Medical Policy

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Title: Interventions for Progressive Scoliosis

Related Policies:	▪ *Lumbar Spinal Fusion*

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Populations	Interventions	Comparators	Outcomes
Individuals: • With juvenile or adolescent idiopathic scoliosis at high risk of progression	Interventions of interest are: • Conventional rigid brace	Comparators of interest are: • Observation	Relevant outcomes include: • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With juvenile or adolescent idiopathic scoliosis at high risk of progression	Interventions of interest are: • Microcomputer-controlled brace	Comparators of interest are: • Observation	Relevant outcomes include: • Change in disease status • Morbid events • Quality of life • Treatment-related

Populations	Interventions	Comparators	Outcomes
			morbidity
Individuals: • With juvenile or adolescent idiopathic scoliosis at high risk of progression	Interventions of interest are: • Flexible brace	Comparators of interest are: • Observation	Relevant outcomes include: • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With juvenile or adolescent idiopathic scoliosis at high risk of progression	Interventions of interest are: • Vertebral body stapling	Comparators of interest are: • Observation	Relevant outcomes include: • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With juvenile or adolescent idiopathic scoliosis at high risk of progression	Interventions of interest are: • Vertebral body tethering	Comparators of interest are: • Observation	Relevant outcomes include: • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity

DESCRIPTION

Orthotic bracing attempts to slow spinal curve progression and reduce the need for fusion surgery in patients with juvenile or adolescent idiopathic scoliosis who are at high-risk of progression. Vertebral body stapling and vertebral body tethering, both fusionless surgical procedures, have been evaluated to determine whether the procedures could be used as alternatives to traditional orthotic bracing. This review does not address patients who are not at high-risk of progression or conventional fusion surgery for scoliosis, such as patients with Cobb angles measuring 45° or more.

OBJECTIVE

The objective of this evidence review is to determine whether surgical and nonsurgical interventions for scoliosis improve the net health outcome for juveniles and adolescents who are at high risk of spinal curve progression.

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."[1,] 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.[2,] Patients 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.[3,] A retrospective review 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° 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).[4,]

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.

Bracing

Bracing is used to reduce the need for spinal fusion by slowing or preventing further progression of the curve during rapid growth. Commonly used brace designs include the Milwaukee, Wilmington, Boston, Charleston, and Providence orthoses. The longest clinical experience is with the Milwaukee cervical-thoracic-lumbar-sacral orthosis. Thoracic-lumbar-sacral orthoses, such as the Wilmington and Boston braces, are intended to improve tolerability and compliance for extended (>18-hour) wear and are composed of lighter weight plastics with a low profile (underarm) design. The design of the nighttime Charleston and Providence braces is based on the theory that increased corrective forces will reduce the needed wear time (i.e., daytime), thereby lessening social anxiety and improving compliance. The smart brace consists of a standard rigid brace with a microcomputer system, a force transducer, and an air-bladder control system to control the interface pressure. Braces that are more flexible than thoracic-lumbar-sacral orthoses or nighttime braces, such as the SpineCor® Scoliosis System, are also being evaluated. The SpineCor is composed of a thermoplastic pelvic base with stabilizing and corrective bands across the upper body.

Surgery

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.[5,]

Research Recommendations

The Scoliosis Research Society provided evidence-based recommendations in 2005,[6,] which were updated in 2015,[7,] for bracing studies to standardize inclusion criteria, methodologies, and outcome measures to facilitate comparison of brace trials. Janicki et al (2007), the first study to use the Scoliosis Research Society criteria, concluded that a brace should prevent progression in 70% of patients to be considered effective.[8,] The Scoliosis Research Society evidence review and recommendations may also aid in the evaluation of fusionless surgical treatments for scoliosis progression in children.

The Scoliosis Research Society review of the natural history of scoliosis indicated that skeletally immature patients and patients with larger curves (between 20° and 29°) are significantly more likely to have more than 5° curve progression.[6,] Brace treatment for idiopathic scoliosis is usually recommended for juveniles and adolescents with curves measuring between 25° and 40° who have not completed spinal growth, with maturity defined as Risser grade 4, or at least 2 years after menarche for girls.[9,10,] Bracing may also be recommended for curves greater than 20° in a patient who has a rapidly progressing curve with more than 2 years of growth remaining.

Success from brace treatment is most frequently defined as progression of less than 5° before skeletal maturity, although alternative definitions may include progression of less than 10° before skeletal maturity or preventing the curve from reaching the threshold for surgical intervention. Surgery is usually recommended when the curve magnitude exceeds 45° to 50° (before or at skeletal maturity), although many patients will not undergo surgery at this point. Based on this information, Scoliosis Research Society provided the following recommendations for brace studies on adolescent idiopathic scoliosis:

- "Optimal inclusion criteria for brace studies consist of: age is 10 years or older when the brace is prescribed, Risser [grade] 0-2, curve 25°-40°, and no prior treatment."
- Outcomes of brace effectiveness should include all of the following:
    - "The percentage of patients with 5° or less curve progression and the percentage of patients who have 6° or more progression at skeletal maturity."
        - The number of patients at the start and end of treatment exceeding 10°, 30°, and 50° Cobb angles, as these risk thresholds have potential health consequences in adulthood, such as back pain and curve progression.
        - "A minimum of 2-year follow-up beyond skeletal maturity for each patient who

was 'successfully' treated with a brace to determine the percentage who subsequently required or had surgery recommended. The surgical indications must be documented."

- Clinically significant outcomes such as aesthetics, deformity progression, disability, pain, and quality of life.

