity among the included studies in terms of surgical techniques, follow-up duration, and outcome measures. The authors concluded that, while PSF demonstrates superior curve correction, coronal alignment, and lower complication and revision rates, VBT better preserved spinal motion, promoted better shoulder symmetry, required shorter instrumentation, reduced postoperative pain, and improved early postoperative function and quality of life. The authors recommended long-term studies be done to further elucidate the durability of VBT outcomes and to optimize surgical decision making in managing idiopathic scoliosis. The Newton et al. (2020), Pehlivanoglu et al. (2021), Siu et al. (2023) and Mathew et al. (2021) studies previously summarized in this policy were included in this meta-analysis.

Lott et al. (2025) conducted a nonrandomized clinical trial comparing anterior VBT to posterior spinal fusion (PSF) in terms of the following primary outcomes: (1) the proportion of patients whose main thoracic curve was corrected to < 50° without a return to the operating room for revision within two years, (2) residual thoracic and lumbar curve magnitude at two years, (3) health-related quality of life (HRQoL) scores, and (4) the frequency of serious complications and healthcare resource utilization. Participants (n = 87) were assessed for eligibility to participate in an FDA-approved investigational device exemption clinical trial for VBT based on presenting to the clinic with a diagnosis of adolescent idiopathic scoliosis that had entered surgical range. Based on clinical characteristics and the family's stated goals of care, VBT and PSF were both discussed, but ultimately the patient and their family selected their preferred treatment. Under guidance from the FDA, a sample of 20 individuals who met the inclusion criteria of a Lenke Type 1 or 2 curve classification, a thoracic curve between 35° and 60°, a lumbar curve < 35°, and a skeletal maturity score of either Risser 0 or Sanders bone age of ≤ 4 were eligible to participate in the trial and undergo VBT. Patients with Lenke 1 and 2 curves who elected to undergo PSF (n = 27) were prospectively analyzed for comparison. No patients who underwent VBT and 22% (n = 6) of those who underwent PSF were lost prior to the minimum study follow-up of two years, leaving 100% (20) and 78% (n = 21) in each group, respectively, for analysis. All patients in the PSF group who were lost to follow-up did not report any complications at one year. Patients who underwent VBT [80% (16) girls] were generally younger, more skeletally immature, and had smaller preoperative curvature at the time of surgery compared with patients who underwent PSF [81% (17) girls]. No differences in gender, height, or revised Scoliosis Research Society-22 (SRS-22) patient questionnaire scores were observed across the two groups at baseline. Participants in both cohorts were followed at the preoperative, first erect, and two-year time points. Radiographic, health-related quality of life, unplanned return to the operating room, complications, and healthcare resource utilization outcomes were compared. Scoliosis curves were reduced to < 50°, without unplanned return to the operating room, at two years in 70% (14 of 20) of participants who underwent VBT and 100% (21 of 21) of participants who had PSF ($p < 0.001$). No individuals who had PSF underwent revisions. Although both groups showed postoperative curve correction, participants who had VBT showed less curve correction at first erect (35% versus 65% correction; $p < 0.001$) and at two years (34% versus 61% correction; $p < 0.001$). No differences were found in any revised SRS-22 domains or total score at two years between the VBT and PSF groups (4.3 ±0.5 versus 4.5 ±0.4; $p = 0.14$). No instrumentation complications occurred in the PSF group. Thirty-five percent (7) of patients who received VBT experienced a tether rupture, and 30% (6) of patients who received a tether required a revision procedure prior to the two-year follow-up. Intraoperative data revealed that VBT resulted in a shorter length of stay (2 ±1 versus 3 ±1 days; $p = 0.02$) and fewer levels instrumented (7 ±1 versus 10 ±1 levels; $p < 0.001$); however, there was increased operative time when compared with PSF (231 ±41 versus 194 ±26 minutes; $p = 0.001$). The authors concluded that pediatric orthopedic spine surgeons should carefully consider discussing the use of vertebral body tethering with their patients who have adolescent idiopathic scoliosis, as this evidence points to the more established technique of PSF leading to better outcomes. Additional research supporting VBT as noninferior to PSF in radiographic and safety measures is needed before the procedure becomes widely available to patients and their families.

