

07.01.92 Minimally-Invasive Surgical Treatments for Scoliosis

Original Effective Date: January 2010

Review Date: August 2026

Revised: August 2026

DISCLAIMER/INSTRUCTIONS FOR USE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

Related Policies:

- None

Summary

Description

Orthotic bracing attempts to slow spinal curve progression and reduce the need for fusion surgery in individuals with juvenile or adolescent idiopathic scoliosis who are at high-risk of progression. This evidence review addresses minimally invasive deformity correction systems such as vertebral body stapling, vertebral body tethering, minimally invasive deformity correction system- ApiFix, and magnetically controlled growing rods (MCGRs) which have been evaluated to determine whether these procedures could be used as alternatives to traditional orthotic bracing for spinal curve progression.

This review does not address conventional fusion surgery for the treatment of scoliosis see [Wellmark Authorization Table](#) for applicable InterQual criteria and medical policy [07.01.91 Surgical Treatment of Sacroiliac Joint Pain](#).

Summary of Evidence

For individuals who have juvenile or adolescent idiopathic scoliosis (AIS) at high-risk of progression who receive vertebral body stapling (VBS), the evidence includes a comparative cohort study, a case-control study, and case series. Relevant outcomes are changes in disease status, morbid events, quality of life (QOL), and treatment-related morbidity. There is a small body of published evidence on surgical interventions for preventing curve progression in juvenile and adolescent idiopathic scoliosis. VBS with memory shape staples may control some thoracic curves between 20° and 35°, but it is less effective than bracing for larger curves. The evidence is composed primarily from a center that developed the technique, along with a few case series from other institutions. Additional studies with larger sample sizes and longer follow-up are needed to evaluate the safety and efficacy of this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have juvenile or adolescent idiopathic scoliosis (AIS) at high-risk of progression who receive vertebral body tethering (VBT), the evidence includes observational studies and a systematic review and meta-analysis of these studies. Relevant outcomes are changes in disease status, morbid events, QOL, and treatment-related morbidity. VBT has been evaluated for thoracic curves at high-risk of progression. A 2025 systematic review found that while VBT offers meaningful perioperative and recovery advantages and comparable short-term patient-reported outcomes in selected skeletally immature patients, it results in less consistent radiographic correction and substantially higher revision rates than posterior spinal fusion. A 2022 systematic review and meta-analysis of 26 studies reported meaningful Cobb angle correction but also substantial safety concerns, with a 74 percent clinical success rate, a 52 percent overall complication rate, and a 16 percent unplanned reoperation rate among patients with more than 36 months of follow-up. Evidence for the FDA-authorized The Tether device is based primarily on a single-center, uncontrolled retrospective cohort of 57 patients. Additional observational studies of the Dynesys system (foundation for The Tether device) demonstrate short-term Cobb angle improvements but provide limited insight into long-term durability, with tether breakage and revision surgery occurring in a significant portion of patients. Published data for the REFLECT system are similarly limited to observational cohorts with short follow-up and minimal reporting on patient-centered outcomes. Controlled studies with long-term follow-up are needed to validate clinical benefits, clarify safety, and determine appropriate patient selection. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have juvenile or adolescent idiopathic scoliosis (AIS) at high-risk of progression who receive magnetically controlled growing rods (MCGRs), the evidence consists of a systematic reviews, observational studies and several small case series. Relevant outcomes are changes in disease status, morbid events, QOL, and treatment-related morbidity. In the systematic review by Migliorini et al (2022) there was a total of 124 complications reported in 504 patients (25%). The most common complications included proximal screw pull out from the rod, connector breakage, detachment of pedicle screw head/screw misplaced and screw/plug loosening. Although reported Cobb angle corrections are promising, serious adverse events occurred, and there are important study design limitations including retrospective nature, limited study size, and surgical approach, eligibility criteria and rehabilitation criteria not adequately discussed or reported. Additional studies are needed to evaluate the safety and efficacy of this minimally invasive surgical procedure to include determining the optimum initial correction, rate of distractions and methods of monitoring spinal growth. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have juvenile or adolescent idiopathic scoliosis (AIS) at high-risk of progression who receive minimally invasive deformity correction system – ApiFix, the evidence consists of single-group observational studies conducted outside of the United States. Relevant outcomes are changes in disease status, morbid events, QOL, and treatment-related morbidity. In the industry sponsored prospective cohort study (Stadhouder et. al. 2021) evaluating the safety and efficacy of ApiFix which included 20 individuals with adolescent AIS, 7 of 20 participants showed signs of surgical failure and study recruitment was stopped, and due to the high complication rate of the remaining individuals which was 11 serious adverse events (pain, breakage/failure of implant, osteolysis) in 10 individuals this study was prematurely terminated. The authors stated: “no distraction was observed and the high rate of serious adverse events within 2 years was considered unacceptable for further clinical application of this device in our institution, despite recent FDA approval.” In the retrospective study by Zygiogiannis et. al. (2023) this study found SSI remains an issue even in the most experienced hands. A strict surgical protocol of surgical asepsis and postoperative dressing changes may assist in the prevention of contamination pathogens. Further randomized trials are needed to gather more evidence on this subject. While retrospective studies by Floman et.al. 2021 and Froehlich et. al. 2023 showed promising results in curve reduction, both studies continued to show that adverse events remained an issue in the cohort of patients studied related to infection, problems associated with anchorage of implant, pedicle screw misplacement, nut loosening and ratchet malformation. Despite the promising results these results are only preliminary, since they are based on relatively small cohort and follow-up did not extend beyond 2 years. Comparative studies are necessary to evaluate the long-term outcomes of using the ApiFix implant in the management of AIS. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Not applicable.

OBJECTIVE

The objective of this evidence review is to determine whether minimally invasive deformity correction systems such as vertebral body stapling, vertebral body tethering, minimally invasive deformity correction system - ApiFix and magnetically controlled growing rods for the treatment of scoliosis improves the net health outcome for juveniles and adolescents who are at high risk of spinal curve progression.

PRIOR APPROVAL

Not Applicable.

POLICY

Vertebral body stapling (VBS) for the treatment of scoliosis is considered **investigational**. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Vertebral body tethering (VBT) for the treatment of scoliosis are considered **investigational**. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

The use of magnetically controlled growing rods (MCGRs) for the treatment of scoliosis is considered **investigational**. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

The use of minimally invasive deformity correction system - ApiFix for the treatment of scoliosis is considered **investigational**. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

POLICY GUIDELINES

Coding

See the [Codes](#) table for details.

BACKGROUND

Scoliosis

Scoliosis is an abnormal lateral and rotational curvature of the vertebral column. Adolescent idiopathic scoliosis is the most common form of idiopathic scoliosis, defined by the U.S. Preventive Services Task Force as “a lateral curvature of the spine with onset at ≥ 10 years of age, no underlying etiology, and risk for progression during puberty.” Progression of the curvature during periods of rapid growth can result in deformity, accompanied by cardiopulmonary complications. Diagnosis is made clinically and radiographically. The curve is measured by the Cobb angle, which is the angle formed between intersecting lines drawn perpendicular to the top of the vertebrae of the curve and the bottom vertebrae of the curve. Patients with adolescent idiopathic scoliosis are also assessed for skeletal maturity, using the Risser sign, which describes the level of ossification of the iliac apophysis.

The Risser sign measures remaining spinal growth by progressive anterolateral to posteromedial ossification. Risser sign ranges from 0 (no ossification) to 5 (full bony fusion of the apophysis). Immature patients will have 0% to 25% ossification (Risser grade 0 or 1), while 100% ossification (Risser grade 5) indicates maturity with no spinal growth remaining. Children may progress from a Risser grade 1 to grade 5 over a brief (e.g., 2-year), period.

Males and females are equally affected by scoliosis, but curve progression is up to 10 times more common in females than males (AAOS, accessed August 2025). Individuals who are overweight or obese have a greater risk of presenting with larger Cobb angles and more advanced skeletal maturity, possibly due to delayed detection. A retrospective review (Heffernan et al 2022) of 341 patients with adolescent idiopathic scoliosis who underwent surgery at a single tertiary pediatric hospital between 2013 and 2018 found that the major curve magnitude at presentation was significantly higher in patients with public compared to private insurance (50.0° versus 45.1° ; $p=.0040$) and in Black compared to White patients (51.8° versus 47.0° ; $p=.042$). Additionally, the odds of having an initial major curve magnitude $<40^\circ$ within the range of nonoperative treatment were 67% lower among Black patients with public insurance compared to Black patients with private insurance (odds ratio [OR], 0.33; 95% CI, 0.13 to 0.83; $p=.019$).

Treatment

Treatment of scoliosis currently depends on 3 factors: the cause of the condition (idiopathic, congenital, secondary), the severity of the condition (degrees of the curve), and the growth of the patient remaining at the time of presentation. Children who have vertebral curves measuring between 25° and 40° with at least 2 years of growth remaining are considered to be at high risk of curve progression. Genetic markers to evaluate the risk of progression are also being evaluated. Because severe deformity may lead to compromised respiratory function and is associated with back pain in adulthood, surgical intervention with spinal fusion is typically recommended for curves that progress to 45° or more.

Surgery

Vertebral Body Stapling and Vertebral Body Tethering

Fusionless surgical procedures, such as vertebral body stapling and vertebral body tethering, are being evaluated as alternatives to bracing. The goal of these procedures is to reduce the rate of spine growth unilaterally, thus allowing the other side of the spine to “catch up.” The mechanism of action is believed to be down-regulation of the growth plate on the convex (outer) side by compression and stimulation of growth on the endplate of the concave side by distraction. In the current stapling procedure, nickel-titanium alloy staples with shape memory are applied to the convex side of the curve. The shape memory allows the prongs to be straight when cooled and clamp down into the bone when the staple returns to body temperature.

Anterolateral tethering uses polyethylene ligaments that are attached to the convex side of the vertebral bodies by pedicle screws or staples. The ligament can be tightened to provide greater tension than the staple. The optimum degree of tension is not known. The polyethylene ligaments are more flexible than staples and are predicted to allow more spinal mobility. The goal of a fusionless growth modulating procedure is to reduce the curve and prevent progression, maintain spine mobility following correction, and provide an effective treatment option for patients who are noncompliant or who have a large curve, but substantial growth is remaining. Observational data suggest that overweight patients may be at higher risk for scoliosis progression after surgery.

Vertebral Body Tethering Procedure Summary

Vertebral Body Tethering (VBT) is a technique for scoliosis correction in selected adolescent idiopathic scoliosis patients.

Vertebral body tethering is performed under general anesthesia with an operating time of 4-6 hours. Double-lumen intubation confirmed by bronchoscopy establishes single-lung insufflation and the patient is positioned lateral decubitus with the curve convexity upward. A 12-mm thoracoscopic portal is placed, carbon dioxide insufflation facilitates lung deflation, and the spinal pleura is opened to expose the lateral vertebral bodies while preserving disc spaces. A total of 3-5 portals may be used to introduce instrumentation.

Using biplanar fluoroscopy, bicortical tether anchors are placed sequentially from caudal to cephalad levels on the convex side, with motor evoked potentials obtained at each level. The tether is introduced through the caudal portal, secured proximally, and sequentially tensioned across anchors, with maximal tension at the curve apex and decreasing tension toward the ends. Radiographs confirm correction. A chest tube is typically placed to re-inflate the lung and may be retained depending on patient status.

Post operative hospitalization is anticipated to be 3-5 days with resumption of baseline activity by 12 weeks. Serial radiographic follow-up continues until skeletal maturity or identification of a clinical concern.

