Vertebral Body Tethering for Scoliosis

Guideline Number: MMG168.F
Effective Date: January 1, 2024

Instructions for Use

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Related Policies
None

Coverage Rationale

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

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline 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 the member specific benefit plan document 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
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
22899	Unlisted procedure, spine

Description of Services

Scoliosis is an abnormal lateral and rotational curvature of the vertebral column. Adolescent idiopathic scoliosis (AIS) is the most common form of idiopathic scoliosis, defined by the U.S. Preventive Services Task Force as “a lateral curvature of the spine with onset at ≥10 years of age, no underlying etiology, and risk for progression during puberty.” This type of scoliosis is referred to as idiopathic because it has no identifiable causes, but clinicians suspect that asymmetric growth, genetic variation,

hormonal imbalance, and/or muscle imbalance, might be involved. Progression of the curvature during periods of rapid growth can result in deformity, accompanied by cardiopulmonary complications.

Fusion less surgical procedures, such as vertebral body tethering, are being evaluated as alternatives to spinal fusion or bracing. The goal of these procedures is to reduce the rate of spine growth unilaterally, thus allowing the other side of the spine to "catch up." Anterolateral tethering uses polyethylene ligaments that are attached to the convex side of the vertebral bodies by pedicle screws or staples. The ligament can be tightened to provide greater tension than the staple. The vertebral Body Tethering System is indicated for skeletally immature patients that require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis. The mechanism of action is believed to be down-regulation of the growth plate on the convex (outer) side by compression and stimulation of growth on the endplate of the concave side by distraction. Patients should have failed bracing and/or be intolerant to brace wear.

Clinical Evidence

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

Raitio et al. (2022) performed a systematic review to evaluate the results and complications of vertebral body tethering (VBT) to correct idiopathic scoliosis using an anterior approach, spinal instrumentation with vertebral body screws, and a cable compressing the convexity of the curve. A comprehensive search of the published literature in PubMed and EMBASE databases was performed based on PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines using 'vertebral body tethering' as a keyword. All articles reporting a minimum of one-year follow-up results of AVBT published up to February 28, 2022, were included. Non-English language papers, animal studies, and case reports (< 3 patients) were excluded. In a total of 23 included studies on 843 patients, the pre-operative main thoracic curve corrected from 49 to 23 degrees in a minimum 2-year follow-up. The complication rate of VBT was 18%. The results showed that 15% of VBT patients required reoperations for pulmonary or tether-related issues (10%) and 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. There were limitations to this review including no randomized controlled clinical trials or prospective follow-up studies comparing the outcomes of AVBT and segmental pedicle screw instrumentation. There are no evidence-based recommendations on which to treat patients with instrumented spinal fusion and to use AVBT. Further research with randomized controlled trials is needed to validate these findings.

Bernard et al. (2022) conducted a retrospective analysis of clinical and radiological data of 20 patients aged between 9 and 17 years old, (with a 19 female: 1 male ratio) between January 2014 to December 2016 with a mean five-year follow-up (4 to 7). The aim of this study was to evaluate the radiological results of patients treated with vertebral body tethering (VBT) in two distinct groups of skeletal maturity and determine if this as a safe technique to obviate fusion in the treatment of carefully selected patients with idiopathic scoliosis. There were ten patients in each group with a total of 23 curves operated on. Vertebral body tethering-growth modulation (VBT-GM) mean age was 12.5 years (9 to 14) with a mean Risser classification of 0.63 (0 to 2) and vertebral body tethering-anterior scoliosis correction (VBT-ASC) was 14.9 years (13 to 17) with a mean Risser classification of 3.66 (3 to 5). Mean preoperative VBT-GM Cobb was 47.4° (40° to 58°) with a Fulcrum unbend of 17.4 (1° to 41°), compared to VBT-ASC 56.5° (40° to 79°) with 30.6 (2° to 69°) unbend. Postoperative VBT-GM was 20.3° and VBT-ASC Cobb angle was 11.2°. The early postoperative correction rate was 54.3% versus 81% whereas Fulcrum Bending Correction Index (FBCI) was 93.1% vs 146.6%. The last Cobb angle on radiograph at mean five years' follow-up was 19.4° (VBT-GM) and 16.5° (VBT-ASC). Patients with open triradiate cartilage (TRC) had three over-corrections. Overall, 5% of patients required fusion. This one patient alone had an over-correction, a second-stage tether release, and final conversion to fusion. In conclusion, the authors noted a high success rate (95%) in helping children avoid fusion at five years post-surgery. VBT is a safe technique for correction of scoliosis in the skeletally immature patient. The authors stated this is the first report at five years that shows two methods of VBT can be employed depending on the skeletal maturity of the patient: GM and ASC. This study is limited by its retrospective observations and due to a heterogeneous patient population.