Al-Naseem et al. (2025) conducted meta-analysis of comparative studies to compare surgical outcomes between posterior spinal fusion (PSF) and VBT for adolescent idiopathic scoliosis (AIS). This systematic review was performed as per the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) Guidelines. A total of 11 comparative studies with 1112 individuals were included. PSF offered a greater percentage coronal curve correction postoperatively ($p = 0.0001$) and at two years ($p < 0.00001$). Time to revision ($p = 0.03$), number of instrumented levels ($p < 0.0001$), estimated blood loss (EBL) ($p = 0.001$), operation duration (OD) ($p < 0.00001$) and postoperative shoulder height difference ($p < 0.00001$) were greater in the PSF group. Odds of unplanned surgical revisions were lower in the PSF group ($p < 0.0001$). Secondary outcome data showed that VBT patients had lower preoperative cobb angles ($p < 0.00001$), a younger age at surgery ($p = 0.002$), less postoperative pain ($p = 0.002$), and lower opioid consumption ($p = 0.02$). VBT tether breakage events were reported at rates of 13-23%. VBT also offered a faster return to sports and greater lumbar flexibility. No significant difference was seen in the length of hospital stay ($p < 0.05$). The authors concluded that PSF and VBT are viable treatment options with different pros and cons. Choice of treatment should consider individual patient characteristics and daily requirements.

Larson et al. (2024) conducted a prospective U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) study (FDA IDE G18003) aimed to evaluate and report on two-year results including perioperative outcomes, radiographic progression, rates and causes of reoperation, and growth over the instrumented regions of the spine in patients with adolescent idiopathic scoliosis (AIS) treated with VBT. The purpose of this study was to obtain insight into outcomes and complications. Forty prospectively enrolled patients with AIS who had a Sanders score of ≤ 4 or a Risser score of ≤ 2 underwent VBT for curves between 40° and 70°. Surgical, radiographic, and patient-reported outcomes were reviewed at a minimum of two-year follow-up. The average age at surgery was 13 (range, 10 to 16) years. The 40 patients were 90% female; 95% White, 2.5% other, and 2.5% unreported; and 92.5% non-Hispanic, 5% Hispanic, and 2.5% unreported. A mean of 8 (range, 5 to 12) levels were instrumented. Most patients were at Sanders 4 (65%) and Risser 0 (63%). Mean length of stay was 3 ±1 days, estimated blood loss was 236 ±158 (range, 25 to 740) mL, and operative time was 4.4 ±1.4 hours. Mean correction of the major curve was 44% (range, 22% to 95%) on the three-month standing radiograph, 49% at one year, and 46% (range, -10% to 93%) at two years. The mean major Cobb angle improved from 51° ±8° (range, 40° to 70°) preoperatively to 27° ±11° (range, 3° to 56°) at two years. Success at two years, defined by a Cobb angle of < 35° and no reoperation, was seen in 30 patients (75%) and was associated with a mean Cobb angle of < 35° on the first postoperative standing radiograph ($p < 0.001$). Twelve patients (30%) demonstrated improvement in the curve with growth. By two years, two (5%) of the patients underwent repeat surgery (one release for overcorrection, one lumbar VBT for lumbar curve progression after thoracic VBT). The Scoliosis Research Society (SRS) satisfaction score improved two years following surgery ($p < 0.001$), but other SRS domains only remained stable over time. Beyond two years, one additional lumbar tether was required after thoracic VBT, one implant was removed, and three fusions were performed, for a 10% fusion rate and overall, 20% reoperation rate at a mean of 3.8 ±1.1 years of follow-up. The rate of cord breakage in the study population was 20%. The authors concluded in skeletally immature patients treated in the U.S. under a prospective Investigational Device Exemption; there was a 75% rate of successful outcomes at two years. Most correction was obtained at the time of surgery, and inadequate intraoperative curve correction was associated with a higher Cobb angle on the first postoperative standing radiograph and failure by two years. This study has limitations. The study sample size was limited. However, few studies have provided prospective data on patients treated with VBT. In summary, the authors went on to state that the best predictor of success in their cohort of skeletally immature children with a minimum two-year follow-up was a primary Cobb angle of < 35° on standing radiographs made at three months postoperatively, highlighting the need for a flexible preoperative curve (less than 30 to 35° on a fulcrum-bending radiograph) and optimizing surgical correction by aggressive intraoperative tensioning of the cord.

