VERTEBRAL BODY TETHERING FOR SCOLIOSIS

Policy Number: SURGERY 113.1 T2 **Effective Date**: March 1, 2020

Instructions for Use

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Related Policies

None

NON-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 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 may apply.

CPT Code	Description
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. The evidence is insufficient to determine the effects of the technology on health outcomes.

Hayes (2019) conducted a literature review of clinical evidence for VBT for Adolescent Idiopathic Scoliosis (AIS). 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. Animal studies, biomechanical simulations, conference abstracts, and studies investigating VBT for types of scoliosis other than AIS were excluded from the search. 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.

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 are 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 for more patients. 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 ± 9.0and corrected to 20.3 ±11.0on 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 ± 3.3pre-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.

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 an August 16, 2019.

REFERENCES

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [*2020T0605A*]

Hayes, Inc. Search and Summary. Vertebral Body Tethering for Adolescent Idiopathic Scoliosis. Lansdale, PA: March 2019.

Newton PO, Kluck DG, Saito W, et al. Anterior spinal growth tethering for skeletally immature patients with scoliosis: a retrospective look two to four years postoperatively. J Bone Joint Surg Am. 2018 Oct 3;100(19):1691-1697.

Samdani AF, Ames RJ, Kimball JS, et al. Anterior vertebral body tethering for immature adolescent idiopathic scoliosis: one-year results on the first 32 patients. Eur Spine J. 2015 Jul;24(7):1533-9.

Samdani AF, Ames RJ, Kimball JS, et al. Anterior vertebral body tethering for idiopathic scoliosis: two-year results. Spine (Phila Pa 1976). 2014 Sep 15;39(20):1688-93.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
03/01/2020	• New Clinical Policy

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford 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 policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

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