A systematic review was performed by Bizzoca et al. (2022) to summarize current evidence about the efficacy and safety of anterior vertebral body tethering (AVBT) in the management of idiopathic scoliosis (IS) in skeletally immature patients. Ovid

Medline, Embase, Cochrane Library, Scopus, Web of Science, Google Scholar and PubMed were searched to identify relevant studies from January 2014 to January 2021. The methodological quality of the studies was evaluated, and relevant data were extracted. Seven clinical trials recruiting 163 patients were included in the review. Five studies out of seven were classified as high quality, whereas the remaining two studies were classified as moderate quality. A total of 151 of 163 AVBT procedures were performed in the thoracic spine, and the remaining 12 tethering in the lumbar spine. Only 117 of 163 (71.8%) patients had a nonprogressive curve at skeletal maturity. A postoperative complication rate of 17.8% was observed, and 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 posterior spinal fusion (PSF) was performed in 18 of 163 (11%) patients. The authors concluded that AVBT is a promising growth-friendly technique for treatment of IS in growing patients. The authors also stated that AVBT has moderate success as well as perioperative complications, revision and conversion to PSF. The main limitation of the present study was the low level of evidence of the included studies since no randomized clinical trials have been published on AVBT. Further research with randomized controlled trials is needed to validate these findings (authors Miyangi et al. (2020) who were previously cited in this policy are included in this review).

Meyers et al. (2022) performed a retrospective study to evaluate the 2–5-year clinical outcomes of vertebral body tethering (VBT), performed by a single surgeon, applied to adolescents after peak height velocity. A review of Risser 3–5 adolescent idiopathic scoliosis (AIS) patients treated with VBT, and minimum 2-year follow-up (FU) was performed. Pre to post op changes in clinical outcomes were compared using Student's t-test or the Mann-Whitney test. A total of 49 patients met criteria, age 15.0 ± 1.9 years, FU 32.5 ± 9.1 months. For thoracic (T) major curvatures, T curvature improved from 51.1 ± 6.9◦to 27.2◦ ± 8.1◦ ($p < 0.01$) and TL from 37.2◦ ± 10.7◦to 19.2◦ ± 6.8◦ ($p < 0.01$). For thoracolumbar (TL) major curvatures, T improved from 37.2◦ ± 10.7◦to 18.8◦ ± 9.4◦ ($p < 0.01$) and TL from 49.0◦ ± 6.4◦to 20.1◦ ± 8.5◦ ($p < 0.01$). Major curve inclinometer measurements and SRS-22 domains, except activity, improved significantly ($p \leq 0.05$). At the latest FU, one (2%) patient required fusion of the T curve and revision of the TL tether due to curve progression in the previously un-instrumented T curve and tether breakage (TB) in the TL. Twenty (41%) patients experienced TB. VBT in AIS patients with limited remaining skeletal growth resulted in satisfactory clinical outcomes at the latest FU. The authors concluded while the VBT procedure is currently indicated for skeletally immature patients for whom growth modulation occurs via the Hueter-Volkmann principle, they provided preliminary data for its use in patients past their peak height velocity. Limitations of this study 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 not sufficient to stratify outcomes based on Risser stage 3, 4, or 5. Future study is required to better elucidate predictors of clinical success in VBT for skeletally mature patients. In addition, the sub-analysis was limited due to the sample size of those who were unsuccessful, however best results were seen in smaller and more flexible curves.

A Hayes evolving evidence review on The Tether (Zimmer Biomet) for skeletally immature patients with progressive idiopathic scoliosis was published on April 7, 2022. This review states that the evidence base comprises very poor-quality, single-arm studies that retrospectively examine pretest-posttest data. While this evidence reports corrections in abnormal spinal angles, comparative evidence is extremely limited for VBT versus standard care (posterior spinal fusion [PSF]) and alternative treatments, such as growing rods. Healthcare guardians and clinicians need to carefully weigh the potential risks against the potential benefits before using The Tether due to a lack of longer-term clinical and safety data beyond 3 years post-index surgery. Hayes authors conclude that based on a review of full-text clinical practice guidelines and position statements, guidance appears to confer no/unclear support for use The Tether VBT system for correcting spinal curvature in skeletally immature patients with progressive idiopathic scoliosis.

