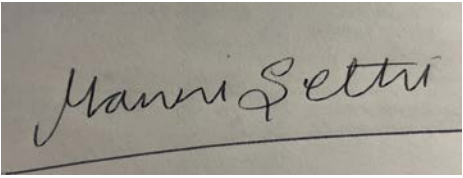


**Prior Authorization Review Panel**  
**MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.  
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<b>Plan: AmeriHealth Caritas Pennsylvania</b>	<b>Submission Date:</b> 1/1/2024
<b>Policy Number:</b> ccp.1502	<b>Effective Date:</b> 12/2021 <b>Revision Date:</b> November 1, 2023
<b>Policy Name: Scoliosis vertebral body tethering and stapling</b>	
<b>Type of Submission – Check all that apply:</b>  New Policy <input checked="" type="checkbox"/> Revised Policy* Annual Review – No Revisions Statewide PDL	
<b>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</b>  <b>Please provide any clarifying information for the policy below:</b>  See tracked changes below.	
<b>Name of Authorized Individual (Please type or print):</b>  Manni Sethi, MD, MBA, CHCQM	<b>Signature of Authorized Individual:</b>  

# Scoliosis vertebral body tethering and stapling

Clinical Policy ID: CCP.1502

Recent review date: 11/2023

Next review date: 3/2025

Policy contains: idiopathic scoliosis, stapling, tethering.

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## Coverage policy

Vertebral body tethering and stapling for idiopathic scoliosis are investigational/not clinically proven and, therefore, not medically necessary.

### Limitations

No limitations were identified during the writing of this policy.

### Alternative covered services

- Spinal bracing.
- Spinal fusion.
- Physical therapy.

## Background

Adolescent idiopathic scoliosis is a lateral curvature of the spine (i.e., the Cobb angle) of at least 10° affecting adolescents 10 to 18 years of age. Its cause is not well understood. Most patients with adolescent idiopathic scoliosis present without serious symptoms. A minority of patients who have greater curve angles may develop substantial rib deformities, which can lead to more serious health conditions later in life. Clinically significant disease is more likely to occur at a Cobb angle of at least 40° (Kuznia, 2020).

The goals of treatment are to reverse, cease, or limit further spinal curvature and consequences of physical discomfort or respiratory compromise that may lead to important social and psychological effects and reduced quality of life. Conservative treatments include various braces, exercise, postural re-education, physical therapy, electrical stimulation, and acupuncture (Karimi, 2018). Surgery and/or bracing are usually reserved for severe cases when the initial Cobb angle is at least 40°; patients with lesser curvatures can be monitored unless signs or symptoms suggest an alternative diagnosis (Kuznia, 2020).

Conservative treatments may be ineffective, and braces raise particular concerns. Each year, 6,800 U.S. patients will develop progressive curvatures not improved by bracing. A Cochrane review of seven studies (n = 662), five of which were randomized trials, stated that while braces prevented curve progression, the low quality of evidence of studies and high failure rates of braces (especially involving quality of life) were concerns (Negrini, 2015). In addition, braces must be worn for an average of 2.9 years, and sometimes as many as six to eight years, raising questions of compliance (Cuddihy, 2015).

Surgical spinal implants and fusion constitute other approaches to refractory scoliosis but may restrict spinal motion and have long-term complications. Clinicians have sought alternatives to this surgery (U.S. Food and Drug Administration, 2019a).

Two recent approaches to improving spinal curvature in scoliosis are described below.

#### Vertebral body tethering

In 2019, the U.S. Food and Drug Administration approved the Tether™ Vertebral Body Tethering System (Zimmer Biomet Spine, Inc., Westminster, Colorado). The Administration used its Humanitarian Device Exemption process, applicable for conditions affecting fewer than 8,000 U.S. patients per year. Tethering is indicated for skeletally immature patients with a major Cobb angle of 30° to 65° whose bone structure can accommodate screw fixations as determined by X-rays. Recipients should have failed bracing or be intolerant to brace wear. The manufacturer is required to conduct post-marketing studies to determine safety and effectiveness (U.S. Food and Drug Administration, 2019a, 2019b).

Tethering involves an incision in the side of the chest and placement of anchors and screws in the same side of each vertebra in the curved section of the spine. The tether (a flexible cord) is connected to the screws and compresses one side of the spine. The tether slows growth on the convex side of the spinal curvature and promotes growth on the concave side. It is permanent, unless problems later develop, and it does not preclude spinal fusion, if necessary (U.S. Food and Drug Administration, 2019a; Zhang, 2020).