- "Skeletal maturity should be considered achieved when <1 cm change in standing height has occurred on measurements made on 2 consecutive visits 6 months apart…. when Risser 4 is present and, in females, when the patient is 2 years after menarche."
- "All patients, regardless of subjective reports of compliance, should be included in the results. This process makes 'intent to treat' analysis possible.... An 'efficacy analysis' … should also be considered."

REGULATORY STATUS

Some braces used to treat scoliosis are considered class I devices by the U.S. Food and Drug Administration (FDA) and are exempt from 510(k) requirements (examples include the Boston scoliosis brace [Boston Orthotics & Prosthetics] and the SpineCor Scoliosis System). This classification does not require submission of clinical data regarding efficacy but only notification of FDA prior to marketing.

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 by the FDA through the 510(k) process 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.

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 states that this device is 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 for use in the same population as The Tether.

Several of the cleared devices are described in Table 1.

Table 1. Scoliosis Bracing Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Coronet Soft Tissue Fixation System	CoNextions Medical	3/4/2020	K200028	Off Label Use for Scoliosis support
Superelastic Staple	Neosteo	2/28/2020	K192447	Off Label Use for Scoliosis support
Mactafix CI Fixation Button With Continuous Loop	Medacta International SA	2/10/2020	K193165	Off Label Use for Scoliosis support

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Motoband Cp Implant System	CrossRoads Extemity Systems, LLC	1/10/2020	K193452	Off Label Use for Scoliosis support
Trimax Implant System	CrossRoads Extemity Systems, LLC	8/16/2019	K190772	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
DynaClipTM Bone Staple	MedShape Inc.	11/5/2018	K181781	Off Label Use for Scoliosis support
DynaBridge	Fusion Orthopedics LLC	10/15/2018	K181815	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
MotoCLIP/HiMAX Implant System	CrossRoads Extremity Systems LLC	6/29/2018	K181410	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
ToggleLoc System	Biomet Inc.	1/5/2018	K173278	Off Label Use for Scoliosis support

POLICY

A. A rigid cervical-thoracic-lumbar-sacral or thoracic-lumbar-sacral orthosis may be considered **medically necessary** for the treatment of scoliosis in juvenile and adolescent individuals at high risk of progression that meets the following criteria:
   1. Idiopathic spinal curve angle between 25° and 40°; **AND**
   2. Spinal growth has not been completed (Risser grade 0-3; no more than 1 year after menarche).
      OR
   3. Idiopathic spinal curve angle greater than 20°; **AND**
   4. There is a documented increase in the curve angle; **AND**
   5. At least 2 years of growth remain (Risser grade 0 or 1; premenarche).

B. Use of an orthosis for the treatment of scoliosis that does not meet the criteria above is considered **experimental / investigational**.

C. Anterior vertebral body tethering (AVBT) with an FDA approved device for the treatment of idiopathic scoliosis is considered **medically necessary** when **ALL** of the following criteria is met*:
   1. Curve progression following conservative management (for example, observation, exercise therapy, or bracing); **And**
   2. Cobb angle 30 to 65 degrees; **And**
   3. Curve flexibility greater than 30%; **And**
   4. Skeletal immaturity, defined as either:
      a. Risser grade 0 - 2; **OR**
      b. Sanders Maturity Scale less than or equal to 4.

*__NOTE:__ Anterior vertebral body tethering procedure will be performed by a qualified orthopedic/spine specialist who has had hands on, in person training and experience in AVBT technique at a facility with appropriate experience and expertise in the AVBT procedure.

D. Revision, replacement, or removal of vertebral body tethering is considered **medically necessary** when there are complications associated with the device (for example, tether breakage or overcorrection).

E. Anterior vertebral body tethering for the treatment of scoliosis is considered **experimental / investigational** when the above criteria are not met and for all other indications, including but not limited to:
   1. Skeletal maturity has been reached
   2. Previous spinal surgery
   3. Poor bone quality/Metabolic Bone Disease/T-Score 1.5 or less
   4. Curves >65 degrees
   5. Kyphosis >50 degrees
   6. Prior Thoracic Surgery
   7. Underlying cardiac or pulmonary disease

F. Vertebral body stapling for the treatment of scoliosis is considered **experimental / investigational**.

POLICY GUIDELINES

A. This policy does not address conventional surgery for scoliosis in individuals with curve angles measuring 45° or more. Brace treatment for idiopathic scoliosis is usually recommended for juveniles and adolescents with curves measuring between 25° and 40° who have not completed spinal growth, with maturity defined as Risser grade 4, or 2 years after menarche. Bracing may also be recommended for curves greater than 20° in an individual who has a rapidly progressing curve with more than 2 years of growth remaining.
    1. A rigid cervical-thoracic-lumbar-sacral orthosis is primarily prescribed for individuals with thoracic apices above T7 for control of upper thoracic sagittal deformities and other spinal deformities not amenable to treatment with lower-profile designs.
    2. A low profile, rigid thoracic-lumbar-sacral orthosis worn full-time (18-23 hours per day) through skeletal maturity is used for most idiopathic curve patterns with a thoracic curve apex at or below T7 (most idiopathic curves).
    3. Nighttime bracing systems are more effective in individuals with isolated flexible thoracolumbar and lumbar curves than in double curves; they may also be indicated in individuals who are noncompliant with a full-time wear program, individuals in whom other types of orthotic management have failed, and patients nearing skeletal maturity who may not require full-time wear.

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

RATIONALE

This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through February 7, 2024.

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 patients 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

CONVENTIONAL RIGID BRACES

Clinical Context and Therapy Purpose

The purpose of a conventional rigid brace 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 a conventional rigid brace.

Orthotic bracing attempts to slow spinal curve progression and reduce the need for fusion surgery.

