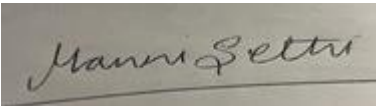


**Prior Authorization Review Panel
MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First Community HealthChoices	Submission Date: 1/2/2025
Policy Number: ccp.1502	Effective Date: 12/2021 Revision Date: November 1, 2024
Policy Name: Scoliosis vertebral body tethering and stapling	
Type of Submission – Check all that apply: <div style="margin-left: 20px;"><input type="checkbox"/> New Policy <input checked="" type="checkbox"/> Revised Policy* <input type="checkbox"/> Annual Review – No Revisions <input type="checkbox"/> Statewide PDL</div>	
<p>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</p> <p>Please provide any clarifying information for the policy below:</p> <p>See tracked changes below.</p>	
Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 



Scoliosis vertebral body tethering and stapling

Clinical Policy ID: CCP.1502

Recent review date: 11/2024

Next review date: 3/2026

Policy contains: idiopathic scoliosis, stapling, tethering.

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First Community HealthChoices, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

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. Treatment options include conservative management, bracing, and surgery. Radiographic surveillance is indicated for patients with curves of 10° to 25°. Bracing is reserved for those with spinal curvature greater than 25° but less than 40° to 45°. However, it has a low compliance rate and variable success. Skeletally immature patients with a Cobb angle of at least 40° are candidates for surgery (Menger, 2023).

Posterior spinal fusion with pedicle screws and bilateral rod placement is the most common surgical approach, but anterior and combined anterior/posterior approaches may be used. Fusion surgery may restrict movement and is associated with serious, long-term complications that may be more disabling than the disorder itself. Non-fusion techniques have been developed to address these concerns (Menger, 2023).

Vertebral body tethering

Vertebral body tethering systems are designed to treat scoliosis while a person is actively growing. The system uses his or her own growth to repair the curve by exploiting the principle of the Heuter-Volkman law, which states that bone growth increases when stretched and decreases when compressed. The procedure 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, 2019, 2023).

The U.S. Food and Drug Administration has approved two vertebral body tethering systems as Humanitarian Use Devices under the Humanitarian Device Exemption process. The Tether™ Vertebral Body Tethering System (Highridge Spine, Westminster, Colorado) was approved in 2019 followed by the REFLECT™ Scoliosis Correction System (Globus Medical, Inc., Audubon, Pennsylvania) in 2023. Both systems are approved 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, 2019, 2023).

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).

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

Guidelines

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. Both organizations 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).

Evidence review

Vertebral body tethering

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 results in the following systematic reviews and meta-analyses suggest vertebral body tethering using an anterior approach may partially preserve motion in instrumented segments of the spine and may 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.

Anterior 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; $n = 538$).

Anterior 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 in 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 occurred in 7.88%. Mean follow-up was 34 months (Vatkar, 2023; nine studies; $n = 196$).

A meta-analysis of children treated for scoliosis included 10 studies ($n = 211$) of anterior 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, respectively. 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 re-operation 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° to 22.7°) versus tethering (46.0° to 22.5°) (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).

Vertebral body stapling

No large systematic reviews or meta-analyses exist for vertebral body stapling. The evidence from small, retrospective case series presented below 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.

Sixty-three patients underwent stapling (mean 10.78 years) and 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).

Thirty-five 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). Another study compared 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).

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 and deleted several individual studies from this policy that were addressed in the new analyses. No policy changes are warranted.

In 2024, we reorganized the findings, deleted several older and redundant references, and made no policy changes.

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On September 23, 2024, 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-

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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.

11/2024: Policy references updated.