

# Medical Policy Vertebral Body Tethering

**Policy Number: 064** 

	Commercial and Qualified Health Plans	Mass General Brigham ACO	Medicare Advantage	OneCare	Senior Care Options (SCO)
Authorization					
Required					
No Prior Authorization	Х	X (22836, 22837, 22838)	Х	Х	Х
Not payable		X (0656T, 0657T, 0790T)			

#### Overview

The purpose of this document is to describe the guidelines Mass General Brigham Health Plan uses to determine medical necessity for vertebral body tethering (VBT) to treat idiopathic scoliosis. The treating provider must be a qualified spine/orthopedic specialist trained and experienced in VBT.

## **Coverage Guidelines**

The use of an FDA approved vertebral body tethering (VBT) device to treat idiopathic scoliosis of the thoracic and/or lumbar spine may be considered medically necessary when ALL of the following conditions are met:

- 1. The treating provider has completed an in-person evaluation and documented the member's suitability for VBT and the rationale for the procedure.
- 2. The member's radiographic imaging confirms all of the following:
  - a. Skeletal immaturity defined as Risser Grade 0-2, or Sanders Skeletal Maturation stage less than 5; and
  - b. Major Cobb angle of 35 to 65 degrees and osseous structure is dimensionally adequate to accommodate screw fixation; and
  - c. Cobb angle decreases in magnitude below 30 degrees on bending films
- 3. The member has progressive curvature that has not responded to <u>one</u> of the following conservative treatment options:
  - a. Failed external bracing defined as curvature progression greater than 5 degrees despite external brace wear;
  - External bracing is not/no longer indicated secondary to skeletal maturity or severe scoliosis (greater than 45 degrees);
  - c. There is clinical documentation of intolerance to external brace wear as prescribed despite reasonable efforts to improve brace comfort, fit, and wear compliance.
- 4. The surgery is to be performed at a facility with appropriate experience and expertise in the VBT procedure.



#### **Exclusions**

- 1. The member has congenital scoliosis.
- 2. The member has achieved Skeletal maturity with no spinal growth remaining.
- 3. The member has hyperkyphosis (40-50 degrees).
- 4. Kyphosis in the lumbar spine or at the thoracolumbar junction.
- 5. Vertebral or chest wall deformity malformation in addition to scoliosis (e.g., pectus excavatum, severe rib prominence defined as trunk rotation greater than 20 degrees as measured by a scoliometer).
- 6. Previous surgery at the spinal levels where scoliotic curve(s) exist, unless related to prior tether correction.
- 7. Member is non-ambulatory.
- 8. Altered muscle function as a result of progressive neuromuscular disease.

#### **Medicare Variation**

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for medical necessity determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. At the time of Mass General Brigham Health Plan's most recent policy review, Medicare has no NCD or LCD for vertebral body tethering.

#### **MassHealth Variation**

Mass General Brigham Health Plan uses guidance from for medical necessity determinations for medical necessity determinations. When there is no guidance from MassHealth for the requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. As of Mass General Brigham Health Plan's most recent policy review, MassHealth considered codes 0656T, 0657T, and 0790T to be non-payable. However, due to the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit, members under 21 years of age who meet coverage guidelines may be eligible for treatment under those codes.

#### **OneCare and SCO Variation**

Mass General Brigham Health Plan uses guidance from CMS for medical necessity determinations for its OneCare and SCO plan members. NCDs, LCDs, LCAs, and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan uses medical necessity guidelines from MassHealth. When there is no guidance from CMS or from MassHealth, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations.

### **Codes**

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

Authorized CPT/HCPCS Codes	Code Description		
	Anterior thoracic vertebral body tethering, including		
22836	thoracoscopy, when performed; up to 7 vertebral segments		



	Anterior thoracic vertebral body tethering, including
22837	thoracoscopy, when performed; 8 or more vertebral segments
	Revision (eg, augmentation, division of tether), replacement, or
	removal of thoracic vertebral body tethering, including
22838	thoracoscopy, when performed
	Anterior lumbar or thoracolumbar vertebral body tethering; up to
0656T	7 vertebral segments
	Anterior lumbar or thoracolumbar vertebral body tethering; 8 or
0657T	more vertebral segments
	Revision (eg, augmentation, division of tether), replacement, or
	removal of thoracolumbar or lumbar vertebral body tethering,
0790T	including thoracoscopy, when performed

## **Summary of Evidence**

Anterior vertebral body tethering (AVBT) is an alternative to standard-of-care posterior spinal fusion (PSF) for skeletally immature patients with adolescent idiopathic scoliosis (AIS) that works by modulating growth and appears to offer better spinal mobility than fusion.

