Cohere Medicare Advantage Policy - Pediatric Vertebral Body Tethering (VBT) and Vertical Expandable Prosthetic Titanium Rib (VEPTR)

Clinical Policy for Medical Necessity Review

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Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Other Notices:

Policy Information:

Specialty Area: Musculoskeletal Care
Policy Name: Cohere Medicare Advantage Policy - Pediatric Vertebral Body Tethering (VBT) and Vertical Expandable Prosthetic Titanium Rib (VEPTR)
Type: [_] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Pediatric Vertebral Body Tethering (VBT) and Vertical Expandable Prosthetic Titanium Rib (VEPTR)

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.

- There are no applicable NCDs and/or LCDs for pediatric vertebral body tethering (VBT) and vertical expandable prosthetic titanium rib (VEPTR).

Description

Vertebral body tethering (VBT) uses hardware such as screws and cords that are implanted near the curved area of a spine with scoliosis. The cords are tightened, thereby purported to straighten the spine to allow for the guided growth of the spine. The procedure requires only small incisions and devices.[1-5] The Pediatric Orthopaedic Society of North America (POSNA) notes that most patients are treated with VBT under the United States Food and Drug Administration (FDA) Humanitarian Device Exemption (HDE) program, which allows off-label use for anterior VBT.[6] The vertical expandable prosthetic titanium rib (VEPTR) is an FDA-approved device that allows the ribcage to expand to straighten the spine and support normal respiration or lung growth. The curved metal rod is attached to the ribs, spine, or pelvis and is expandable to accommodate growth.[7-9]

Medical Necessity Criteria

Indications

Pediatric vertebral body tethering (VBT) and vertical expandable prosthetic titanium rib (VEPTR) are considered appropriate if **ANY** of the following is **TRUE**:

- Vertebral body tethering (VBT) is considered appropriate with **ALL** of the following:

- Failure of conservative management for greater than 3 months, including **ALL** of the following[10]:
  - Anti-inflammatory medications, non-opioid analgesics, or prescription medications (e.g., oral steroids, neuropathic pain medications) if not contraindicated; **AND**
  - Physical therapy, including a physician-directed home exercise program; **AND**
  - **ANY** of the following:
    - Corticosteroid injection if medically appropriate; **OR**
    - Documentation that corticosteroid injection is contraindicated; **AND**
- Spinal curve flexibility is greater than 30%[1]; **AND**
- Radiographic confirmation of **ANY** of the following:
  - Radiographs demonstrated a Cobb angle of 30 to 65 degrees[1,6]; **OR**
  - Moderate lumbar stenosis[5]; **OR**
  - Absence of gross angular or translatory instability of the spine at index or adjacent levels[5]; **AND**
- Skeletal immaturity with **ANY** of the following:
  - Risser grade 0 or 1; **OR**
  - Sanders Maturity Scale less than or equal to 4; **AND**
- The procedure is performed at a Center of Excellence (COE) specialized in anterior spinal surgery[11]; **OR**

- Vertical expandable prosthetic titanium rib (VEPTR) is considered appropriate with **ALL** of the following:
  - Failure of conservative management for greater than 3 months, including **ALL** of the following[10]:
    - Anti-inflammatory medications, non-opioid analgesics, or prescription medications (e.g., oral steroids, neuropathic pain medications) if not contraindicated; **AND**
    - Physical therapy, including a physician-directed home exercise program; **AND**
    - **ANY** of the following:
      - Corticosteroid injection if medically appropriate; **OR**
      - Documentation that corticosteroid injection is contraindicated; **AND**
  - **ANY** of the following:
    - Progressive thoracic insufficiency syndrome[7]; **OR**

        - Scoliosis (e.g., congenital, neuromuscular, idiopathic, syndromic)[7]; **OR**
        - Complex spinal deformities; **OR**
        - Chest wall defects; **AND**
    - The patient is skeletally immature, between 6 months and skeletal maturity, with **ANY** of the following[7]:
        - Risser grade 0 or 1[12]; **OR**
        - Sanders Simplified Skeletal Maturity Scale (SMSS) less than or equal to 4[13]; **AND**
    - The procedure is performed at a COE specialized in anterior spinal surgery[11]; **AND**
    - Preoperative evaluation has been done with the evaluation of **ALL** of the following:
        - Appropriate nutrition status as indicated by **ANY** of the following[14]:
            - Albumin less than 3.5 g/dL; **OR**
            - Total lymphocyte count less than 1,500 cells/mm3; **OR**
            - Transferrin level less than 200 mg/dL; **AND**
        - Cardiac status; **AND**
        - Pulmonary function.

