# Medical Policy

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***Current Policy Effective Date: 5/1/24**
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# Title: Vertebral Body Tethering and/or Stapling for Scoliosis

## Description/Background

Scoliosis is a lateral (toward the side) curvature in the normally straight vertical line of the spine. There are many types of scoliosis including:

- Congenital scoliosis: caused by a bone abnormality present at birth
- Neuromuscular scoliosis: a result of abnormal muscles or nerves (e.g., spina bifida, cerebral palsy)
- Degenerative scoliosis: may result from traumatic bone collapse (e.g., previous back surgery, osteoporosis)
- Idiopathic scoliosis: the most common type of scoliosis that has no specific identifiable cause.

Scoliosis Curves are initially detected on school screening exams, by a child's pediatrician or family doctor, or by a parent. Some clues to scoliosis include uneven shoulders, a prominent shoulder blade, uneven waist, or leaning to one side. The diagnosis of scoliosis and the determination of the type of scoliosis are made by bone exam and an x-ray to evaluate the magnitude of the curve.

Treatments for scoliosis include braces or surgery. Bracing is the usual treatment choice for adolescents who have a spinal curve between 25° and 40°, particularly if their bones are still maturing and if they have at least 2 years of growth remaining. The purpose of bracing is to halt progression of the curve. Those who have curves beyond 40° to 50° are often considered for scoliosis surgery, spinal fusion with instrumentation and/or bone grafting. The goal is to make sure the curve does not progress.

Fusionless surgical procedures such as vertebral body tethering and vertebral body stapling are being evaluated as an alternative to bracing. Both procedures use orthopedic devices off-label.

Vertebral body tethering (VBT) is a minimally invasive technique in which pedicle screws are placed into the front of the vertebral bodies and attached to a flexible cable at the bend of the curve. The cable is tightened, which may provide some immediate correction of the curve as well as a possible continued improvement as the spine grows.

Vertebral body stapling (VBS) is a minimally invasive surgical technique in which special malleable metal staples are attached to adjacent vertebral bodies that make up the bend of the curve. These nickel-titanium alloy staples are cooled and while in an open position, are placed on the appropriate vertebral segments. As the staples are warmed by the body, they clamp down so they are unable to dislodge. The staples are supposed to keep the curve from progressing by slowing the growth on the convex (protruding) side of the curve while allowing the spine's own natural growth on the concave (recessed) side.

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## Regulatory Status

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, TN) 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. FDA product code: JDR.

A new vertebral body tethering device (The Tether; Zimmer Biomet Spine) received an FDA Humanitarian Device Exemption (HDE) (H190005, product code QHP) on 6/4/2019. The FDA HDE states that this device is indicated for "skeletally immature patients that require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, with a major Cobb angle of 30 to 65 degrees whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. Patients should have failed bracing and/or be intolerant to brace wear."

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## Medical Policy Statement

Vertebral body tethering (VBT) and vertebral body stapling (VBS) are considered experimental/investigational. The safety and effectiveness of these procedures have not been proven.

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## Inclusionary and Exclusionary Guidelines

N/A

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## CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

## ***Established codes:***

N/A

## ***Other codes (investigational, not medically necessary, etc.):***

22836 22837 22838 22899 0656T 0657T
0790T

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## Rationale

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

### Conventional Rigid Braces

#### Clinical Context and Therapy Purpose

The purpose of a conventional rigid brace is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as observation, in patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

The following **PICO** was used to select literature to inform this review.

#### Populations

The relevant population of interest are individuals with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

#### Interventions

The therapy being considered is a conventional rigid brace.

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

### Comparators

Comparators of interest include observation conducted by orthopedists and primary care providers in an outpatient clinical setting. Self-treatment includes physical exercise and stretching.

### Outcomes

The general outcomes of interest are change in disease status, morbid events, QOL, and treatment-related morbidity. Change in disease status was reported as 24% more improvement than just observation.

**Table 1. Outcomes of Interest for Individuals juvenile or adolescent idiopathic scoliosis at high-risk of progression**

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

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

### Review of Evidence

### 24-Hour Brace

### Nonrandomized Comparative Study

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.[8] 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 one 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.

### Retrospective Study

Aulisa et al (2017) investigated whether scoliotic curve correction was maintained long-term in patients with AIS who were treated with the rigid brace.[9] From a database of patients treated with a rigid brace, 93 patients who had completed treatment at least 10 years prior agreed to participate and underwent a follow-up examination. Participants had a mean age of 32.6 years and had been treated with the brace for a mean 5.3 years. Mean follow-up was 15 years post-treatment. The mean pre-brace Cobb angle was 32°, which was reduced to 19° following brace removal. At short-term follow-up (5 years), the mean Cobb angle was 21°; at long-term follow-up, the angle had increased to 22°. The change in Cobb angle from brace removal to long-term follow-up was not statistically significant. Subgroup analyses on patients with pre-brace Cobb angles of 30° or less compared with pre-brace Cobb angles greater than 30°, showed no significant difference in angle increase at long-term follow-up. Tables 2 and 3 summarize the key characteristics and results of these trials.

