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

Populations	Interventions	Comparators	Outcomes
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 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 evaluate the efficacy 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 (eg, 2-year), period.

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 (ie, 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, 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. Both procedures use orthopedic devices off-label. 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.

Research Recommendations

The Scoliosis Research Society provided evidence-based recommendations in 2005,[2] which were updated in 2015,[3] for bracing studies to standardize inclusion criteria, methodologies, and outcome measures to facilitate comparison of brace trials. Janicki et al (2007) reported 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.[4] 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.[2] 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.[5,6] 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).

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 new titanium clip-screw system (HemiBridge™ System; SpineForm) has been tested on 6 patients with adolescent idiopathic scoliosis, and investigational approval has now been granted by the FDA for the next cohort of 30 patients.[7,]

A new 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."

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
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

Device	Manufacturer	Date Cleared	510(k) No.	Indication
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 patients 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 in females)

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 in females).

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

C. Vertebral body stapling and vertebral body tethering for the treatment of scoliosis are considered **experimental / investigational**.

POLICY GUIDELINES

This policy does not address conventional surgery for scoliosis in patients 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 for girls. 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.

- A rigid cervical-thoracic-lumbar-sacral orthosis is primarily prescribed for patients with thoracic apices above T7 for control of upper thoracic sagittal deformities and other spinal deformities not amenable to treatment with lower-profile designs.
- 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).
- Nighttime bracing systems are more effective in patients with isolated flexible thoracolumbar and lumbar curves than in double curves; they may also be indicated in patients who are noncompliant with a full-time wear program, patients 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 19, 2021.

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.

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 patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

The question addressed in this evidence review is: Do surgical and nonsurgical interventions for scoliosis improve the net health outcome for juveniles and adolescents who are at high-risk of spinal curve 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. Patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression are actively managed by physical therapists, pediatricians, primary care providers, and in severe cases orthopedic surgeons in an outpatient clinical setting.

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 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 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.[8] 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) and a preference cohort (n=126). 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

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.[9] 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 (2013)	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 (2017)	Retrospective	Italy	1980-2016	Patients who had completed treatment with a rigid brace at least 10 years prior (n=93)	Lyon or PASB 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 (2013)					
Bracing	72%	82			
Control	48%	81.9			
OR	1.93				
P-value		0.97			
Aulisa (2017)			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

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.[4.] 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. A retrospective study with long-term follow-up (mean, 15 years; range,10-35 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.

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 patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

The question addressed in this evidence review is: Do surgical and nonsurgical interventions for scoliosis improve the net health outcome for juveniles and adolescents who are at high-risk of spinal curve 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. Patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression are actively managed by physical therapists, pediatricians, primary care providers, and in severe cases orthopedic surgeons in an outpatient clinical setting.

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 with scoliosis.[10] 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 quality of brace wear during the first 12 months (ie, “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 patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

The question addressed in this evidence review is: Do surgical and nonsurgical interventions for scoliosis improve the net health outcome for juveniles and adolescents who are at high-risk of spinal curve 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. Patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression are actively managed by physical therapists, pediatricians, primary care providers, and in severe cases orthopedic surgeons in an outpatient clinical setting.

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.[11] Follow-up for 38 patients to a mean of 45.1 months (range, 24-77 months) after skeletal maturity was reported by Guo et al (2014).[12] 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 a 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%; $p<0.05$). 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 post maturity, 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.[13,14,] 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, 7-16 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 patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

The question addressed in this evidence review is: Do surgical and nonsurgical interventions for scoliosis improve the net health outcome for juveniles and adolescents who are at high-risk of spinal curve 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. Patients with juvenile or adolescent idiopathic scoliosis at high-risk of

progression are actively managed by physical therapists, pediatricians, primary care providers, and in severe cases orthopedic surgeons in an outpatient clinical setting.