An analysis estimated that 20.9% of a group of 359 children with scoliosis were candidates for vertebral body tethering, using U.S. Food and Drug Administration criteria (Sanders bone age ≤ 4, primary thoracic curve 35° to 60°, and lumbar curve < 35°). Subjects considered not appropriate for tethering included those with a non-thoracic primary curve, those too mature at presentation, those with a lumbar curve > 34°, those with a main thoracic curve out of range, and those with multiple exclusionary criteria (Krakow, 2021).

#### Vertebral body stapling

Initial attempts to correct scoliosis using vertebral body staples were discontinued after staples sometimes loosened after crossing the intervertebral disc. The recent introduction of Nitinol, a temperature-sensitive shape memory metal alloy made of nickel and titanium, has allowed vertebral body stapling to be performed without concerns over subsequent loosening of staples (Newton, 2020).

While no uniform indications exist for vertebral body stapling, some have proposed using the technique for children with moderate idiopathic scoliosis (structural coronal curve of 25° to 40°), along with intolerance of braces and a Risser sign of 0 – 2 (Bumpass, 2015; Zhang, 2020).

The staple is shaped like a clamp, and after being placed in an ice bath, is bent straight, and inserted into the spine. The staple then returns to its original clamp shape, preventing it from dislodging. The procedure includes a small chest incision on the convex side of the curve; patients are braced for a month to stabilize the surgery (Washington University Physicians, undated).

As of the current writing, no approval from the U.S. Food and Drug Administration has been granted for vertebral body stapling in scoliosis patients.

## Findings

A practice guideline on scoliosis from the International Society on Scoliosis Orthopaedic and Rehabilitation Treatment mentioned conservative treatments, bracing, physiotherapy, and surgery, but not vertebral body tethering or stapling as treatment options (Negrini, 2018). The American Academy of Family Physicians expressed similar conclusions (Kuznia, 2020).

The American Association of Neurological Surgeons fact sheet on scoliosis lists only observation, bracing, and surgery as potential treatments (American Association of Neurological Surgeons, undated).

In a joint statement by the Pediatric Orthopaedic Society of North America and the Scoliosis Research Society, both organizations believe that non-fusion technology provides significant functional promise and benefits compared to fusion technology and support regulatory-approved usage of such devices in skeletally immature patients via shared decision making with health care professionals, considering the risks and the motion-preserving benefits. Neither organization supports the use of anterior non-fusion instrumentation in skeletally mature individuals for the management of scoliosis or other spinal deformities (Pediatric Orthopaedic Society of North America, 2020).

The evidence of the safety and efficacy of vertebral body tethering for idiopathic scoliosis in the skeletally immature consists of lower quality retrospective case series, and, to a lesser extent, matched cohort studies and registry analyses, compared to evidence from randomized controlled trials supporting posterior spinal fusion. Success following vertebral body tethering was defined primarily as Cobb angle  $< 35^\circ$  or  $< 40^\circ$  at follow-up. Sagittal alignment, thoracic rotation, and reoperation rates were reported inconsistently. The average follow-up period ranged from two to three years.

The evidence suggests vertebral body tethering may partially preserve motion in instrumented segments of the spine and potentially avoid the long-term sequelae of fusion techniques (e.g., adjacent segment disease and proximal junctional kyphosis). Vertebral body tethering has similar coronal deformity correction rates, but also greater rates of complications and reoperations compared to posterior spinal fusion. The main concerns are tether breakage and overcorrection, which appear to increase at longer follow-up. Understanding the parameters leading to success or failure (e.g., the ideal amount of tethering to be applied to different curves in different categories of skeletal maturity or the use of double-sided tethering) and longer-term follow-up are needed.

A review of nine studies ( $n = 175$ ) of children who received vertebral body tethering for idiopathic scoliosis found the mean correction on the coronal plane was 52%, with no significant change in sagittal parameters. The revision rate was 18.9%. No meta-analysis was performed due to lack of randomized trials (Baroncini, 2021b).

A meta-analysis of children treated for scoliosis included 10 studies ( $n = 211$ ) of vertebral body tethering and 14 ( $n = 1,069$ ) of posterior spinal fusion. Mean follow-up was 33.7 and 46.9 months for tethering and fusion. Tethering had worse complication rates (11.8% versus 1.0% in studies with mean tracking for less than 36 months; and 25.2% versus 2.9% in those with mean tracking for more than 36 months). Tethering had higher reoperation rates (2.9% versus 1.3% in studies with mean follow-up of less than 36 months, and 24.7% versus 1.8% in those with mean follow-up of more than 36 months). Thoracic curve reductions after 36 months were greater for fusion ( $53.3^\circ$  to  $22.7^\circ$ ) versus tethering ( $46.0^\circ$  to  $22.5^\circ$ ) (Shin, 2021).