Baroncini et al. (2021) performed a retrospective review to determine the relevance of dynamic scoliosis correction (known as vertebral body tethering (VBT) in the United States) via bilateral anterior thoracic approach and instrumentation of the spine, for treatment of scoliosis in pediatric patients who are still growing. The study included the first 25 pediatric patients with double-curve scoliosis, whom the authors performed the VBT procedure on beginning June 2017. Due to a lack of complete perioperative data and variations in postoperative care, the authors performed 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 ($P < .05$). 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 pulmonary embolism without

cardiopulmonary consequences. Another patient developed pleural effusion at 6-weeks post-surgery outside of the 30-day interval. Patients whose symptoms began after discharge (4) required hospitalization. Those with recurrent pleural effusions required invasive treatment including reinsertion of chest tube (2), and explorative thoracoscopy with reinsertion of chest tube (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 = .02), surgical time (first 12 patients = 328 minutes, next 13 patients = 280 minutes, P = .03), and blood loss (first 12 patients = 480 mL, next 13 patients = 197 mL, P = .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 = .01). The authors conclude that the study adds important information to the orthopedic literature showing that the procedure is feasible and does not require staging, however, complication rates are high. Additional research is required to understand root causes of the reported complications. In addition, the study is limited by its retrospective observations and small sample size. Further research with randomized controlled trials is needed before clinical usefulness of this procedure is proven.

Hayes (2021) conducted a literature review of clinical evidence for vertebral body tethering (VBT) for Progressive Pediatric and Adolescent Idiopathic Scoliosis (AIS). The review consisted of full-text clinical studies. No systematic reviews were identified. The authors concluded that VBT appears to give benefits for some patients, however, the currently available evidence is of low quality and limited to small observational studies. Additional evidence is needed to evaluate comparative efficacy and safety and to guide patient selection. Although the FDA approved a Humanitarian Device Exemption (HDE) in 2019, an ECRI Product Brief (2019, 2021) reached similar conclusions, stating that evidence is inconclusive with too few data on outcomes of interest.

Hegde et al. (2021) conducted a prospective study to evaluate the safety and efficacy of anterior vertebral body tethering (AVBT) in skeletally mature children with adolescent idiopathic scoliosis (AIS). The study included 10 patients with AIS who were operated on between 2018 and 2019 with the AVBT technique. There was a minimum of 1-year follow-up. inclusion criteria for the study were skeletally mature children (Risser < 4 and Sanders > 7) with a single structural AIS curve (40 - 80) with >50% flexibility on dynamic radiographs. To be eligible for AVBT, the curve should correct to >50% on dynamic radiographs. Data were recorded pre-operatively and post-operatively at the first visit, at 6 months, and at 12 months. All 10 patients were female. The mean age of the cohort at the time of surgery was 14.9 ± 2.7 years (range 12–17 years). The mean follow-up period was 24.1 ± 3.6 months (range 13 to 32 months). The mean height and weight values of the cohort were 157 cm and 44.4 kg, respectively. The mean body mass index was 18.04 kg/m2 . Mean Risser and Sanders scores were 4.2 ± 0.6 and 7.2 ± 0.6, respectively. Nine out of 10 patients were post-menarche at the time of surgery. Three patients had major thoracic curves, and 7 patients had major thoracolumbar/lumbar curves. Mean pre-operative Cobb angle was 52.08 ± 11.68 (range 428 to 808). All underwent tethering with a mean of 7 ± 0.9 (range 6–9) levels with the upper instrumented vertebra being T5 and the lower instrumented vertebra being L4. The mean Cobb angle at the final follow-up was 15.38 ± 8.78 (range 38 to 288). There was a 71% correction (P < .0001). The mean pre-operative thoracic kyphosis was 21.78, which decreased to 15.58 on first erect and then gradually increased to 20.38 at the most recent follow-up (P < .0001). The mean pre-operative lumbar lordosis was 45.48, which reduced to 43.38 on first erect and increased to 47.58 at the most recent follow up (P < .0001). Mean pre-operative and post-operative SRS-22 scores were 78.0 ± 3.2 and 92.5 ± 3.1, respectively. The authors conclude that AVBT is a promising alternative to spinal fusion to stabilize progressive AIS, however, the small sample size and lack of a comparison group limit the generalizability of the findings. The significance of this study is limited by the small sample size and short follow-up. Well-designed studies with larger patient populations are needed to further describe safety and long-term clinical outcomes.