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).[15.] 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°-34°), there was a nonstatistically significant trend for stapling to be more effective (progression <10°, 81%) compared with bracing (61%; p=0.16). 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°-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. A total of 52 patients (66 curves) were matched according to age at the start of treatment (10.6 years versus 11.1 years, respectively) and gender (see Tables 5 and 6). In smaller thoracic curves (25°–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, 7.8-11.1 years) and an average preoperative Cobb angle of 30° (standard deviation [SD], 6°); the mean follow-up was 83 months (range, 72-95 months) (see Tables 5 and 6).[16.] 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, 7.0-14.6 years) and scoliotic curves of 25° to 40° (see Tables 5 and 6).[17.] Not all patients could (or would) wear a brace. At a mean follow-up to maturity of 48 months (range, 25-79 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=0.01). 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, 6.3-9.7 years) who were considered extremely likely to require fusion (ie, curves of 30° to 39° in a young child), (see Tables 5 and 6).[18.] At an average 3.4-year follow-up (range, 2.2-5.4 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 (see Tables 5 and 6).[19.] 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%-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, (see Tables 5 and 6).[20.] 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 the 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 5 and 6).[21.] 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, 4-13 years), with an average follow-up of 3.2 years (range 2-5.3 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)[16.]	U.S.	Case series	7	9.3	27.3° to 37.9°	NR	6
Cuddihy et al (2015)[15.]	U.S.	Case control	123	11	25° to 44°	0	2
Bumpass et al (2015)[17.]	U.S.	Case series	33	11	25° to 40°	0	2
Theologis et al (2013)[18.]	U.S.	Case series	12	8	30° to 39°	NR	2
Laituri et al (2012)[19.]	U.S.	Case series	7	9	25° to 41°	NR	2
O'Leary et al (2011)[20.]	U.S.	Case series	11	7	68° to 105°	0	1
Betz et al (2010)[21.]	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)[16.]	VBS	2	4	1		
		>10° Progressed	*Stable/Improved*	*p*	**Progressed ≥50°**	**Subsequent Fusion**
Cuddihy et al (2015)[15.]	VBS	Thoracic curves 25°-34°: (19)	Thoracic curves 25°-34°: (81) Thoracic curves	>0.05 for all comparisons of VBS vs brace	NR	NR

Study	Tx	Change in Curve				
		Thoracic curves 35°-44°: (82) Lumbar curves 25°-34°: (20) Lumbar curves 35°-44°: (40)	35°-44°: (18) Lumbar curves 25°-34°: (80) Lumbar curves 35°-44°: (60)			
	Brace	Thoracic curves 25°-34°: (39) Thoracic curves 35°-44°: (50) Lumbar curves 25°-34°: (19) Lumbar curves 35°-44°: (100)	Thoracic curves 25°-34°: (61) Thoracic curves 35°-44°: (50) Lumbar curves 25°-34°: (81) Lumbar curves 35°-44°: (0)			
		>10° Progressed	**Stable**	**>10° Corrected**		
Bumpass et al (2015)[17.]	VBS	13 (39)	14 (42)	6 (18)	9 (27)	11 (31)
Theologis et al (2013)[18.]	VBS	0 (0)	5 (42)	7 (58)	0 (0)	0 (0)
Laituri et al (2012)[19.]	VBS	0 (0)	2 (29)	5 (71)	0 (0)	0 (0)
O'Leary et al (2011)[20.]	VBS	3 (27)	6 (55)	2 (18)	0 (0)	8 (73)
		Baseline Curve	**>10° Progressed**	**Stable/Improved**		
Betz et al (2010)[21.]	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 patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

The question addressed in this evidence review is: Do surgical and nonsurgical interventions for scoliosis improve the net health outcome for juveniles and adolescents who are at high-risk of spinal curve 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. Patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression are actively managed by physical therapists, pediatricians, primary care providers, and in severe cases orthopedic surgeons in an outpatient clinical setting.

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

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.[22] In this study, pediatric patients who had failed brace treatment (e.g., greater than 5 degrees 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 degrees in 75.4% of participants and 45 to 65 degrees 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.

As noted in a 2015 review article, other devices used for vertebral body tethering are under development, and the optimum tension for vertebral body tethering is currently unknown.[23]

Samdani et al (2014, 2015) published 2 retrospective reviews on the off-label use of the Dynesys system (Zimmer) for anterior vertebral body tethering for idiopathic scoliosis.[24,25] 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,[25] and 11 consecutive patients had a 2-year follow-up.[24] 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, 7-9 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 (2020) published an additional prospective evaluation on the use of the Dynesys system (Zimmer) for anterior vertebral body tethering for

idiopathic scoliosis.[26.] Included patients had skeletal immaturity (N=21; average age, 11.1 years) with curve progression (curve >40°) despite the use of a brace; the average follow-up was 27.4 months. Results demonstrated that an average of 7.1 levels of tethering was undertaken. The average thoracic curve magnitudes improved from 48.2° to 16° and 10° at the first postoperative and last follow-up, respectively (p<0.001). There were no major complications reported.