Hoernschemeyer et al. (2024) conducted a retrospective, single-center cohort study to evaluate mid-term outcomes in their first 31 consecutive patients who had undergone VBT. The authors assessed clinical and radiographic data including standard deformity measures, skeletal maturity status, and any additional complications. The mean lookback period was 68.4 ±8.2 months (range, 51.6 to 88.7 months) from the date of surgery. There were 29 patients (28 non-Hispanic White, 27 female) treated with VBT who returned for additional follow-up. Coronal deformity measures and sagittal deformity measures were assessed at all additional postoperative time points to identify changes in the magnitude of the deformity and to identify any additional complications, including suspected broken tethers and surgical revisions. The authors reported that the success rate dropped to 64% with longer follow-up as deformity measures increased with the largest deformity increases seen in the thoracolumbar curves. The authors also reported that the revision rate increased to 24% following two additional surgical revisions in patients who exhibited overcorrection and were skeletally immature at the time of instrumentation, and that four additional suspected broken tethers were identified (for a rate of 55%) with one occurring beyond four years. According to the authors, seven of the 16 patients with suspected broken tether were considered as having clinically successful treatment and no additional patients in the study group underwent PSF. There was a mean increase of 4° (range, 2° to 8°) in main thoracic deformity measures, and 8° (range, 6° to 12°) of mean increase in thoracolumbar deformity measures. The authors concluded that they observed a decrease in postoperative success as progression of the deformity was observed in most subgroups with an increase in the revision and suspected broken tether rates. The limitations of the study include the retrospective, single-center design, the lack of a comparison group, the homogeneity of the study population, and the small sample size.

Trobisch et al. (2024) conducted a retrospective analysis of a prospectively collected single center database of 290 patients who have had VBT for AIS. Patients for this study were included if they have had re-tethering after failed VBT and a minimum follow up of 24 months after index surgery as well as a minimum follow up of 12 months after revision surgery. Revision surgeries included tether exchange, tether reinforcement, and/or mono- and bi-segmental lateral fusion. Main outcome of interest was curve magnitude at latest follow up. Eleven patients were identified who received VBT for 16 curves of which 13 curves have had failed index surgery. Mean follow up from index surgery was 40 months, the time between index and revision surgery was 22 months, and latest follow up after revision surgery 19 months. Re-tethering resulted in an additional correction of 42% for thoracic and 63% for thoracolumbar curves. These results remained clinically stable with only minor loss of correction at final follow up. No patient underwent or was indicated for spinal fusion. The authors concluded that re-tethering is feasible and able to achieve additional correction and a sustainable result. This study does have several limitations, including a retrospective design and a low number of patients. However, it presents the first study to analyze the outcome after re-tethering and may facilitate patient communication and defining outcome expectations.