Meyers et al. (2021) conducted a retrospective analysis of 90-day complication rates in patients with adolescent idiopathic scoliosis (AIS) who underwent anterior vertebral body tethering (AVBT) by a single surgeon. The study included 184 patients. Approaches included thoracic (71), thoracolumbar (45), and double (68). Of the 184 consecutive AVBT cases, 143 (77.7%) were female and 41 (22.3%) were male. The mean age at surgery was 15.0 ± 2.4 years and differed between males (16.1 ± 1.9) and females (14.7 ± 2.4, p = 0.001). The mean pre-operative Cobb angle was 54.3 ± 10.5 and was similar between genders (p = 0.06). There were 22 (12.0%) patients who had a rib resection and the mean number of ribs resected was 2.5 ± 1.2. Mean operative time was 186.5 ± 60.3 min and mean estimated blood loss (EBL) was 167.2 ± 105.0 mL. No patient received an allogenic blood transfusion. Patients received either a thoracic tether (71 [38.6%]), thoracolumbar tether (45 [24.5%]), or both (68 [37.0%]) and of these, 121 (65.8%) had single-corded tethers while 63 (34.2%) had double-corded tethers on at least one curve. Major complications included hospital re-admission or re-operation, prolonged use of invasive materials such as chest tubes, or resultant spinal cord or nerve root injury. Minor complications resolved without invasive intervention. Mean operative time and blood loss were 186.5 ± 60.3 min and 167.2 ± 105.0 ml, respectively. No patient required allogenic blood transfusion. 6 patients experienced major (3.3%), and 6 had minor complications (3.3%). Major complications included 3 chylothoraces, 2 hemothoraces, and 1 lumbar radiculopathy secondary to screw placement requiring re-operation. Minor complications included

1 patient with respiratory distress requiring supplementary oxygen, 1 superficial wound infection, 2 cases of prolonged nausea, and 1 Raynaud phenomenon. In 184 patients who underwent AVBT for AIS, major and minor complication rates were both 3.3%. While the authors concluded that AVBT demonstrated some success, complications may be more pulmonary in nature than those seen with spinal fusion. The authors also note that surgeons who perform AVBT should be cautious when using rib resection to optimize screw trajectory due to related major complications. The findings of this study need to be validated by well-designed studies with multiple providers. Further investigation is needed. Therefore, no conclusions can be made regarding the relative efficacy, effectiveness, or safety of treatment.

Pehlivanoglu et al. (2021) conducted a retrospective cohort study comparing the effectiveness of vertebral body tethering (VBT) and posterior spinal fusion (PSF) in skeletally immature patients with adolescent idiopathic scoliosis (AIS). The study included 43 patients divided into two separate groups: 1) VBT (n = 21); and 2) PSF (n = 22). The mean follow-up duration for both groups was 39.4 months. Major curve magnitude (degrees) revealed pre-operative VBT = 48.2; and PSF = 48.8 (P = NR) [NR = Not Reported]. Last follow-up: VBT – 9.1; and PSF = 9.7 (P=NR). Coronal balance revealed pre-operative VBT = 1.9; and PSF = 1.8 (P=NR). Last follow-up VBT = 0.8; and PSF = 0.3 (P=NR). Sagittal balance revealed pre-operative VBT = 1.2; and PSF = 1.0 (P=NR). Last follow-up VBT = 0.4; and PSF = 0.3 (P=NR). Lumbar range of motion (ROM) (degrees) revealed Flexion VBT = 78.2; and PSF = 58.1 (P < 0.001), Extension VBT = 34.6; and PSF = 19.4 (P < 0.001), Lateral Bend VBT = 34.4; and PSF = 18.3 (P < 0.001), and Rotation VBT = 45.4; and PSF = 24.1 (P < 0.001). Average lumbar bending flexibility (cm) revealed Anterior VBT = 3.7; and PSF = 23.4 (P < 0.001). Lateral VBT = 22.4; and PSF = 11.3 (P = 0.003). Average trunk endurance (seconds) revealed Flexor VBT = 65.1; and PSF = 19.2 (P < 0.001). Extensor VBT = 60.8; and PSF = 28.7 (P < 0.001). SRS-22 total score pre-operative VBT = 3.2; and PSF 3.2 (P = NS) [NS = Not Statistically Significant]. Last follow-up VBT – 56.9; and PSF = 53.1 (P < 0.001). Complications were not reported. The authors concluded that this study is first-time literature being presented. They suggest that lumbar ROM was greater among VBT patients compared with PSF patients with mean follow-up of 39.4 months. In addition, they note QOL scores being higher following VBT versus PSF. Strengths include PSF comparison group with between group statistical comparison. Limitations, however, include retrospective design, small sample size, and both analysis for curve magnitude and safety outcomes were not reported. Additional studies with larger study populations are needed to further establish the efficacy and safety of this procedure.