Anterior vertebral tethering is associated with complications that may arise from both the surgical approach and the implanted device. Approach-related complications include pulmonary events such as pneumonia, pneumothorax, and hemothorax. In addition, the anterior approach places adjacent anatomical structures at risk, including major vascular structures, visceral organs including the heart, lungs, liver, kidneys, spleen, and bowel; and neurologic structures such as the spinal cord and spinal nerve roots.

Implant-related complications primarily involve mechanical and fixation issues. These include rupture of the tether as well as malposition or loosening of the anchoring components, which may compromise device stability and intended biomechanical correction including producing treatment limiting overcorrection.

While VBT had originally been developed for adolescent idiopathic scoliosis, some studies have explored its use in selected patients with non-idiopathic scoliosis and early-onset scoliosis. Non-idiopathic patients may also carry higher infection and pulmonary complication risks, making the less invasive nature of VBT particularly appealing due to reduced pain and earlier mobilization. The VBT procedure has also demonstrated improved curve correction, fewer implant-related complications, and fewer unplanned surgeries compared to other procedures, while preserving spinal mobility and soft tissues until definitive fusion.

Magnetically Controlled Growing Rods

Traditional growing rods have been utilized for the treatment EOS when spinal curvature is too significant to control with bracing or casting but require multiple surgeries that can increase complication rates. A minimally invasive surgery using magnetically controlled growing rods (MCGR) was developed to avoid multiple surgeries. One such magnetic distraction rod is the MAGnetic Expansion Control (MAGEC®) System which per the FDA approval is intended for “skeletally mature patients younger than 10 years of age with severe progressive spinal abnormalities (e.g., Cobb angle of 30° or more; thoracic spine height < 22 centimeters) associated with or at risk of thoracic insufficiency syndrome (TIS). TIS is defined as the inability of the thorax to support normal respiration or lung growth.” After the initial procedure physicians utilize an external remote control outside of the body to lengthen the MCGR as the child grows.

Minimally Invasive Deformity Correction System

The minimally invasive deformity correction system ApiFix is a fusion-less surgical treatment for scoliosis. This system is a ratchet-based, expandable rod which attaches to the spine using pedicle screws. This internal brace, like the vertebral body tethering and stapling, achieves correction without the need for spinal fusion. It is implanted posteriorly on one side of the spine. The ApiFix system is indicated for treatment of adolescent idiopathic scoliosis (AIS) for treatment of single curves, classified as Lenke 1 (thoracic major curve) or Lenke 5 (thoracolumbar/lumbar major curve), having a Cobb angle of 35-60 degrees which reduces to less than or equal to 30 degrees on lateral side-bending radiographs, and thoracic kyphosis less than 55 degrees as measured from T5 to T12. For individuals with curves of lower magnitudes (i.e., less than 40 degrees) the use of this system is based on the risk for curve progression.

Regulatory Status

Staples, using a shape memory nickel-titanium alloy, have been cleared for marketing by the FDA through the 510(k) process for various bone fixation indications. For example, nitinol staples (Sofamor Danek) are indicated for fixation with spinal systems. Other memory shape staples cleared for marketing for bone fixation include the OSStaple™ (BioMedical Enterprises) and the reVERTO™ Dynamic Compression Device. FDA product code: JDR. Vertebral body stapling in scoliosis is considered off-label use.

Several of the FDA cleared devices are described in Table 1.

Table 1. Stapling Devices Cleared by the U.S. Food And Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Superelastic Staple	Neosteo	2/28/2020	K192447	Off Label Use for Scoliosis support
Colink Plating System, Fracture and Correction System, Rts Implant System, Neospan Compression Staple System	In2Bones USA, LLC	8/8/2019	K190385	Off Label Use for Scoliosis support
Trimed Nitinol Staple System	TriMed, Inc.	7/1/2019	K190166	Off Label Use for Scoliosis support
Vertex Nitinol Staple System	Nvision Biomedical Technologies, LLC	4/4/2019	K182943	Off Label Use for Scoliosis support
Geo Staple System	Gramercy Extremity Orthopedics LLC	1/11/2019	K182212	Off Label Use for Scoliosis support
DynaClip™ Bone Staple	MedShape Inc.	11/5/2018	K181781	Off Label Use for Scoliosis support
MotoCLIP/HiMAX Step Staple Implant System	CrossRoads Extremity Systems LLC	8/9/2018	K181866	Off Label Use for Scoliosis support
DePuy Synthes Static Staples	Synthes (USA) Products LLC	7/24/2018	K180544	Off Label Use for Scoliosis support
Clench Compression Staple	F & A Foundation LLC d.b.a. Reign Medical	4/6/2018	K173775	Off Label Use for Scoliosis support
Orbitum Bone Staple Implant X and VI	Orthovestments LLC	2/23/2018	K173693	Off Label Use for Scoliosis support
ExoToe Staple	ExoToe LLC	1/11/2018	K172205	Off Label Use for Scoliosis support

A vertebral body tethering device (The Tether™; Zimmer Biomet Spine) received an FDA Humanitarian Device Exemption (HDE) (H190005, product code QHP) on 6/4/2019. The FDA HDE allows marketing of the device as indicated for "skeletally immature patients that require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, with a major Cobb angle of 30 to 65 degrees whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. Patients should have failed bracing and/or be intolerant to brace wear." The REFLECT™ Scoliosis Correction System (Globus Medical), another vertebral tethering system, was granted HDE by the FDA on 5/15/2023 and intended use in the same population as The Tether.

The Eclipse MAGEC® Spinal Bracing and Distraction System has been cleared for marketing by the FDA through the 510(k) process under Product Code PGN (February 27, 2014) which is specific to “growing rod system-magnetic actuation.” The FDA approval is indicated for “Skeletally immature patients less than 10 years of age with severe progressive spinal deformities (e.g., Cobb angle of 30° or more; thoracic spine height less than 22 cm) associated with or at risk of Thoracic Insufficiency Syndrome (TIS). TIS is defined as the inability of the thorax to support normal respiration or lung growth.”

Table 2. U.S. Food and Drug Administration MAGEC® Cleared Devices

Device	510(k) No.	Cleared	Indications
MAGEC® System	K171791	August 31, 2017	“Skeletally immature patients less than 10 years of age with severe progressive spinal deformities (e.g., Cobb angle of 30° or more; thoracic spine height less than 22 cm) associated with or at risk of Thoracic Insufficiency Syndrome (TIS). TIS is defined as the inability of the thorax to support normal respiration or lung growth.”
MAGEC® Spinal Bracing and Distraction System	K160352	October 21, 2016	Same as above
MAGEC® Spinal Bracing and Distraction System (NuVasive Specialized Orthopedics Inc.)	K161751	September 2, 2016	Same as above
MAGEC® 2 Spinal Bracing and Distraction System	K150885	May 29, 2015	Same as above
MAGEC® Spinal Bracing and Distraction System	K141278	March 24, 2015	Same as above
MAGEC® Spinal Bracing and Distraction System	K140178	September 18, 2014	Same as above

The minimally invasive deformity correction system (MID-C) from ApiFix received HDE from the FDA in 2019. The FDA HDE states this device is indicated for “patients with adolescent idiopathic scoliosis (AIS) for treatment of single curves classified as Lenke 1 (thoracic major curve) or Lenke 5 (thoracolumbar/lumbar major curve), having a Cobb angle of 40 to 60 degrees which reduces to less than or equal to 30 degrees on lateral side-bending radiographs, and thoracic kyphosis less than 55 degrees as measured from T5 to T12. The use of the MID-C system in patients with curves of lower magnitudes (i.e., less than 40 degrees) is based on the risk for curve progression.”

RATIONALE

This evidence review was created in January 2010 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through August 2026.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Vertebral Body Stapling

Clinical Context and Therapy Purpose

The purpose of vertebral body stapling (VBS) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as observation, in individuals with juvenile or adolescent idiopathic scoliosis at high risk of progression.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with juvenile or adolescent idiopathic scoliosis at high risk of progression.

Interventions

The therapy being considered is VBS.

This is a fusionless surgical procedure intended to replace the use of traditional braces.

Comparators

Comparators of interest include observation conducted by orthopedists and primary care providers in an outpatient clinical setting. Self-treatment includes physical exercise and stretching.

Outcomes

The general outcomes of interest are change in disease status, morbid events, QOL, and treatment-related morbidity. The existing literature evaluating VBS as a treatment for juvenile or adolescent idiopathic scoliosis at high risk of progression has varying lengths of follow-up, ranging from 2 to 4 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary

to fully observe outcomes. Therefore, 4 years of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Nonrandomized Comparative Study

In a multicenter study, Cuddihy et al (2015) reported on a matched comparison of vertebral body stapling (VBS) and bracing for immature patients with moderate (25° to 44°) idiopathic scoliosis (see Tables 1 and 2). Forty-two consecutive patients in the VBS group (57 curves) met inclusion criteria, and 52 patients in the bracing group (66 curves) were matched by initial Cobb angle, age at the start of treatment, follow-up of at least 2 years, and sex. The average curve size was 31° , and the average follow-up was 40.8 months in the VBS group and 105 months in the bracing group (maturity). For smaller thoracic curves (25° to 34°), there was a non-statistically significant trend for stapling to be more effective (progression $<10^{\circ}$, 81%) compared with bracing (61%; $p=.16$). For larger thoracic curves ($>35^{\circ}$), VBS did not halt curve progression, with a success rate of 18% compared with 50% for bracing. For lumbar curves (25° to 34°), results were comparable for VBS and bracing. There were insufficient numbers of patients with lumbar curves of 35° or greater to compare results.

Observational Studies

Several case series and 1 case-control study evaluating VBS are described below and in Tables 1 and 2.

Cuddihy et al (2015) compared vertebral body stapling (VBS) to bracing in a matched cohort of skeletally immature patients with moderate idiopathic scoliosis. A total of 52 patients (66 curves) were matched according to age at the start of treatment (10.6 years vs. 11.1 years, respectively) and gender (see Tables 1 and 2). For smaller thoracic curves (25° to 34°) there was a nonsignificant trend toward better results with VBS versus bracing. For those with thoracic curves $\geq 35^{\circ}$, VBS was not found to be effective, and for lumbar curves 25° to 35° , results appear to be similar for both VBS and bracing.

Murray et al (2020) described vertebral body stapling (VBS) in 7 patients with a mean age of 9.3 years (range, 7.8 to 11.1 years) and an average preoperative Cobb angle of 30° (SD, 6°); the mean follow-up was 83 months (range, 72 to 95 months). At the first postoperative visit and most recent follow-up visit, the average Cobb angle was 20° (SD, 7°) and 37° (SD, 22°), respectively. One patient showed improvement of greater than 10° from preoperative to final postoperative Cobb angle, 4 patients showed no change in their curve, and 2 showed progression of their curves by greater than 10° compared with preoperative imaging.

Bumpass et al (2015) described vertebral body stapling (VBS) in 31 consecutive patients with a mean age of 10.5 years (range, 7.0 to 14.6 years) and scoliotic curves of 25° to 40°. Not all patients could (or would) wear a brace. At a mean follow-up to maturity of 48 months (range, 25 to 79 months), curves less than 35° had a control rate (<10° progression) of 75% while curves with a Cobb angle of at least 35° had a control rate of 22% (p=.01). The overall control rate was 61%, with 11 (31%) patients requiring subsequent fusion and 2 (6%) overcorrections.

