BlueCross BlueShield of Alabama

Name of Policy:
Interventions for Progressive Scoliosis

Policy #: 464
Category: DME/Surgical

Latest Review Date: May 2018
Policy Grade: C

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

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.

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." 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, e.g., 2-year, period.

Treatment

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

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 (more than 18-hour) wear and are composed of lighter-weight plastics with a low-profile (underarm) design. The design of the nighttime Charleston and Providence braces is based on the theory that increased corrective forces will reduce the needed wear time (i.e., daytime), thereby lessening social anxiety and improving

compliance. The smart brace consists of a standard rigid brace with a microcomputer system, a force transducer, and an air-bladder control system to control the interface pressure. Braces that are more flexible than 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.

The Cheneau brace is a thermo-plastic scoliosis brace modeled on a hyper- corrected positive plaster cast of the patient. This is a 3-dimensional (3-D) correctional brace that has significant pressure and expansion areas built into the brace, which provides correction in all 3 anatomical planes. It follows the general correction principle as was written by Dubousset -- detorsion and sagittal plane normalization, which would affect correction of the coronal and transversal planes, resulting in some elongation of the spine, without any significant distraction force. The Rigo System Cheneau (RSC) brace is a scoliosis brace that is based on the original theories of Dr. Cheneau, however Dr. Rigo furthered the designs by combining his new scoliosis classification types, to design the RSC brace also known as El corse de RSC. The brace is manufactured with an Ortholutions CAD CAM technique.

Surgery

Fusionless surgical procedures, such as vertebral body stapling and vertebral body tethering, are being evaluated as an alternative to bracing. Both procedures use orthopedic devices off-label and were tested in a goat model of scoliosis before use in humans. The goal of vertebral stapling is to unilaterally reduce the rate of spine growth, thus allowing the other side to "catch up". The mechanism 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 (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. Anterolateral tethering utilizes 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 mobility of the spine. It is hoped that a fusion-less growth modulating procedure will improve the curve along with preventing 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 remaining.

Research Recommendations

The Scoliosis Research Society (SRS) provided evidence-based recommendations in 2005. updated in 2015, for bracing studies to standardize inclusion criteria, methodologies, and outcome measures to facilitate comparison of brace trials. Janicki et al reported the first study to use the SRS criteria concluded that a brace should prevent progression in 70% of patients to be considered effective. 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 indicates that skeletally immature patients and patients with larger curves (between 20° and 29°) are significantly more likely to have

more than 5° curve progression. 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 post-menarche for girls. Bracing may also be recommended for curves greater than 20° in a patient who has a rapidly progressing curve with more than 2 years of growth remaining.
Success from brace treatment is most frequently defined as progression of less than 5° before skeletal maturity, although alternative definitions in the literature 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°–50° (before or at skeletal maturity), although many patients will not undergo surgery at this point. Based on this information, the SRS 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 [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."

Policy:

Effective for dates of service on or after December 30, 2017:

A cervical-thoracic-lumbar-sacral or thoracic-lumbar-sacral orthosis meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage 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)

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

Custom fabricated orthoses for the treatment of scoliosis created by 3-D or CAM-CAD technologies (i.e., Rigo-Cheneau) does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Vertebral body stapling and vertebral body tethering for the treatment of scoliosis does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational.**

Use of the vertical expandable titanium prosthetic rib (with or without expansion thoracoplasty) for the treatment of scoliosis in patients without thoracic insufficiency **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria is considered **investigational.**

The vertical expandable prosthetic titanium rib (VEPTR) is described in more detail in policy ***#299, Vertical Expandable Prosthetic Titanium Rib***.

The COPES Scoliosis Treatment Recovery System is described in policy ***#019, COPES Scoliosis Treatment Recovery System.***

Effective for dates of service June 1, 2015 through December 29, 2017:

A cervical-thoracic-lumbar-sacral or thoracic-lumbar-sacral orthosis meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage 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)

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

Vertebral body stapling and vertebral body tethering for the treatment of scoliosis does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational.**

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Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administer benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

This policy has been updated regularly with searches of the MEDLINE database. The most recent review 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 Brace

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, NCT00448448) that compared bracing versus watchful waiting. Patients were enrolled who met current criteria for bracing: skeletally immature (Risser grade 0-2); premenarchal 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 the randomized trial, the final study included both a randomized (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, was significantly correlated 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.