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 (Table 2) are change in disease status, morbid events, quality of life, and treatment-related morbidity. Change in disease status was reported as 24% more improvement than just observation. The existing literature evaluating a conventional rigid brace as a treatment for juvenile or adolescent idiopathic scoliosis at high risk of progression has varying lengths of follow-up, ranging from 5 to 35 years. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

Table 2. Outcomes of Interest for Individuals with Juvenile or Adolescent Idiopathic Scoliosis at High-risk of Progression

Outcomes	Details
Change in Disease Status	The use of a standard brace showed significant improvement in spinal curvature and strength compared to observation alone
Quality of Life	The use of the standard brace requires wearing it for at least 12 hours a day, which does limit motor function; however, motor function was reportedly increased

Outcomes	Details
	after the use of the brace

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

24-HOUR BRACE

Nonrandomized Comparative Study

Weinstein et al (2013) reported on results from the National Institutes of Health-sponsored multicenter Bracing in Adolescent Idiopathic Scoliosis Trial that compared bracing with watchful waiting.[11,] Patients enrolled met current criteria for bracing: skeletally immature (Risser grade 0-2); pre- or postmenarchal by no more than 1 year; the primary angle between 20° and 40°; curve apex caudal to T7; as well as no previous surgical or orthotic treatment for adolescent idiopathic scoliosis. Due to difficulty recruiting into this randomized trial, the final trial included both a randomized cohort (n=116; 87% female) and a preference cohort (n=126; 95% female). The primary outcomes were curve progression to 50° or more (treatment failure) or skeletal maturity without 50° or more of progression (treatment success). The trial began in 2007 with an estimated 500 patients but was stopped early by the data safety and monitoring board due to the efficacy of bracing found in the interim analysis. The rate of treatment success was 72% after bracing compared with 48% after observation, with a propensity score-adjusted odds ratio for treatment success of 1.93. Intention-to-treat analysis of the randomized cohort showed the number needed to treat to prevent 1 case of curve progression warranting surgery was 3.0. Hours of brace wear, measured with a temperature sensor embedded in the brace, correlated significantly with the rate of treatment success. The effectiveness of brace wear of fewer than 6 hours per day was similar to observation (41%), while success rates of 90% to 93% were found in patients who wore a brace for at least 12.9 hours per day.

Retrospective Study

Aulisia et al (2021) conducted a nested cohort study of 163 patients with adolescent idiopathic scoliosis who received progressive action short bracing.[12,] Outcomes were compared between patients with Cobb angles less than 30° and more than 30° after 10 years of follow-up. The mean age at brace removal was 13.46 years. The mean pre-brace Cobb angle in the first group was 37.26°, which decreased to 22.98° after brace weaning, then increased to 25.07° at 10 years. In the second group, the mean pre-brace Cobb angle was 24.4°, which decreased to 8.69° after brace weaning, then increased to 9.98° at 10 years. There was no significant difference in the mean progression of curve magnitude between groups at 10 years follow-up.

Aulisa et al (2017) investigated whether scoliotic curve correction was maintained long-term in patients with adolescent idiopathic scoliosis who were treated with the rigid brace.[13,] From a database of patients treated with a rigid brace, 93 patients who had completed treatment at least 10 years prior agreed to participate and underwent a follow-up examination. Participants had a mean age of 32.6 years and had been treated with the brace for a mean of 5.3 years. Mean follow-up was 15 years posttreatment. The mean pre-brace Cobb angle was 32°, which was reduced to 19° following brace removal. At short-term follow-up (5 years), the mean Cobb angle was 21°; at long-term follow-up, the angle had increased to 22°. The change in Cobb angle from brace removal to long-term follow-up was not statistically significant. Subgroup analyses on patients with pre-brace Cobb angles of 30° or less compared with pre-brace Cobb angles greater than 30° showed no significant difference in angle increase at long-term follow-up.

Tables 3 and 4 summarize the key characteristics and results of these trials.

Table 3. Summary of Key Nonrandomized Trials Characteristics

Study	Study Type	Country	Date	Participants	Treatment (1)	Treatment (2)	Follow Up
Weinstein et al (2013)[11,]	Multicenter, with a randomized and nonrandomized cohort	United States, Canada	2007-2011	Adolescents with idiopathic scoliosis (N=242)	Rigid thoracolumbosacral orthosis	Control	Average 22 months
Aulisa et al (2021)[12,]	Nonrandomized controlled cohort nested in a prospective database	Italy	1980-2018	Patients who had completed brace treatment at least 10 years prior (N=163)	Progressive action short brace		Mean 13.41 years post-treatment
Aulisa et al (2017)[13,]	Retrospective	Italy	1980-2016	Patients who had completed treatment with a rigid brace at least 10 years prior (N=93)	Lyon or progressive action short brace		Mean 15 years post-treatment

Table 4. Summary of Key Nonrandomized Trials Results

Study	Rate of Treatment Success	Average PedsQL scores	Pre-brace Mean Cobb Angle (degrees)	Post-brace Mean Cobb Angle (degrees)	Mean Cobb Angle at 10 Year Follow-up (degrees)
Weinstein et al (2013) [11,]					
Bracing	72%	82			
Control	48%	81.9			

Study	Rate of Treatment Success	Average PedsQL scores	Pre-brace Mean Cobb Angle (degrees)	Post-brace Mean Cobb Angle (degrees)	Mean Cobb Angle at 10 Year Follow-up (degrees)
OR	1.93				
p -value		.97			
Aulisa et al (2021)[12,]					
Cobb angle >30° group			37.26 (+/- 7.5)	22.98 (+/- 9.7)	25.07 (+/- 11.2)
Cobb angle <30° group			24.40 (+/- 2.6)	8.69 (+/- 7.3)	9.98 (+/- 7.8)
Aulisa et al (2017)[13,]			32.17 (+/- 9.4)	19.39 (+/- 10.8)	22.12 (+/- 12.11)

OR: odds ratio; PedsQL: Pediatric Quality of Life Inventory (score range, 0-100).