This technique was first reported in a 2010 case report by Crawford and Lenke, who treated an eight-year-old boy with AIS, and progression of the major curve to 40° despite bracing. A thoracotomy was performed, screws were placed at teach level from T6 to T12, the screws were compressed, and a polypropylene tether was locked to the screws. An immediate correction of the curve to 25° was observed, and the curve continued to correct as the child grew over the course of 48-month follow-up.

Subsequent retrospective and prospective case series, including those by Samdani et al. (2014, 2015, 2021), Cobetto et al. (2018), Newton et al. (2018), Rushton et al. (2021), and others showed that VBT produced good correction of curves and variable but generally acceptable complication rates with follow-up of 2-5 years. These studies were limited to skeletally immature patients, defined in most of these studies as Risser  $\leq 2$  and/or Sanders  $\leq 4$ .

Subsequent research has highlighted the longer-term risk of tether breakage. A large multicenter study by the Harms study group of 208 patients who underwent thoracic VBT at 10 centers found tether breakage in 36% of patients, 88% of which occurred at or beyond 24 months of follow-up; a Kaplan-Meier survival analysis indicated that 50% of patients will experience tether breakage by 36 months postoperatively (Cahill et al. 2024).

VBT has been compared with PSF in a retrospective, propensity-matched multicenter study of 237 patients who underwent VBT and 237 who underwent PSF (Newton et al. 2022) with follow-up of 2.2±0.5. The VBT group was younger, had lower Risser scores, and had smaller thoracic curves than the PSF group. At latest follow-up, the corrected curve was 27° in the VBT group and 20° in the PSF group (p<0.001). Residual curve >50° was present in 3% in the VBT group and 0% in the PSF group. Reoperations were required in 16% of the VBT group and 1.3% of the PSF group. Improvements in pain and self-image scores were smaller in the VBT group than in the PSF group. A meta-analysis by Shin et al. (2021) compared outcomes in published 10 studies of VBT (211 patients) and 14 studies of PSF (1069 patients). Pooled complication rates for VBT and PSF were 26% and 2%, respectively, and pooled reoperation rates were 14.1% and 0.6%, respectively, with higher reoperation rates in studies with longer follow-up. This meta-analysis was limited by likely confounding, however, due to heterogeneous study populations.

More recently, some studies have reported outcomes in patients with greater degrees of skeletal maturity. Hoernschemeyer et al. (2020) reported outcomes of VBT with ≥2 years of follow up a series of 31 patients, of whom 48% were Risser ≤1 and 11 were Risser 3-4. Although they did not analyze outcomes by degree of



preoperative skeletal maturity, they concluded that "the best candidates for VBT include patients with a Sanders stage of 3 to 5, a Cobb angle between 45° and 70°, and curve flexibility under bending and traction that measured ≤30°." Alanay et al. (2020) performed a retrospective analysis, stratified by Sanders score, of 31 patients with AIS who were treated with VBT and followed for 27.1±12 months. Following the initial curve correction of 25°, median follow-up correction was 29°, 9°, 6°, and 0° in patients who had Sanders scores at the time of the operation of 2, 3, 4-5, and 6-7, respectively. Overcorrection occurred in 19.4%, pulmonary complications in 12.9%, and mechanical complications in 19.4%. The authors concluded that Sanders 1 and 2 patients were prone to overcorrection; Sanders 3 patients were the best candidates, and Sanders 4-5 patients were "probably good candidates, however longer follow-up is warranted for stronger evidence on long-term survival." In contrast, Sanders 6-7 patients were assessed to have significant risk of tether breakage. Subsequently, Hegde et al. (2021) reported a small prospective case series of 10 patients with Risser ≥4, Sanders ≥7, and ≥50% flexibility of the major curve on dynamic radiographs who were treated with VBT at age 14.9±2.7 years. With mean follow-up of 24.1±3.6 months, there was a 71% correction of the major Cobb angle, and no complications were reported. Bernard et al. (2022) reported good outcomes and no complications in a small series of 10 patients who had VBT at Risser 3-5 and ≥50% flexibility. Meyers et al. (2022) published a retrospective review of 49 patients with AIS who underwent VBT at age 15±1.9 years and Risser 3-5. After at least 2 years of follow-up, mean curvature improved significantly, and 76% had improvement in the major curve to ≤30°, but 41% experienced tether breakage.