Theologis et al (2013) described vertebral body stapling (VBS) in 12 children younger than 10 years old (range, 6.3 to 9.7 years) who were considered extremely likely to require fusion (i.e., curves of 30° to 39° in a young child), (see Tables 5 and 6). At an average 3.4-year follow-up (range, 2.2 to 5.4 years), curves had decreased by a mean of 10° (range, -3° to 20°). All curves in this high-risk population were successfully treated, with either no change (within 10°) or improvement in the curve (>10°).

Laituri et al (2012) retrospectively reviewed 7 children ages 8 to 11 years old who had undergone vertebral body stapling (VBS) and had at least 2 years of follow-up. All children either had curve progression, despite bracing, or were unable to wear a brace. Before stapling, the mean angle was 34.1°. The mean percentage correction was 36% (range, 16.2% to 56%). None of the children had curve progression or required postoperative bracing or spinal fusion.

O'Leary et al (2011) reported that vertebral body stapling (VBS) in young children with large Cobb angles was ineffective. Patients with adolescent idiopathic scoliosis were not included in this report. Diagnoses included myelodysplasia, congenital scoliosis, juvenile and infantile idiopathic scoliosis, Marfan syndrome, paralytic scoliosis, and neuromuscular scoliosis. At an average 22-month follow-up, curves averaged 69°, and 8 of 11 patients had undergone or were scheduled to undergo further spinal surgery for curve progression. It is unknown whether the young age at surgery, the severe preoperative curve, or the nature of underlying scoliosis contributed to the high failure rate.

Betz et al (2010) reported on 29 patients with juvenile or adolescent idiopathic scoliosis (from a database of 93 patients) who met the study inclusion criteria (see Tables 3 and 4). Selected were patients with idiopathic scoliosis, a coronal curve magnitude of 20° to 45°, Risser grade 0 or 1, and staples with tines proportional to staple size (beginning in 2002). The average age at the time of stapling was 9.4 years (range, 4 to 13 years), with an average follow-up of 3.2 years (range, 2 to 5.3 years). For thoracic curves greater than 35° at baseline, 75% progressed to greater than 50° (the threshold for recommending spinal fusion). For thoracic curves less than 35° at baseline, 6% of patients progressed to greater than 50° (the threshold for surgery).

Table 3. Summary of Key Observational Study Characteristics for Vertebral Body Stapling

Study	Country	Study Design	N ^a	Participants			Minimum FU, y
				Mean Age, y	Curve	Risser Grade	
Murray et al (2020)	U.S.	Case series	7	9.3	27.3° to 37.9°	NR	6
Cuddihy et al (2015)	U.S.	Case control	123	11	25° to 44°	0	2
Bumpass et al (2015)	U.S.	Case series	33	11	25° to 40°	0	2
Theologis et al (2013)	U.S.	Case series	12	8	30° to 39°	NR	2

Study	Country	Study Design	N ^a	Participants			Minimum FU, y
				<i>Mean Age, y</i>	<i>Curve</i>	<i>Risser Grade</i>	
Laituri et al (2012)	U.S.	Case series	7	9	25° to 41°	NR	2
O'Leary et al (2011)	U.S.	Case series	11	7	68° to 105°	0	1
Betz et al (2010)	U.S.	Case series	29	9	20° to 45°	0	2

FU: follow-up; NR: not reported; U.S.: United States

^a Number of patients in all studies, except for Bumpass et al (2015) and Cuddihy et al (2015), where N is the number of curves.

Table 4. Summary of Key Observational Study Outcomes for Vertebral Body Stapling

Study	Tx	Change in Curve				
		>10° Progressed	Stable	>10° Improved		
Murray et al (2020)	VBS	2	4	1		
		>10° Progressed	Stable/Improved	p	Progressed ≥50°	Subsequent Fusion
Cuddihy et al (2015)	VBS	Thoracic curves 25° to 34°: (19) Thoracic curves 35° to 44°: (82) Lumbar curves 25° to 34°: (20) Lumbar curves 35° to 44°: (40)	Thoracic curves 25° to 34°: (81) Thoracic curves 35° to 44°: (18) Lumbar curves 25° to 34°: (80) Lumbar curves 35° to 44°: (60)	>.05 for all comparisons of VBS vs. brace	NR	NR
	Brace	Thoracic curves 25° to 34°: (39) Thoracic curves 35° to 44°: (50) Lumbar curves 25° to 34°: (19) Lumbar curves 35° to 44°: (100)	Thoracic curves 25° to 34°: (61) Thoracic curves 35° to 44°: (50) Lumbar curves 25° to 34°: (81) Lumbar curves 35° to 44°: (0)			
		>10° Progressed	Stable	>10° Corrected		
Bumpass et al (2015)	VBS	13 (39)	14 (42)	6 (18)	9 (27)	11 (31)
Theologis et al (2013)	VBS	0 (0)	5 (42)	7 (58)	0 (0)	0 (0)
Laituri et al (2012)	VBS	0 (0)	2 (29)	5 (71)	0 (0)	0 (0)
O'Leary et al (2011)	VBS	3 (27)	6 (55)	2 (18)	0 (0)	8 (73)
		Baseline Curve	>10° Progressed	Stable/Improved		
Betz et al (2010)	VBS	<35° ≥35°	4 (22) 6 (75)	14 (78) 2 (25)	1 (6) 6 (75)	NR NR

Values are n (%) unless otherwise indicated.

NR: not reported; Tx: treatment; VBS: vertebral body stapling.

Section Summary: Vertebral Body Stapling

Evidence on the use of VBS for individuals with idiopathic scoliosis consists of a nonrandomized comparative study, a case-control study, and several small case series. Results from the nonrandomized comparative study and case-control study have indicated that VBS might slow curve progression in children with thoracic curves less than 35° and is at least as effective as bracing, but VBS appears to be less effective than bracing in patients with Cobb angles of 35° or more. Results from these studies are considered preliminary because few individuals have been followed to skeletal maturity. Studies from other centers are consistent with results from those of the inventor of the procedure. Complications can include broken staples, staple dislodgement, curve overcorrection, congenital diaphragmatic hernia rupture, contralateral pleural effusion, pneumothorax, and superior mesenteric artery syndrome. Investigators have commented that their approach is almost always to recommend bracing first and offer stapling only if the child or adolescent has difficulty wearing the brace. Notably, for patients with thoracic curves of 35° or greater, Cuddihy et al (2015) now perform vertebral body tethering (see next section) instead of VBS.

Vertebral Body Tethering

Clinical Context and Therapy Purpose

The purpose of vertebral body tethering (VBT) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as observation, in individuals with juvenile or adolescent idiopathic scoliosis at high risk of progression.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with juvenile or adolescent idiopathic scoliosis at high risk of progression.

Interventions

The therapy being considered is VBT.

This is a fusionless surgical procedure intended to replace the use of traditional braces.

Comparators

Comparators of interest include observation conducted by orthopedists and primary care providers in an outpatient clinical setting. Self-treatment includes physical exercise and stretching.

Outcomes

The general outcomes of interest are change in disease status, morbid events, QOL, and treatment-related morbidity. The existing literature evaluating VBT as a treatment for juvenile or adolescent idiopathic scoliosis at high risk of progression has varying lengths of follow-up, ranging from 1 to 15 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

An evolving evidence review by Hayes, Inc. (May 2025) found that the level of support in clinical studies and systematic reviews is minimal and shows no support or unclear support for use of VBT in the treatment of progressive idiopathic scoliosis. The evidence regarding Tether (Zimmer Biomet Spine Inc) system is based on very poor-quality single-arm studies that are retrospective and looking at pretest-post-test data. The evidence reports corrections in abnormal spinal angles; however, the comparative evidence is limited for VBT versus standard of care. Also, with VBT there is a much higher incidence of complications reported.

Abdelaal et al (2025) published a systematic review and meta-analysis comparing anterior VBT with posterior spinal fusion (PSF) for adolescent idiopathic scoliosis. Ten comparative cohort studies comprising 1168 patients were included. At 2-year follow-up, VBT was associated with less radiographic correction than PSF in the main thoracic curve (MD, +5.03°; 95% CI, 1.87 to 8.20) and proximal thoracic curve (MD, +3.27°; 95% CI, 1.16 to 5.38), while no significant differences were observed in main thoracic Cobb angle overall or in lumbar curve correction. VBT also demonstrated perioperative advantages, including significantly shorter operative time (MD, -99.23 min), less blood loss (MD, -405.44 mL), and shorter hospital stay (MD, -1.34 days). However, VBT carried a significantly higher revision surgery risk compared with PSF (odds ratio, 5.54; 95% CI, 2.81 to 10.94). Study authors concluded that while VBT offers meaningful perioperative and recovery advantages and comparable short-term patient-reported outcomes in selected skeletally immature patients, it results in less consistent radiographic correction and substantially higher revision rates than PSF.

Zhu et al (2022) published a systematic review and meta-analysis of 26 studies representing 1045 subjects (mean age range, 11.1 to 14.9 years) treated with vertebral body tethering (VBT) for scoliosis, finding that the Cobb angle of the major curve was significantly corrected from 40.0° to 59.0° at baseline to 15.9° to 38.0° immediately post-surgery and 10° to 38° at final follow-up. The overall clinical success rate was 73.02% (95% CI, 68.31% to 78.05%). The pooled overall unplanned reoperation rate after VBT was 8.66% (95% CI, 5.53% to 13.31%; 23 studies). The top 3 reinterventions were conversion to posterior spinal fusion (3.51%; 95% CI, 2.45% to 5.01%), tether removal (2.3%; 95% CI, 1.47% to 3.58%), and tether replacement (1.09%; 95% CI, 0.57% to 2.08%). The overall complication incidence rate was 36.8% (95% CI, 23.9% to 49.7%; 24 studies). Most common complications included curve progression with tether breakage (16.79%; 95% CI, 7.43% to 26.15%), pulmonary complications (6%; 95% CI, 4.66% to 7.68%), and overcorrections (4.55%; 95% CI, 3.4% to 6.06%). A subgroup analysis of patients with more than 36 months follow-up time indicated that these patients had increased clinical

success (73.88% vs. 65.93%), unplanned reoperation (15.8% vs. 4.55%), and complication rates (52.17% vs. 23.79%) compared to those with less than 36 months follow-up, respectively. Thus, based on the increased reoperation and complication rates observed with longer follow-up, the authors concluded that further improvements to the implant and refinement of patient selection criteria are warranted and should be assessed in the context of high-quality randomized controlled trials. Study demographics and outcomes based on race, ethnicity, and sex were not reported, potentially limiting the generalizability of these findings.

Observational Studies/Case Series

The Tether System

On 6/4/2019, the U.S. Food and Drug Administration (FDA) granted a Humanitarian Device Exemption (HDE) to a new vertebral body tethering (VBT) device called The Tether (Zimmer Biomet Spine, HDE #H190005, product code QHP). Available evidence for The Tether includes a multicenter retrospective cohort study of 57 pediatric patients. In this study, Miyanji et al (2020) reported outcomes of skeletally immature patients with idiopathic scoliosis treated with anterior VBT. Fifty-seven patients (mean age, 12.7 years; range, 8.2 to 16.7 years; 95% female) with a mean preoperative Sanders score of 3.3 and Risser grade of 0.5 underwent anterior VBT for predominantly main thoracic curves (96.5%). Clinical success was set as correction of the major coronal Cobb angle to $<35^\circ$ without any patients having undergone or awaiting fusion at the most recent follow-up. The mean major Cobb angle improved from 51° (range, 31° to 81°) preoperatively to 24.6° at first postoperative visit (mean correction, 45.6%), with further correction to 16.3° at 1 year. At a mean follow-up of 40.4 months, the final mean major curve measured 23° (mean correction, 42.9%). Clinical success was achieved in 44 patients (77%). A total of 16 complications occurred (28.1%), and 9 unplanned revision procedures were performed in 8 patients (15.8%). Six patients (10.5%) ultimately required posterior spinal fusion for curve progression or inadequate correction. Radiographic evidence of confirmed or suspected tether breakage was noted in 24 patients (42%), most commonly at T9/T10, T10/T11, and T11/T12, occurring at a mean of 32.5 months postoperatively.

