Cohere Medicare Advantage Policy - Vertebral Body Tethering

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: June 12, 2024

Important Notices

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Other Notices:

Guideline Information:

Specialty Area: Disorders of the Musculoskeletal System
Guideline Name: Cohere Medicare Advantage Policy - Vertebral Body Tethering

Date of last literature review: 6/12/2024
Document last updated: 6/12/2024
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Vertebral Body Tethering

Benefit Category

Not applicable.

Recommended Clinical Approach

Vertebral body tethering 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 guided growth of the spine. The procedure requires only small incisions, and devices are available for pediatric, skeletally immature patients. In 2019, the U.S. Food and Drug Administration (FDA) approved the first device for use in idiopathic adolescent scoliosis surgeries. [1-4]

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of vertebral body tethering (VBT). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, adverse reactions, and infection.

The potential clinical harms of using these criteria may include:

- Inadequate management of spinal deformities due to inappropriate denials: Vertebral body tethering is not effective in adults because it relies on growth modulation, which is absent in mature skeletal structures[1]. Adults may benefit more from spinal fusion surgeries, which stabilize and correct spinal deformities through a different mechanism.
- Risks with inappropriate surgical procedures: This technique is not recommended for skeletally mature patients and therefore should not be utilized in adults, as there is no skeletal growth remaining and no proven benefit.[1,5] If this procedure is done in an adult surgical risk could include infection, bleeding requiring a transfusion, injury to neurovascular structures, anesthetic risk, and the need for repeat or

additional procedures due to ongoing pain or deformity, or overcorrected deformity.
- Adverse effects from delayed or denied treatment: This is not applicable as it is not appropriate for use in skeletally mature patients.
- Increased healthcare costs and complications: This is not expected as this procedure is not indicated for skeletally mature patients.

The clinical benefits of using these criteria include:

- Improved patient outcomes: Adult patients do not benefit from vertebral body tethering procedures, by denying this procedure this allows adult patients to have the correct procedure for their spine condition. In an adolescent this can prevent further deformity and improve appearance in select cases.[1]
- Reduction in complications and adverse effects: This criteria helps to avoid usage of an unproven procedure in adults and its associated risks. This procedure is not indicated for an adult population and may only be indicated for adolescent patients. It provides a growth-modulating, fusionless alternative, avoiding the irreversible consequences associated with spinal fusion.
- Enhanced overall patient satisfaction and healthcare experience: Ensuring that vertebral body tethering is used appropriately, and not in the adult population leads to better patient outcomes and higher satisfaction rates due to effective treatment and reduced complications.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate the risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

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 in scoliosis.

Non-Indications

- ➔ **Vertebral body tethering** is not 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 in scoliosis.

Level of Care Criteria

None

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
0656T	Vertebral body tethering, anterior; up to 7 vertebral segments
0657T	Vertebral body tethering, anterior; 8 or more vertebral segments
0790T	Revision (eg, 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 (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed
22899	Unlisted procedure, spine

Medical Evidence

The United States Food and Drug Administration has granted approval to the Tether Vertebral Body Tethering System, for skeletally immature patients with progressive idiopathic scoliosis, after failing or not tolerating brace wear (2023).[1]

In 2016, the International Society for the Advancement of Spine Surgery (ISASS) did not recommend decompression with interlaminar stabilization in patients with degenerative lumbar scoliosis (Cobb angle greater than 25° lumbar segmental.)[3]

References

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Clinical Guideline Revision History/Information

Original Date: May 29, 2024		
Review History		
Version 2	6/12/2024	422.101 Disclaimer added