Photopoulos et al. (2024) conducted a radiographic evaluation of prospectively collected data from a multi-center, international pediatric spine registry to radiographically evaluate if VBT can maintain differential peri-apical vertebral growth at medium-term follow-up of four years. A prospective, international, multi-center database was queried to identify idiopathic scoliosis patients treated with thoracic VBT. Concave vs. convex vertebral body height, vertebral wedging, and disc wedging of the three peri-apical vertebrae were measured by two independent observers at five timepoints (pre-operative to four-year follow-up). Sixty-five skeletally immature patients (60 female, mean 12.8 years old, 21 with open triradiate cartilages) met inclusion criteria. Mean pre-operative maximum scoliosis of 50 ±8° decreased post-operatively to 27 ±9° ($p < 0.001$), which remained stable at four-year follow-up 30 ±17° ($p = 0.38$ vs. post-operative). Mean instrumented scoliosis was 21 ±14° at four-year follow-up, which was different than four-year maximum scoliosis ($p < 0.001$). Mean pre-operative kyphosis of 30 ±12° did not change post-operatively ($p = 1.0$) and remained stable at four-year follow-up (35 ±18°; $p = 0.05$). Mean individual convex vertebral height increased from 17.7 ±1.9 mm to 19.8 ±1.5 mm ($p < 0.001$), while mean individual concave height increased from 14.8 ±1.9 mm to 17.6 ±1.6 mm ($p < 0.001$). Summing the peri-apical heights, the difference in height from pre-operative to four-year follow-up was greater on the concave (8.3 ±4.7 mm) than on the convex side (6.2 ±4.7 mm) ($p < 0.001$). Mean individual vertebral wedging decreased from 6 ±2° at pre-operative to 4 ±2° at four-year follow-up ($p < 0.001$). Mean total vertebral and disc wedging started at 29 ±7° pre-operatively, decreased to 16 ±6° at postoperative ($p < 0.001$), then further decreased to 14 ±8° at four-year follow-up ($p < 0.001$). Patients with open triradiate cartilages at the time of surgery had a larger height change over the four years compared to those with closed triradiate cartilages ($p < 0.001$). The authors concluded that patients with idiopathic scoliosis treated with VBT demonstrated differential vertebral growth which was maintained at minimum four-year follow-up. This effect was more pronounced in patients whose triradiate cartilages were open at the time of surgery. Future studies should include assessment using other maturity indicators, including Sanders Maturity Scale, physiological maturity, and biomarkers. Those future studies may be able to identify if there is a subgroup where VBT is too late to be effective for growth modulation and there is only the effect of immediate correction.

Eaker et al. (2024) conducted a retrospective single-center review to investigate the outcomes of VBT for the treatment of thoracolumbar (TL) major AIS with a minimum two-year follow-up (FU). Inclusion criteria were AIS, Lenke 5/6 curvature, and skeletally immature Variables were compared using Student's t-tests, Wilcoxon rank sum tests, Chi-square, and Fisher's exact tests. A total of 37 consecutive individuals, age 14.1 ±1.6 years, 86.5% F, 35.9 ±11.5-month FU, were examined. Overall, 27 participants had Lenke 5 and 10 (73%), and Lenke 6 (27%) curvatures. Instrumentation of the TL curve alone was performed in 59.5%, and thoracic (T) and TL in 40.5% of patients. Overall, 45.9% of patients had two tethers placed in the TL spine; no patients had double tethers placed at the main thoracic curves. The TL (51 ±8◦ to 20 ±11◦; p < 0.0001) and T (37 ±13◦ to 17 ±10◦; p < 0.0001) curvatures improved from baseline to the latest FU. Overall, 89% of patients achieved major Cobb < 35◦; the three patients who did not, experienced at least one cord breakage or required posterior spinal fusion (PSF). T5-T12 kyphosis increased (p = 0.0401) and lumbar lordosis was maintained (p = 0.9236). Both the TL inclinometer (16 ±4º to 4 ±2◦; p < 0.0001) and T (6 ±4◦ to 4 ±3◦; p = 0.0036) measurements improved. There was a 49% tether breakage rate as follows: 60% for single-cord TL constructs and 35% for double cords (p = 0.0991). There was an 8.1% re-operation rate as follows: one conversion to T PSF and revision of the TL tether; one release of the T tether and revision of the TL tether; one screw revision for radiculopathy. One patient was re-admitted for poor pain control. The authors concluded that patients with TL major curvature treated with VBT experienced a high rate of clinically successful outcomes with maintenance of lumbar lordosis and relatively low complication rates at the latest FU. Large, multi-center series with comparison to the standard of care spinal fusion would potentially provide more generalizable information and provide an important comparison to the standard approach.