NIGHTTIME BRACES

Systematic Review

Costa et al (2021) conducted a systematic review and meta-analysis to compare different bracing methods in patients with adolescent idiopathic scoliosis, including full-time and nighttime wear of rigid braces and soft braces.[14,] Thirty-three studies were included, approximately 25 of which were conducted in patients at high risk of progression (e.g., Cobb angle between 25° and 40°, Risser grade 0-2). All but one of the 32 studies used rigid braces, 2 studies used nighttime braces, and 2 studies used part-time braces. The meta-analysis was limited to 16 studies with a medium or low risk of bias that defined progression as less than or equal to 5°. Success with full-time rigid bracing was 73.2% (95% CI, 60.9% to 85.5%), with nighttime rigid bracing was 78.7% (95% CI, 72.4% to 85%), with soft bracing was 62.4% (95% CI, 55.1% to 69.6%), and with observation only was 50% (95% CI, 44% to 56%).

Retrospective Trial

Using Scoliosis Research Society criteria, Janicki et al (2007) reported on outcomes from a database of patients with adolescent idiopathic scoliosis who had used a thoracic-lumbar-sacral orthosis or a nighttime orthosis.[8,] This retrospective analysis identified 160 patients treated orthotically for idiopathic scoliosis between 1992 and 2004. Patients with incomplete follow-up were phoned and asked to return if needed. From the cohort of 160 patients, 83 met the Scoliosis Research Society inclusion criteria and had complete data. Due to poor outcomes with the thoracic-lumbar-sacral orthosis, which the investigators suspected were predominantly due to a lack of compliance, the methodology of the review changed from using a thoracic-lumbar-sacral orthosis to recommending a nighttime orthosis. Thus, the 48 patients treated with a thoracic-lumbar-sacral orthosis and 35 treated with a nighttime orthosis were not concurrent. For patients with an initial curve between 25° and 40°and who were treated with a thoracic-lumbar-sacral orthosis, 85% progressed to greater than 5°, 56% progressed to greater than 45°, and 79% progressed to surgery. With the nighttime orthosis, 69% progressed to greater than 5°, 45% progressed to greater than 45°, and 60% progressed to surgery. Thus, only 21% in the thoracic-lumbar-sacral orthosis group and 40% in the nighttime orthosis group were considered to have had successful orthotic management. Subgroup analyses showed little benefit of either brace type in patients with an initial curve between 36° and 40°, with 86% of the thoracic-lumbar-sacral orthosis group and 91% of the nighttime orthosis group progressing to surgery.

Section Summary: Conventional Rigid Brace
The highest quality study on bracing is a sizable National Institutes of Health-sponsored trial from 2013, which had both randomized and observational arms comparing standard rigid bracing with watchful waiting. This trial was stopped after interim analysis because of a significant benefit of bracing for the prevention of progression and need for spinal fusion. Two retrospective studies with long-term follow-up (mean, 13 to 15 years; range,10 to 35 years) demonstrated that curve corrections from rigid bracing were stable. Another retrospective study demonstrated that nighttime bracing was more effective than a 24-hour brace for avoiding surgery and preventing curve progression, but investigators attributed this finding to likely noncompliance with the 24-hour brace. A meta-analysis found higher success with rigid braces (both full-time and nighttime) compared to soft braces and observation only.

MICROCOMPUTER-CONTROLLED BRACES (SMART BRACE)

Clinical Context and Therapy Purpose
The purpose of a microcomputer-controlled brace 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 a microcomputer-controlled brace.

Orthotic bracing attempts to slow spinal curve progression and reduce the need for fusion surgery.

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, quality of life, and treatment-related morbidity. The existing literature evaluating a microcomputer-controlled brace as a treatment for juvenile or adolescent idiopathic scoliosis at high risk of progression has varying lengths of follow-up. 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

Randomized Controlled Trial

Lou et al (2012) published a pilot RCT that compared a microcomputer-controlled brace (smart brace) with a standard rigid brace in 12 patients (10 female, 2 male) with scoliosis.[15,] Patients were randomized to wear the smart brace for 1 year followed by 1 year with a standard brace or to wear the standard brace for 2 years. Both groups were followed for 3 years after treatment. Compliance, measured by time brace worn, with the microcomputer-controlled brace was similar to that for the standard brace group (66% vs. 62%). However, results suggested improvements in the quality of brace wear during the first 12 months (i.e., "tightness at prescribed level") with the smart brace (67%) compared with the standard brace (54%). The smart brace was associated with improved outcomes. None of the patients in the smart brace group had significant progression in spinal curves (a Cobb angle change <5°), whereas 2 of 6 patients in the standard thoracic-lumbar-sacral orthosis group had a significant change in Cobb angle (7° and 20°) over the 3-year study; 1 patient in the thoracic-lumbar-sacral orthosis group required subsequent fusion surgery.

Section Summary: Microcomputer-Controlled Braces (Smart Brace)

A pilot RCT using a microcomputer-controlled brace (smart brace) reported improved outcomes compared with a conventional rigid brace; however, the small number of subjects enrolled in the pilot (N =12) limits conclusions drawn from these results. No studies on the smart brace have been identified since the 2012 pilot.

FLEXIBLE BRACES

Clinical Context and Therapy Purpose

The purpose of a flexible brace 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 a flexible brace.