Section Summary: Vertebral Body Tethering

There is limited published evidence on vertebral body tethering. The Tether™ is the only vertebral body tethering device that the FDA has approved for marking based on an 6/4/19 Humanitarian Device Exemption. 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. Larger, controlled studies are needed to verify these findings.

Summary of Evidence

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive a conventional rigid brace, the evidence includes a high-quality nonrandomized controlled trial and 2 retrospective studies. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Bracing has been considered the only option to prevent curve progression in juvenile or adolescent idiopathic scoliosis. The highest quality study on bracing is a sizable 2013 National Institutes of Health-sponsored trial that, using both randomized and observational arms, compared bracing with watchful waiting. This trial was stopped after interim analysis because of a significant benefit of bracing for the prevention of spinal fusion. A retrospective study with long-term follow-up (mean, 15 years) has also shown that curvature corrections with bracing were maintained. 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. Based on several factors (evidence of efficacy, lack of alternative treatment options, professional society recommendations, potential to prevent the need for a more invasive procedure), bracing with a conventional rigid brace is considered an option for the treatment of scoliosis in patients with a high-risk of curve progression. Curves have a high-risk of progression when they measure 25° or more, and spinal growth has not been completed, or when a 20° curve is progressively worsening and at least 2 years of growth remain. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive a microcomputer-controlled brace, the evidence includes a pilot RCT. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. A pilot randomized trial using a microcomputer-controlled brace reported improved outcomes compared with the use of a standard rigid brace; however, the low number of individuals included in the trial (N=12) ultimately limited the interpretation of these results. 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 at high-risk of progression who receive a flexible brace, the evidence includes a randomized and a nonrandomized comparative study. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. One RCT evaluating a flexible brace did not show equivalent outcomes compared with conventional brace designs. Another study has suggested the flexible brace might improve outcomes compared with no treatment, but this study had design flaws, which interfered with drawing significant conclusions from the study. 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 at high-risk of progression who receive VBS, the evidence includes a comparative cohort study, a case-control study, and case series. Relevant outcomes are change in disease status, morbid events, quality of life, 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. Vertebral body stapling 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 at high-risk of progression who receive vertebral body tethering, the evidence includes case series. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Vertebral body tethering has been evaluated for thoracic curves at high-risk of progression. Currently, there is very limited evidence on this technique, with published case series on the Dynesys system reporting 1-year follow-up in 32 patients, 2-year follow-up in 11 patients, and an additional prospective study reporting approximately 2-year follow-up in 21 patients. 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 is lacking on other important health outcomes, and there are important study design limitations including lack of a control group. Additional studies, with a larger number of total subjects and longer follow-up, are needed to evaluate the safety and efficacy of this surgical procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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.

Society on Scoliosis Orthopedic and Rehabilitation Treatment

The guidelines from the Society on Scoliosis Orthopedic and Rehabilitation Treatment (2016) included recommendations on the following conservative treatments for idiopathic scoliosis[27.]: 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.

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[28.] 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 generally for patients whose curves are less than 25° who are still growing, or for curves less than 50° in patients who have completed their growth."

- "Bracing is for patients with curves that measure between 25° and 40° during their growth phase. The goal of the brace is to prevent the curve from getting bigger."
- "Surgical treatment is used for patients whose curves are greater than 45° while still growing or greater than 50° when growth has stopped. The goal of surgical treatment is two-fold: First, to prevent curve progression and secondly to obtain some curve correction…. Implants are used to correct the spine and hold the spine in the corrected position until the spine segments which have been operated on are fused as one bone."
- "Alternative treatments to prevent curve progression or prevent further curve progression such as chiropractic medicine, physical therapy, yoga, etc. have not demonstrated any scientific value in the treatment of scoliosis."

Vertebral body stapling (VBS)was not addressed on the Society's website.

Scoliosis Research Society/Pediatric Orthopedic Society of North America

A joint Scoliosis Research Society/Pediatric Orthopedic 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:[29.]