Lonner et al. (2024) retrospectively examined VBT and posterior spinal fusion (PSF) cohorts collected from a multi-center prospective AIS registry for patients treated with arthrodesis, and retrospective registry for those treated with VBT, aimed to compare radiographic outcomes between VBT and PSF in patients with double curvatures in which both curves were instrumented. Twenty-nine AIS patients matched by Lenke, age (±2 years), triradiate cartilage closure status, major Cobb angle (±8°), and T5–T12 kyphosis (±10°). Variables were compared using Wilcoxon rank-sum tests, Student's t tests, and chi-Square. Clinical success was defined as a major curve < 35°. Group baseline demographics were similar. Major thoracic (T) curve types had better major [VBT 51.5 ±7.9° to 31.6 ±12.0° (40%) vs. PSF 54.3 ±7.4° to 17.4 ±6.5° (68%); p = 0.0002] and secondary curve correction in the PSF group. 71% of major T VBT patients were clinically successful versus 100% of PSF. Major thoracolumbar (TL) curve types experienced comparable major [VBT 52.3 ±7.0° to 18.3 ±11.4° (65%) vs. PSF 53.0 ±5.2° to 23.8 ±10.9° (56%); p = 0.2397] and secondary curve correction. 92% of major TL VBT patients were clinically successful versus 75% in the PSF group. There was no difference in T5–12 kyphosis or lumbar lordosis between groups for any curve type. There were four patients (13.8%) with major complications in the VBT group compared to zero (0%) in the PSF. The authors concluded that patients with double major AIS who underwent VBT with major T curve types had less correction than PSF; however, those with major TL curves experienced similar radiographic outcomes regardless of procedure. Complications were greater for VBT. Limitations of this study include lack of long-term follow-up, lack of patient-reported outcome data, lack of Sanders scores skeletal maturity assessment, inability to match cohorts based on skeletal maturity due to relatively small cohorts, use of both single and double row tether constructs in the lumbar spine, and subtle differences in indications for VBT vs PSF and technique for both procedures across sites. Longer-term follow-up is needed to determine the clinical success of VBT in comparison to PSF as it is a growth modulation technique and the longevity of the cords, health of instrumented and non-instrumented motion segments and thus, durability of outcomes is still under consideration.

Alasadi et al. (2024) conducted a systematic literature review of VBT for the treatment of AIS in relation to radiographic and clinical outcomes, complications, and learning curve. The review included 26 studies that reported the minimum two-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 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. This study was included in the Hayes 2022, updated 2025 evolving evidence 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 that 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. 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 update for their evolving evidence review of The Tether™ - Vertebral Body Tethering System (Zimmer Biomet Spine, Inc.) for skeletally immature patients with progressive idiopathic scoliosis which identified 17 newly published clinical trials (one propensity score-matched comparison, two prospective cohort studies, and 14 retrospective studies that included six studies with comparators), 14 systematic reviews (five with meta-analyses), and two guidelines that may meet their inclusion criteria set out in their initial report. In their annual review, Hayes reviewed only the abstracts of these published articles and concluded that they were unlikely to change their position of minimal support based on the clinical trials and systematic reviews and that they would not change their no/unclear level of support based on their review of the two clinical practice guideline abstracts. Their initial 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-post test 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 three 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. The Alasadi et al. (2024), Raitio et al. (2022) and Zhu et al. (2022) studies summarized in this policy were included in the 2025 update (Hayes, 2022; updated 2025).

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 two 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-operative 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 towards 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 (three replacements) or overcorrection (one 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.

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 two and up to three 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 that 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; updated 2024 evolving evidence review.)

Wong et al. (2023) performed a systematic review to compare the range of motion (ROM) outcomes between anterior VBT and PSF in treating AIS. Inclusion criteria were patients with AIS treated with VBT or PSF or both, and clearly defined ROM outcomes; exclusion criteria were scoliosis other than AIS, biomechanical or cadaveric studies, non-English publications, case reports, conference summaries, unpublished literature, commentaries, and reviews. Primary outcome was ROM. Secondary outcomes included Cobb angle correction, quality of life (QOL), complications, muscle strength, and endurance. Twelve studies were included in this review. The authors found moderate evidence to support that VBT results in superior ROM outcomes than PSF while achieving comparable Cobb angle correction with low evidence. The comparison of QOL outcomes between VBT and PSF remained inconclusive. In addition to the complications noted conventionally in PSF, VBT could result in over-correction and distal adding-on. The authors also found very low evidence to support that AIS patients treated with VBT have superior muscle strength and endurance when compared to those treated with PSF. The authors concluded that VBT provides better preservation of ROM and muscle strength postoperatively when compared with PSF, while achieving comparable curve correction. Future studies should explore the spinal growth trajectory to determine the window of opportunity for VBT in AIS.