A cost-utility analysis compared tethering to fusion as a first-line surgical treatment for patients older than 10 years of age with moderate to severe scoliosis refractory to conservative therapy. Tethering had higher discounted costs (\$96,897 versus \$51,351 per patient) and higher quality-adjusted life years than fusion. The incremental cost-effectiveness ratio for tethering versus fusion was \$84,391 per quality-adjusted life year gained (Polly, 2021).

#### Studies of tethering versus fusion

A study comparing 62 children with scoliosis who had fusion with 20 children who had vertebral body tethering showed the tethering group had a greater thoracic flexibility in bending from radiographs, correcting 59% versus 43% ( $P = .005$ ). Quality of life scores on each of five Scoliosis Research Society domains were similar between groups (Qiu, 2021).

In a prospective cohort study, 26 participants who underwent vertebral body tethering were compared to those who underwent posterior spinal fusion matched by age, gender, Risser sign, and major curve magnitude. The vertebral body tethering group experienced significantly lower operative time, anesthesia time, blood loss, and length of stay ( $P < .001$ ,  $P = .003$ ,  $P < .001$ , and  $P < .001$ , respectively). Ninety-six percent of the fusion group achieved curve correction to  $< 35^\circ$  compared to 77% of the vertebral body tethering group. At two years, cord breakage occurred in 19% of participants with vertebral body tethering. Three patients developed complications in both study groups (Mathew, 2022).

Using data from a multicenter U.S. registry, Mackey (2022) compared outcomes of posterior spinal fusion, magnetically controlled growing rods, and vertebral body tethers in eight- to 11-year-old participants ( $n = 130$ ) with idiopathic early onset scoliosis. The vertebral body tethering cohort included more females ( $P < .0005$ ), was older ( $P < .0005$ ), more skeletally mature ( $P < .0005$ ), and had smaller major curves ( $P < .0005$ ). In older participants with idiopathic early onset scoliosis, all three surgical approaches controlled curves effectively and increased spinal height, but vertebral body tethering and posterior spinal fusion had a lower risk for an unplanned revision and improved quality of life.

#### Retrospective studies of tethering

A questionnaire to 31 participants with scoliosis (mean 14.5 years) showed that three months after tethering, 97% had returned to school, 61% resumed physical education, 97% carried a backpack, 68% ran, 82% rode a bike; and 94% resumed preoperative athletic levels. In addition, 63% of respondents resumed noncontact sports; 61% contact sports; and 53% collision sports (Baroncini, 2021a).

In a retrospective analysis of 184 participants who underwent anterior vertebral body tethering by a single surgeon, the 90-day major and minor complication rates were both 3.3%. Major complications included three chylothoracies, two hemothoracies, and one lumbar radiculopathy secondary to screw placement requiring re-operation. Minor complications included respiratory distress requiring supplementary oxygen, superficial wound infection, prolonged nausea, and Raynaud phenomenon (Meyers, 2021).

#### Retrospective studies of stapling

No large systematic reviews or meta-analyses exist for vertebral body stapling. The evidence from small, retrospective case series suggests vertebral body stapling and bracing yields similar reductions in thoracic curvature in patients with moderate idiopathic scoliosis. Vertebral body stapling requires a minimally invasive thoracoscopic or mini-open retroperitoneal approach and no additional full-time bracing, although it may be used adjunctively with bracing in select patients. However, its long-term safety and efficacy require further study. Other reviews of modest size have produced results, described below.

A retrospective review (n = 14) followed children with idiopathic scoliosis treated with Nitinol staples to skeletal maturity (an average of 61 months). The mean preoperative thoracic curve was 35°. Ten of 14 either progressed minimally ( $\leq 10^\circ$ ) or improved, while three went on to uncomplicated fusion (Haber, 2020).

A study (n = 63) who underwent stapling (mean 10.78 years) were followed for an average of 3.62 years. The mean Cobb angle for stapled thoracic curves declined from 29.5° before surgery to 21.8° at most recent follow-up; corresponding figures for stapled lumbar curves were 31.1° to 21.6°. Of those with thoracic and lumbar curve staples, 74% and 82% avoided progression and/or fusion (Cahill, 2018).