Aulisa et al investigated whether scoliotic curve correction was maintained long-term in patients with AIS who were treated with the rigid brace. 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 Brace

Using the new SRS criteria, Janicki et al (2007) reported outcomes from a database of patients with AIS who had used a TLSO or a nighttime orthosis. 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°-40° and treated with a TLSO, 85% progressed to greater than 5°, 56% progressed to > 45°, and 79% progressed to surgery. With the nighttime orthosis, 69% progressed to greater than 5°, 45% progressed to >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 analysis 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 has both randomized and observational arms comparing standard rigid bracing to watchful waiting. This study 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 Brace (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. 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 (i.e., "tightness at prescribed level") with the smart brace (67%) compared with the standard brace (54%). The smart brace was associated with improved outcomes. None of the patients in the smart brace group had significant progression in spinal curves (a Cobb angle change <5°), whereas 2 of 6 patients in the standard 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 Brace (Smart Brace)
A pilot randomized study using a smart brace reported improved outcomes in comparison to use of a conventional rigid brace; however, the small number of included subjects limits the interpretation of these results. No studies on the smart brace have been identified since this 2012 pilot study.

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. 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). 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. 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 equivalent outcomes when compared to conventional rigid brace designs. A non-randomized comparative study suggests that the flexible brace may improve outcomes compared to no treatment, but this study is limited by self-selection and potential differences in patient characteristics between the groups.

Custom Fabricated Orthoses

Rigo et al reported a retrospective series that included 105 idiopathic scoliotic patients treated with a Chêneau brace. With an average age of 12.5 years old and a mean Risser sign of 0.9, the initial major Cobb angle was 36.8 degrees corrected to 25.9 degrees in the brace (31.1 % of the primary correction), and the major torsion angle was 16.8 degrees corrected to 12.9 degrees in the brace (22.2 % of the primary correction). A total of 37 patients have finished the treatment with a mean follow-up of 16.8 months. For this group, the initial Cobb and torsion angles were not significantly changed (36.4 degrees Cobb to 34.1 degrees Cobb at follow-up, and 16.9 degrees Perdriolle to 15.7 degrees Perdriolle at follow-up). The proportion of patients without progression greater than 5 degrees Cobb (n = 20) and with an improved final Cobb angle (n = 10) was greater than failures (n = 7). However, due to the catastrophic nature of some progressions, which generally coincide with a high Cobb angle right from the start, with low primary correction, and with non-compliance, the final Cobb angle showed a slight tendency to decrease but without reaching high significance. These results demonstrate that the Chêneau brace can effectively prevent the progression of Cobb and torsion angles, even in cases of bad prognosis.

Weiss et al stated that in patients with idiopathic scoliosis (IS), reduced thoracic kyphosis and reduced lumbar lordosis frequently occur in correlation with the lateral spinal curvature. Normalization of the sagittal profile and hyper- correction of the deviation in frontal and coronal plane are the main issues of the latest concept of bracing. The purpose of this study was

to investigate the influence of sagittal counter forces (SCF) on the scoliotic deformity. A case series of 4 patients with IS treated with 2 braces designed to improve the sagittal profile (Rigo-System-Chêneau-brace and with a sagittal counter force brace, SCF- brace). The short-term effect (30 mins) of both braces was evaluated using surface topography (Formetric surface topography system, Diers International, Wiesbaden). One patient (Cobb angle 92 degrees) showed no short-term correction in the frontal and coronal planes; others (Cobb angles between 39 and 48 degrees) exhibited valuable correction in frontal and coronal planes. There was no short-term correction in the sagittal plane for either brace. The authors concluded that the application of SCF seems to have similar short-term effects as 3-D correction and should be addressed more in future concepts of scoliosis bracing.

Grivas and Kaspiris stated that there is a lack of a systematic examination of the braces commonly used in Europe. Thus, the objective of this report was the description of the European braces widely used. The history, design rationale, indications, biomechanics, outcomes and comparison between some braces were reported. Chêneau Brace is used in France and other European Countries. There are 2 Cheneau derivatives, namely the RSC brace used in Spain and the ScoliOlogiC "Chêneau light" used in Germany. The Lyonnaise brace is used in France and Italy. The Dynamic Derotating brace is used in Greece. The TriaC brace is used in the Netherlands. The Sforzesco brace based on the SPoRT concept and the Progressive Action Short brace are used in Italy. Correction of spinal deformities is achieved in conservative treatment with passive and active brace mechanisms. The mode of operation of modern braces is in accordance with various principles of correction, namely active or passive extension with the aid of a neck ring and correction by lateral pads, lateral pressure according to 3- point principle, compression, bending the trunk towards the opposite side, active bracing and correction by means of pressure exerted by bands during movement and by means of metallic blades.