Orthotic bracing attempts to slow spinal curve progression and reduce the need for fusion surgery.

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, quality of life, and treatment-related morbidity. The existing literature evaluating a flexible brace as a treatment for juvenile or adolescent idiopathic scoliosis at high-risk of progression has varying lengths of follow-up, ranging from 3 to 45 months. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 45 months 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

Randomized Controlled Trial

Wong et al (2008) conducted an RCT comparing the clinical efficacy and compliance of rigid with flexible spinal bracing in 43 patients who had moderate adolescent scoliosis.[16,] Follow-up for 38 patients to a mean of 45.1 months (range, 24 to 77 months) after skeletal maturity was reported by Guo et al (2014).[17,] Female patients with a Cobb angle between 20° and 30°, apical vertebra below T5, age between 10 and 14 years, and Risser sign of 2 or less were randomized to the flexible SpineCor orthosis or a rigid underarm brace. Subjects were asked to wear the brace 23 hours per day, with 1 hour for bathing and physical exercises. Follow-up visits took place after the first month of intervention and then every 3 months after that. Acceptance of the brace was measured with a 16-question visual analog scale assessing pain, skin irritation, and daily activities. If the curve progressed >5° while using the SpineCor brace, patients were required to switch to a rigid brace. At the end of the 45-month study period, a significantly higher percentage of the subjects (35.0%) in the flexible brace group showed curve progression of >5° compared with subjects in the rigid brace group (5.6%; $p<.05$). One patient in each group required surgery due to rapid curve progression. Patients' acceptance of the 2 orthoses was similar. The rigid brace caused significantly more problems in hot weather (85% vs. 27%, respectively) as well as difficulties with donning and doffing, while the flexible braces posed difficulties with toileting. At the 45-month follow-up, the rate of curve progression was 1.5° per year postmaturity, with no additional patients proceeding to surgery.

Nonrandomized Comparative Study

Plewka et al (2013) compared the efficacy of the SpineCor brace (n=45) with physical therapy plus observation (n=45) in children and adolescents with scoliosis.[18,19,] The control group consisted of children who qualified for brace treatment but whose parents did not consent to treatment or in whom the treatment was not possible for social reasons. Baseline measures of the 2 groups were similar, with an average age of 12 years (range, 7 to 16 years). After 2 years of treatment, patients treated with the SpineCor brace showed significant improvements in clinical parameters (stable, 45%; reduction, 33%; progression, 22%) compared with the no-treatment group (stable, 53%; reduction, 0%; progression, 53%). Compliance with brace wear was good, with 95% of the patients reporting

regular brace wear.

Section Summary: Flexible Braces
One RCT evaluating a flexible brace did not show outcomes equivalent to those for conventional rigid brace designs. A nonrandomized comparative study suggested the flexible brace might improve outcomes compared with no treatment; however, this study was limited by self-selection and potential differences in patient characteristics between groups.

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, quality of life, 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 VBS and bracing for immature patients with moderate (25° to 44°) idiopathic scoliosis (see Tables 5 and 6).[20,] 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° to34°), there was a nonstatistically significant trend for stapling to be more effective (progression <10°, 81%) compared with bracing (61%; p=.16). For larger thoracic curves (>35°), 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 5 and 6.

Cuddihy et al (2015) compared VBS to bracing in a matched cohort of skeletally immature patients with moderate idiopathic scoliosis.[20,] 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 5 and 6). In smaller thoracic curves (25° to 34°) there was a nonsignificant trend toward better results with VBS versus bracing. For those with thoracic curves ≥35°, 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 VBS in 7 patients with a mean age of 9.3 years (range, 7.8 to11.1 years) and an average preoperative Cobb angle of 30° (standard deviation [SD], 6°); the mean follow-up was 83 months (range, 72 to 95 months).[21,] 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 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°.[22,] 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 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).[23,] 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 VBS

and had at least 2 years of follow-up.[24,] 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 VBS in young children with large Cobb angles was ineffective.[25,] 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.[26,] 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 5. 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)[21,]	U.S.	Case series	7	9.3	27.3° to 37.9°	NR	6
Cuddihy et al (2015)[20,]	U.S.	Case control	123	11	25° to 44°	0	2
Bumpass et al (2015)[22,]	U.S.	Case series	33	11	25° to 40°	0	2
Theologis et al (2013)[23,]	U.S.	Case series	12	8	30° to 39°	NR	2
Laituri et al (2012)[24,]	U.S.	Case series	7	9	25° to 41°	NR	2
O'Leary et al (2011)[25,]	U.S.	Case series	11	7	68° to 105°	0	1
Betz et al (2010)[26,]	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 6. Summary of Key Observational Study Outcomes for Vertebral Body Stapling

Study	**Tx**	**Change in Curve**				
		>10° Progressed	***Stable***	***>10° Improved***		
Murray et al (2020)[21],	VBS	2	4	1		
		>10° Progressed	***Stable/Improved***	***p***	**Progressed ≥50°**	**Subsequent Fusion**
Cuddihy et al (2015)[20],	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)[22],	VBS	13 (39)	14 (42)	6 (18)	9 (27)	11 (31)
Theologis et al (2013)[23],	VBS	0 (0)	5 (42)	7 (58)	0 (0)	0 (0)
Laituri et al (2012)[24],	VBS	0 (0)	2 (29)	5 (71)	0 (0)	0 (0)
O'Leary et al (2011)[25],	VBS	3 (27)	6 (55)	2 (18)	0 (0)	8 (73)
		Baseline Curve	**>10° Progressed**	**Stable/Improved**		
Betz et al (2010)[26],	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 patients 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 patients 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, pneumothoraces, 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 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 vertebral body tethering.