Rushton et al. (2021) performed a prospective case study to determine the efficacy of anterior vertebral body tethering (AVBT) in skeletally immature patients. The study included 112 patients, who underwent 116 primary tethering procedures (108 thoracic and 8 lumbar tethers). Four patients had primary tethering of both lumbar and thoracic curves. At surgery the mean age was 12.7 ± 1.4 years (8.2-16.7) and Risser 0.5 ± 0.9 (0 - 3). Follow up mean was 37 ± 9 months (15 - 64). Preoperative mean coronal Cobb angle of the 130 tethered curves was 50.8 ± 10.2 (31-81) and corrected significantly to 26.6 ± 10.1 (-3 - 61) at FE radiograph (P < 0.001). Further significant improvement was seen from FE to 1-year, to mean 23.1 ± 12.4 (-37 - 57) (P < 0.001). There was a small but significant increase between 1-year and FU to 25.7 ± 16.3 (-32-58) (P < 0.001), which appeared to reflect tether breakage. Untethered minor curves were corrected from 31.0 ± 9.5 (3-57) to 20.3 ± 10.3 (0 - 52) at FU (P < 0.001). Rib hump was corrected from 14.1 ± 4.8 (0-26) to 8.8 ± 5.4 (0 - 22) at FU (P < 0.01). Twenty-five patients (22%) had 28 complications. Fifteen patients (13%) requiring 18 revision operations including six completed and one awaited fusion(s). The authors concluded that AVBT of immature cases is associated with satisfactory deformity correction in most cases. However, the authors note that complication and revision rates suggest the need for improved implants and patient selection. The value of AVBT is currently unclear given the paucity of available data. Long-term evaluations of the results and prospective randomized studies are still needed.

Shin et al. (2021) conducted meta-analysis and systematic review comparing post-operative outcomes between patients with adolescent idiopathic scoliosis (AIS) undergoing posterior spinal fusion (PSF) and anterior vertebral body tethering (AVBT). The primary objective was to compare complication and reoperation rates at available follow-up times. Secondary objectives included comparing mid-term Scoliosis Research Society (SRS) - 22 scores, and coronal and sagittal-plane Cobb angle corrections. Systematic review of outcome studies following AVBT and/or PSF procedures was completed. The inclusion criteria included the following: AVBT and/or PSF procedures; Lenke 1 or 2 curves; an age of 10 to 18 years for >90% of the patient population; <10% non-AIS scoliosis etiology; and follow-up of ≥1 year. A single-arm, random-effects meta-analysis was performed. Deformity corrections, complication and reoperation rates, and postoperative SRS-22 scores were recorded. The study included 10 AVBT studies (211 patients) and 14 PSF studies (1,069 patients). The mean follow-up durations were similar for both groups. Pooled complication rates were 26% for AVBT versus 2% for PSF, and reoperation rates were 14.1% for AVBT versus 0.6% for PSF with nonoverlapping confidence intervals (CIs). The pooled reoperation rate among studies with follow-up times of ≥36 months was 24.7% in AVBT versus 1.8% in PSF. 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 AVBT

compared with PSF. Reoperation rates were greater in AVBT studies with longer follow-up (≥ 36 months). Deformity correction, clinical outcomes, and mid-term SRS-22 scores were similar. While a potential fusionless treatment for AIS merits excitement, clinicians should consider AVBT with caution. Future long-term randomized prospective studies are needed. (Authors Samdani et al. (2014), Sandami et al. (2015), and Newton et al. (2018) which were previously cited in this policy are included in this systematic and meta-analysis review).