Vertebral Body Stapling

Nonrandomized Comparative Study

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 (see Tables 1 and 2). Forty-two consecutive patients in the VBS group (57 curves) met inclusion criteria, and 52 patients in the bracing group (66 curves) were matched by initial Cobb angle, age at the start of treatment, follow-up of at least 2 years, and sex. 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%) than 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

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° (see Tables 1 and 2). 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.

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 (i.e., curves of 30° to 39° in a young child) (see Tables 1 and 2). 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). 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 reported that vertebral stapling in young children with large Cobb angles was ineffective (see Tables 1 and 2). Diagnoses included myelodysplasia, congenital scoliosis, juvenile and infantile idiopathic scoliosis, Marfan syndrome, paralytic scoliosis, and neuromuscular scoliosis. Patients with idiopathic adolescent scoliosis 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 if 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). 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)	U.S.	Case control	123	11	25° to 44°	0	2
Bumpass et al (2015)	U.S.	Case series	33	11	25° to 40°	0	2
Theologis et al (2013)	U.S.	Case series	12	8	30° to 39°	NR	2
Laituri et al (2012)	U.S.	Case series	7	9	25° to 41°	NR	2
O'Leary et al (2011)	U.S.	Case series	11	7	68° to	0	1

					105°		
Betz et al (2010)	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)	VBS Brace	19 (33) 25 (38)	38 (67) 41 (62)	>0.05	NR	NR
		>10° Progressed	**Stable**	**>10° Corrected**		
Bumpass et al (2015)	VBS	13 (39)	14 (42)	6 (18)	9 (27)	11 (31)
Theologis et al (2013)	VBS	0 (0)	5 (42)	7 (58)	0 (0)	0 (0)
Laituri et al (2012)	VBS	0 (0)	2 (29)	5 (71)	0 (0)	0 (0)
O'Leary et al (2011)	VBS	3 (27)	6 (55)	2 (18)	0 (0)	8 (73)
		Baseline Curve	**>10° Progressed**	**Stable/ Improved**		
Betz et al (2010)	VBS	<35°	4 (22)	14 (78)	1 (6)	NR
		>35°	6 (75)	2 (25)	6 (75)	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 indicate 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, as 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 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/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

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

In 2014 and 2015, Samdani et al published 2 retrospective reviews on the off-label use of the Zimmer Dynesys for anterior vertebral body tethering (VBT) for idiopathic scoliosis. The

authors reported that they pursued vertebral body tethering at their institution due to lack of success with vertebral body stapling for thoracic curves greater than 35°. At the time of these reports, 32 patients had a minimum of 1-year follow-up, and 11 consecutive patients had 2-year follow-up. The mean age at surgery was 12 years, and all patients were skeletally immature. Three patients also had vertebral body stapling of their lumbar curves; for the 11 patients with 2-year follow-up, an average of 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 randomized controlled trial (RCT). Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Bracing has been considered the only available option to prevent curve progression in juvenile or adolescent idiopathic scoliosis. The highest quality study on bracing is a large National Institutes of Health–sponsored trial from 2013 that has both randomized and observational arms comparing bracing versus watchful waiting. This study 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 to be 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 smart 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 study using a smart brace reported improved outcomes in comparison 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 when compared to conventional rigid brace designs. Another study suggests that the flexible brace may improve outcomes compared to no treatment, but this study has design flaws which limit conclusions. 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 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 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.

Practice Guidelines and Position Statements

Society on Scoliosis Orthopaedic and Rehabilitation Treatment

The 2011 SOSORT guidelines include recommendations on the following interventions for scoliosis: Observation, physiotherapeutic-specific exercises, special inpatient rehabilitation, bracing: (nighttime rigid bracing, soft bracing, part-time rigid bracing, full-time bracing). The guideline does not address vertebral stapling or vertebral tethering. SOSORT states that the likelihood that a curve will 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, and patient age and sexual maturity. The following is a summary of the 20 recommendations in the guideline specific to bracing:

- For treatment of infantile, juvenile, and adolescent idiopathic scoliosis, if curve >20+5° Cobb, and patient still growing and demonstrating progression of deformity
- Braces should be worn full time or not <18 hours/day at the beginning of treatment; subsequent length of time is dependent on severity, age, stage, results, and compliance
- Bracing is applied by a well-trained therapeutic team including a physician, orthotist, and therapist, knowledgeable in all phases (prescription, construction, correction, follow-up)

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

The Scoliosis Research Society

The Scoliosis Research Society (SRS) stated in 2010 that the treatment of adolescent idiopathic scoliosis falls into 3 main categories (observation, bracing, and surgery) and is based on the risk of curve progression. 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. Since 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 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° 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 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 and vertebral body tethering are not addressed on the Society's website.

