

2.01.83

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Interventions for Progressive Scoliosis

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. Recently 2 fusionless surgical procedures, vertebral body stapling and vertebral body tethering, have been evaluated as an alternative to bracing to slow or correct curve progression in pediatric patients with scoliosis. This review does not address patients who are not at high risk of progression or conventional fusion surgery for scoliosis in patients with Cobb angles measuring 45° or more.

Background

Scoliosis is an abnormal lateral and rotational curvature of the vertebral column. Treatment of scoliosis currently depends on 3 factors: the cause of the condition (idiopathic, congenital, or secondary), the severity of the condition (degrees of 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 risk of progression are also being evaluated. Since 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 is used in an attempt 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 (CTLSO). Thoracic-lumbar-sacral orthoses (TLSO), 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. Braces that are more flexible than TLSOs 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.

Fusionless surgical procedures, such as vertebral body stapling and vertebral body tethering, are being evaluated as an alternative to bracing. It is hoped that fusionless procedures improve the curve as well as prevent its progression, maintain spine mobility following correction, and provide an effective

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treatment option for patients who are non-compliant or refuse to wear a brace. In the current stapling procedure, nickel-titanium alloy staples with shape memory are applied to the convex (outer) 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. The goal of vertebral stapling is to unilaterally reduce the rate of spine growth, thus allowing the other side to “catch up.” The memory shape staple was tested in a goat model of scoliosis for safety and efficacy prior to its use in humans. A concern is that stapling spans the flexible discs, and the immobilized discs may be subject to degeneration. The vertical expandable prosthetic titanium rib, described in more detail in policy number 7.01.110, is also being explored for treatment of infantile and juvenile scoliosis that has advanced beyond 45°. Anterolateral tethering and external fixation devices are also being evaluated.

Regulatory Status

Some braces used for the treatment of 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 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, Memphis, TN) 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™ and the reVERTO™. FDA product code: JDR. Vertebral body stapling in scoliosis is considered off-label use.

Related Policies

2.04.74 DNA-Based Testing for Adolescent Idiopathic Scoliosis
 7.01.110 Vertical Expandable Prosthetic Titanium Rib
 7.01.141 Lumbar Spinal Fusion

Policy

**This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

A 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°; 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°; AND
- There is documented increase in the curve angle; AND
- At least 2 years' growth remains (Risser grade 0 or 1; pre-menarche in females).

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

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Vertebral body stapling and vertebral body tethering for the treatment of scoliosis are considered **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 4, or 2 years post-menarche for girls. (1, 2) 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 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).
- 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 had failed, and patients nearing skeletal maturity who may not require full-time wear.

Rationale

The Scoliosis Research Society (SRS) provided evidence-based recommendations in 2005 for bracing studies to facilitate comparison of brace trials.¹ The first study to use the SRS criteria concluded that a brace should prevent progression in 70% of patients to be considered effective.² 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°) have a higher risk of progression than 5° curve progression.¹ 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 4, or at least 2 years after menarche for girls.^{3,4} 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

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provided the following recommendations for brace studies on adolescent idiopathic scoliosis (AIS):

- “Optimal inclusion criteria for brace studies consist of: age is 10 years or older when the brace is prescribed, Risser 0-2, curve 25°-40°, and no prior treatment.” [Risser sign is defined by the amount of calcification present in the iliac apophysis and measures remaining spinal growth by progressive anterolateral to posteromedial ossification. 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.]
- Assessment 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 percentage of patients who progress beyond 45°, indicating the possible need for surgery.
 - 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.
 - 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.”

CONVENTIONAL RIGID BRACES

24-Hour Brace

In 2013, Weinstein et al reported results from the National Institutes of Health–sponsored multicenter Bracing in Adolescent Idiopathic Scoliosis Trial (BrAIST) that compared bracing to watchful waiting.⁵ Patients enrolled met current criteria for bracing: skeletally immature (Risser grade 0-2); pre- or postmenarchal by no more than 1 year; primary angle between 20° and 40°; curve apex caudal to T7; as well as no previous surgical or orthotic treatment for AIS. Due to difficulty recruiting into this randomized trial, the final study 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 this degree 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 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 less 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.

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Nighttime Braces

Using the new SRS criteria, Janicki et al reported outcomes from a database of patients with AIS who had used a thoracic-lumbar-sacral orthosis (TLSO) or a nighttime orthosis.² 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 SRS 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, practice had been 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 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 large National Institutes of Health–sponsored trial from 2013 that had both randomized and observational arms comparing standard rigid bracing to 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.

Microcomputer-Controlled Braces (Smart Brace)

Lou et al published a pilot randomized study that compared a microcomputer-controlled brace (smart brace) to a standard rigid brace in 12 patients with scoliosis.⁶ Compliance, measured by time brace worn, with the microcomputer-controlled brace in the first year of bracing (2 years of total bracing) was similar to the standard brace group (66% vs 62%). However, results found improvements in quality of brace wear during the first 12 months (i.e., “tightness at prescribed level”) with the smart brace (67%) compared to the standard brace (54%). The smart brace was associated with improved outcomes. None of the patients in the smart brace group had a significant change 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.

