Kansas City
An Independent Licensee of the Blue Cross and Blue Shield Association

Interventions for Progressive Scoliosis

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Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for interventions for progressive scoliosis when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

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 which meets the following criteria:

- Idiopathic spinal curve angle between 25 and 40 degrees; AND
- Spinal growth has not been completed (Risser grade 0-3; no more than 1 year post-menarche in females)

OR

- Idiopathic spinal curve angle greater than 20 degrees; AND
- There is documented increase in the curve angle; AND
- At least 2 years growth remain (Risser grade 0 or 1; pre-menarche in females)

When Policy Topic is not covered

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

Vertebral body stapling and vertebral body tethering for the treatment of scoliosis is considered **investigational**.

Considerations

This policy does not address conventional surgery for scoliosis in patients with curve angles measuring 45 degrees or more. Brace treatment for idiopathic scoliosis is usually recommended for juveniles and adolescents with curves measuring between 25 and 40 degrees who have not completed spinal growth, with maturity defined as Risser 4, or 2 years post-menarche for girls. Bracing may also be recommended for curves greater than 20 degrees 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 for 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 (the majority of idiopathic curves).
- Night time 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 had failed, and patients nearing skeletal maturity who may not require full-time wear.

Description of Procedure or Service

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 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

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.

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 randomized controlled trial. 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. 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. A study with long-term follow-up (mean, 15 years) has also shown that curvature corrections with bracing were maintained. 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 a meaningful 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 randomized controlled trial. 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 ultimately limited the interpretation of these results. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 randomized controlled trial evaluating a flexible brace did not show equivalent outcomes compared with conventional brace designs. Another study has suggested that 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 the effects of the technology on health outcomes.

For individuals who have juvenile or adolescent idiopathic scoliosis at high risk of progression who receive vertebral body stapling, the evidence includes a comparative cohort 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 study with larger sample sizes and longer follow-up is needed to evaluate the safety and efficacy of this procedure. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 case series reporting 1-year follow-up in 32 patients and 2-year follow-up in 11 patients. 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 the effects of the technology on health outcomes.

Background

Scoliosis

Scoliosis is an abnormal lateral and rotational curvature of the vertebral column. Adolescent idiopathic scoliosis (AIS) 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 AIS 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 (SRS) provided evidence-based recommendations in 2005.[2] 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 SRS criteria concluded that a brace should prevent progression in 70% of patients to be considered effective.[4] The SRS evidence review and recommendations may also aid in the evaluation of fusionless surgical treatments for scoliosis progression in children.

The SRS 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, SRS provided the following recommendations for brace studies on AIS:

- "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 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 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 AIS, and investigational approval has now been granted by FDA for the next cohort of 30 patients.[7]

Rationale

This evidence review was created in May 2010 and has been updated regularly with searches of the MEDLINE database. The most recent update was performed through February 5, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one 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

24-Hour Brace

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 (AIS). 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 that 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.

Aulisa et al (2017) investigated whether scoliotic curve correction was maintained long-term in patients with AIS 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 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.

Nighttime Braces

Using Scoliosis Research Society criteria, Janicki et al (2007) reported on outcomes from a database of patients with AIS who had used a thoracic-lumbar-sacral orthosis (TLSO) 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 TLSO, which the investigators suspected were predominantly due to a lack of compliance,

the methodology of the review changed from using a TLSO to recommending a nighttime orthosis. Thus, the 48 patients treated with a TLSO 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 TLSO, 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 TLSO 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 TLSO 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 study with long-term follow-up (mean, 15 years; range,10-35 years) demonstrated that curve corrections from rigid bracing were stable.

Microcomputer-Controlled Braces (Smart Brace)
Lou et al (2012) published a pilot randomized study 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 TLSO group had a significant change in Cobb angle (7° and 20°) over the 3-year study; 1 patient in the TLSO group required subsequent fusion surgery.

Section Summary: Microcomputer-Controlled Braces (Smart Brace)
A pilot randomized study 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 limits conclusions drawn from these results. No studies on the smart brace have been identified since the 2012 pilot.

Flexible Braces

Randomized Clinical 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 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.[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%) and 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 that 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

Nonrandomized Comparative Study

In a multicenter study, Cuddihy et al (2015) reported on a matched comparison of vertebral body stapling (VBS) and bracing for immature patients with moderate

(25° to 44°) idiopathic scoliosis (see Tables 1 and 2).[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. Average curve size was 31° and 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.