A study of 35 brace-intolerant participants with a structural coronal curve of 25° to 40° (mean 10.5 years of age) underwent surgery using Nitinol staples. Those with curves less than 35° had a control rate of 75%, and patients younger than 10 years had a 62% curve control rate; 31% required subsequent fusions, and 14% developed small pneumothoraces (Bumpass, 2015).

A comparison of idiopathic scoliosis treatments included 42 children who underwent vertebral body stapling (follow-up mean 40.8 months) and 52 who were assigned a brace (mean follow-up 105 months). The success rate of stapling (i.e., reduction of thoracic curves from 25° – 34° to 10° or lower) was 81% versus 61% for bracing ( $P = .16$ ). Stapling and bracing both had low success rates for children with thoracic curves 35° – 44°. For lumbar curves 25° – 34°, both approaches had a success rate of 80% (Cuddihy, 2015).

An early review of stapling involved 12 females younger than age 10 with thoracic or lumbar scoliosis curves 30° to 39° followed more than 24 months. All were treated successfully, and average curve magnitude reduced after surgery (to 19.0°) and at most recent follow-up (to 23.0°), indicating efficacy in young children (Theologis, 2013).

A review of 28 participants (mean 9.4 years of age) followed from 2.0 to 5.3 years were successful (improved or stabilized curvature) for 86% of thoracic curves  $<35^\circ$ , and for 100% of lumbar curves (Trobisch, 2011).

In 2022, we added new individual studies reporting on the safety and efficacy of vertebral body tethering, and one joint position statement. The results confirm previous findings. No policy changes are warranted.

In 2023, we added five systematic reviews and meta-analyses of vertebral body tethering for idiopathic scoliosis in the skeletally immature. To avoid redundancy, we deleted several individual studies from this policy that were addressed in the new analyses. The new analyses of retrospective, nonrandomized studies described below confirm previous findings and warrants no policy changes:

- Vertebral body tethering produced a significant and maximal correction of main thoracic, proximal thoracic, and thoracolumbar curves, rib hump, and lumbar prominence at Year 1 after surgery. There was loss of correction in the main thoracic curve at Year 2. There were no corrections of thoracic and lumbosacral lordosis. The most frequent complications were overcorrection (8.0%), and tether breakage (5.9%). Revision rates were 10.1%. Follow-up was generally less than 36 months (Mariscal, 2023; 13 studies; n = 538).
- Vertebral body tethering significantly reduced and then maintained the major curve Cobb angle from preoperative baseline up to two years after surgery (mean difference = - 25.8°, 95% confidence interval - 28.9 to -22.7,  $P < .01$ ). The overall complication rate was 23%, but the consequences of the complications were unknown. The most common complication was tether breakage 21.9%, and the spinal fusion rate was 7.2% (Roser, 2023; 19 studies; average study size 35.4 participants).
- After at least two years of follow up, anterior vertebral body tethering resulted in a significant correction of the main thoracic curve of scoliosis (mean preoperative Cobb angle = 48.5°, mean Cobb angle at final follow-up = 20.1°,  $P = .01$ ). Complications were overcorrection (14.3% of participants), mechanical (27.5%), and pulmonary (9.7%). Tether revision occurred in 7.85%, and revision to a spinal fusion in 7.88%. Mean follow-up was 34 months (Vatkar, 2023; nine studies; n = 196).

- Compared to posterior spinal fusion, anterior vertebral body tethering can achieve superior range of motion outcomes (moderate quality evidence), superior muscle strength and endurance (very low quality), comparable Cobb angle correction (low quality), and an inconclusive impact on quality of life outcomes. The most common complication was over-correction (Wong, 2023; 12 studies; sample sizes ranged from five to 225).
- At final follow up, vertebral body tethering resulted in an average percent correction of 15.6% to 106.5% of the main tethered curve and -31.8 to 20.0% correction of thoracic kyphosis. The most common complications were tether breakage (n = 145; 21.3%), pulmonary (n = 49; 6.9%), and overcorrection (n = 30; 4.2%). The revision rate was 13.1% (Zhang, 2022; 25 studies).

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On September 7, 2023, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “lumbar vertebrae/surgery” (MeSH), “thoracic vertebrae/surgery” (MeSH), “scoliosis” (MeSH), “idiopathic scoliosis,” “stapling,” and “tethering.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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## Policy updates

11/2021: initial review date and clinical policy effective date: 12/2021.

11/2022: Policy references updated.

11/2023: Policy references updated.