Non-Indications

Pediatric vertebral body tethering (VBT) and vertical expandable prosthetic titanium rib (VEPTR) are not considered appropriate if **ANY** of the following is **TRUE**:

- **ANY** of the following for VBT:
    - The patient is skeletally mature[6]; **OR**
    - The patient is non-ambulatory[6]; **OR**
    - Growing rods are being used (FDA device recall); **OR**
    - Active or chronic infection (e.g., systemic, local)[2,5,7]; **OR**
    - Known allergy to titanium alloys or magnetic resonance contrast agents[2,5,7]; **OR**
    - **ANY** of the following conditions:
        - Axial back pain only, with no leg, buttock, or groin pain[2,5]; **OR**
        - Back or leg pain, unknown etiology[2,5]; **OR**
        - Morbid obesity body mass index (BMI) greater than 40)[2,5]; **OR**
        - Congenital scoliosis[6]; **OR**
        - Vertebral malformations[6]; **OR**

        - Chest malformations[6]; **OR**
        - Altered muscle function or control[6]; **OR**
        - Severe facet hypertrophy that requires extensive bone removal, which would cause instability[2,5]; **OR**
        - Grade II or greater spondylolisthesis[2,5]; **OR**
        - Isthmic spondylolisthesis or spondylolysis (pars fracture)[2,5]; **OR**
        - Degenerative lumbar scoliosis (Cobb angle greater than 25° lumbar segmental)[2,5]; **OR**
        - Osteopenia[2,5]; **OR**
        - Osteoporosis[2,5]; **OR**
        - Metabolic bone disease (e.g., Paget disease, osteomalacia)[5]; **OR**
        - Rheumatoid arthritis or an autoimmune disease that requires chronic steroid use[5]; **OR**
        - Cauda equina syndrome[2,5]; **OR**
        - Active malignancy of an invasive malignancy (excluding nonmelanoma skin cancer, primary bony tumor), unless the patient has had no clinical signs or symptoms of the malignancy for at least 5 years with treatment that has curative intent[5]; **OR**
    - More than 2 vertebral levels require surgical decompression[5]; **OR**
    - Previous surgical procedure resulted in gross translatory instability of the lumbar spine[5]; **OR**
    - Previous fusion of **ANY** of the following[2,5]:
        - Implantation of a total disc replacement; **OR**
        - Complete laminectomy at index level; **OR**
    - Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma, tumor, or infection[2,5]; **OR**
    - Radiographs demonstrate gross angular or translatory instability of the spine at index or adjacent levels with sagittal plane translation greater than 4.0 mm as spondylolisthesis or retrolithesis[5]; **OR**
- **ANY** of the following for VEPTR[7]:
    - Bone strength of the ribs or the spine cannot support where the VEPTR would be attached; **OR**
    - Missing ribs nearest and furthest away from where the VEPTR device needs to be placed and attached; **OR**
    - The diaphragm cannot work properly; **OR**
    - Lack of soft tissue for coverage of VEPTR; **OR**
    - Active or chronic infection (e.g., systemic, local); **OR**

- Known allergy to titanium alloys or magnetic resonance contrast agents; **OR**
- The patient is skeletally mature (about age 14 for girls and age 16 for boys) with problems other than chest wall instability; **OR**
- The patient is younger than 6 months of age.