Dynesys System

Larson et al (2024) reported on results of a prospective FDA investigational device exemption study that included Zimmer Biomet Tether System or Dynesys System Components. Forty patients (mean age, 13 years; range, 10 to 16 years; 90% female; 95% White) with adolescent idiopathic scoliosis and a Sanders score ≤ 4 or a Risser score ≤ 2 underwent vertebral body tethering (VBT) for curves between 40° and 70° . At the designated radiographs, the mean correction of the major curve at 3 months was 44% (range, 22% to 95%), 49% at 1 year, and 46% (range, -10% to 93%) at 2 years. The mean major Cobb angle improved from $51^\circ \pm 8^\circ$ (range, 40° to 70°) at baseline to $27^\circ \pm 11^\circ$ (range, 3° to 56°) at 2 years after VBT. Success at 2 years (Cobb angle of $<35^\circ$ and no reoperation) was seen in 30 patients (75%) and was associated with a mean Cobb angle of $<35^\circ$ on the first postoperative radiograph ($p < .001$). By 2 years, 2 (5%) of the patients underwent repeat surgery. The SRS satisfaction score improved 2 years following surgery ($p < .001$), but other SRS domains only remained stable over time. Beyond 2 years, 1 additional lumbar tether was required after thoracic VBT, 1 implant was removed, and 3 fusions were performed. The rate of cord breakage in the study population was 20%.

Samdani et al (2014, 2015) published 2 retrospective reviews on the off-label use of the Dynesys system for anterior vertebral body tethering (VBT) for idiopathic scoliosis. They reported pursuing VBT at their children's hospital due to lack of success with vertebral body stapling (VBS) for thoracic curves greater than 35° . At the time of these reports, 32 patients had a minimum of 1-year follow-up, and 11 consecutive patients had a 2-year follow-up. The mean age at surgery was 12 years, and all patients were skeletally

immature. Three patients also had VBS for their lumbar curves. For the 11 patients with 2-year follow-up, on average, 7.8 levels (range, 7 to 9 levels) were tethered. Thoracic Cobb angle averaged 44.3° preoperatively, was corrected to 20.3° after surgery, and improved to 13.5° at 2 years. The lumbar curve improved from 25.1° preoperatively to 7.2° at 2 years. Two patients required that tension be reduced after 2 years due to overcorrection.

Pehlivanoglu et al (2021) conducted a prospective cohort study of 13 skeletally immature patients (mean age, 11.8 years) who underwent vertebral body tethering (VBT) with the Dynesys system for adolescent idiopathic scoliosis with double curves. At baseline, the mean thoracic/thoracolumbar and lumbar curve magnitudes were 48.2° and 45.3°, respectively. An average of 11.8 levels of tethering were undertaken. Postoperatively, mean thoracic/thoracolumbar curve magnitudes were 14.3° to 17.3°. At the last follow-up (mean, 36.4 months), the mean thoracic/thoracolumbar curve magnitudes were 8.2° to 9.7°. No major complications were reported.

Meyers et al (2022) performed a retrospective review of adolescent scoliosis patients (N=49; 74% female) treated with vertebral body tethering (VBT) via the Dynesys system after reaching peak height velocity (Risser stage 3-5). Mean patient age was 15 ± 1.9 years with mean follow-up duration 32.5 ± 9.1 months. In patients with thoracic major curvatures (n=24), the Cobb angle improved from 51.1 ± 6.9° to 27.2 ± 8.1° (47.7% correction; p<.01). In those with thoracolumbar major curves, curvature improved from 37.2 ± 10.7° to 18.8 ± 9.4° (49.5% correction; p<.01). Improvements in major curve inclinometer measurements and Scoliosis Research Society (SRS)-22 patient questionnaire domains improved significantly (p≤.05), except for the SRS-22 activity domain. Overall, 37/49 (76%) of patients were deemed clinically successful with residual major curves ≤30°. At final follow-up, 2 major complications were reported. At 3.1 years after VBT, 1 patient required posterior fusion of the thoracic curve due to curve progression and revision of the thoracolumbar tether due to tether breakage. A second patient developed late onset superior mesenteric artery syndrome (SMAS) 1 year postoperatively which required Ladd's derotation surgery. Overall, 20 (41%) patients experienced tether breakage. However, only 4 of 19 (21%) patients with broken tethers failed to meet criteria for clinical success which was comparable to the 7 of 29 (24%) patients with intact tethers. Thus, treatment success in subjects with limited remaining skeletal growth was feasible. While treatment success was not impacted by age or Risser stage, patients with treatment failures reported slightly larger major Cobb angles at baseline.

REFLECT System

Baroncini et al 2022 reported a retrospective, 2-center cohort study in 86 patients in Europe who underwent vertebral body tethering (VBT) with the REFLECT system. The majority of patients were female (84%) with a mean age of 13.2 years. Nearly half of patients (42%) were Risser stage 0. At 2-year follow-up, Cobb angles at the thoracic level had decreased from 52.4 ± 13.9° to 28.5 ± 13.6° at the thoracic level and from 47.6 ± 14.3° to 26.6 ± 12.7° at the lumbar level. Six patients had postoperative complications including 5 recurrent pleural effusions and one case of psoas irritation. Sagittal alignment parameters were also analyzed, and the findings indicated increased thoracic kyphosis and maintenance of lumbar lordosis. No other clinical outcomes were reported.

Hegde et al 2023 reported another retrospective analysis of the REFLECT system in 75 patients from a single center in India. The mean age of patients was 14.96 years and 94% were female. At a mean follow-up of approximately 2 years, Cobb angles at the thoracic level decreased from 52 ± 7.74° to 16.92 ± 5.06° and mean thoracolumbar/lumbar Cobb angles decreased from 51.45 ± 11.26° to 14.24 ± 4.85°. The SRS-22(revised) score was 78.0 ± 3.2 preoperatively and 92.5 ± 3.1 postoperatively.

Unspecified Vertebral Body Tethering System

Nugraha et al (2026) conducted a prospective, multicenter cohort study evaluating outcomes of VBT in adolescents with idiopathic scoliosis. The study included 127 skeletally immature patients treated between 2019 and 2022 across 9 institutions, with a minimum follow-up of 2 years (average 2.4 years). Success was defined as a major curve $\leq 35^\circ$ at final follow-up without conversion to posterior spinal fusion. The mean preoperative major curve measured $50 \pm 8^\circ$, with an average initial correction to $29 \pm 8^\circ$ on first-erect radiographs, corresponding to a $39 \pm 18\%$ correction. At the final follow-up, the mean curve magnitude remained stable at $26 \pm 11^\circ$, representing a $45 \pm 23\%$ correction, despite a reported tether breakage rate of 29%. Overall, patients achieving a first-erect curve $\leq 35^\circ$ had a significantly higher success rate (88%) compared with those with $>35^\circ$ at first erect (60%; $p=.002$). Limitations of the study included relatively short follow-up, variability in surgical techniques across centers, and lack of a fusion control group.

Stein et al (2024) conducted a retrospective cohort study of 106 skeletally immature patients who underwent lumbar anterior VBT for adolescent idiopathic scoliosis. At baseline, the mean lumbar coronal curve magnitude measured 49.6° . At first follow-up, this corrected to 18.7° , and at the latest follow-up (mean, 4.1 years), the average lumbar curve measured 19.9° . Overall, 76.4% of patients achieved a lumbar curve $<30^\circ$ at the final follow-up, and 85% had reached skeletal maturity. A total of 18.9% (20/106) of patients underwent 23 reoperations, most commonly for overcorrection (43%), with tether breakage accounting for 13% of revision procedures. Six patients (5.4%) of the cohort required a later posterior spinal fusion.

Vorhies et al (2024) performed a retrospective multicenter review of 171 patients who underwent VBT for idiopathic scoliosis. A total of 55 patients (32%) experienced 69 complications, with the most common classified as Modified Clavien-Dindo-Sink (mCDS) Classification Grade IIIb (unplanned surgical intervention), representing 42% of all complications. Overall, 49% of complications required surgical intervention or ICU admission. Tether breakage occurred in 22 patients, with an average time to failure of 31 months. Twelve patients required conversion to posterior spinal fusion. Neurologic complications were uncommon (5 total), including 2 cerebrospinal fluid leaks. No Grade IVb or Grade V (life-ending) complications occurred. Compared with PSF data from prior literature, VBT demonstrated a substantially higher proportion of severe complications (49% vs 7% Grade III+).

Braun et al (2024) reported a retrospective case series describing their first 10 years of experience using anterior VBT for the treatment of adolescent idiopathic scoliosis. The study included 74 patients treated between 2010 and 2020; 52 patients (47 females, 5 males) with a minimum of 2-year follow-up were included in the primary analysis. Patients encompassed a broad range of curve magnitudes (33° to 70°), Lenke curve types (1 to 6), and skeletal maturity (Risser -1 to 5). Among the 52 patients, 46 (88%) were considered satisfactorily treated with VBT, defined as achieving at least a 5° overall curve correction without the need for fusion. Mean major curve magnitude improved from 48.6° preoperatively to 23.2° postoperatively and was maintained at 24.0° at final follow-up (mean, 3.3 years; range, 2 to 10 years; $p<.001$ for preoperative to postoperative and preoperative to final correction), with no significant loss of correction over time. Skeletal maturity of Risser ≥ 4 was achieved in all but one patient by final follow-up. Complications were common; implant-related complications occurred in 38% of patients, most frequently tether rupture, which was radiographically observed in 25% but required revision in only 6%. Four patients (8%) required additional procedures (tether replacement or removal) to achieve satisfactory outcomes. However, 6 patients (12%) were not successfully treated with VBT and ultimately required conversion to posterior spinal fusion for overcorrection (2 patients) or inadequate correction (4 patients).

Section Summary: Vertebral Body Tethering

There is limited, high-quality, published evidence supporting VBT. A 2025 systematic review found that while VBT offers meaningful perioperative and recovery advantages and comparable short-term patient-reported outcomes in selected skeletally immature patients, it results in less consistent radiographic correction and substantially higher revision rates than PSF. A 2022 systematic review and meta-analysis of 26 studies reported meaningful Cobb angle correction but also substantial safety concerns, with a 74 percent clinical success rate, a 52 percent overall complication rate, and a 16 percent unplanned reoperation rate among patients with more than 36 months of follow-up. Evidence for the FDA-authorized Tether device remains sparse and is based primarily on a small, single-center, uncontrolled retrospective cohort of 57 patients summarized in the Humanitarian Device Exemption report, which showed promising radiographic correction. Additional observational studies of the Dynesys system demonstrate short-term Cobb angle improvements but provide limited insight into long-term durability, with tether breakage and revision surgery occurring in a significant portion of patients. Published data for the REFLECT system are similarly limited to observational cohorts with short follow-up and minimal reporting on patient-centered outcomes. Although early radiographic results across devices appear favorable, the overall evidence base remains constrained by small samples, lack of control groups, heterogeneous populations, short duration of follow-up, and high complication and reoperation rates. Larger controlled studies with long-term follow-up are needed to validate clinical benefits, clarify safety, and determine appropriate patient selection.