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, quality of life, and treatment-related morbidity. The existing literature evaluating vertebral body tethering 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
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.[27,] 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
As noted in the Regulatory section above, on 6/4/2019, the U.S. Food and Drug Administration (FDA) granted a Humanitarian Device Exemption to a new vertebral body tethering device called The Tether (Zimmer Biomet Spine, HDE #H190005, product code QHP). Available evidence for The Tether includes only 1 small retrospective cohort study of 57 pediatric patients that is yet unpublished and is only summarized in the FDA's Humanitarian Device Exemption Summary of Safety and Probable Benefit report.[28,] In this study, pediatric patients who failed brace treatment (e.g., greater than 5° of progression and/or intolerance to brace wear) received vertebral body tethering with Dynesys vertebral body screws, which are similar to those of the marketed version of The Tether but that have a slightly higher screw profile. Study participants were 86.4% female, with a mean age of 12.4 years. At baseline, mean Cobb angles were 30° to 44° in 75.4% of participants and 45° to 65° in 24.6% of participants. After 2 years, among the 44 subjects with 24-month data (out of the original 57), 43 met the probable benefit success criteria of achievement of a Cobb angle of 40°or less. Overall, the mean Cobb angles improved from 40.4° to 14.3° (+65%). Although assessment of quality of life at the last follow-up visits were described as "positive" based on the Pediatric Quality of Life Inventory, the

clinical importance of this data is unclear as no baseline assessments were completed for comparison. A total of 8 participants had serious adverse events (14%), including overcorrection of the instrumented curve (8.8%), definite cord break (1.8%), development of a new curve (1.8%), and spondylolisthesis (1.8%). Other common adverse events were back pain (24.6%), overcorrection of the instrumented curve (21.1%), nausea/vomiting (21.1%), and extremity pain (21.1%). A total of 8 patients (6%) required surgical revision due to adverse events.

Other studies not included in the Zhu et al (2022) systematic review[27,] are discussed below.

Samdani et al (2014, 2015) published 2 retrospective reviews on the off-label use of the Dynesys system for anterior vertebral body tethering for idiopathic scoliosis.[29,30,] They reported pursuing vertebral body tethering at their children's hospital due to lack of success with VBS for thoracic curves greater than 35°. At the time of these reports, 32 patients had a minimum of 1-year follow-up,[30,] and 11 consecutive patients had a 2-year follow-up.[29,] 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 with the Dynesys system for adolescent idiopathic scoliosis with double curves.[31,] 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 VBT via the Dynesys system after reaching peak height velocity (Risser stage 3-5).[32,] 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 SRS-22 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.

Baroncini et al 2022 reported a retrospective, 2-center cohort study in 86 patients in Europe who underwent VBT with the REFLECT system.[33,] 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. Sagital 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.[34,] 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.

Section Summary: Vertebral Body Tethering
There is limited published evidence on vertebral body tethering. Available evidence for The Tether is limited to a small, single-center, uncontrolled, unpublished retrospective cohort study of 57 pediatric patients. Although reported Cobb angle corrections are promising, serious adverse events occurred, data are lacking on other important health outcomes, and there are important study design limitations, including lack of a control group. Additional early reports of a correction in Cobb angle from published reports on the Dynesys system are also promising, but little is known about longer-term outcomes with this procedure. Published data for the REFLECT VBT are limited to observational studies, and data are lacking on important health outcomes. A meta-analysis of vertebral body tethering studies with more than 36 months follow-up reported a 74% clinical success rate, a 52% complication rate, and a 16% unplanned reoperation rate. Most commonly reported complications were tether breakages, pulmonary complications, and overcorrections. Larger, controlled studies are needed to verify these preliminary findings.

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.[2,]

- Observation is appropriate when the curve is mild (<25°) 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°-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 and vertebral body stapling (VBS) are not addressed on the Society's website.

National Institute of Arthritis and Musculoskeletal and Skin Diseases
The National Institute of Arthritis and Musculoskeletal and Skin Diseases has an educational website page on scoliosis in children and adolescents (last reviewed, July 2023).[35,] When treatment is needed, an orthopedic spine specialist should suggest the best treatment for each patient based on the patient's age, how much more he or she is likely to grow, the degree and pattern of the curve, and the type of scoliosis.

- Observation may be advised if "the curve is mild" and " the child's skeleton is still growing."
- Doctors may advise "If the curve is moderate" and the "child or teen is still growing...using a brace to keep the curve from getting any worse."
- Surgery may be advised if the "child or teen is still growing and the scoliosis continues to progress."

The Institute also stated that regular exercise helps children remain physically fit and helps strengthen muscles.

The educational page does not address VBS or vertebral body tethering.

National Institute for Health and Care Excellence
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.[36,] 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.[37,] 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 45º or 50º 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 still growing, have a progressive curvature that measures less than 35º, and who are able to tolerate open or endoscopic exposure of the spine. By placing special vertebral body staples or tethers on the convex side of the curve, growth is inhibited on that side. The idea is that the scoliosis may then correct through more growth on the concave side of the curve."

Scoliosis Research Society/Pediatric Orthopaedic Society of North America

A joint Scoliosis Research Society/Pediatric Orthopaedic Society of North America position statement (2020) on payor coverage for anterior fusionless scoliosis technologies for immature patients with idiopathic scoliosis drew the following conclusions after a review of scientific evidence on anterior vertebral growth modulation:[38,]

- "...payors should provide coverage for any FDA approved devices under FDA stated clinical indications and requirements (limited to surgeons with active IRB approval) at the same level as traditional spinal instrumentation/fusion and growing rod procedures for management of skeletally immature patients (Risser ≤ 2 or Sanders ≤ 5) with idiopathic scoliosis (as defined above, 30 to 65 degrees Cobb angle)."
- "For those patients who meet criteria for use of The Tether™ or other similarly FDA approved growth modulation systems, the decision for fusion versus growth modulation is best made between the patient, guardians, and treating physician - accounting for individual needs, values, and perspectives."
- "The SRS and POSNA do not support the use or reimbursement for anterior nonfusion instrumentation in skeletally mature individuals for the management of scoliosis or other spinal deformities."