Definitions

Center of Excellence (COE): A facility specialized to provide an "exceptionally high concentration of expertise and related resources centered on particular medical areas and delivered in a comprehensive, interdisciplinary fashion."[11]

Moderate stenosis: A reduction of more than 25% of the anteroposterior dimension versus the next normal, adjacent level. This includes a comparison of nerve root crowding and a patient's normal level as demonstrated by imaging (e.g., CT, MRI).[5]

Instability: White and Panjabi's classification for stability specifies a "sagittal plane translation greater than 4.0 mm or 15% or local sagittal plane rotation greater than 15° at L1–2, L2–3, and L3–4; greater than 20° at L4–5 based on standing flexion-extension radiographs)."[5]

Skeletal maturity: The Scoliosis Research Society defines skeletally immature as patients "Risser 2 and under OR Sanders 5 and less, as under current understanding, growth modulation depends on meaningful remaining skeletal growth."[6]

Level of Care Criteria

Inpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	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

22838	Revision (e.g., augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed
22899	Unlisted procedure, spine
0656T	Vertebral body tethering, anterior; up to 7 vertebral segments
0657T	Vertebral body tethering, anterior; 8 or more vertebral segments
0790T	Revision (e.g., augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for vertebral body tethering (VBT) may include:

- Adverse effects from delayed or denied treatment, such as tether breakage and reoperation. Cahill et al. (2024) reported that a study of 208 patients demonstrated tether breakage in 50% of the group by 36-month follow-up.[15] Roser et al. (2023) reported similar outcomes.[16] Raitio et al. (2022) conducted a systematic review, which demonstrated that 15% of patients required reoperation.[17] Further research is needed, specifically on the long-term outcomes of VBT for patients with scoliosis.[16]

The clinical benefits of using these criteria for VBT may include:

- Improved patient selection results in better long-term outcomes. These include improved growth modulation, maintaining spine mobility, reduced complication rates, and resumption of activities. VBT "does not impact the pulmonary function even in the case of bilateral surgery with deflation of both lungs".[18] In addition, the procedure can delay or avoid spinal fusion - one study reported that less than 5% of patients required conversion.[17]
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

The potential clinical harms of using these criteria for vertical expandable prosthetic titanium rib (VEPTR) may include:

- Adverse effects from delayed or denied treatment, such as hook migration, respiratory distress, wound dehiscence, recurrent infection, and hardware exposure.[19,20]

The clinical benefits of using these criteria for VEPTR may include:

- Improved patient selection results in better long-term outcomes, including respiratory function[21], curve and head shift improvement, stabilized hemithoracic height and width, and increased thoracic spine height.[8] The device has also demonstrated improved spine formation for patients with cerebral palsy and restrictive lung disease.[20]
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Roser et al. (2023) performed a systematic review of cases using a tethering system and performed a meta-analysis of 16 studies. Vertebral body tethering (VBT) resulted in a statistically significant reduction in Cobb angle, with an average reduction of 25 degrees. The most common complication was tether breakage; however, the consequences are unknown.[16]

Baroncini et al. (2022) conducted a study of 105 patients to analyze risk factors of tether breakage following VBT. Most patients are asymptomatic following a breakage and do not require additional procedures. However, when breakage occurs within 1 year, the loss of correction is higher. The authors analyzed "the influence of patient demographic, pre- and postoperative radiographic parameters, and intraoperative correction technique on the risk of early tether breakage in patients who underwent VBT." A significant indicator is the presence of large, rigid curves on the spine; of the 58 curves that demonstrated breakage, 71% were lumbar, and 29% were thoracic. A total of 95 curves were observed that did not have breakage (71% thoracic, 29% lumbar). Overall, the patient's skeletal maturity and age did not demonstrate a correlation to breakage.[18]

Zhu et al. (2022) performed a systematic review and a single-arm meta-analysis of VBT to treat scoliosis. A total of 1045 patients from 26 studies were included. Overall, the authors note a 73.02% success rate; however, 15.8% of patients required additional surgery. Over half of the patients (52.17%) reported complications, including curve progression with tether breakage, pulmonary complications, and overcorrection.[22]

Shin et al. (2021) performed a meta-analysis that included 211 patients from 10 studies on the efficacy of anterior VBT vs posterior spinal fusion to treat adolescent idiopathic scoliosis. The authors compared complication and reoperation rates. Patients demonstrated higher complication rates with anterior VBT. The authors note the need for long-term, randomized, prospective studies to analyze the efficacy of VBT for the adolescent population.[23]

Bednar et al. (2021) compared magnetically controlled growing rods with other distraction techniques through a systematic review and meta-analysis. A review of 18 studies showed that magnetically controlled growing rods were as clinically effective as other technologies. A lower complication rate was also noted, as well as greater serum titanium levels in patients with magnetically controlled growing rods, but the clinical impact is unclear.[24]

United States Food and Drug Administration (FDA)

In 2023, the FDA approved the Tether Vertebral Body Tethering System for skeletally immature patients with progressive idiopathic scoliosis who have failed or not tolerated brace wear.[1] The FDA approved OrthoPediatrics (eLLi) Growing Rod System for scoliosis in 2024.