Magnetically Controlled Growing Rods

Clinical Context and Therapy Purpose

The purpose of magnetically controlled growing rods (MCGR) is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with juvenile or adolescent idiopathic scoliosis at high risk of progression.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with juvenile or adolescent idiopathic scoliosis at high risk of progression.

Interventions

The therapy being considered is magnetically controlled growing rods (MCGRs). One such magnetic distraction rod is the MAGnetic Expansion Control (MAGEC®) System.

The MAGEC® System is a distraction-based system that is designed to avoid the repeated anesthetics and open surgical lengthening that occurs with traditional growing rod (TGR) systems. The titanium MAGEC rod includes an actuator portion that holds a small internal magnet that can be turned noninvasively by an external remote control, allowing for lengthening or shortening of the MAGEC rod.

Comparators

Comparators of interest include observation conducted by orthopedists and primary care providers in an outpatient clinical setting. Self-treatment includes physical exercise and stretching.

Outcomes

The general outcomes of interest are change in disease status, functional outcomes, morbid events, QOL, and treatment-related morbidity. The existing literature evaluating magnetically controlled growing rods (MCGRs) as a treatment for juvenile or adolescent idiopathic scoliosis at high risk of progression has varying lengths of follow-up.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Multiple systematic reviews have been published that have investigated the efficacy and feasibility of magnetically controlled growing rods (MCGR) in the treatment of children with early onset scoliosis (EOS) (Migliorini 2022, Guan 2020, Thakar 2019). In the most recent review and comprehensive systematic review (2022) Migliorini et. al. conducted a systematic review investigating the efficacy and feasibility of magnetically controlled growing rods (MCGR) in the treatment of children with early onset scoliosis (EOS). Only studies reporting data in patients younger than 10 years with a preoperative Cobb Angle greater than 40° were eligible. Data from 23 clinical studies (504 patients) were included in this study. Fifty-six percent (282 of 504) were females. The average length of the follow-up was 28.9 ± 16.0 months. The mean age of the patients was 8.7 ± 1.9 years old. The mean BMI was 17.7 ± 7.6 kg/m². The mean kyphosis angle had reduced by the last follow-up ($P = 0.04$), as did the overall mean Cobb angle ($P < 0.0001$), while the overall T1–S1 length increased ($P = 0.0002$). Overall, a total of 124 complications were reported in 504 patients (25%) including the following most frequent complications: proximal screw out of the rod, loss initial height, proximal pull out of the hooks, screw/plug loosening, and reoperation for trimming of outstanding rod. Study limitations included a limited study size along with the retrospective design, and the length of follow-up was too short in most of the included studies. The procedures for assessing outcomes and subject selection were often biased and not adequately described. Further high-quality studies involving a larger number of patients and longer follow-up are required to determine the efficacy of magnetically controlled growing rods (MCGR) in the treatment of early onset scoliosis (EOS).

In an evidence analysis research brief (July 2025) an update to the health technology assessment by Hayes Inc. (November 2018), continues to find the level of support in observational studies and systematic reviews minimal and shows no support for use of magnetically controlled growing rods (MCGRs) in the treatment of idiopathic scoliosis. While limited evidence may suggest that MCGRs improved the overall curve correction and may perform as well as traditional growing rods (TGRs), the evidence is based on very poor-quality retrospective observational studies that included single-arm study design and systematic reviews. Limitations of the evidence includes small sample sizes, limited follow-up,

a lack of evidence regarding patient outcomes and comparative analyses of MCGRs compared with TGRs. Also, with MCGRs the most common adverse events included screw failure, screw pull-out or failure of fixation 7%-30%, rod breakage 10%-57% and device failure 4%-50%.

Observational Studies

Saarinen et al (2025) performed a retrospective review of prospectively collected data to investigate how clinical, radiographic and health-related quality-of-life (HRQoL) outcomes differ between children with idiopathic early onset scoliosis (EOS) treated with magnetically controlled growing rods (MCGRs) versus traditional growing rods (TGRs). The authors collected data from 11 countries using an international database that included patients diagnosed with EOS according to Scoliosis Research Society criteria; underwent primary intervention using TGRs or MCGRs from 2002 through 2018; aged 9 years or less; a major coronal curve of 30° or greater at the index procedure; and at least 3 lengthening's and at least 5-years of follow-up. Of the 124 patients identified the cohort consisted of 92 children with TGRs (n=54) and MCGRs (n=38). Mean age at index surgery was 6.4 years for both groups. The mean preoperative major coronal curve was 77° in the TGR group and 67° in the MCGR group (p=.04). Preoperative bracing was utilized in 15 patients in the MCGR cohort and 28 in TGR. Extracted data points were preoperatively, immediately after the index procedure and at 5-year follow-up; utilizing standing posterior and lateral radiographs to measure the major coronal curve using the Cobb technique (thoracic height from the upper endplate of T1 to the lower endplate of T12; and spinal height from the upper endplate of T1 to the upper endplate of S1), Early-Onset Scoliosis 24-Item Questionnaire (EOSQ-24) and clinical (age, height, number of lengthening procedures, complications, operative time, levels of instrumentation and type of instrumentation). Patients who underwent final fusion were additionally evaluated at last visit before final fusion. At 5-year follow-up, mean ($\pm$ standard deviation) major curves were 46° $\pm$ 18° in the TGR group and 38° $\pm$ 15° in the MCGR group (p=.03). Median annual thoracic growth (T1-T12) was 4.1 mm (interquartile range, 4.7 mm) in the TGR group and 3.2 mm (interquartile range, 5.6 mm) in the MCGR group (p=.29). More complications occurred in the TGR group (mean 2.1 per patient) than in the MCGR group (mean 1.0 per patient) (risk ratio, 2.1; 95% confidence interval: 1.3–3.2). More revisions occurred in the TGR group (2.0 per patient) than in the MCGR group (0.9 per patient) (risk ratio, 2.2; 95% confidence interval: 1.4–3.4). Both groups achieved maximum scores in HRQoL domains of pulmonary function, transfer, physical function, daily living, and financial impact; no other measured domains differed between groups. This study had several limitations to include small sample size, heterogenous clinical practices that included different lengthening protocols and differences in spinal instrumentation (e.g., pedicle screws versus hooks), operating time frames affecting comparability, and EOSQ-24 questionnaire-24 was utilized in only 83% of the MCGR group and 45% of the TGR groups. The most frequent complications were implant related. Four patients underwent 6 revisions because of MCGR lengthening failure. Two patients with MCGRs had neurologic complications: 1 patient presented with dural lesion, and 1 had an unspecified neurologic complication.

Among the observational studies included in Migliorini 2022 the most noteworthy is that by Abdelaal et. al. (2020) which was a retrospective review of consecutive cases of magnetically controlled growing rods (MCGR) in children with early onset scoliosis (EOS) in their institution between 2012 and 2018 with 4.1 years of follow-up. This cohort consisted of 44 children (25 females and 19 males), with a mean age of 7.9 years (3.7 to 13.6). There were 41 primary cases and three revisions from other rod systems. The majority (38 children) had dual rods. The group was a mixed etiology including idiopathic (20), neuromuscular (13), syndromic (9), and congenital (2). The mean follow-up was 4.1 years, with a minimum of two years. Nine children graduated to definitive fusion. The authors evaluated radiological parameters of deformity correction (Cobb angle), and spinal growth (T1-T12 and T1-S1 heights), as well as complications during the course of treatment. The mean Cobb angles pre-operatively, postoperatively, and at last follow-up were 70° (53 to 103), 35° (15 to 71) and 39° (15 to 65) respectively (p < 0.001).

Further, there was a mean of 14° (-6 to 27) of additional Cobb angle correction upon graduation from MCGR to definitive fusion. Both T1-T12 and T1-S1 showed significant increase in heights of 27 mm and 45 mm respectively at last follow-up ($p < 0.001$). Ten children (23%) developed 18 complications requiring 21 unplanned operations. Independent risk factors for developing a complication were single rod constructs and previous revision surgery.

Section Summary: Magnetically Controlled Growing Rods

Evidence on the use of MCGRs for individuals with idiopathic scoliosis consists of a systematic review, nonrandomized study, observational studies and several small case series. While results on the use of MCGRs may have shown a decrease in Cobb angle, the use of MCGRs should be used with caution as serious adverse events occurred and further studies are needed to determine the optimum initial correction, rate of distractions and methods of monitoring spinal growth.

Minimally Invasive Deformity Correction System - ApiFix

Clinical Context and Therapy Purpose

The purpose of minimally invasive deformity correction system is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as observation, in individuals with juvenile or adolescent idiopathic scoliosis at high risk of progression.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with juvenile or adolescent idiopathic scoliosis at high risk of progression.

Interventions

The therapy being considered is minimally invasive deformity correction system. One such minimally invasive deformity correction system (MID-C) - ApiFix.

This is a minimally-invasive fusionless surgical procedure intended replace the use of traditional braces or casts.

Comparators

Comparators of interest include observation conducted by orthopedists and primary care providers in an outpatient clinical setting. Self-treatment includes physical exercise and stretching.

Outcomes

The general outcomes of interest are change in disease status, functional outcomes, morbid events, QOL, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

In an evolving evidence review (February 2026) by Hayes regarding ApiFix (ApiFix LTD.) for the treatment of adolescent idiopathic scoliosis, based on the review of the evidence no RCTs were identified evaluating ApiFix compared to other technology, placebo or sham.

Single-Group, Noncomparative Observational Studies

In 2023, Zygiogiannis et. al. conducted a retrospective review of 44 patients who underwent surgical treatment of adolescent idiopathic scoliosis (AIS) with an ApiFix device at a single center under three different surgeons between the years 2016 and 2022. The inclusion criteria were scoliosis of Lenke 1A type and patients with a minimum of one year of radiological and physical follow-up. The basic procedures and steps of maintaining asepsis were the same for all patients. The pre-surgical chemoprophylaxis protocol included coverage with vancomycin 1 g every 12 hours for 24 hours postoperatively. The Scoliosis Research Society (SRS) outcome survey was completed by all the included patients, either during their most recent follow-up visit or remotely. The objective of this study was to determine the prevalence and recurrence of surgical site infection (SSI) following surgery for AIS with ApiFix. Out of the 44 patients analyzed three patients (6.81%) with a median age of 14.8 years developed SSI, with a recurrence in one patient (2.27%). The initial course of therapy included IV antibiotics following oral administration and dressing changes. Two of the patients needed irrigation and debridement (I&D) while instrumentation removal for one case was necessary due to recurrent infection and clinical deterioration leading to sepsis. Also, there was a removal of ApiFix device due to treatment completion, in the removal of one screw resulted in pus leakage. Two cultures revealed *Staphylococcus capitis* and the third showed *Staphylococcus epidermidis*. The authors concluded: “SSI, especially after AIS correction, remains a troublesome entity even in the most experienced hands. The statistical significance found in a small sample size and the fact that all patients were from a single spine center were limiting factors of this study. SSI may prove devastating for children since prolonged hospitalization may often be necessary. A strict surgical protocol of surgical asepsis and postoperative dressing changes may contribute to the prevention of contamination with pathogens. This study suggests that even in minimally invasive surgical procedures involving healthy patients, there is always the risk of infection when an orthopedic implant is involved. Further randomized trials are needed to gather more evidence on this subject.”