- "…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."

American Academy of Orthopedic Surgeons

Information updated on the American Academy of Orthopedic 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.[30.]

- 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 stapling and vertebral body tethering 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, December 2019).[31.] 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 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.

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).[32.] 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			
NCT02589106	Safety and Efficacy of Anisotropic Textile Braces for Adolescent Idiopathic Scoliosis	15	Dec 2024
NCT01761305	CONTRAIS: CONservative TReatment for Adolescent Idiopathic Scoliosis. A Randomised Controlled Trial	135	Dec 2023
NCT02897453[a]	Retrospective Review With Prospective Surveillance of Safety and Efficacy in a Clinical Series of Spinal Tethering Patients	55	Oct 2022

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04296903	Post-approval Registry Study to Evaluate the Continued Safety and Probable Benefit of the MID-C System for 5 Years Post-Implantation in Adolescent Idiopathic Scoliosis (AIS)	200	May 2028
NCT04116723	Trial of Personalized Flexible Bracing Treatment of Adolescents Idiopathic Scoliosis	100	Dec 2023
NCT03802656	Safety and Feasibility of a Vertebral Body Tethering Technique for Pediatric Idiopathic Scoliosis	40	Feb 2025
NCT03506334	Prospective Pilot Study of Anterior Vertebral Body Tethering Using Zimmer Biomet Tether System or Dynesys System Components to Treat Pediatric Scoliosis	80	Jul 2027
NCT04590807	Posterior Spinal Fusion With Pedicle Screws vs. Anterior Vertebral Body Tethering in Adolescent Idiopathic Scoliosis	70	Dec 2025
NCT04505579	The Tether™ - Vertebral Body Tethering System Post Approval Study	200	Dec 2027

[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

22899	Unlisted procedure, spine
0656T	Vertebral body tethering, anterior; up to 7 vertebral segments
0657T	Vertebral body tethering, anterior; 8 or more vertebral segments
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
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
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

ICD-10 Diagnoses

M410.0	Infantile idiopathic scoliosis, site unspecified
M410.2	Infantile idiopathic scoliosis, cervical region
M410.3	Infantile idiopathic scoliosis, cervicothoracic region
M410.4	Infantile idiopathic scoliosis, thoracic region
M410.5	Infantile idiopathic scoliosis, thoracolumbar region
M410.6	Infantile idiopathic scoliosis, lumbar region
M410.7	Infantile idiopathic scoliosis, lumbosacral region
M410.8	Infantile idiopathic scoliosis, sacral and sacrococcygeal region
M411	Juvenile and adolescent idiopathic scoliosis
M411.1	Juvenile idiopathic scoliosis
M411.12	Juvenile idiopathic scoliosis, cervical region
M411.13	Juvenile idiopathic scoliosis, cervicothoracic region

M411.14	Juvenile idiopathic scoliosis, thoracic region
M411.15	Juvenile idiopathic scoliosis, thoracolumbar region
M411.16	Juvenile idiopathic scoliosis, lumbar region
M411.17	Juvenile idiopathic scoliosis, lumbosacral region
M411.19	Juvenile idiopathic scoliosis, site unspecified
M411.2	Adolescent scoliosis
M411.22	Adolescent idiopathic scoliosis, cervical region
M411.23	Adolescent idiopathic scoliosis, cervicothoracic region
M411.24	Adolescent idiopathic scoliosis, thoracic region
M411.25	Adolescent idiopathic scoliosis, thoracolumbar region
M411.26	Adolescent idiopathic scoliosis, lumbar region
M411.27	Adolescent idiopathic scoliosis, lumbosacral region
M411.29	Adolescent idiopathic scoliosis, site unspecified
M41.2	Other idiopathic scoliosis
M41.20	Other idiopathic scoliosis, site unspecified
M41.22	Other idiopathic scoliosis, cervical region
M41.23	Other idiopathic scoliosis, cervicothoracic region
M41.24	Other idiopathic scoliosis, thoracic region
M41.25	Other idiopathic scoliosis, thoracolumbar region
M41.26	Other idiopathic scoliosis, lumbar region
M41.27	Other idiopathic scoliosis, lumbosacral region
Q67.5	Congenital deformity of spine

REVISIONS

12-18-2021	Policy added to the bcbsks.com web site.

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