

Cohere Medicare Advantage Policy -**Vertebral Body Tethering**Clinical Guidelines for Medical Necessity Review

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Important Notices

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Policy Information:

Specialty Area: Disorders of the Musculoskeletal System

Policy Name: Cohere Medicare Advantage Policy - Vertebral Body Tethering

Type: [X] Adult (18+ yo) | [_] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Vertebral Body Tethering

Related CMS Documents

Please refer to the <u>CMS Medicare Coverage Database</u> for the most current applicable CMS National Coverage.

There are no applicable NCDs and/or LCDs for vertebral body tethering.

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 purporting to straighten the spine; this allows for the guided growth of the spine. The procedure requires only small incisions. The first device to be used for VBT was approved in 2019 by the United States Food and Drug Administration (FDA).¹⁻⁴

Medical Necessity Criteria

Indications

Vertebral body tethering is considered appropriate if **ALL** of the following are **TRUE**:

• This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Non-Indications

Vertebral body tethering is not considered appropriate if **ALL** of the following are **TRUE**:

This is not applicable as there are no indications.

Level of Care Criteria

Inpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
0656Т	Vertebral body tethering, anterior; up to 7 vertebral segments
0657T	Vertebral body tethering, anterior; 8 or more vertebral segments
0790Т	Revision (e.g., augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed
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

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

Evaluation of Clinical Harms and Benefits

Refer to the Medical Evidence section for various citations and references to studies conducted to date that are inconsistent, inadequately powered, or otherwise do not allow for solid scientific conclusions. Potential harms and benefits of applying an "unproven and not medically necessary" designation to this procedure might include, but are not limited to, the following:

Potential Harms of applying the clinical criteria included in this policy include, but are not limited to, denying opportunities to improve individual and population health outcomes for individuals with pain and dysfunction secondary to scoliotic curvature of the spine. For example, limiting scoliosis surgery correction for adolescents to this procedure may increase patient and population reliance upon excessive pain medication, including opioids, diminished functionality contributing to the development of additional medical problems, and loss of economic opportunity.

Potential Benefits include safeguarding patients and populations from unproven technologies, procedures, and medical interventions until safety, efficacy, and expected outcomes of proposed treatment are fully established via peer-reviewed scientific literature. This safeguards patients from failed tethering procedures, which can lead to pain, inflammation, and ongoing deformity, which in turn may require additional surgeries.

Medical Evidence

Baroncini et al. (2022) conducted a study of 105 patients to analyze risk factors of tether breakage following vertebral body tethering (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.⁵

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. Similar results were found by Cahill et al. (2024). In a study of 208 patients, tether breakage was found in 50% by 36-month follow-up. Additional research is needed, specifically on the long-term outcomes of VBT for patients with scoliosis. 6.7

Shin et al. (2021) performed a meta-analysis that included 211 patients from 10 studies on the efficacy of anterior VBT versus posterior spinal fusion (PSF) to treat adolescent idiopathic scoliosis (AIS). 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.⁸

References

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Clinical Guideline Revision History/Information

Original Date: May 29, 2024			
Review History			
Version 2	06/12/2024	422.101 disclaimer added.	
Version 3	05/22/2025	Annual review. Literature review - Medical Evidence section updated to support non-coverage based on a lack of evidence (Cahill et al., 2024; Baroncini et al., 2022; Zhu et al., 2022; and Shin et al., 2021).	
Version 3.1	07/01/2025	Added Harms & Benefits section.	