Section Summary: Microcomputer-Controlled Braces (Smart Brace)

A pilot randomized study using a microcomputer-controlled brace (smart brace) reported improved outcomes in compared to a conventional rigid brace; however, the small number of subjects enrolled limits interpretation of these results. No studies on the smart brace have been identified since the 2012 pilot.

Flexible Braces

Wong et al prospectively studied the clinical efficacy and acceptance of rigid or flexible spinal bracing in 43 patients with moderate adolescent scoliosis in 2008.⁷ Follow-up to a mean of 45.1 months after

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skeletal maturity was reported in 2014.⁸ 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 thereafter. Acceptance of the brace was measured with a 16-question visual analog scale assessing pain, skin irritation, and daily activities. If the curve progressed more than 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 more than 5° compared with 5.6% of subjects in the rigid brace group ($p < 0.05$). 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. Follow-up for a mean of 45 months (range, 24-77 months) after the brace was worn showed a rate of progression of 1.5° per year postmaturity, with no additional patients proceeding to surgery.

Plewka et al reported the efficacy of the SpineCor brace ($n=45$) compared to physical therapy and observation ($n=45$) in children and adolescents with scoliosis.^{9,10} The control group comprised children who qualified for brace treatment but whose parents did not agree 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 about 12 years (range, 7-16 years). After 2 years of treatment, patients treated with the SpineCor brace showed significant improvements in clinical parameters. There was no significant difference in measurements between baseline and follow-up in control patients. Stabilization or improvement of the angle was observed in 78% of the SpineCor-treated patients (45% stabilized, 33% improved) compared with 53% of the control group (53% stabilized, none improved). 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 conventional rigid brace designs. A nonrandomized comparative study suggested that the flexible brace may improve outcomes compared to no treatment, but this study was limited by self-selection and potential differences in patient characteristics between groups.

Vertebral Body Stapling

Seven studies on vertebral body stapling (VBS) for scoliosis were identified.¹¹⁻¹⁷

In a 2015 multicenter study, Cuddihy et al reported on a matched comparison of VBS and bracing for immature patients with moderate (25° to 44°) idiopathic scoliosis.¹⁷ Forty-two consecutive patients in the VBS group met inclusion criteria and 52 patients in the bracing group 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° to 34°), there was a nonstatistically significant trend for stapling to be more effective (progression $< 10^\circ$, 81%) than bracing (61%; $p=0.16$). For larger thoracic curves ($> 35^\circ$) VBS did not halt curve progression, with a success rate of 18% compared to 50% for

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bracing. For lumbar curves (25° to 34°), results were comparable for VBS and bracing. There were insufficient numbers of patients with lumbar curves of 35° or greater to compare results.

Betz et al (2010) reported on 29 patients with juvenile or AIS who met the study inclusion criteria (of a database of 93 patients).¹² Included in the reporting were patients with idiopathic scoliosis, a coronal curve magnitude of 20° to 45°, Risser 0 or 1, staples with tines proportional to staple size (beginning in 2002), and a minimum 2-year follow-up. Average age at the time of stapling was 9.4 years (range, 4-13 years), with 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° (threshold for recommending spinal fusion). For thoracic curves less than 35° at baseline, 6% of patients progressed to greater than 50° (threshold for surgery).

A 2013 report from the same group described vertebral body stapling 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).¹⁶ 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°).

Other groups have reported positive outcomes with VBS in children with low-to-moderate idiopathic scoliosis who have failed a trial of bracing. A 2015 series by Bumpass et al described VBS in 31 consecutive patients with a mean age of 10.5 years (range, 7.0-14.6 years) and curves of 25° to 40°.¹⁸ All patients could not or would not 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. In 2012, a separate group of investigators retrospectively reviewed 7 children ages 8 to 11 years who had undergone VBS and had at least 2 years of follow-up.¹⁹ All children either had curve progression, despite bracing, or were unable to wear a brace. Before stapling, the mean angle was 34.1° (range, 25°-41°). The curves of 5 children improved more than 10°, and 2 children had no change in the postoperative angle (<10°). 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 reported that VBS in young children with large Cobb angles was not effective.²⁰ Diagnoses included myelodysplasia, congenital scoliosis, juvenile and infantile idiopathic scoliosis, Marfan syndrome, paralytic scoliosis, and neuromuscular scoliosis. Patients with AIS were not included in this report. The average age at surgery was 6 years, and preoperative curves averaged 68°. 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.

Section Summary: Vertebral Body Stapling

Early results have indicated that VBS may be able to 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 the inventor of the procedure. Complications can include broken

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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 a difficult time wearing the brace. Notably, for patients with thoracic curves of 35° or greater, Cuddihy et al now perform vertebral body tethering (see next section) instead of VBS.

Vertebral Body Tethering

In 2014 and 2015, Samdani et al published 2 retrospective reviews on the off-label use of the Dynesys system (Zimmer) for anterior vertebral body tethering (VBT) for idiopathic scoliosis.^{21, 22} Authors reported that they pursued VBT at their institution 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,²¹ and 11 consecutive patients had 2-year follow-up.²² Mean age at surgery was 12 years, and all patients were skeletally immature. Three patients also had VBS of 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. Samdani et al from a children's hospital and Zimmer Biomet are conducting a phase 2 safety and efficacy study for Food and Drug Administration approval of the procedure.