Based on the available evidence, experts have emphasized the importance of limiting use to appropriately selected patients. Parent and Shen (2020) recommend offering VBT to Lenke type 1 patients with Cobb angles 40-70° who are premenarchal, Risser 0 with open triradiate cartilage, and Sanders <4 who are failed bracing or who are at risk for bracing failure. Similarly, Newton (2020) considers appropriate candidates to have Risser 0-1, Sanders 3-4, and primary thoracic curves of 45-65°. Shah (2024) states that although studies have shown good short-term outcomes in patients with more skeletal maturity, the tether "will eventually fatigue and break, ... and it is unclear whether curve correction will be maintained at longer follow-up in these patients, perhaps necessitating revision to fusion ultimately." The Pediatric Orthopedic Society of North America (POSNA) and the Scoliosis Research Society (SRS) published a position paper (2020) recommending payor coverage of VBT for skeletally immature patients, defined as Risser ≤2 or Sanders ≤5, and stating that VBT is not indicated in skeletally mature patients. A subsequent SRS position statement (Dahl, Fletcher and Pahys 2023) emphasized that "current scientific results do not show a significant, clinically relevant difference in outcome compared to PSF, and an increased risk of revision surgery should be expected if VBT is chosen." Furthermore, the SRS pointed out that most studies only included patients with Cobb angles <65 degrees, Risser 0-1 and Sanders score <5, and that "future studies will be needed to assess the utility of VBT in patients with larger curves, nonidiopathic etiologies, and skeletally mature patients. While VBT has been used in older teenagers and some adults, there is no published data to support this practice at this time."

Throughout these studies, a consistent theme emerges: while VBT offers compelling advantages in preserving spinal mobility and providing growth modulation, its success depends heavily on careful patient selection, surgical expertise, and vigilant long-term monitoring. The collective research underscores both AVBT's transformative potential in scoliosis treatment and the importance of continued refinement of surgical techniques and patient selection criteria. Criteria in this Mass General Brigham Health Plan medical policy are based on the evidence and expert opinions described in this literature review, and consistent with the FDA label and position papers by POSNA and SRS. Based on these sources, VBT is considered medically necessary only for individuals with skeletal immaturity as defined by POSNA and SRS, since the available evidence has not established its safety and efficacy in patients with greater degrees of skeletal maturity.

## **Effective**



January 2026: Off-cycle review. Updated prior authorization table and added variation for OneCare and SCO members.

August 2025: Annual update. Fixed typos. Updated code disclaimer.

April 2025: Off-cycle review. Summary of Evidence added. References updated.

January 2025: Off-cycle review. Removed from prior authorization. Clarified language in Medicare Variation.

August 2024: Annual update. Updated Prior Authorization table to reflect change in MassHealth's coverage of VBT. Updated code definitions. Added language for MassHealth and Medicare Advantage.

January 2024: Off-cycle review. Codes updated.

July 2023: Effective date.

#### References

Alanay A, Yucekul A, Abul K, et al. Thoracoscopic vertebral body tethering for adolescent idiopathic scolioisis. Spine 2020;45:e1483-e1492.

Baker CE, Milbrandt TA, Larson AN. Anterior Vertebral Body Tethering for Adolescent Idiopathic

Scoliosis: Early Results and Future Directions. Orthop Clin North Am. 2021 Apr;52(2):137-147.

Baroncini A, Trobisch PD, Migliorini F. Learning curve for vertebral body tethering: analysis on 90 consecutive patients. Spine Deform. 2021 Jan;9(1):141-147. Epub 2020 Aug 21. PMID: 32827085.2013 AHA/ACC/TOS

Bernard J, Bishop T, Herzog J, et al. Dual modality of vertebral body tethering: Anterior scoliosis correction versus growth modulation with mean follow-up of five years. *Bone Jt Open* 2022;3(2):123-129.

Cahill PJ, Miyanji F, Lullo BR, et al. Incidence of tether breakage in anterior vertebral body tethering. J Pediatr Orthop. 2024;44:e323-328.

Cobetto N, Aubin CE, Parent S. Surgical Planning and Follow-up of Anterior Vertebral Body Growth Modulation in Pediatric Idiopathic Scoliosis Using a Patient-Specific Finite Element Model Integrating Growth Modulation. Spine Deform 2018;6:344-350.