Case Series

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 1 and 2).[16] 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 1 and 2).[17] 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 1 and 2).[18] 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 1 and 2).[19] Patients with AIS 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 1 and 2).[20] 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 1. 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	
Cuddihy et al (2015)[15]	U.S.	Case control	123	11	25° to 44°	0	2
Bumpass et al (2015)[16]	U.S.	Case series	33	11	25° to 40°	0	2
Theologis et al (2013)[17]	U.S.	Case series	12	8	30° to 39°	NR	2
Laituri et al (2012)[18]	U.S.	Case series	7	9	25° to 41°	NR	2
O'Leary et al (2011)[19]	U.S.	Case series	11	7	68° to 105°	0	1
Betz et al (2010)[20]	U.S.	Case series	29	9	20° to 45°	0	2

FU: follow-up; NR: not reported.
[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 2. Summary of Key Observational Study Outcomes for VBS

Study	Tx	Change in Curve			Progressed ≥50°	Subsequent Fusion
		>10° Progressed	Stable/Improved	p		
Cuddihy et al (2015)[15]	VBS Brace	19 (33) 25 (38)	38 (67) 41 (62)	>0.05	NR	NR
		>10° Progressed	**Stable**	**>10° Corrected**		
Bumpass et al (2015)[16]	VBS	13 (39)	14 (42)	6 (18)	9 (27)	11 (31)
Theologis et al (2013)[17]	VBS	0 (0)	5 (42)	7 (58)	0 (0)	0 (0)
Laituri et al (2012)[18]	VBS	0 (0)	2 (29)	5 (71)	0 (0)	0 (0)
O'Leary et al (2011)[19]	VBS	3 (27)	6 (55)	2 (18)	0 (0)	8 (73)
		Baseline Curve	**>10° Progressed**	**Stable/Improved**		
Betz et al (2010)[20]	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 and several small case series. Early results 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 (VBT; see next section) instead of VBS.

Vertebral Body Tethering

As noted in a 2015 review article, the devices used for VBT are under development, and the optimum tension for VBT is currently unknown.[21]

Samdani et al (2014, 2015) published 2 retrospective reviews on the off-label use of the Dynesys system (Zimmer) for anterior VBT for idiopathic scoliosis.[22,23] They reported pursuing VBT 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,[23] and 11 consecutive patients had a 2-year follow-up.[22] 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.

Section Summary: Vertebral Body Tethering

There is limited published evidence on VBT. Early reports of a correction in Cobb angle are promising, but little is known about longer term outcomes with this procedure; additional study is needed.

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 RCT. 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. 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. A study with long-term follow-up (mean, 15 years) has also shown that curvature corrections with bracing were maintained. 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 a meaningful 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 ultimately limited the interpretation of these results. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 that 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 the effects of the technology on health outcomes.

For individuals who have juvenile or adolescent idiopathic scoliosis at high risk of progression who receive VBS, the evidence includes a comparative cohort 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. VBS with memory shape staples may control some thoracic curves between 20° and 35°, but it is less effective than bracing for larger curves. The evidence is composed primarily from a center that developed the technique, along with a few case series from other institutions. Additional study with larger sample sizes and longer follow-up is needed to evaluate the safety and efficacy of this procedure. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have juvenile or adolescent idiopathic scoliosis at high risk of progression who receive VBT, the evidence includes case series. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. VBT has been evaluated for thoracic curves at high risk of progression. Currently, there is very limited evidence on this technique, with case series reporting 1-year follow-up in 32 patients and 2-year follow-up in 11 patients. 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 the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

Society on Scoliosis Orthopaedic and Rehabilitation Treatment

The 2011 guidelines from the Society on Scoliosis Orthopaedic and Rehabilitation Treatment included recommendations on the following interventions for scoliosis[24]: observation, physical therapy–specific 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 (VBS) or vertebral body tethering (VBT). The Society indicated the likelihood that a curve would progress would depend on a number of factors, including age at diagnosis, type and severity of the curve, sex, and skeletal maturity. Approximately 25% to 75% of curves found at screening remain unchanged, and 3% to 12% of curves improve. 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:

- For the treatment of infantile, juvenile, and adolescent idiopathic scoliosis in patients with "curves above 20 ± 5° Cobb, still growing, and demonstrated progression of deformity."
- 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)…."
- Brace 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.[25] 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."

VBS and VBT were not addressed on the Society's website.