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 the 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 in reducing 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 also included in the Hayes 2022; updated 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; updated 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. 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 one week, two weeks, and six weeks after surgery. The study results revealed decreased pain scores at two and six 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 two and six 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 two-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 two-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 two-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 two-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 two 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 percentage 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 average loss of correction of 5° (range -2 to 34°). The authors concluded that 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 meta-analysis. The study results revealed VBT displayed a statistical reduction in Cobb angle from pre-operative to final (minimum two 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 two 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 are 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).

Newton et al. (2022) conducted a retrospective comparison study utilizing a large, multicenter database and propensity matching to compare outcomes of anterior VBT to PSF in patients with idiopathic scoliosis. Patients with thoracic idiopathic scoliosis who underwent VBT with a minimum two-year follow-up retrospectively underwent two methods of propensity-guided matching to PSF patients from an idiopathic scoliosis registry. Radiographic, clinical, and Scoliosis Research Society 22-Item Questionnaire (SRS-22) data were compared preoperatively and at the ≥ two-year follow-up. A total of 237 VBT patients were matched with 237 PSF patients. In the VBT group, the mean age was 12.1 ±1.6 years, the mean follow-up was 2.2 ±0.5 years, 84% of patients were female, and 79% of patients had a Risser sign of 0 or 1, compared with 13.4 ±1.4 years, 2.3 ±0.5 years, 84% female, and 43% Risser 0 or 1 in the PSF group. The VBT group was younger ($p < 0.001$), had a smaller mean thoracic curve preoperatively (48 ±9°; range, 30° to 74°; compared with 53 ±8°; range, 40° to 78° in the PSF group; $p < 0.001$), and had less initial correction (41% ±16% correction to 28° ±9° compared with 70% ±11% correction to 16° ±6° in the PSF group; $p < 0.001$). Thoracic deformity at the time of the latest follow-up was 27° ±12° (range, 1° to 61°) for VBT compared with 20° ±7° (range, 3° to 42°) for PSF ($p < 0.001$). A total of 76% of VBT patients had a thoracic curve of < 35° at the latest follow-up compared with 97.4% of PSF patients ($p < 0.001$). A residual curve of > 50° was present in seven VBT patients (3%), three of whom underwent subsequent PSF, and in zero PSF patients (0%). Forty-six subsequent procedures were performed in 38 VBT patients (16%), including 17 conversions to PSF and 16 revisions for excessive correction, compared with four revision procedures in three PSF patients (1.3%; $p < 0.01$). VBT patients had lower median preoperative SRS-22 mental-health component scores ($p < 0.01$) and less improvement in the pain and self-image scores between preoperatively and the ≥ two-year follow-up ($p < 0.05$). In the more strictly matched analysis (n = 108 each), 10% of patients in the VBT group and 2% of patients in the PSF group required a subsequent surgical procedure. The authors concluded that at a mean follow-up of 2.2 years, 76% of thoracic idiopathic scoliosis patients who underwent VBT had a residual curve of < 35° compared with 97.4% of patients who underwent PSF. A total of 16% of cases in the VBT group required a subsequent surgical procedure compared with 1.3% in the PSF group. An additional four cases (1.3%) in the VBT group had a residual curve of > 50° that may require revision or conversion to PSF. There were several limitations to this study. Although data for the PSF cohort were collected prospectively, those for the VBT cohort were collected retrospectively, and thus the impact of patients lost to follow-up was unknown. Not all relevant factors could be captured in this retrospective series, such as the impact on pulmonary function, and SRS-22 questionnaires were not routinely collected at some VBT sites. The differences in the unrestricted matching highlight the real challenges of such a comparison, as VBT patients tended to be younger and have smaller curves. Although the study follow-up was ≥ two years, not all patients had reached skeletal maturity at the end of the follow-up. Longer follow-up is absolutely required, particularly as tether failure had been identified in nearly 20% of patients at the time of the latest follow-up. Longer follow-up series have reported rates of tether failure approaching 50%. Tether breakage in patients beyond skeletal maturity may have little impact if substantial growth modulation has occurred, whereas tether failure in those prior to skeletal maturity may allow substantial curve progression.

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 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 three-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 require 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; updated 2024 and 2025 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 two 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 two-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; updated 2024 and 2025 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 two to five years when applied to adolescents after peak height velocity. The study included 49 consecutive patients with AIS treated by a single surgeon, a minimum two-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 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 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, the 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; updated 2024 evolving evidence review.)