In 2023, Froehlich et. al. conducted a retrospective study of 36 patients (25 females and 11 males) who underwent the ApiFix procedure between 2018 and October 2020 at two spine centers. Half of these patients had received bracing as a form of prior conservative management. The ApiFix procedure was assessed in accordance with the indications and contraindications listed in the HDE FDA approval: indications were AIS with a single major curve 35-60 degrees, and angle of ≤ 30 degrees on lateral side

bending radiographs and Lenke type 1 and type 5, while intra-spinal malformations/deformities, segmentation disorders, a latera bending curve > 30 degrees, a major curve > 60 degrees and secondary scoliosis were contraindicative. Risser 5 was not an exclusion criterion. All patients received an ApiFix implant with the optional extender with three pedicle screws. The primary endpoint was the assessment of longitudinal changes in scoliotic curve correction which was based on measurements of the major curve, minor curve and sagittal thoracic modifier (kyphosis) at 6 weeks, 6 months, 12 months and 24 months after surgery. Treatment with ApiFix resulted in a significant correction of deformity. The average preoperative thoracic major curve (Lenke 1) of 43 ± 7 degrees was significantly reduced to 20 ± 8 degrees at the last follow-up at 24 months ($p = 0.002$, paired t-test). For patients with Lenke type 5, the improvement was even more pronounced. The preoperative lumbar curve (Lenke 5) of 43 ± 7 degrees decreased to 15 ± 8 degrees at 24 months ($p = 0.043$, Wilcoxon test). Similar effects between preoperative and 24-month values were observed for the minor curves (Lenke type 1: 29 ± 7 degrees to 20 ± 8 degrees, $p = 0.005$, as determined via paired t-tests; Lenke type 5: 34 ± 11 degrees to 26 ± 5 degrees, $p = 0.028$, as determined via Wilcoxon tests). In the cohort of 36 patients, revisions were required in 11 cases (31%) during the 24-month follow-up period. Four of these cases were patients that outgrew their implant, which was replaced with a longer ApiFix implant. The other seven revisions (19%) were due to various reasons, mainly being infection ($n=3$) and problems associated with the anchorage of the implant. Limitations of this study include the lack of a suitable comparison group, small patient cohort which did not allow for a subdivision of skeletal immature and mature patients with regard to outcome and the follow-up period was only 24-months. The authors concluded “our results show that dynamic correction of AIS with ApiFix system in combination with possible growth control during skeletal immaturity is a good treatment alternative compared to fusion surgery and the VBT system, provided patients are carefully selected with regard to treatment criteria. Despite the promising results of our study these results are only preliminary, since they are based on relatively small cohort and follow-up did not extend beyond 2 years. Further studies are necessary to evaluate the long-term outcomes of using the ApiFix implant and furthermore, the loss of curve correction after implant removal has to be investigated.”

In 2021, Stadhouder et. al. conducted an industry sponsored prospective cohort study of 20 patients with adolescent AIS that evaluated the efficacy of the ApiFix device designed to gradually correct the deformity without spinal fusion. Inclusion criteria were 12 to 17 years of age, skeletal immaturity (defined as Risser stage 1 to 4), a single structural curve (Lenke type 1 or 5), a major Cobb angle of 40° to 55° , reduction of the major curve to less than 35° on x-ray, and apical vertebral rotation of less than 15° . With an average of 12 months of follow-up postoperatively, 7 of 20 participants showed signs of surgical failure and study recruitment was stopped. Subsequently, another 3 participants showed implant failures at further follow-up. Reasons for implant failures included pain, breakage/failure and osteolysis. Six of the participants required removal of the implant, 2 participants had a revision to a new implant, and 2 participants had revisions to posterior spinal fusion. The 10 remaining participants were followed for a mean of 3.8 years. In this group, the mean major curve measured 45.4 degrees preoperatively, 31.4 degrees at 2 weeks postoperatively, and 31.0 degrees at the time of the latest follow-up. The mean minor curve measured 31.3 degrees preoperatively, 26.1 degrees at 2 weeks postoperatively, and 24.2 degrees at the time of the latest follow-up. Despite postoperative exercises, no significant change in major or minor curve deformity was observed from 2 weeks postoperatively to the latest follow-up. No adding-on (curve progression cranial or caudal to the instrumentation), proximal junctional kyphosis, or distal junctional kyphosis was observed. Lumbar lordosis and thoracic kyphosis remained unaltered. No changes in the scolimeter rotation measures were observed. Patient reported outcomes are included in Table 5.

Table 5. Patient-Reported Outcomes

Outcome	Baseline (n=10)	Latest Follow-up (n=8)	p Value
Function	2.7 ± 0.3	4.0 ± 0.3	<0.001
Pain	2.4 ± 0.6	4.3 ± 0.6	<0.001

Outcome	Baseline (n=10)	Latest Follow-up (n=8)	p Value
Self-image	2.5 ± 0.5	4.4 ± 0.3	<0.001
Mental health	3.0 ± 0.3	4.4 ± 0.5	<0.001
Satisfaction with management	1.9 ± 1.2	4.5 ± 0.5	<0.001
Total	2.6 ± 0.4	4.0 ± 0.4	<0.001

In these remaining participants 11 serious adverse events in 10 patients were recorded (including 2 events in a single patient) which included 6 events of osteolysis related to one of the pedicle screws, with one case involving breakage of a screw; three patients had failure of the ApiFix device as a result of breakage of screw (1 patient), failure of the ratchet mechanism (1 patient), or breakage of a screw and the device (1 patient); and two implants were removed at the patient's request because of continuing pain without any abnormal radiographic findings with one of these patients with a prior revision of the implant in the past. In summary, in the 10 patients there was a final reduction of the main curve to an average Cobb angle of 31 degrees and no further curve correction was seen postoperatively despite supervised exercise program. Due to high complication rate this study was prematurely terminated. The authors concluded "The ApiFix device did not allow postoperative curve correction for which its ratchet mechanism is designed and all but 1 of the 10 failures were classified as an unexpected serious adverse effect that was directly related to the implant design."

In 2021, Floman et. al. conducted a retrospective, single-group, multicenter study to determine if posterior dynamic deformity correction (PDDC) device could modulate growth in skeletally immature patients with AIS. From a registry of AIS patients (Floman et. al 2020) treated with PDDC between 2015 and 2018 individuals with a minimum of 2 years of radiologic follow-up following surgery were identified, the total number of patients evaluated was 45 (n=45) of which included 41 females and 4 males aged 11-17 years. There were 16 participants in the Risser 0-1 stage, 15 participants in the Risser 2-3 stage, and 14 participants in the Risser 4-5 stage at the time of surgery. There were 35 participants with Lenke type 1 curves and 10 participants with Lenke type 5 curves. The three groups were compared in regard to the magnitude of main curve reduction and the extent of remodeling in the coronal plane wedging of the apical vertebra following surgery with PDDC. The mean pre-operative curve was 46°. Curves were reduced to 26.4°, 20.4° and 26.2°, respectively, at final follow-up [$p < 0.05$]. At the last follow-up visit thoracic kyphosis increased on average by 7° in the Lenke 1 curves while lumbar lordosis decreased by 4° in the Lenke 5 curves. The average pre-operative coronal apical wedging of 7.4° (3.8°–15°) was reduced to 5.7° (1°–15°) at final follow-up ($p < 0.05$). Delta wedging for the entire cohort was 1.7° (–0.5°–9°) ($p < 0.05$). Patients with Risser 0–1 grading ($n = 16$) had pre-operative wedging of 9.5° (6°–14.5°) compared to wedging of 5.4° (1°–8°) after surgery ($p < 0.05$); Risser 2–3 patients ($n = 15$) had pre-operative wedging of 7.7° (4°–15°) vs. post-operative wedging of 7.0° (3°–15°); Risser 4–5 patients ($n = 14$) had pre-operative wedging of 4.8° (3.8°–6.5°) versus post-operative wedging of 4.7° (3.7°–6.5°). The change in wedging before and after surgery was as follows: Risser 0–1 = 4.1° (0°–9°) ($p < 0.05$); Risser 2–3 = 0.7° (0°–4°), Risser 4–5 = 0.1° (–0.5°–1.2°). Delta wedging in Risser 0–1 patients was significantly different from the delta value for Risser 2–3 and for Risser 4–5. Four patients underwent revision surgery: one case was converted to vertebral body tethering (VBT) as a result of partial screw pull out. In three other patient's pedicle screw misplacement, nut loosening, or ratchet malfunction were detected, revision surgery entailed re-instrumentation with the PDDC implant. None of the cases were converted to a fusion procedure. Limitations of this study include small cohort, retrospective analysis, and the lumping together or Risser 0 and Risser 1 cases. Also, related to measurements of the wedge apical vertebra which is three dimensional only the coronal wedge deformation was measured. Another aspect of curve morphology that was not evaluated was the shape of the intervertebral disc which is also affected by the altered mechanics in a spinal curvature.

Section Summary: Minimally Invasive Deformity Correction System – ApiFix

The minimally invasive deformity correction system – ApiFix FDA approval for marketing is based on Humanitarian Device Exemption (HDE). The clinical data utilized for the HDE was based on studies performed outside of the United States (U.S.). As part of the HDE approval a post-approval study (PAS) to provide ongoing safety and probable benefit of ApiFix is to be conducted to include a minimum of 10 U.S. centers with a minimum number of 200 patients enrolled in this study. On October 23, 2019 the PAS was approved and as of this date 5 of the 20 potential clinical sites had been selected for patient enrollment with a total of 6 patients enrolled. This study is estimated to last a total of 84 months from the date of PAS approval.

Evidence on the use of minimally invasive deformity correction system – ApiFix with AIS consists of single-group, noncomparative observational studies, no RCTs were found. In the industry sponsored prospective cohort study (Stadhouder et. al. 2021) evaluating the safety and efficacy of ApiFix which included 20 patients with adolescent AIS, 7 of 20 participants showed signs of surgical failure and study recruitment was stopped, and due to the high complication rate of the remaining patients which was 11 serious adverse events (pain, breakage/failure of implant, osteolysis) in 10 patients this study was prematurely terminated. The authors stated: “no distraction was observed and the high rate of serious adverse events within 2 years was considered unacceptable for further clinical application of this device in our institution, despite recent FDA approval.” In the retrospective study by Zygiogiannis et. al. (2023) this study found SSI remains an issue even in the most experienced hands. A strict surgical protocol of surgical asepsis and postoperative dressing changes may assist in the prevention of contamination pathogens. Further randomized trials are needed to gather more evidence on this subject. While retrospective studies by Floman et.al. 2021 and Froehlich et. al. 2023 showed promising results in curve reduction, both studies continued to show adverse events remained an issue in the cohort of patients studied related to infection, problems associated with anchorage of implant, pedicle screw misplacement, nut loosening and ratchet malformation. Despite the promising results these results are only preliminary, since they are based on relatively small cohort, did not include comparison to a control group receiving a suitable alternative treatment and follow-up did not extend beyond 2 years. Further studies are necessary to evaluate the long-term outcomes of using the ApiFix implant in the management of AIS.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Orthopaedic Surgeons

Information updated on the American Academy of Orthopaedic Surgeons' OrthoInfo website indicates that the type of treatment required for idiopathic scoliosis in children and adolescents depends on the kind

and degree of the curve, child's age, and the number of remaining growth years until the child reaches skeletal maturity.

- Observation is appropriate when the curve is mild ($<25^{\circ}$) or if the child is near skeletal maturity.
- The goal of bracing is to prevent scoliotic curves from worsening. Bracing can be effective if the child is still growing and has a "spinal curve between 25° and 45° ".
- Surgery may be recommended if the curve is "greater than 45° to 50° " or if bracing did not stop the curve from reaching this point. An implant made up of rods, hooks, screws, and/or wires is used to straighten the spine.