American Academy of Orthopaedic Surgeons
Information updated in 2015 on the American Academy of Orthopaedic Surgeons' 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.[26]

- Observation is appropriate when the curve is mild (<20°) 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°" and the child is still growing. If the patient has reached skeletal maturity, surgery may still be recommended for scoliotic curves that exceed 50° to 55°. An implant made up of rods, hooks, screws, and/or wires is used to straighten the spine.
- VBS and VBT 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 updated its educational website page on scoliosis in children and adolescents in December 2015.[27] 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 patient is still growing (is skeletally immature) and the curve is mild."
- Doctors may advise patients "to wear a brace to stop a curve from getting any worse in patients who are still growing with moderate spinal curvature. As a child nears the end of growth, the indications for bracing will depend on how the curve affects the child's appearance, whether the curve is getting worse, and the size of the curve."
- Surgery may be advised "to correct a curve or stop it from worsening when the patient is still growing, has a curve that is severe, and has a curve that is worsening."

The Institute also stated that studies of the following treatments have not demonstrated prevention of curve progression or worsening: "manipulation by a chiropractor, electrical stimulation, dietary supplements, and exercise." The educational page does not address VBS or VBT.

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (USPSTF) has published recommendations for idiopathic scoliosis screening. In 2004, USPSTF recommended against the routine screening of asymptomatic adolescents for idiopathic scoliosis (grade D recommendation). In 2018, USPSTF updated their recommendation to state that there is insufficient evidence to assess screening of adolescents for idiopathic scoliosis (grade I recommendation).[28] 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."

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02589106	Anisotropic Textile Braces for Adolescent Idiopathic Scoliosis	15	Dec 2020
NCT01761305	Trial on Three Treatments for Scoliosis (CONTRAIS)	135	Dec 2021
NCT02897453[a]	Retrospective Review With Prospective Surveillance of Safety and Efficacy in a Clinical Series of Spinal Tethering Patients	55	Dec 2023

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

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Billing Coding/Physician Documentation Information

There is no specific CPT code for the insertion of vertebral body staples or vertical expandable titanium prosthetic ribs. The procedure would most likely be reported with the unlisted code 22899.

L1000 Cervical-thoracic-lumbar-sacral orthotic (CTLSO) (Milwaukee), inclusive of furnishing initial orthotic, including model

L1001 Cervical-thoracic-lumbar-sacral orthotic (CTLSO), immobilizer, infant size, prefabricated, includes fitting and adjustment

L1005 Tension based scoliosis orthotic and accessory pads, includes fitting and adjustment

L1010 Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, axilla sling
L1020 Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, kyphosis pad
L1025 Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, kyphosis pad, floating
L1030 Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, lumbar bolster pad
L1040 Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, lumbar or lumbar rib pad
L1050 Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, sternal pad
L1060 Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, thoracic pad
L1070 Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, trapezius sling
L1080 Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, outrigger
L1085 Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, outrigger, bilateral with vertical extensions
L1090 Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, lumbar sling
L1100 Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, ring flange, plastic or leather
L1110 Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO) or scoliosis orthotic, ring flange, plastic or leather, molded to patient model
L1120 Addition to cervical-thoracic-lumbar-sacral orthotic (CTLSO), scoliosis orthotic, cover for upright, each
L1200 Thoracic-lumbar-sacral orthotic (TLSO), inclusive of furnishing initial orthotic only
L1210 Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), lateral thoracic extension
L1220 Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), anterior thoracic extension
L1230 Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), Milwaukee type superstructure
L1240 Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), lumbar derotation pad
L1250 Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), anterior ASIS pad
L1260 Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), anterior thoracic derotation pad
L1270 Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), abdominal pad
L1280 Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), rib gusset (elastic), each
L1290 Addition to thoracic-lumbar-sacral orthotic (TLSO), (low profile), lateral trochanteric pad

L1300 Other scoliosis procedure, body jacket molded to patient model
L1310 Other scoliosis procedure, postoperative body jacket
L1499 Spinal orthotic, not otherwise specified

ICD-10 Codes
M41.00-M41.27 Idiopathic scoliosis code range
Q67.5 Congenital deformity of spine

Additional Policy Key Words

N/A

Policy Implementation/Update Information

11/1/10 New policy; may be considered medically necessary.
11/1/11 No policy statement changes.
11/1/12 Material on VEPTR [vertical expandable prosthetic titanium rib] moved to policy 7.01.110
11/1/13 No policy statement changes.
11/1/14 No policy statement changes.
11/1/15 Vertebral body tethering added as investigational.
11/1/16 No policy statement changes.
11/1/17 No policy statement changes
11/1/18 No policy statement changes.