Crawford CH, Lenke LG. Growth modulation by means of anterior tethering resulting in progressive correction of juvenile idiopathic scoliosis: a case report. J Bone Joint Surg Am. 2010;92:202-9.

Dahl BT, Fletcher ND, Pahys JM. Vertebral body tethering (VBT) in idiopathic pediatric spinal deformity. 2023. Accessed 3/13/2025 at https://www.srs.org/Education/Quality-and-Safety/Informational--Position-Statements.

Hegde SKJ, Venkatesan M, Akbari KK, Badikillaya VM. Efficacy of anterior vertebral body tethering in skeletally mature children with adolescent idiopathic scoliosis: a preliminary report. Int J Spine Surg 2021;15(5):995-1003.

Hoernschemeyer DG, Boeyer ME, Robertson ME et. al. Anterior Vertebral Body Tethering for Adolescent Scoliosis with Growth Remaining: A Retrospective Review of 2 to 5-Year Postoperative Results. J Bone Joint Surg Am. 2020 Jul 1;102(13):1169-1176. doi: 10.2106/JBJS.19.00980. PMID: 32618924.

Meyers J, Eaker L, Zhang J, von Treuheim TP, Lonner B. Vertebral body tethering in 49 adolescent patients after peak height velocity for the treatment of idiopathic scoliosis: 2-5 year follow-up. J Clin Med 2022;11:3161.

Newton PO. Spinal growth tethering: indications and limits. Ann Transl Med 2020;8(2):27.

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;100:1691-7.



Newton PO, Parent S, Miyangi F, et al. Anterior vertebral body tethering compared with posterior spinal fusion for major thoracic curves: A retrospective comparison by the Harms Study Group. J Bone Joint Surg Am. 2022;104:2170-7.

Parent S, Shen J. Anterior vertebral body growth-modulation tethering in idiopathic scoliosis: surgical technique. J Amer Acad Orthop Surg, 2020:28(17), 693-699.

Pediatric Orthopaedic Society of North America and Scoliosis Research Society. Joint SRS/POSNA position statement on payor coverage for anterior fusionless scoliosis technologies for immature patients with idiopathic scoliosis. 2020. Accessed 3/13/2025 at

https://posna.org/POSNA/media/Documents/Position%20Statements/Why-Should-Insurance-Cover-AVBT-April-2020.pdf

Rushton PRP, Nasto L, Parent S, Turgeon I, Aldebeyan S, Miyanji F. Anterior vertebral body tethering for treatment of idiopathic scoliosis in the skeletally immature: Results of 112 cases. Spine 2021;46:1461-1467.

Samdani AF, Pahys JM, Ames RJ, et al. Prospective Follow-up Report on Anterior Vertebral Body Tethering for Idiopathic Scoliosis: Interim Results from an FDA IDE Study. J Bone Joint Surg Am. 2021 Sep 1;103(17):1611-1619. PMID: 34185722.

Samdani AF, Ames RJ, Kimball JS, et al. Anterior vertebral body tethering for idiopathic scoliosis: two-year results. Spine (Phila Pa 1976). 2014;39(20): 1688-93. PMID 24921854

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;24:1533-9.

Scoliosis Research Society (SRS), American Academy of Orthopaedic Surgeons (AAOS), Pediatric

Orthopaedic Society of North America (POSNA), and American Academy of Pediatrics (AAP) Position

Statement: Screening for the Early Detection of Idiopathic Scoliosis in Adolescents. <u>1122-Screening-for-the-Early-Detection-of-Idiopathic-Scoliosis-in-Adoles</u> 12-28.pdf (posna.org)

Shah SA, Kraft DB, Miyanji F. Anterior vertebral body tethering: a review of the available evidence. JAAOS 2024;32(6):247-56.

Shin M, Arguelles GR, Cahil PJ, Flynn JM, Baldwin KD, Anari JB. Complications, reoperations, and mid-term outcomes following anterior vertebral body tethering versus posterior spinal fusion: a meta-analysis. JBIS Open Access 2021:e21.00002.

U.S. Food and Drug Administration (FDA), Center for Devices and Radiologic Health (CDRH). The Tether™ - Vertebral Body Tethering System. Summary of Safety and Effectiveness Data. Humanitarian Device Exemption (HDE) (H190005). Rockville, MD: FDA; August 16, 2019. Available at:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=H190005