Vertebral body tethering (VBT) and vertebral body stapling (VBS) are not addressed on the Society's website.

National Institute for Health and Care Excellence

In 2023, the National Institute for Health and Care Excellence (NICE) published an interventional procedure guidance on minimally invasive fusionless posterior-approach surgery to correct idiopathic scoliosis in children and young people. The Recommendation stated "The procedure is recommended for use in research because overall, there is not enough good quality evidence on its safety and efficacy."

In 2022, the National Institute for Health and Care Excellence (NICE) published an interventional procedures guidance on vertebral body tethering for idiopathic scoliosis in children and young people. Recommendations stated that "evidence on the safety of vertebral body tethering for idiopathic scoliosis in children and young people is limited but raises concerns of serious complications. Evidence on its efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research."

Scoliosis Research Society

The Scoliosis Research Society has indicated that the treatment of adolescent idiopathic scoliosis falls into 3 main categories (observation, bracing, surgery) and is based on the risk of curve progression. In general, adolescent idiopathic scoliosis curves progress in 2 ways: first, during the rapid growth period of the patient and, second, into adulthood if the curves are relatively large. Because scoliosis gets larger during rapid growth, the potential for growth is evaluated taking into consideration the patient's age, the status of whether females have had their first menstrual period, as well as radiographic parameters. The Risser grading system rates a child's skeletal maturity on a scale of 0 to 5. Patients who are Risser grade 0 and 1 are growing rapidly, while patients who are 4 and 5 have stopped growing. The Society made the following recommendations:

- Observation is "recommended for patients whose curves are less than 25° or 30° who are still growing, or people who have stopped growing and have curves that aren't changing or causing problems."
- Bracing is "recommended for curves larger than 25° , but smaller than 45° to 50° in someone who is still growing."
- Surgical treatment is "recommended for people with curves usually greater than 45° or 50° and/or who are at high risk of continued worsening even after they are finished growing."
- Statements on VBS and tethers include: "This technique can be used in children who are growing, have a progressive curvature that measures less than 35° , and who are able to tolerate open or endoscopic exposure of the spine. By placing special vertebral body stapes or tethers on

the convex side of the curve, growth is inhibited on that side. The idea that the scoliosis may then correct through more growth on the concave side of the curve."

In 2023, the Scoliosis Research Society released a position statement on vertebral body tethering (VBT) in idiopathic pediatric spinal deformity. They stated that "VBT may be an effective treatment modality in some pediatric patients with idiopathic scoliosis. The decision regarding choice of treatment should be made in close dialogue with patients and families, especially underlining that the current scientific results do not show a significant, clinically relevant difference in outcome compared to posterior spinal fusion (PSF), and an increased risk of revision surgery should be expected if VBT is chosen."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

REFERENCES

1. U.S. Preventive Services Task Force (USPSTF). Final Recommendation Statement: Adolescent Idiopathic Scoliosis: Screening. 2018; <https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/adolescent-idiopathic-scoliosis-screening>.
2. American Academy of Orthopaedic Surgeons (AAOS). Idiopathic Scoliosis in Children and Adolescents. April 2021; <https://orthoinfo.aaos.org/en/diseases--conditions/idiopathic-scoliosis-in-children-and-adolescents>, Accessed August 12, 2025
3. Margalit A, McKean G, Constantine A, et al. Body Mass Hides the Curve: Thoracic Scoliometer Readings Vary by Body Mass Index Value. J Pediatr Orthop. Jun 2017; 37(4): e255-e260. PMID 27861214
4. Mishreky A, Parent S, Miyanji F, et al. Body mass index affects outcomes after vertebral body tethering surgery. Spine Deform. May 2022; 10(3): 563-571. PMID 35013996
5. Negrini S, Hresko TM, O'Brien JP, et al. Recommendations for research studies on treatment of idiopathic scoliosis: Consensus 2014 between SOSORT and SRS non-operative management committee. Scoliosis. 2015; 10: 8. PMID 25780381
6. Wall EJ, Reynolds JE, Jain VV, et al. Spine Growth Modulation in Early Adolescent Idiopathic Scoliosis: Two-Year Results of Prospective US FDA IDE Pilot Clinical Safety Study of Titanium Clip-Screw Implant. Spine Deform. Sep 2017; 5(5): 314-324. PMID 28882349
7. Cuddihy L, Danielsson AJ, Cahill PJ, et al. Vertebral Body Stapling versus Bracing for Patients with High-Risk Moderate Idiopathic Scoliosis. Biomed Res Int. 2015; 2015: 438452. PMID 26618169
8. Murray E, Tung R, Sherman A, et al. Continued vertebral body growth in patients with juvenile idiopathic scoliosis following vertebral body stapling. Spine Deform. Apr 2020; 8(2): 221-226. PMID 32026438
9. Bumpass DB, Fuhrhop SK, Schootman M, et al. Vertebral Body Stapling for Moderate Juvenile and Early Adolescent Idiopathic Scoliosis: Cautions and Patient Selection Criteria. Spine (Phila Pa 1976). Dec 2015; 40(24): E1305-14. PMID 26655807
10. Theologis AA, Cahill P, Auriemma M, et al. Vertebral body stapling in children younger than 10 years with idiopathic scoliosis with curve magnitude of 30° to 39°. Spine (Phila Pa 1976). Dec 01 2013; 38(25): E1583-8. PMID 23963018
11. Laituri CA, Schwend RM, Holcomb GW. Thoracoscopic vertebral body stapling for treatment of scoliosis in young children. J Laparoendosc Adv Surg Tech A. Oct 2012; 22(8): 830-3. PMID 23039706

12. O'leary PT, Sturm PF, Hammerberg KW, et al. Convex hemiepiphysiodesis: the limits of vertebral stapling. *Spine (Phila Pa 1976)*. Sep 01 2011; 36(19): 1579-83. PMID 21681138
13. Betz RR, Ranade A, Samdani AF, et al. Vertebral body stapling: a fusionless treatment option for a growing child with moderate idiopathic scoliosis. *Spine (Phila Pa 1976)*. Jan 15 2010; 35(2): 169-76. PMID 20081512
14. 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; 30(3): 10225536221137753. PMID 36420934
15. U.S. Food and Drug Administration (FDA). SUMMARY OF SAFETY AND PROBABLE BENEFIT (SSPB): The Tether Vertebral Body Tethering System. 2019; https://www.accessdata.fda.gov/cdrh_docs/pdf19/H190005b.pdf
16. Courvoisier A, Eid A, Bourgeois E, et al. Growth tethering devices for idiopathic scoliosis. *Expert Rev Med Devices*. Jul 2015; 12(4): 449-56. PMID 26027921
17. Samdani AF, Ames RJ, Kimball JS, et al. Anterior vertebral body tethering for idiopathic scoliosis: two-year results. *Spine (Phila Pa 1976)*. Sep 15 2014; 39(20): 1688-93. PMID 24921854
18. Samdani AF, Ames RJ, Kimball JS, et al. Anterior vertebral body tethering for immature adolescent idiopathic scoliosis: one-year results on the first 32 patients. *Eur Spine J*. Jul 2015; 24(7): 1533-9. PMID 25510515
19. Pehlivanoglu T, Oltulu I, Erdag Y, et al. Double-sided vertebral body tethering of double adolescent idiopathic scoliosis curves: radiographic outcomes of the first 13 patients with 2 years of follow-up. *Eur Spine J*. Jul 2021; 30(7): 1896-1904. PMID 33611658
20. Meyers J, Eaker L, Zhang J, et al. Vertebral Body Tethering in 49 Adolescent Patients after Peak Height Velocity for the Treatment of Idiopathic Scoliosis: 2-5 Year Follow-Up. *J Clin Med*. Jun 02 2022; 11(11). PMID 35683548
21. Negrini S, Donzelli S, Aulisa AG, et al. 2016 SOSORT guidelines: orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth. *Scoliosis Spinal Disord*. 2018; 13: 3. PMID 29435499
22. Scoliosis Research Society (SRS). Adolescent Idiopathic Scoliosis. n.d.; <http://www.srs.org/professionals/online-education-and-resources/conditions-and-treatments/adolescent-idiopathic-scoliosis>
23. Scoliosis Research Society (SRS)/Pediatric Orthopaedic Society of North America (POSNA). Joint SRS/POSNA Position Statement on Payor Coverage for Anterior Fusionless Scoliosis Technologies for Immature Patients with Idiopathic Scoliosis. April 2020; <https://posna.org/POSNA/media/Documents/Position%20Statements/Why-Should-Insurance-Cover-AVBT-April-2020.pdf>
24. National Institute of Arthritis and Musculoskeletal and Skin Diseases. Questions and Answers about Scoliosis in Children and Adolescents. December 2019; <https://www.niams.nih.gov/health-topics/scoliosis>
25. National Institute for Health and Care Excellence (NICE). Interventional procedures guidance: Vertebral body tethering for idiopathic scoliosis in children and young people [IPG728]. June 29, 2022; <https://www.nice.org.uk/guidance/ipg728>. Accessed August 2026
26. National Institute for Health and Care Excellence (NICE) Minimally invasive fusionless posterior-approach surgery to correct idiopathic scoliosis in children and young people. [IPG765] June 22, 2023; <https://www.nice.org.uk/guidance/ipg765>. Accessed August 2026
27. National Institute of Health and Care Excellence (NICE) MAGEC system for spinal lengthening in children with scoliosis. Medical Technologies Guidance [MTG18] June 18, 2014; <https://www.nice.org.uk/guidance/mtg18>. Accessed August 2025
28. Hayes, a symplr company Evolving Evidence Review. The Tether (Zimmer Biomet) for Skeletally Immature Patients with Progressive Idiopathic Scoliosis. May 29, 2025
29. Hayes, a symplr company Evolving Evidence Review ApiFix (ApiFix Ltd.) for Treatment of Adolescent Idiopathic Scoliosis. February 26, 2024/Annual Review February 10, 2026