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 three-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 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 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.

Lenz et al. (2021) conducted a systematic review to identify the most contributing patient-specific and radiological risk factors and their influence on curve progression in idiopathic scoliosis. A systematic literature search was conducted in the common databases. The identified and analyzed factors of each study were rated to design a top five scale of the most relevant factors. Twenty-eight investigations with 8255 patients were identified by literature search. Patient-specific risk factors for curve progression from the initial curve were age (at diagnosis < 13 years), family history, bone mineral status [< 110 mg/cm³ in quantitative computed tomography (CT)] and height velocity (7-8 cm/year, peak 11.6 ±1.4 years). Relevant radiological criteria indicating curve progression included skeletal maturity, marked by Risser stages (Risser < 1) or Sanders Maturity Scale (SMS < 5), the initial extent of the Cobb angle (> 25° progression) and curve location (thoracic single or double curve). The authors concluded that this systematic review summarized the current state of knowledge as the basis for creation of patient-specific algorithms regarding a risk calculation for a progressive scoliotic deformity. At an individual's initial presentation, prediction of further curve progression is key in managing therapy. Curve magnitude is the most relevant predictive factor, followed by status of skeletal maturity and curve location. An algorithm for risk analysis of curve progression would serve as a great support for patients and their families.

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 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.

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, 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 5, 2025)

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Policy History/Revision Information

<table>
<tr><th>Date</th><th>Summary of Changes</th></tr>
<tr><td>05/01/2026</td><td>
Coverage Rationale

Revised language to indicate:

Vertebral body tethering (VBT) surgery may be medically necessary for idiopathic scoliosis when all the following criteria are met:

The individual meets all the following clinical criteria:

There is physician documentation to establish failed conservative management (e.g., bracing, observation, or physical therapy) prior to the initial procedure with curvature progression to at least 45 degrees
The Cobb Angle of the major coronal curve is 45 to 65 degrees for the single curve planned for surgery and none of the spinal curves present are greater than 65 degrees
Skeletal immaturity is defined by the Sanders Maturity Score of 2 to 5
The Cobb Angle decreases in magnitude to 30 degrees or less on bending films
Osseous structure is dimensionally adequate to accommodate screw fixation
The VBT instrumentation does not extend above T4 or below L4

The facility where the surgical procedure will be performed has all the following:

An established, on-site surgical pediatric scoliosis program
Inpatient pediatric physical therapy is available for post-operative training
Intraoperative advanced imaging capability
A pediatric anesthesiologist on staff
A pediatric intensive care unit

The surgery will be performed by the pediatric orthopedic spine surgeon with experience in scoliosis and surgical procedures such as VBT and who has determined that the procedure is appropriate for the individual
The pediatric orthopedic spine surgeon is listed as an investigator on a prospective research study being performed at the pediatric spine center that has an approved Institutional Review Board protocol that is actively recruiting participants for VBT utilizing The Tether™ Vertebral Body Tethering System, which has FDA approval under a Humanitarian Device Exemption and for which the member is a study cohort candidate
The individual and family have engaged in a Shared Decision-Making conversation with the pediatric orthopedic spine surgeon

Revision surgery for VBT may be medically necessary when one or more of the following are present:

Tether breakage or other hardware failure
Under- or over-correction of curves
Removal of tether and/or anchor screws for surgical complication (e.g., impingement on vital organs, infection, intractable pain)

VBT surgery is not medically necessary when the above criteria are not met
Refer to the U.S. Food and Drug Administration (FDA) section [of the policy] for information regarding FDA labeling and Humanitarian Device Exemption for VBT

Medical Records Documentation Used for Reviews

Added language to indicate:

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service
Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested
The patient's medical record must contain documentation that fully supports the medical necessity for the requested services
This documentation includes but is not limited to relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures
Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request

Definitions

Added definition of:

Cobb Angle

</td></tr>
</table>

Date	Summary of Changes
	◦ Lenke Classification System ◦ Institutional Review Board (IRB) ◦ Sanders Skeletal Maturity Staging System ◦ Shared Decision-Making **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version CS170TN.H

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, 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.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.