Yucekul et al. (2021) conducted a prospectively followed consecutive patient cohort to determine changes in the intermediate and adjacent levels at least two years following thoracoscopic vertebral body tethering (VBT) surgery was performed between 2014 and 2017. Outcome measure included degeneration of the intervertebral discs using the Pfirrmann classification; degeneration of facet joints using a scale of 0 to 3. A total of 25 patients with a mean of 38.6 ± 10.6 months (24 - 62) of follow-up were included in the study. The mean age at surgery was 12.2 (10 - 14), and the median Sanders stage was 3 (1 - 7). A mean of 7.7 ± 1.1 (6 - 11) levels were tethered. The mean preoperative main thoracic curve magnitude of 46 ± 7.7 was corrected to 23.3 ± 5.9 postoperatively, which was subsequently modulated to 12 ± 11.5 during the follow-up. At the time of the MRI (mean 29 ± 9.5 (24 - 62) months), the median Sanders stages was 7 (5 - 8). A total of 217 levels of discs and bilateral facet joints were evaluated in the preoperative and follow-up MRI images. Analyses of disc and facet scores revealed no significant differences between patients. Deterioration of previously degenerated discs was noted in one patient (from grade 2 to 3), while previously healthy lower adjacent facet joints were degenerated (grade 2) in another patient. The authors concluded that intermediate discs and facet joints were preserved after growth modulation with VBT surgery at a mean of 29 months of follow-up. Well designed, comparative studies with larger patient populations and longer follow-up are needed to further describe safety and the clinical effects of relative stabilization and altered biomechanical loads.

Qui et al. (2020) performed a retrospective cohort study by collecting data from a multicenter database of patients who underwent posterior spinal fusion and from a single center database of patients from an FDA approved investigational device exemption trial who received anterior vertebral body tethering (AVBT). This study compared patients who underwent AVBT with those treated with standard-of-care posterior spinal fusion (PSF) to determine inherent differences in patients and families who seek cutting-edge treatments. The authors studied demographics, preoperative clinical and radiographic variables, and health-related quality of life (HRQOL). No differences in demographics, clinical variables, and radiographic measures were detected between the PSF and AVBT cohorts. The AVBT group showed more thoracic flexibility on bending radiographs, correcting on average 59% compared with 43% for PSF patients (P = .005). Patients had similar HRQOL total scores and scores across each of the 5 domains of the Scoliosis Research Society Questionnaire Version 22. Study limitations included a methodology that compared a multicenter database to that of a single center perspective and lack of randomization, which could have introduced biases in the analyses. The authors stated that to combat this limitation, there is an analogous multicenter trial being planned. It is also essential that as many data points for predefined variables be collected. In addition, the study did not report outcomes of the treatment options due to lack of sufficient follow up. Research on this new technology is ongoing which will result in future development of this new emerging technology.

Newton et al. (2020) conducted a retrospective cohort study comparing the outcomes of patients with thoracic idiopathic scoliosis between a group of patients who underwent AVBT and a matched cohort of patients treated with posterior spinal fusion and instrumentation (PSF). The inclusion criteria were determined based on the AVBT cohort: primary thoracic idiopathic scoliosis with a curve magnitude between 40 and 67, Risser stage of ≤ 1, age of 9 to 15 years, no prior spine surgery, index surgery between 2011 and 2016, and minimum follow-up of 2 years. Demographic, radiographic, clinical, and patient-reported outcomes and revisions were compared between groups. There were 23 patients in the AVBT cohort and 26 patients in the PSF cohort. The mean follow-up (and standard deviation) was similar between groups: 3.4 ± 1.1 years for the AVBT group and 3.6 ± 1.6 years for the PSF group (p = 0.6). Preoperatively, the groups were similar in all measurements of radiographic and clinical deformity, with mean main thoracic curves of 53 ± 8 for the AVBT group and 54 ± 7 for the PSF group (p = 0.4). At the time of final follow-up, the AVBT cohort had significantly more residual deformity, with a mean thoracic curve of 33 ± 18 compared with 16 ± 6 for the PSF group (p < 0.001). There were 9 revision procedures in the AVBT cohort (with 3 conversions to PSF and 3 more pending) and none in the PSF cohort. Revisions occurred at a mean postoperative time of 2.3 years (range, 1.2 to 3.7 years). Twelve patients (52%) had evidence of broken tethers; of these patients, 4 underwent revision. The post-intervention patient-reported outcomes were similar. Both AVBT and PSF resulted in postoperative correction; however, 2-year correction was better maintained in the PSF group. There were no differences in post-intervention patient-reported outcomes. AVBT resulted in less deformity correction and more revision procedures than PSF, suggesting inferior outcomes compared to the established approach, but resulted in the delay or prevention of PSF in many patients. Study limitations included the potential for selection bias for patients int eh AVBT group. Most patients were skeletally mature at the post-op follow-up. Although the

immediate follow-up shows valuable information for those who may be considered AVBT candidates. Larger studies with longer-term follow-up are both needed to fully understand the procedures' strengths, weaknesses and indications.