Society on Scoliosis Orthopaedic and Rehabilitation Treatment

The guidelines from the Society on Scoliosis Orthopaedic and Rehabilitation Treatment (2016) included recommendations on the following conservative treatments for idiopathic scoliosis[39,]: assessment, bracing, physiotherapy, physiotherapeutic scoliosis-specific exercises and other conservative treatments for idiopathic scoliosis, exercises, special inpatient rehabilitation, and bracing (nighttime rigid bracing, soft bracing, part-time rigid bracing, full-time bracing). The guidelines did not address vertebral body stapling or vertebral body tethering. Treatment decisions should be individualized based on the probability of progression, curve magnitude, skeletal maturity, patient age, and sexual maturity. The following is a summary of the 20 recommendations in the guidelines specific to bracing:

- Bracing is recommended to treat adolescent, juvenile, and infantile idiopathic scoliosis "as the first step in an attempt to avoid or at least postpone surgery to a more appropriate age."
- "It is recommended not to apply bracing to treat patients with curves below 15º ± 5º Cobb, still growing (Risser 0 to 3), and with demonstrated progression of deformity or elevated risk of worsening, unless otherwise justified in the opinion of a clinician specialized in conservative treatment of spinal deformities."
- "It is recommended that each treating team provide the brace that they know best, which means the brace they are more experienced and with perceived outcomes. This is due to the actual knowledge; there is no brace that can be recommended over the others."
- Braces should be "worn full time or no less than 18 hours per day at the beginning of treatment …" and "in proportion with the severity of deformity, the age of the patient, the stage, aim and overall results of treatment, and the achievable compliance."
- "[B]racing is applied by a well-trained therapeutic team, including a physician, an orthotist, and a therapist, according to … (prescription, construction, … correction, follow-up)…."

- Braces should be "specifically designed for the type of the curve to be treated": to treat frontal, horizontal, and sagittal planes; not to restrict respiratory function; to be least invasive; to ensure patient compliance.

U.S. Preventive Services Task Force Recommendations
The U.S. Preventative Services Task Force (USPSTF) has published recommendations for idiopathic scoliosis screening. The USPSTF (2004) recommended against the routine screening of asymptomatic adolescents for idiopathic scoliosis (grade D recommendation). The USPSTF (2018) updated their recommendation to state that there is insufficient evidence to assess screening of adolescents for idiopathic scoliosis (grade I recommendation).[40,] Review conclusions for scoliosis treatments are listed below:

"The USPSTF found inadequate evidence on treatment with exercise and surgery. It found adequate evidence that treatment with bracing may slow curvature progression in adolescents with mild or moderate curvature severity (Cobb angle <40° to 50°); however, evidence on the association between reduction in spinal curvature in adolescence and long-term health outcomes in adulthood is inadequate. The USPSTF found inadequate evidence on the harms of treatment."

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 7.

Table 7. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05830825	The Tether™ - Vertebral Body Tethering System Post-Market Clinical Follow-Up Study in UK	100	Dec 2031
NCT04889339	Validation of a New Generation of Orthopedic Brace for Treating Adolescent Idiopathic Scoliosis by Using Growth Modulation	58	Jan 2024
NCT04992845[a]	Fusionless Treatment of Idiopathic Scoliosis With the SCOLI-TETHER System During The Growth Period	51	May 2025
NCT05001568	Validation of a New Optimized Nighttime Providence Brace for Personalized Treatment of Adolescent Idiopathic Scoliosis	58	Jan 2025
NCT04805437	3D Designed Boston Brace Versus Standard Boston Brace in Halting Progression in Idiopathic Scoliosis: a Randomized Controlled Trial (PRISCOPRO)	170	Apr 2037
NCT01761305	CONTRAIS: CONservative TReatment for Adolescent Idiopathic Scoliosis. A Randomised Controlled Trial	135	Dec 2030
NCT02897453[a]	Retrospective Review With Prospective Surveillance of Safety and Efficacy in a Clinical Series of Spinal Tethering Patients	56	Oct 2022 (unknown)
NCT04296903[a]	Post-approval Registry Study to Evaluate the Continued Safety and Probable Benefit of the MID-C	200	May 2028

NCT No.	Trial Name	Planned Enrollment	Completion Date
	System for 5 Years Post-Implantation in Adolescent Idiopathic Scoliosis (AIS)		
NCT04116723	Trial of Personalized Flexible Bracing Treatment of Adolescents Idiopathic Scoliosis	100	Dec 2025
NCT03506334	Prospective Pilot Study of Anterior Vertebral Body Tethering Using Zimmer Biomet Tether System or Dynesys System Components to Treat Pediatric Scoliosis	80	May 2024
NCT04590807	Posterior Spinal Fusion With Pedicle Screws vs. Anterior Vertebral Body Tethering in Adolescent Idiopathic Scoliosis	70	Dec 2025
NCT04505579[a]	The Tether™ - Vertebral Body Tethering System Post Approval Study	200	Dec 2027
NCT04914507	A Prospective Analysis of Long-Term Clinical Outcomes and 3D Spine Growth in Anterior Vertebral Body Tethering	106	Sep 2029