In 2019, the United States Food and Drug Administration (FDA) approved the first device for use in idiopathic adolescent scoliosis surgeries. The Tether™ – Vertebral Body Tethering System received Humanitarian Use Device (HUD) designation on March 28, 2019. The humanitarian device exemption (HDE) was approved on August 16, 2019, by the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (H190005).[1-3,5]

The Indication for Use statement was modified to grant permission for the HUD designation. The HUD designation was for "use in the treatment of juvenile and adolescent idiopathic scoliosis in patients, age 5 to 19 years, who are skeletally immature and have a Risser Score of less than 5, that require surgical treatment or have failed non-surgical treatments to obtain and maintain correction of severe, progressive spinal deformities with a Cobb angle of greater than or equal to 30°." Modifications for approval included[1]:

- Removed age ranges.
- Removed "juvenile and adolescent," as chronological age and skeletal maturity vary among populations.
- Specified that the patient should have dimensionally adequate osseous structures representative of the age range and diagnosis.
- Removed reference to a specific skeletal maturity scoring system, as there are different existing methods, and the HUD analysis was not closely linked to a specific method.
- Identified a Cobb angle range to better reflect the study population.

References

1. United States Food & Drug Administration (FDA). FDA executive summary: The Tether Vertebral Body Tethering System (H190005). Published Spring 2024. https://www.fda.gov/media/178434/download

2. United States Food & Drug Administration (FDA). Summary of safety and effectiveness data (SSED): Coflex Interlaminar Technology (PMA P110008). Published October 17, 2012. https://www.accessdata.fda.gov/cdrh_docs/pdf11/p110008b.pdf

3. United States Food & Drug Administration (FDA). 510(k) summary: Zimmer Spine Dynesys Spinal System. Published February 14, 2006. https://www.accessdata.fda.gov/cdrh_docs/pdf6/K060638.pdf

4. United States Food & Drug Administration (FDA). Humanitarian device exemption (HDE): Vertebral expandable prosthetic titanium rib (VEPTR) (HDE no. H030009). Updated November 27, 2012. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=376145

5. Guyer R, Musacchio M, Cammisa FP Jr, et al. ISASS recommendations/coverage criteria for decompression with interlaminar stabilization - Coverage indications, limitations, and/or medical necessity. *Int J Spine Surg*. 2016 Dec 5;10:41. doi:10.14444/3041

6. Pediatric Orthopaedic Society of North America (POSNA) Board of Directors, Scoliosis Research Society (SRS) Board of Directors. Joint SRS/POSNA position statement on payor coverage for anterior fusionless scoliosis technologies for immature patients with idiopathic scoliosis. Published April 2, 2020. https://posna.org/POSNA/media/Documents/Position%20Statements/Why-Should-Insurance-Cover-AVBT-April-2020.pdf

7. United States Food & Drug Administration (FDA). SYNTHES spine - vertical expandable prosthetic titanium rib (VEPTR) (HDE no. H030009). Updated November 27, 2012. https://www.accessdata.fda.gov/cdrh_docs/pdf3/h030009d.pdf

8. Samdani AF, St Hilaire T, Emans JB, et al. The usefulness of VEPTR in the older child with complex spine and chest deformity. *Clin Orthop Relat Res*. 2010 Mar;468(3):700-4. doi:10.1007/s11999-009-0886-7

9. Children's Hospital of Philadelphia. Vertical expandable prosthetic titanium rib (VEPTR). Updated 2025. https://www.chop.edu/treatments/vertical-expandable-prosthetic-titanium-rib-veptr

