

Effective: January 1, 2024

<p>Prior Authorization Required If <u>REQUIRED</u>, submit supporting clinical documentation pertinent to service request to the FAX numbers below</p>	<p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p>
<p>Notification Required IF <u>REQUIRED</u>, concurrent review may apply</p>	<p>Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p>

Applies to:

Commercial Products

- Harvard Pilgrim Health Care Commercial products; 800-232-0816
- Tufts Health Plan Commercial products; 617-972-9409
- CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

- Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
- Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055
- Tufts Health RItogether – A Rhode Island Medicaid Plan; 857-304-6404
- Tufts Health One Care --A dual-eligible product; 857-304-6304

Senior Products

- Harvard Pilgrim Health Care Stride Medicare Advantage; 866-874-0857
- Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965
- Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965
- Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

Scoliosis is a spinal deformity characterized by lateral and rotational curvature of the spine. The most common form of scoliosis is idiopathic scoliosis, which occurs in approximately 3 percent of individuals under age 16, most often in the early adolescent years. The majority of adolescents do not display progressive curves, but a subset of individuals with adolescent idiopathic scoliosis may exhibit a rapid progression of curvature. Prevention and/or correction of curve progression caused by idiopathic scoliosis includes non-operative (e.g., external bracing, scoliosis specific exercises) and surgical (e.g. spinal fusion, growing rods, anterior vertebral body tethering) options.

The primary goal of nonoperative treatment of adolescent idiopathic scoliosis (AIS) is to prevent curve progression. For AIS individuals with growth remaining and a curve magnitude between 25 and 45 degrees, conservative treatment with a rigid thoracolumbosacral orthosis (TLSO) is indicated. Brace wear for at least 13 hours per day is indicated until skeletal maturity to limit curve progression

Anterior vertebral body tethering (AVBT) is a non-fusion surgical option for the treatment of idiopathic scoliosis. To date, the FDA has given humanitarian device exemption approval for one such device, The Tether™ - Vertebral Body Tethering System. Anchors and vertebral body screws are placed on the convex side of the spinal curve and the tether, a flexible tensioning cord made of synthetic polymer, is then secured along the convex side of the vertebrae. The tether provides tension across the convex side which partially straightens the spinal curvature. After surgery, the tether continues to correct the spinal curvature as the adolescent continues to grow.

Anchors and vertebral body screws are placed laterally from a thoracoscopic or thoracotomy approach into the vertebral body on the convex side of a spinal deformity. A polymer tensioning cord is secured to the vertebral body screws and provides a lateral tension band across the convex side of the spine. This tension partially corrects the curvature, and subsequently can arrest or correct the deformity through modulation of remaining spinal growth.

The Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) and MassHealth for coverage determinations for its Dual Product Eligible plan members. CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals and MassHealth Medical Necessity Determinations are the basis for coverage determinations. When CMS and MassHealth do not provide guidance, the Plan internally developed medical necessity guidelines are used. CMS and MassHealth coverage guidelines are not established for this service.

For the service of Anterior Vertebral Body Tethering (AVBT), evidence is sufficient for coverage. AVBT is done with a Tethering System, which received FDA approval in April 2019. AVBT is a treatment option for members who do not respond to conservative non-surgical treatments, such as external bracing, to help correct spinal curvature as a result of idiopathic scoliosis. This FDA approval is based on the results from the clinical trials showing a reduction in the curvature of the spine and expected benefits outweigh the risks for use of this device for treatment of select skeletally immature patients with progressive pediatric idiopathic scoliosis. The Tethering System allows access to a new treatment option to improve quality of life and has the benefit that the system continues to correct the spinal curvature as the member continues to grow.

The use of this criteria in the utilization management process will ensure access to evidence based clinically appropriate care. See References section below for all evidence accessed in the development of these criteria.

Clinical Guideline Coverage Criteria

The Plan considers anterior vertebral body tethering as medically necessary when documentation confirms **ALL** of the following:

1. Idiopathic scoliosis of thoracic and/or lumbar spine
2. Radiographic imaging confirms the following:
 - a. Major Cobb angle of 35 to 65 degrees and osseous structure is dimensionally adequate to accommodate screw fixation; **and**
 - b. Cobb angle decreases in magnitude below 30 degrees on bending films
3. Progressive curvature that has not responded to **one** of the following conservative treatment options:
 - a. Failed external bracing defined as curvature progression greater than 5 degrees despite external brace wear; **or**
 - b. External bracing is not/no longer indicated secondary to skeletal maturity or severe scoliosis (greater than 45 degrees); **or**
 - c. Documentation of intolerance to external brace wear as prescribed despite reasonable efforts to improve brace fit, comfort, and brace wear compliance
4. Radiographic imaging confirms skeletal immaturity, defined as at least one of the following:
 - a. Risser grade 0-2 and under; **or**
 - b. Sanders Skeletal Maturation Stage (SMS) less than 5
5. Tethering device must be FDA approved; **and**
6. Qualified orthopedic/spine specialist trained and with experience in AVBT technique has completed in person evaluation and has documented member's suitability for AVBT and the rationale for AVBT procedure; **and**
7. Anterior vertebral body tethering procedure will be performed by qualified orthopedic/spine specialist trained and with experience in AVBT technique at a facility with appropriate experience and expertise in AVBT procedure

Limitations

The Plan will not cover AVBT for the following:

1. Skeletal maturity achieved with no spinal growth remaining
2. Congenital scoliosis
3. 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 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

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes

Code	Description
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
0656T	Vertebral body tethering, anterior; up to 7 vertebral segments
0657T	Vertebral body tethering, anterior; up to 8 or more vertebral segments

References:

1. Baker, C., Milbrandt, T., Potter, D., & Larson, A. N. (2020). Anterior Lumbar Vertebral Body Tethering in Adolescent Idiopathic Scoliosis. *JPOSNA*®, 2(3). Retrieved from <https://www.jposna.org/ojs/index.php/jposna/article/view/145>
2. Joint SRS/POSNA Position Statement on Payor Coverage for Anterior Fusionless Scoliosis
3. Technologies for Immature Patients with Idiopathic Scoliosis
4. Payor Coverage for Anterior Fusionless Scoliosis Technologies for Immature Patients with Idiopathic Scoliosis | Scoliosis Research Society. Srs.org. <https://www.srs.org/about-srs/quality-and-safety/position-statements/payor-coverage>. Published 2022. Accessed April 22, 2022.
5. <https://www.fda.gov/medical-devices/recently-approved-devices/tethertm-vertebral-body-tethering-system-h190005>
6. Mignemi M, Tran D, Ramo B, Richards BS. Repeat Surgical Interventions Following "Definitive" Instrumentation and Fusion for Idiopathic Scoliosis: 25-Year Update. *Spine Deform*. 2018;6(4):409-416. doi:10.1016/j.jspsd.2017.12.006
7. Baker, C., Milbrandt, T., Potter, D., & Larson, A. N. (2020). Anterior Lumbar Vertebral Body Tethering in Adolescent Idiopathic Scoliosis. *JPOSNA*®, 2(3). Retrieved from <https://www.jposna.org/ojs/index.php/jposna/article/view/145>
8. Samdani AF, Belin EJ, Bennett JT, et al. Unplanned return to the operating room in patients with adolescent idiopathic scoliosis: are we doing better with pedicle screws?. *Spine (Phila Pa 1976)*. 2013;38(21):1842-1847. doi:10.1097/BRS.0b013e3182a42a99
9. Newton PO, Bartley CE, Bastrom TP, Kluck DG, Saito W, Yaszay B. Anterior Spinal Growth Modulation in Skeletally Immature Patients with Idiopathic Scoliosis: A Comparison with Posterior Spinal Fusion at 2 to 5 Years Postoperatively. *The Journal of bone and joint surgery American volume*. May 6 2020;102(9):769-777. doi:10.2106/jbjs.19.01176
10. Baroncini A, Trobisch PD, Migliorini F. Learning curve for vertebral body tethering: analysis on 90 consecutive patients. *Spine Deform*. 2021;9(1):141-147. doi:10.1007/s43390-020-00191-5
11. Hoernschemeyer DG, Boeyer ME, Robertson ME, Loftis CM, Worley JR, Tweedy NM, Gupta SU, Duren DL, Holzhauser CM, Ramachandran VM. 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.
12. Samdani AF, Ames RJ, Kimball JS et al (2014) Anterior vertebral body tethering for idiopathic scoliosis: two-year results. *Spine* 39:1688–1693. <https://doi.org/10.1097/BRS.0000000000000472>.
13. Newton PO, Kluck DG, Saito W et al (2018) Anterior spinal growth tethering for skeletally immature patients with scoliosis: a retrospective look two to four years postoperatively. *J Bone Jt Surg Am* 100:1691–1697. <https://doi.org/10.2106/JBJS.18.00287>.
14. <https://scoliosiscarecenters.com/kyphosis/>
15. <https://www.srs.org/professionals/online-education-and-resources/conditions-and-treatments/kyphosis-in-the-adolescent-and-young-adult#:~:text=When%20the%20%22roundness%22%20of%20the%20upper%20spine%20increases,result%20of%20wedged%20vertebrae%20that%20develop%20during%20adolescence.>

16. 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.
https://posna.org/POSNA/media/Documents/Position%20Statements/1122-Screening-for-the-Early-Detection-of-Idiopathic-Scoliosis-in-Adoles_12-28.pdf
17. Shannon, B., Mackenzie, W. G. S., Hariharan, A., & Shah, S. (2021). Update in Nonoperative Management of Adolescent Idiopathic Scoliosis to Prevent Progression. *JPOSNA*®, 3(4). Retrieved from <https://www.jposna.org/ojs/index.php/jposna/article/view/361>
18. Raitio A, Syvänen J, Helenius I. Vertebral Body Tethering: Indications, Surgical Technique, and a Systematic Review of Published Results. *J Clin Med*. 2022;11(9):2576. Published 2022 May 4. doi:10.3390/jcm11092576
19. *The tetherTM – vertebral body Tethering System*. FDA Executive Summary. (2021).
<https://www.fda.gov/media/147902/download>

Approval And Revision History

March 16, 2022: Reviewed by the Medical Policy Approval Committee (MPAC) for effective date May 1, 2022.

Subsequent endorsement date(s) and changes made:

- November 16, 2022: Reviewed by MPAC, renewed without changes
- November 16, 2023: Reviewed by MPAC, renewed without changes
- November 2023: Rebranded Unify to One Care, updated overview, and coding updated per AMA CPT® the following codes were added: 22836 and 22837 effective January 1, 2024

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.