Hayes (2019) conducted a literature review of clinical evidence for VBT for Adolescent Idiopathic Scoliosis (AIS). The authors noted that there is a paucity of peer-reviewed, published literature addressing VBT specifically for AIS. The search results for this report were limited to including only abstracts addressing AIS. The authors concluded that there is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management for vertebral body tethering for adolescent idiopathic scoliosis. An ECRI Product Brief (2019; updated 2021) reached similar conclusions, stating that the evidence is inconclusive.

Newton et al. (2018) conducted a retrospective review of patients with thoracic scoliosis who underwent anterior spinal growth tethering (ASGT) with a minimum of 2 years of follow-up. Patient demographics, perioperative data, and radiographic outcomes were reported. Seventeen patients met the inclusion criteria. The etiology was idiopathic for 14 and syndromic for 3. The mean follow-up was 2.5 years (range, 2 to 4 years). Preoperatively, all patients were at Risser stage 0, with a mean age at surgery of 11 ± 2 years (range, 9 to 14 years). There was an average of 6.8 ± 0.5 vertebrae tethered per patient. The average thoracic curve magnitude was 52 ± 10 (range, 40 to 67) preoperatively, 31 ± 10 immediately postoperatively, 24 ± 17 at 18 months postoperatively, and 27 ± 20 at latest follow-up (51% correction; range, 5% to 118%). Revision surgery was performed in 7 patients: 4 tether removals due to complete correction or overcorrection, 1 lumbar tether added, 1 tether replaced due to breakage, and 1 revised to a posterior spinal fusion. In 3 additional patients, posterior spinal fusion was indicated due to progression. Eight (47%) of the patients had a suspected broken tether. A "successful" clinical outcome was defined as a residual curve of <35 and no posterior spinal fusion indicated or performed at latest follow-up. Ten (59%) of the 17 were considered clinically successful. The authors concluded that despite most patients having some remaining skeletal growth at the time of review, the results of the current study demonstrate that at mid-term follow-up, ASGT showed a powerful, but variable, ability to modulate spinal growth and did so with little perioperative and early postoperative risk. Fusion was avoided for 13 of the 17 patients. The overall success rate was 59%, with a 41% revision rate. While the study participants' condition improved, in the absence of a comparative group, it is not possible to conclude whether the changes can be attributed to the procedure or other concurrent treatments.

Samdani et al. (2015) also published 1-year results of anterior VBT. Clinical and radiographic data were retrospectively analyzed. The authors reviewed 32 patients who underwent thoracic VBT with a minimum 1-year follow-up. Patients underwent tethering of an average of 7.7 levels (range 7-11). Their early results indicate that anterior VBT is a safe and potentially effective treatment option for skeletally immature patients with idiopathic scoliosis. These patients experienced an improvement of their scoliosis with minimal major complications. While the study participants' condition improved, in the absence of a comparative group, it is not possible to conclude whether the changes can be attributed to the procedure or other concurrent treatments.

Samdani et al (2014) reported the 2-year results of the initial cohort undergoing anterior vertebral body tethering (VBT). Retrospective review was performed on their first 11 consecutive patients who underwent anterior VBT with at least 2-year follow-up. All underwent tethering of an average of 7.8 ± 0.9 (range of 7 to 9) levels, with the most proximal being T5 and the most distal L2. Pre-operative thoracic Cobb angle averaged 44.2 ± 9.0 and corrected to 20.3 ± 11.0 on first erect, with progressive improvement at 2 years (Cobb angle = 13.5 ± 11.6, % correction = 70 %). Similarly, the pre-operative lumbar curve of 25.1 ±8.7 demonstrated progressive correction (first erect = 14.9 ± 4.9, 2 years = 7.2 ± 5.1, % correction = 71 %). Thoracic axial rotation as measured by a scoliometer went from 12.4 ± 3.3 pre-operatively to 6.9 ±3.4 at the most recent measurement). No major complications were observed. As anticipated, 2 patients returned to the operating room at 2 years post-operatively for loosening of the tether to prevent overcorrection. The authors concluded that anterior VBT is a promising technique for skeletally immature patients with idiopathic scoliosis. Two major limitations of this study are a lack of comparison group undergoing a different treatment and the large loss of follow-up. Only 11 out of the 65 participants who underwent VBT reached the two-year follow-up cutoff necessary to be included in the study. This raises a significant concern for biased findings and the possibility of unreported adverse events.