American Academy of Orthopaedic Surgeons

Information updated in 2015 from the American Academy of Orthopaedic Surgeons (AAOS) website indicates that the type of treatment required for idiopathic scoliosis in children and adolescents depends on the kind and degree of the curve, the child's age, and the number of remaining growth years until the child reaches skeletal maturity.

- 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 curvature between 25° and 45°.
- Surgery may be recommended if the curve is more than 45° and the child are 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. Bone graft from the bone bank, or from the patient's hip region, is also used to help the operated portion of the spine heal solid.

- At present, the main research focus in idiopathic scoliosis is investigation into genetic factors as a cause of scoliosis.
- Vertebral body stapling and vertebral body tethering are not addressed on the Society's website.

National Institute of Arthritis and Musculoskeletal and Skin Diseases
The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) updated their educational website page on scoliosis in children and adolescents in December 2015. When treatment is needed, an orthopedic spine specialist will 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 > 45°, 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: chiropractic manipulation, electrical stimulation, dietary supplements, and exercise. The educational page does not address vertebral body stapling or vertebral body tethering.

U.S. Preventive 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."

Key Words:
Adolescent idiopathic scoliosis (AIS), Vertebral stapling, Vertebral body stapling, Scoliosis bracing, Scoliosis stapling, Milwaukee Brace, Wilmington Brace, Boston Brace, Charleston

Brace, Providence Brace, SpineCor Brace, Vertebral body tethering, fusionless surgery, Rigo-Cheneau, custom thermoplastic TLSO, El corse de RSC, 3-D scoliosis braces

Approved by Governing Bodies:

Some of the braces used for the treatment of scoliosis are considered Class I devices by the U.S. Food and Drug Administration (FDA). Examples include the Boston scoliosis brace and the SpineCor® Scoliosis System.

Staples, using a shape memory nickel-titanium alloy, have 510(k) clearance from the FDA for a variety of indications for bone fixation. For example, Nitinol staples (Sofamor Danek, Memphis Tenn.) are indicated for fixation with spinal systems. Other memory shape staples that have 510(k) clearance for bone fixation include the OSStaple™ and the reVERTO™. 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.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Coding:

There is no specific CPT code for the insertion of vertebral body staples, vertebral body tethering, or vertical expandable titanium prosthetic ribs.

CPT Codes:	**22899**	Unlisted procedure, spine
HCPCS Codes:	**L0999**	Addition to spinal orthotic, not otherwise specified
	L1000-L1499	Code range for orthotic devices (CTLSO and TLSO) for use in scoliosis

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Policy History:

Medical Policy Panel, May 2010
Medical Policy Group, January 2011 **(2)**
Medical Policy Administration Committee, February 2011
Available for comment February 9 – March 25, 2011
Medical Policy Group January 2012 **(2)**: 2012 Update- Description, Key Points and References
Medical Policy Group, October 2012 **(2)**: Updates to Key Points and References
Medical Policy Group, June 2013 **(4)**: Updates to Description, Key Points and References, no changes were made to the policy statement.
Medical Policy Group, February 2014 **(4):** Updates to References. No change to policy statement.
Medical Policy Group, July 2014 **(4)**: Update to References only.
Medical Policy Panel, May 2015
Medical Policy Group, June 2015 (**2**): 2015 Updates to Description, Key Points, Key Words, Coding, and References; policy statement updated to include "vertebral body tethering" for the treatment of scoliosis does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered investigational; no change to intent.
Available for comment June 9 through July 23, 2015
Medical Policy Group, January 2016 **(2)**: updated reference information to policy 299 for information on (VEPTR).
Medical Policy Panel, November 2016
Medical Policy Group, November 2016 **(7):** 2016 Updates to Description, Key Points, and References. No change in Policy Statement.
Medical Policy Panel, August 2017
Medical Policy Group, September 2017 **(7):** 2017 Updates to Key Points and References. No change in Policy Statement.
Medical Policy Group, November 2017 **(7):** Policy statement updated- Investigational statement added re: "Custom fabricated orthoses for the treatment of scoliosis created by 3-D or CAM-CAD technologies (i.e., Rigo-Cheneau)." Updates to Description, Key Points, Key Words, and References. Added L0999 to Coding Section.
Medical Policy Administration Committee, November 2017
Available for comment November 14 through December 29, 2017
Medical Policy Panel, April 2018
Medical Policy Group, May 2018 **(7):** Updates to Description, Key Points, Approved by Governing Bodies and References. No change in Policy Statement.