10. Shah SC, Birknes JK, Sagoo S, et al. Vertical expandable prosthetic titanium rib (VEPTR): Indications, technique, and management review. *Surg Technol Int*. 2009 Apr;18:223-9. PMID: 19585438

11. Elrod JK, Fortenberry JL Jr. Centers of excellence in healthcare institutions: What they are and how to assemble them. *BMC Health Serv Res*. 2017 Jul 11;17(Suppl 1):425. doi:10.1186/s12913-017-2340-y

12. Hacquebord JH, Leopold SS. In brief: The Risser classification - a classic tool for the clinician treating adolescent idiopathic scoliosis. *Clin Orthop Relat Res*. 2012 Aug;470(8):2335-8. doi:10.1007/s11999-012-2371-y

13. Chazono M, Obata S. A simplified skeletal maturity scale and thumb ossification composite index to assess skeletal maturity and predict height velocity in Japanese females with adolescent idiopathic scoliosis. *Spine Surg Relat Res*. 2021 Jan 12;5(4):244-251. doi:10.22603/ssrr.2020-0176

14. Williams DGA, Wischmeyer PE. Perioperative nutrition care of orthopedic surgery patient. *Tech Orthop*. 2020 Mar;35(1):15-18. doi:10.1097/bto.0000000000000412

15. Cahill PJ, Miyanji F, Lullo BR, et al. Incidence of tether breakage in anterior vertebral body tethering. *J Pediatr Orthop*. 2024 Apr 1;44(4):e323-e328. doi:10.1097/BPO.0000000000002619

16. Roser MJ, Askin GN, Labrom RD, et al. Vertebral body tethering for idiopathic scoliosis: A systematic review and meta-analysis. *Spine Deform*. 2023 Nov;11(6):1297-1307. doi:10.1007/s43390-023-00723-9

17. Raitio A, Syvänen J, Helenius I. Vertebral body tethering: Indications, surgical technique, and a systematic review of published results. *J Clin Med*. 2022 May 4;11(9):2576. doi:10.3390/jcm11092576

18. Baroncini A, Trobisch P, Eschweiler J, et al. Analysis of the risk factors for early tether breakage following vertebral body tethering in adolescent idiopathic scoliosis. *Eur Spine J*. 2022 Sep;31(9):2348-2354. doi:10.1007/s00586-022-07231-w

19. Peiro-Garcia A, Bourget-Murray J, Suarez-Lorenzo I, et al. Early complications in vertical expandable prosthetic titanium rib and magnetically controlled growing rods to manage early onset scoliosis. *Int J Spine Surg*. 2021 Apr;15(2):368-375. doi:10.14444/8048

20. Elmallah R, Fortin T, Thimothee J, et al. Outcomes of vertical expandable prosthetic titanium ribs in children with early-onset scoliosis secondary to cerebral palsy. *Cureus*. 2021 Mar 4;13(3):e13690. doi:10.7759/cureus.13690

21. Studer D, Hasler CC. Long term outcome of vertical expandable prosthetic titanium rib treatment in children with early onset scoliosis. *Ann Transl Med*. 2020 Jan;8(2):25. doi:10.21037/atm.2019.09.158

22. Zhu F, Qiu X, Liu S, et al. Minimum 3-year experience with vertebral body tethering for treating scoliosis: A systematic review and single-arm meta-analysis. *J Orthop Surg (Hong Kong)*. 2022 Sep-Dec;30(3):10225536221137753. doi:10.1177/10225536221137753

23. Shin M, Arguelles GR, Cahill PJ, et al. Complications, reoperations, and mid-term outcomes following anterior vertebral body tethering versus posterior spinal fusion: A meta-analysis. *JB JS Open Access*. 2021 Jun 23;6(2):e21.00002. doi:10.2106/JBJS.OA.21.00002

24. Bednar ED, Bergin B, Kishta W. Comparison of magnetically controlled growing rods with other distraction-based surgical technologies for early-onset scoliosis: A systematic review and meta-analysis. *JBJS Rev*. 2021 Jan 20;9(1):e20.00062. doi:10.2106/JBJS.RVW.20.00062

Clinical Guideline Revision History/Information

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