Section Summary: Vertebral Body Tethering

There is limited published evidence on VBT. As noted in a 2015 review article, the devices used for VBT are under development and the optimum tension for VBT is currently unknown.²³ 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.

Practice Guidelines and Position Statements

Society on Scoliosis Orthopaedic and Rehabilitation Treatment and Scoliosis Research Society

In 2015, the Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) and the Scoliosis Research Society (SRS) nonoperative management committee published consensus-based recommendations for nonoperative research studies on treatment of idiopathic scoliosis.²⁴ Eighteen recommendations were developed using the Delphi method. These recommendations addressed research needs, clinically significant outcomes, radiographic outcomes, other key outcomes (quality of life, adherence to treatment), and standardization of methods of nonoperative research.

Society on Scoliosis Orthopaedic and Rehabilitation Treatment

The 2011 SOSORT guidelines include recommendations on the following interventions for scoliosis²⁵: observation, physiotherapeutic-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 stapling or vertebral tethering. SOSORT indicated the likelihood that a curve will

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progress depends on a number of factors, including age at diagnosis, type and severity of curve, sex, and skeletal maturity. Approximately 25% to 75% of curves found at screening may remain unchanged, and 3% to 12% of curves may 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 guideline specific to bracing:

- For the treatment of infantile, juvenile, and adolescent idiopathic scoliosis in patients with “curves above $20 \pm 5^\circ$ 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; to not restrict respiratory function; to be least invasive; to ensure patient compliance.

Scoliosis Research Society

SRS states that the treatment of AIS falls into 3 main categories (observation, bracing, surgery) and is based on the risk of curve progression.²⁶ In general, AIS 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, 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 0 and 1 are growing rapidly, while patients who are 4 and 5 have stopped growing.

- Observation is generally for patients whose curves are $<25^\circ$ who are still growing, or for curves $<50^\circ$ 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 $>45^\circ$ while still growing or $>50^\circ$ when growth has stopped. The goal of surgical treatment is 2-fold: First, to prevent curve progression and, second, 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 1 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) and vertebral body tethering (VBT) are 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

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kind and degree of the curve, child's age, and the number of remaining growth years until the child reaches skeletal maturity.²⁷

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°”. There are several types of braces, most being the underarm type.

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.

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) updated its educational website page on scoliosis in children and adolescents in December 2015.²⁸ 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, 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.”

NIAMS 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) published recommendations for idiopathic scoliosis screening in 2004.²⁹ USPSTF recommended against the routine screening of asymptomatic adolescents for idiopathic scoliosis (grade: D recommendation). The recommendation is currently being updated; the final research plan posted on USPSTF’s website.³⁰ No estimated date of completion is provided.

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 randomized controlled trial (RCT). Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-

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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 2013 large National Institutes of Health–sponsored trial that, using both randomized and observational arms, compared bracing to watchful waiting. This trial was stopped after interim analysis because of a significant benefit of bracing for the prevention of spinal fusion. Based on evidence of efficacy, lack of alternative treatment options, professional society recommendations, and 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 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 to use of a standard rigid brace; however, the small number of included subjects limits 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 non-randomized 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 to conventional brace designs. Another study has suggested that the flexible brace may improve outcomes compared to no treatment, but this study had design flaws limiting conclusions to be drawn. 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 or vertebral body tethering, 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 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 longer follow-up is needed to evaluate the safety and efficacy of this procedure. Vertebral body tethering has been evaluated for thoracic curves at high risk of progression. There is very limited evidence to date on this technique, with case series reporting 1-year follow-up in 32 patients and 2-year follow-up in 11 patients. Additional studies from other centers, 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.

Medicare National Coverage

There is no national coverage determination (NCD).

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Policy History

Date	Action	Reason
December 2011	New Policy	
December 2012	Update Policy	Policy and reference updated, material on VEPTR (vertical expanded prosthetic titanium rib) moved to policy 7.01.110, added policy guidelines.
September 2013	Update Policy	Policy updated with literature review. References 6 and 8 added. Policy statement unchanged.
September 2014	Update Policy	Policy updated with literature review. References 5, 9, 11, 17, 18, 22 added; policy statements unchanged.
September 2015	Update Policy	Policy updated with literature review. References 18, 20-23 added; vertebral body tethering added as investigational.
March 2017	Update Policy	Policy updated with literature review through October 3, 2016; references 17-18 and 23 added; references 27-28 updated. Policy statements unchanged.

Keywords

Adolescent idiopathic scoliosis (AIS)	Wilmington Brace
Vertebral stapling	Boston Brace
Vertebral body stapling	Charleston Brace
Scoliosis bracing	Providence Brace
Scoliosis stapling	Smart Brace
Milwaukee Brace	SpineCor Brace

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 17, 2017 and is effective April 15, 2017.

Deborah M. Smith, MD, MPH