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
22836	Vertebral body tethering; up to 7 vertebral segments
22837	Vertebral body tethering; 8 or more vertebral segments
22838	Revision, replacement, or removal of vertebral body
22899	Unlisted procedure, spine
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
L1000	Cervical-thoracic-lumbar-sacral orthosis (CTLSO) (MILWAUKEE), inclusive of furnishing initial orthosis, including model
L1001	Cervical thoracic lumbar sacral orthosis, immobilizer, infant size, prefabricated, includes fitting and adjustment
L1005	Tension based scoliosis orthosis and accessory pads, includes fitting and adjustment
L1006	Scoliosis orthosis, sagittal-coronal control provided by a rigid lateral frame, extends from axilla to trochanter, includes all accessory pads, straps and interface, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1010	Addition to cervical-thoracic-lumbar-sacral orthosis (CTLSO) or scoliosis orthosis, axilla sling
L1020	Addition to CTLSO or scoliosis orthosis, kyphosis pad
L1025	Addition to CTLSO or scoliosis orthosis, kyphosis pad, floating
L1030	Addition to CTLSO or scoliosis orthosis, lumbar bolster pad
L1040	Addition to CTLSO or scoliosis orthosis, lumbar or lumbar rib pad
L1050	Addition to CTLSO or scoliosis orthosis, sternal pad
L1060	Addition to CTLSO or scoliosis orthosis, thoracic pad
L1070	Addition to CTLSO or scoliosis orthosis, trapezius sling
L1080	Addition to CTLSO or scoliosis orthosis, outrigger
L1085	Addition to CTLSO or scoliosis orthosis, outrigger, bilateral with vertical extensions
L1090	Addition to CTLSO or scoliosis orthosis, lumbar sling
L1100	Addition to CTLSO or scoliosis orthosis, ring flange, plastic, or leather
L1110	Addition to CTLSO or scoliosis orthosis, ring flange, plastic, or leather, molded to patient model

CPT/HCPCS	
L1120	Addition to CTLSO, scoliosis orthosis, cover for upright, each
L1200	Thoracic-lumbar-sacral-orthosis (TLSO), inclusive of furnishing initial orthosis only
L1210	Addition to TLSO, (low profile), lateral thoracic extension
L1220	Addition to TLSO, (low profile), anterior thoracic extension
L1230	Addition to TLSO, (low profile), Milwaukee type superstructure
L1240	Addition to TLSO, (low profile), lumbar derotation pad
L1250	Addition to TLSO, (low profile), anterior ASIS pad
L1260	Addition to TLSO, (low profile), anterior thoracic derotation pad
L1270	Addition to TLSO, (low profile), abdominal pad
L1280	Addition to TLSO, (low profile), rib gusset (elastic), each
L1290	Addition to TLSO, (low profile), lateral trochanteric pad
L1300	Other scoliosis procedure, body jacket molded to patient model
L1310	Other scoliosis procedure, post-operative body jacket
L1499	Spinal orthosis, not otherwise specified

REVISIONS	
12-18-2021	Policy added to the bcbsks.com web site.
07-12-2022	Updated Description Section
	Updated Policy Section ▪ Section A2 removed "in females" from the end of the statement (Risser grade 0-3; no more than 1 year after menarche). ▪ Section A5 removed "in females" from the end of the statement (Risser grade 0 or 1; premenarche).
	Updated Policy Guideline Section ▪ Section A removed "for girls" from the end of the statement Brace treatment for idiopathic scoliosis is usually recommended for juveniles and adolescents with curves measuring between 25° and 40° who have not completed spinal growth, with maturity defined as Risser grade 4, or 2 years after menarche.
	Updated Rationale Section
	Update References Section
05-23-2023	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed ICD-10 Codes
	Updated References Section
01-01-2024	Updated Coding Section ▪ Updated Nomenclature for 0656T and 0657T (eff. 01-01-2024) ▪ Added new codes 22836, 22837, 22838 and 0790T (eff. 01-01-2024)
05-28-2024	Updated Description Section
	Updated Rationale Section
	Updated References Section
Posted 10-22-2024 Effective 11-06-2024	Updated Policy Section ▪ Removed: "Vertebral body stapling and vertebral body tethering for the treatment of scoliosis are considered experimental / investigational." ▪ Added: C. Anterior vertebral body tethering (AVBT) with an FDA approved device for the treatment of idiopathic scoliosis is considered medically necessary when All of the following criteria is met*:

REVISIONS	
	1. Curve progression following conservative management (for example, observation, exercise therapy, or bracing); and 2. Cobb angle 30 to 65 degrees; and 3. Curve flexibility greater than 30%; and 4. Skeletal immaturity, defined as either: c. Risser grade 0 - 2; or d. Sanders Maturity Scale less than or equal to 4. *NOTE: Anterior vertebral body tethering procedure will be performed by a qualified orthopedic/spine specialist who has had hands on, in person training and experience in AVBT technique at a facility with appropriate experience and expertise in the AVBT procedure. D. Revision, replacement, or removal of vertebral body tethering is considered medically necessary when there are complications associated with the device (for example, tether breakage or overcorrection). E. Anterior vertebral body tethering for the treatment of scoliosis is considered experimental / investigational when the above criteria are not met and for all other indications, including but not limited to: 5. Skeletal maturity has been reached 6. Previous spinal surgery 7. Poor bone quality/Metabolic Bone Disease/T-Score 1.5 or less 8. Curves >65 degrees 9. Kyphosis >50 degrees 10. Prior Thoracic Surgery 11. Underlying cardiac or pulmonary disease F. Vertebral body stapling for the treatment of scoliosis is considered experimental / investigational.
	Updated Coding Section ▪ Added L1006 (eff. 10-01-2024)

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