30. Hayes, a symplr company Evidence Analysis Research Brief Magnetically Controlled Growing Rods for Treatment of Early-Onset Scoliosis. July 1, 2025
31. Hayes, a symplr company. Health Technology Assessment Magnetically Controlled Growing Rods for Treatment of Early-Onset Scoliosis. November 27, 2018/Annual Review February 1, 2021
32. UpToDate. Adolescent idiopathic scoliosis: Management and prognosis. Topic last updated July 2025. Also available at <https://www.uptodate.com>
33. Abdelaal A, Munigangaiah S, Trivedi J, Davidson N. Magnetically controlled growing rods in the treatment of early onset scoliosis: a single centre experience of 44 patients with mean follow-up of 4.1 years. *Bone & joint open*. 2020; 1(7):405-414
34. Akbarnia BA, Pawelek JB, Cheung KM, et al. Traditional growing rods versus magnetically controlled growing rods for the surgical treatment of early-onset scoliosis: a case-matched 2-year study. *Spine deformity*. 2014; 2(6):493-497
35. Guan D, Zhang Y, Xu J. Clinical outcome of magnetically controlled growing rod in early-onset scoliosis: a systematic review. *Clinical spine surgery*. 2020; 33(4):150-155
36. Hickey BA, Towriss C, Baxter G, et al. Early experience of MAGEC magnetic growing rods in the treatment of early onset scoliosis. *European spine journal: official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society*, 2014; 23(1):S61-S65
37. Subramanian T, Ahmad A, Mardare DM, et al. A six-year observational study of 31 children with early-onset scoliosis treated using magnetically controlled growing rods with a minimum follow-up of two years. *The bone & joint journal*. 2018; 100-B(9):1187-1200
38. Teoh KH, Winson DM, James SH, et al. Magnetic controlled growing rods for early-onset scoliosis: a 4-year follow-up. *The spine journal: official journal of the North American Spine Society*, 2016; 16(4):S34-S39
39. Thakar C, Kieser DC, Mardare M, et al. Systematic review of the complications associated with magnetically controlled growing rods for the treatment of early onset scoliosis. *European spine journal: official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society*. 2018; 27(9):2062-2071
40. Thompson W, Thakar C, Rolton DJ, et al. The use of magnetically-controlled growing rods to treat children with early-onset scoliosis: early radiological results in 19 children. *Bone Joint J*. 2016; 98-B(9):1240-1247
41. Tognini M, Hothi H, Dal Gal E, et al. Understanding the implant performance of magnetically controlled growing spine rods: a review article. *European spine journal: official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society*. 2021; 30(7):1799-1812
42. Migliorini F, Chiu W, Scrofanì R, et al. Magnetically controlled growing rods in the management of early onset scoliosis: a systematic review. *J Orthop Surg Res*. 2022 Jun 11;17(1):309
43. Floman Y, El-Hawary R, Millgram MA, et al. Surgical management of moderate adolescent idiopathic scoliosis with a fusionless posterior dynamic deformity correction device: Interim results with bridging 5-6 disc levels at 2 or more years of follow-up. *J Neurosurg Spine*. 2020 Jan 10 [Online ahead of print]. PMID 3192388
44. Floman Y, El-Hawary R, Lonner BS, et al. Vertebral growth modulation by posterior dynamic deformity correction device in skeletally immature patients with moderate adolescent idiopathic scoliosis. *Spine Deform*. 2021;9(1):149-153. PMID 32827087
45. Floman Y, Burnei G, Gavrilu S, et al. Surgical management of moderate adolescent idiopathic scoliosis with ApiFix®: A short peri-apical fixation followed by post-operative curve reduction with exercises. *Scoliosis*. 2015;10:4. PMID 25685175
46. Holewijn RM, de Kleuver M, van der Veen AJ, et al. A novel spinal implant for fusionless scoliosis correction: A biomechanical analysis of the motion preserving properties of a posterior periapical concave distraction device. *Global Spine J*. 2017;7(5):400-409. PMID 28811983

47. Stadhouder A, Holewijn RM, Haanstra TM, et al. High failure rates of a unilateral posterior peri-apical distraction device (ApiFix) for fusionless treatment of adolescent idiopathic scoliosis. *J Bone Joint Surg Am*. 2021; 103(19):1834-1843. PMID 3410170
48. ApiFix. <https://www.apifix.com>
49. FDA HDE Approval for H170001 Minimally Invasive Deformity Correction (MID-C) System. August 2019. Also available at <https://www.fda.gov>
50. FDA Executive Summary prepared for the Spring 2021 FDA's Pediatric Advisory Committee H170001 Minimally Invasive Deformity Correction (MID-C) System. Also available at <https://www.fda.gov/media/147901/download>
51. Hawary RE, Zaaroor-Regev D, Floman Y, et.al. Brace treatment in adolescent idiopathic scoliosis: risk factors for failure a literature review. *Spine J* 2019 Dec;19(12):1917-1925. PMID 31325626
52. Zygogiannis K, Pappa E, Antonopoulos SI, et. al. Surgical site infection following the correction of adolescent idiopathic scoliosis with ApiFix: A retrospective study analyzing its incidence and recurrence. *Cereus* 2023 Feb 1;1592): e34494. PMID 36874301
53. Froehlich S, Mittelmeier W, Desai B, et. al. Surgical treatment of adolescent idiopathic scoliosis with ApiFix minimal invasive dynamic correction system – a preliminary report of a 24-month follow-up. *Life (Basel)*. 2023;13(10) doi:10.3390/life13102032
54. Baroncini A, Courvoisier A, Berjano P, et al. The effects of vertebral body tethering on sagittal parameters: evaluations from a 2-years follow-up. *Eur Spine J*. Apr 2022; 31(4): 1060-1066. PMID 34910244
55. Hegde S, Badikillaya V, Kanade U, et al. Are We Looking at a Paradigm Shift in the Management of Adolescent Idiopathic Scoliosis? Comprehensive Retrospective Analysis of 75 Patients of Nonfusion Anterior Scoliosis Correction with 2-5-Year Follow-up: A Single Center Experience. *Asian Spine J*. Jun 2023; 17(3): 529-537. PMID 37211667
56. Larson AN, Todderud JE, Mathew SE, et al. Vertebral Body Tethering in Skeletally Immature Patients: Results of a Prospective U.S. FDA Investigational Device Exemption Study. *J Bone Joint Surg Am*. Dec 24 2024. PMID 39719007
57. Saarinen A, Flynn J, Thompson G et. al. Traditional versus magnetically controlled growing rods for idiopathic early-onset scoliosis: Outcomes at 5-year follow-up.
58. Thouement C, Saghbini E, Eloy G et. al. Spine to pelvis “T-Construct” using magnetic controlled growing rods in non-walkers neuromuscular early-onset scoliosis: A preliminary study. *Orthop Tramadol Surg Res*. 2025 May;111(3):104012. PMID 39362523
59. Saarinen A, Andras L, Boachie-Adjei, et. al. High preoperative body mass index is associated with implant breakage in patients treated with magnetically controlled growing rods for early-onset scoliosis. *J Pediatr Orthop*. 2025 Sep 1;45(8):492-498. PMID 40323772
60. O Al-Nassem A, Al-Naseem A, Al Balishi B, et. al Posterior spinal fusion versus vertebral body tethering for paediatric scoliosis: a meta-analysis of comparative studies. *Spine Deform*. 2025 May;13(3):681-694. doi: 10.1007/s43390-025-1050-x Epub 2025 Feb 4. PMID 39904840
61. Stamiris S, Sofos C, Sarridimitriou A, et. al., Comparative meta-analysis of vertebral body tethering and posterior spinal fusion in patients with idiopathic scoliosis. Evaluation of radiographic, perioperative, clinical, patient-reported outcomes, and complication rates. *Spine Deform*. 2025 June 8. doi:10.1007/s43390-025-0111-2-z. Online ahead of print. PMID 40484922
62. Abdelaal M, Ghandour M, Mert Ü, et al. Anterior Vertebral Body Tethering Versus Posterior Spinal Fusion in Adolescent Idiopathic Scoliosis: A Systematic Review and Meta-Analysis of Comparative Outcomes. *J Clin Med*. Sep 23, 2025; 14(19). PMID 41095787
63. Miyajima F, Pawelek J, Nasto LA, et al. Safety and efficacy of anterior vertebral body tethering in the treatment of idiopathic scoliosis. *Bone Joint J*. Dec 2020; 102-B (12): 1703-1708. PMID 33249889

64. Nugraha HK, Haber LL, Hoernschemeyer DG, et al. Outcomes of Vertebral Body Tethering in Adolescent Idiopathic Scoliosis: A Prospective, Multicenter Study. JB JS Open Access. 2026; 11(1). PMID 41523658
65. Stein AA, Samdani AF, Schupper AJ, et al. Lumbar Vertebral Body Tethering: Single Center Outcomes and Reoperations in a Consecutive Series of 106 Patients. Spine (Phila Pa 1976). Nov 15, 2024; 49(22): 1548-1554. PMID 38375615
66. Vorhies JS, Hauth L, Garcia S, et al. A New Look at Vertebral Body Tethering (VBT): Through the Modified Clavien-Dindo-Sink (mCDS) Classification. J Pediatr Orthop. May-Jun 2024; 44(5): e389-e393. PMID 38454491
67. Braun JT, Federico SC, Lawlor DM, et al. Anterior vertebral tethering for adolescent idiopathic scoliosis: our initial ten-year clinical experience. Spine Deform. Sep 2024; 12(5): 1355-1367. PMID 38796815
68. Scoliosis Research Society (SRS). Vertebral body tethering (VBT) in idiopathic pediatric spinal deformity. May 2023; <https://www.srs.org/Education/Quality-and-Safety/Informational--Position-Statements>
69. Dubin J, Bouloussa H, Schwend R. FDA oversight and the magnetic expansion control rod. JAMA Surg October 2025;160;(12): 1295-1296.doi:10.1001/jamasurg.2025.4257
70. Raitio A, Syvanen J, Helenius I. Vertebral body tethering: Indications, surgical techniques, and a systematic review of published results. J Clin Med. 2022 May 4;11(9): 2576.doi:10.2106/JBJS.OA.25.00309. PMID 35566702
71. Hoernschemeyer D, Boeyer M, Robertson M, et. al. Anterior vertebral body tethering for adolescent scoliosis with growth remaining: a retrospective review of 2 to 5-year postoperative results. JBJS 102, no.13 (2020): 1169-1176
72. Firoz M, Pawelek J, Nasto L et. al. Safety and efficacy of anterior vertebral body tethering in the treatment of idiopathic scoliosis: a multicentre review of 57 consecutive patients. The Bone & Joint Journal 102, no. 12 (2020): 1703-1708.
73. Baker C, Kiebzak G, Neal K. Anterior vertebral body tethering shows mixed results at 2-year follow-up. Spine deformity 9, no. 2 (2021): 481-489
74. Wong HK, John N, Ruiz P et. al. Non-fusion surgical correction of thoracic idiopathic scoliosis using a novel, braided vertebral body tethering device: minimum follow-up of 4-years. JBJS Open-Access 4, no. 4 (2019)
75. Baker CE, Milbrandt TA, and Larson AN. Anterior vertebral body tethering for adolescent idiopathic scoliosis: Early results and future directions. The Orthopedic Clinics of North America 52 (2), 99. 137-147
76. Roser M, Askin G, Labrom R et. al. Vertebral body tethering for idiopathic scoliosis: A systematic review and meta-analysis. Spine Deformity 11, no. (2023): 1297-1307
77. Lau K, Kwan KYH, Wont TKT et. al. Current status of vertebral body tethering for adolescent idiopathic scoliosis: An umbrella review. Orthopedic Research and Reviews 2024 pp. 305-315

CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	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 (when specified for one of the following: magnetically controlled growing rods [MCGR]; ApiFix)
	0656T	Anterior lumbar or thoracolumbar vertebral body tethering; up to 7 vertebral segments
	0657T	Anterior lumbar or thoracolumbar vertebral body tethering; 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
HCPCS		
	None	
Type of Service	Surgery	
Place of Service	Inpatient	

POLICY HISTORY

Date	Reason	Action
August 2026	Annual Review	Policy Revised
August 2025	Annual Review	Policy Renewed
July 2024	Annual Review	Policy Renewed

Date	Reason	Action
December 2023	Interim Review	Policy Revised
September 2023	Interim Review	Policy Revised
July 2023	Annual Review	Policy Revised – content moved from retired policy “Miscellaneous Surgical Treatments of Back Pain”
January 2022	Interim Review	Policy Revised
July 2021	Annual Review	Policy Revised
July 2020	Annual Review	Policy Revised
October 2019	Interim Review	Policy Revised
July 2019	Annual Review	Policy Revised
July 2018	Annual Review	Policy Revised
July 2017	Annual Review	Policy Revised
July 2016	Annual Review	Policy Revised
October 2015	Annual Review	Policy Revised
August 2015	Annual Review	Policy Revised
September 2014	Annual Review	Policy Revised
October 2013	Annual Review	Policy Revised
November 2012	Annual Review	Policy Renewed
November 2011	Annual Review	Policy Renewed
October 2010	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

*CPT® is a registered trademark of the American Medical Association.