Clinical Practice Guidelines

British Scoliosis Research Foundation (BSRF)

A 2022 statement published by the BSRF indicates that they follow the British Scoliosis Society's (BSS) position statement on Vertebral Body Tethering (VBT). Although early results in the US and UK look promising, there are currently no long-term results for VBT. There are still several checks and balances which will be considered by bodies such as NICE before NHS England

decide whether NHS funding for this procedure will become available in England, and which surgeons and centers will be able to undertake it. Additional research is required.

British Scoliosis Society (BSS)

An executive position statement on vertebral body tethering (VBT) for scoliosis published by the BSS (2016) states there are no long-term results for Vertebral Body Tethering although early results in the US and UK look promising. However, there is a need to introduce this technique in a controlled and responsible way. The society urges NICE to review this procedure and for NHS England to develop a Policy for introduction. The BSS feels that the introduction of non-fusion instrumentation for scoliosis should be done in a small number of centers who would be committed to careful patient selection and informed consent. These centers would use the British Spine Registry to monitor the results of surgery and any complications for many years before any decision regarding wider adoption.

National Institute for Health and Care Excellence (NICE)

NICE interventional procedures guidance published on June 29, 2022, for vertebral body tethering (VBT) for idiopathic scoliosis (IS) in children and young people states that evidence on the safety of vertebral body tethering for IS in children and young people is limited but raises concerns of serious complications. Evidence on its efficacy is inadequate in quality and quantity. Therefore, this should only be used in the context of research. Further research should include randomized controlled trials or analysis of registry data and the procedure should only be performed in specialist centers by spinal surgeons with specific training in anterior spinal surgery.

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

A joint position statement published April 2, 2020 (updated 2021), by the SRS and POSNA states that both societies firmly concur that payors should provide coverage for any FDA approved devices under FDA stated clinical indications and requirements (limited to surgeons with active IRB approval) at the same level as traditional spinal instrumentation/fusion and growing rod procedures for management of skeletally immature patients (Risser ≤ 2 or Sanders ≤ 5) with idiopathic scoliosis (as defined above, 30 to 65 degrees Cobb angle). For those patients who meet criteria for use of The Tether™ or other similarly FDA approved growth modulation systems, the decision for fusion versus growth modulation is best made between the patient, guardians, and treating physician - accounting for individual needs, values, and perspectives. However, the SRS and POSNA 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.

Scoliosis Association UK (SAUK)

A statement published by the SAUK on April 27, 2018, on vertebral body tethering (VBT) for scoliosis states long term follow up studies confirm that traditional correction of the curve with screws and rods is effective. However, VBT is a very new procedure that is used for selected cases, typically in younger patients and needs careful assessment and good quality follow-up data. Researchers need to establish that the procedure does indeed achieve safe correction while preserving flexibility and maintenance of the correction in the long term. SAUK's view is that careful evaluation of the short and the long-term outcome of VBT should be a priority for research, as should the feasibility of expanding the use of the technique to a wider spectrum of children, perhaps at a more advanced developmental stage.

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 FDA granted a Humanitarian Device Exemption approval to Zimmer Biomet Holdings, Inc.'s (Warsaw, IN, U.S.) Tether™ - Vertebral Body Tethering System for treating idiopathic scoliosis in skeletally immature patients considering spinal fusion surgery, the company announced on August 16, 2019. This device is indicated for skeletally immature patients that require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, with a major Cobb angle of 30 to 65 degrees whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. Patients should have failed bracing and/or be intolerant to brace wear. See the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf19/H190005D.pdf (Accessed August 15, 2022).

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Guideline History/Revision Information

Date	Summary of Changes

01/01/2024	**Applicable Codes**
	• Updated list of applicable CPT codes to reflect annual edits:
	  ○ Added 22836 and 22837
	  ○ Revised description for 0656T and 0657T
	Supporting Information
	• Updated *Clinical Evidence* and *References* sections to reflect the most current information
	• Archived previous policy version MMG168.E

Instructions for Use

This Medical Management Guideline provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this guideline, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Management Guideline 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 West Medical Management Guidelines 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.

Member benefit coverage and limitations may vary based on the member's benefit plan Health Plan coverage provided by or through UnitedHealthcare of California, UnitedHealthcare Benefits Plan of California, UnitedHealthcare of Oklahoma, Inc., UnitedHealthcare of Oregon, Inc., UnitedHealthcare Benefits of Texas, Inc., or UnitedHealthcare of Washington, Inc.