

Vertebral Body Tethering for Scoliosis (for Louisiana Only)

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Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

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

Applicable Codes

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

CPT Code	Description
0656T	Vertebral body tethering, anterior; up to 7 vertebral segments
0657T	Vertebral body tethering, anterior; 8 or more vertebral segments
22899	Unlisted procedure, spine

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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. 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.

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 a 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.

Miyajima et al. (2020) conducted a retrospective multicenter case series to determine the clinical efficacy of anterior vertebral body tethering (AVBT) in skeletally immature patients with idiopathic scoliosis. The authors note that spinal fusion remains the gold standard in the treatment of idiopathic scoliosis. Yet, anterior vertebral body tethering (AVBT) is gaining widespread interest, despite the limited data on its efficacy. All consecutive skeletally immature patients with idiopathic scoliosis treated with AVBT enrolled in a longitudinal, multicenter, prospective database between 2013 and 2016 were analyzed. All patients were treated by one of two surgeons working at two independent centers. Data was collected prospectively in a multicenter database and supplemented retrospectively where necessary. Patients with a minimum follow-up of two years were included in the analysis. Clinical success was considered a major coronal Cobb angle of $< 35^\circ$ at the most recent follow-up. A total of 57 patients were included in the study. Their mean age was 12.7 years (SD 1.5; 8.2 to 16.7), with 95% being female. The mean preoperative Sanders score and Risser grade was 3.3 (SD 1.2), and 0.05 (0 to 3), respectively. The majority were thoracic tethers (96.5%) and the mean follow-up was 40.4 months (SD 9.3). The mean preoperative major curve of 51° (SD 10.9° ; 31° to 81°) was significantly improved to a mean of 24.6° (SD 11.8° ; 0° to 57°) at the first postoperative visit (45.6% (SD 17.6%; 7% to 107%); $p < 0.001$) with further significant correction to a mean of 16.3° (SD 12.8° ; -12° to 55° ; $p < 0.001$) at one year and a significant correction to a mean of 23° (SD 15.4° ; -18° to 57°) at the final follow-up (42.9% (-16% to 147%); $p < 0.001$). Clinical success was achieved in 44 patients (77%). Most patients reached skeletal maturity, with a mean Risser score of 4.3 (SD 1.02), at final follow-up. The complication rate was 28.1% with a 15.8% rate of unplanned revision procedures. The authors concluded that AVBT is associated with satisfactory correction of deformity and an acceptable complication rate when used in skeletally immature patients with idiopathic scoliosis. Improved patient selection and better implant technology may improve the 15.8% rate of revision surgery in these patients. The study is limited by lack of contemporary comparison group. Also, a

minimum two-year follow-up is not an adequate standard for these patients and clearly longer follow-up is required to make any conclusive statements about the true value of this technique. The authors also concluded that further examination of the true effectiveness and long-term risks of this technique remains critical.

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 on the basis of 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 in the 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 include 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) reached similar conclusions, stating that 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 or not 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 or not 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 year = 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 limitation of this study are a lack of comparison group undergoing a different treatment and the large lost to 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.

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 in 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. Refer to the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf19/H190005D.pdf.

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Policy History/Revision Information

Date	Summary of Changes
07/01/2021	Applicable Codes <ul style="list-style-type: none">Updated list of applicable CPT codes to reflect quarterly edits; added 0656T and 0657T Supporting Information <ul style="list-style-type: none">Archived previous policy version CS170LA.B

Instructions for Use

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

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