**Table 2. Summary of Key Nonrandomized Trials Characteristics**

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

**Table 3. Summary of Key Nonrandomized Trials Results**

| Study | Rate of Treatment Success | Average PedsQL scores | Pre-brace Mean Cobb | Post-brace Mean Cobb | Mean Cobb Angle at 10 |
|---|---|---|---|---|---|

| | | | Angle (degrees) | Angle (degrees) | Year Follow-up (degrees) |
|---|---|---|---|---|---|
| **Weinstein et al (2013) 11,** | | | | | |
| **Bracing** | 72% | 82 | | | |
| **Control** | 48% | 81.9 | | | |
| **OR** | 1.93 | | | | |
| **p-value** | | .97 | | | |
| **Aulisa et al (2021)12,** | | | | | |
| **Cobb angle >30° group** | | | 37.26 (+/- 7.5) | 22.98 (+/- 9.7) | 25.07 (+/- 11.2) |
| **Cobb angle <30° group** | | | 24.40 (+/- 2.6) | 8.69 (+/- 7.3) | 9.98 (+/- 7.8) |
| **Aulisa et al (2017)13,** | | | 32.17 (+/- 9.4) | 19.39 (+/- 10.8) | 22.12 (+/- 12.11) |

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

## Nighttime Braces

### Systematic Review

Costa et al (2021) conducted a systematic review and meta-analysis to compare different bracing methods in patients with adolescent idiopathic scoliosis, including full-time and nighttime wear of rigid braces and soft braces. [27] Thirty-three studies were included, approximately 25 of which were conducted in patients at high risk of progression (eg, Cobb angle between 25° and 40°, Risser grade 0-2). All but one of the 32 studies used rigid braces, 2 studies used nighttime braces, and 2 studies used part-time braces. The meta-analysis was limited to 16 studies with a medium or low risk of bias that defined progression as ≤5°. Success with full-time rigid bracing was 73.2% (95% CI, 60.9% to 85.5%), with nighttime rigid bracing was 78.7% (95% CI, 72.4% to 85%), with soft bracing was 62.4% (95% CI, 55.1% to 69.6%), and with observation only was 50% (95% CI, 44% to 56%).

### Retrospective Trial

Using the new SRS criteria, Janicki et al (2007) reported outcomes from a database of patients with AIS who had used a thoracic-lumbar-sacral orthosis (TLSO) or a nighttime orthosis.[4] 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 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 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 sizable National Institutes of Health-sponsored trial from 2013, which had both randomized and observational arms comparing standard rigid bracing with watchful waiting. This trial was stopped after interim analysis because of a significant benefit of bracing for the prevention of progression and need for spinal fusion. A study with long-term follow-up (mean, 15 years; range,10-35 years) demonstrated that curve corrections from rigid bracing were stable.

**Microcomputer Controlled Braces (Smart Brace)**

**Clinical Context and Therapy Purpose**
The purpose of a microcomputer-controlled brace is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as observation, in patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

The following **PICO** was used to select literature to inform this review.

**Populations**
The relevant population of interest are individuals with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

**Interventions**
The therapy being considered is a microcomputer-controlled brace. Orthotic bracing attempts to slow spinal curve progression and reduce the need for fusion surgery.

**Comparators**
Comparators of interest include observation conducted by orthopedists and primary care providers in an outpatient clinical setting. Self-treatment includes physical exercise and stretching.

**Outcomes**
The general outcomes of interest are change in disease status, morbid events, QOL, and treatment-related morbidity.

***Study Selection Criteria***
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

**Review of Evidence**

**Randomized Controlled Trial**
Lou et al (2012) published a pilot RCT that compared a microcomputer-controlled brace (smart brace) with a standard rigid brace in 12 patients with scoliosis.[10] Patients were randomized to wear the smart brace for 1 year followed by 1 year with a standard brace or to wear the

standard brace for 2 years. Both groups were followed for 3 years after treatment. Compliance with the microcomputer-controlled brace in the first year of bracing (2 years of total bracing) was similar in the two groups. The smart brace was associated with greater pad pressure and improved outcomes. None of the patients in the smart brace group had a significant change in their 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 years of the study.

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

## FLEXIBLE BRACES

### Clinical Context and Therapy Purpose
The purpose of a flexible brace is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as observation, in patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

The following **PICO** was used to select literature to inform this review.

### Populations
The relevant population of interest are individuals with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

### Interventions
The therapy being considered is a flexible brace.
Orthotic bracing attempts to slow spinal curve progression and reduce the need for fusion surgery.

### Comparators
Comparators of interest include observation conducted by orthopedists and primary care providers in an outpatient clinical setting. Self-treatment includes physical exercise and stretching.

### Outcomes
The general outcomes of interest are change in disease status, morbid events, QOL, and treatment-related morbidity.

### Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

**Randomized Controlled Trial**

Wong et al reported a prospective study of clinical efficacy and acceptance of rigid or flexible spinal bracing in 43 patients with moderate adolescent scoliosis in 2008. Follow-up to a mean of 45.1 months after skeletal maturity was reported in 2013.[11] 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. The subjects were requested 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. 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°more than SpineCor brace, patients were required to switch to a rigid brace. At the end of a 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 two orthoses was similar. Although the rigid brace caused significantly more problems with heat (85% vs. 27%, respectively), as well as difficulties with donning and doffing, the patients using the elastic braces had 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 after the post-maturity, with no additional patients proceeding to surgery.

**Nonrandomized Comparative Study**

Plewka et al (2013) reported the efficacy of the SpineCor brace (n=45) compared with physical therapy and observation (n=45) in children and adolescents with scoliosis.[12,13] 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 because of social reasons. Baseline measures of the two groups were similar with an average age of about 12 years (range, 7-16). After 2 years of treatment, the 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 and 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 those for conventional rigid brace designs. A nonrandomized comparative study suggested the flexible brace might improve outcomes compared with no treatment; however, this study was limited by self-selection and potential differences in patient characteristics between groups.

**Vertebral Body Stapling**

**Clinical Context and Therapy Purpose**

The purpose of vertebral body stapling (VBS) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as observation, in patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

The following **PICO** was used to select literature to inform this review.

**Populations**
The relevant population of interest are individuals with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

**Interventions**
The therapy being considered is VBS.
This is a fusionless surgical procedure intended to replace the use of traditional braces.

**Comparators**
Comparators of interest include observation conducted by orthopedists and primary care providers in an outpatient clinical setting. Self-treatment includes physical exercise and stretching.

**Outcomes**
The general outcomes of interest are change in disease status, morbid events, QOL, and treatment-related morbidity.

**Study Selection Criteria**
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

**Review of Evidence**

**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.[18] 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°, 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 to 50% for bracing. For lumbar curves (25° to 34°), results were comparable for VBS and bracing. There were insufficient numbers of patients with lumbar curves of 35° or greater to compare results.

**Observational Studies**
Several case services evaluating VBS are described below and in Tables 4 and 5.

Cuddihy et al (2015) compared VBS to bracing in a matched cohort of skeletally immature patients with moderate idiopathic scoliosis. [18] A total of 52 patients (66 curves) were matched according to age at the start of treatment (10.6years v s. 11.1 years, respectively) and gender

(see Tables 4 and 5). In smaller thoracic curves (25° to 34°) there was a nonsignificant trend toward better results with VBS versus bracing. For those with thoracic curves ≥35°, VBS was not found to be effective, and for lumbar curves 25° to 35°, results appear to be similar for both VBS and bracing.

Murray et al (2020) described VBS in 7 patients with a mean age of 9.3 years (range, 7.8 to11.1 years) and an average preoperative Cobb angle of 30° (standard deviation [SD], 6°); the mean follow-up was 83 months (range, 72 to 95months) (see Tables 5 and 6). [29] At the first postoperative visit and most recent follow-up visit, the average Cobb angle was 20° (SD, 7°) and 37° (SD, 22°), respectively. One patient showed improvement of greater than 10° from preoperative to final postoperative Cobb angle, 4 patients showed no change in their curve, and 2 showed progression of their curves by greater than 10° compared with preoperative imaging.

Bumpass et al (2015) described VBS in 31 consecutive patients with a mean age of 10.5 years (range, 7.0-14.6 years) and scoliotic curves of 25° to 40° (see Tables 5 and 6).[14] Not all patients could (or would) wear a brace. At a mean follow-up to maturity of 48 months (range, 25-79 months), curves less than 35° had a control rate (<10°progression) of 75% while curves with a Cobb angle of at least 35° had a control rate of 22% (p=0.01). The overall control rate was 61%, with 11 (31%) patients requiring subsequent fusion and 2 (6%) overcorrections.

Theologis et al (2013) described VBS in 12 children younger than 10 years old (range, 6.3-9.7 years) who were considered extremely likely to require fusion (i.e., curves of 30° to 39° in a young child), (see Tables 5 and 6).[15] At an average 3.4-year follow-up (range, 2.2-5.4 years), curves had decreased by a mean of 10° (range, -3° to 20°). All curves in this high-risk population were successfully treated, with either no change (within 10°) or improvement in the curve (>10°).

Laituri et al (2012) retrospectively reviewed 7 children ages 8 to 11 years old who had undergone VBS and had at least 2 years of follow-up (see Tables 5 and 6).[16] All children either had curve progression, despite bracing, or were unable to wear a brace. Before stapling, the mean angle was 34.1°. The mean percentage correction was 36% (range, 16.2%-56%). None of the children had curve progression or required postoperative bracing or spinal fusion.

O'Leary et al (2011) reported that VBS in young children with large Cobb angles was ineffective, (see Tables 5 and 6).[17] Patients with AIS were not included in this report. Diagnoses included myelodysplasia, congenital scoliosis, juvenile and infantile idiopathic scoliosis, Marfan syndrome, paralytic scoliosis, and neuromuscular scoliosis. At an average 22-month follow-up, curves averaged 69°, and 8 of 11 patients had undergone or were scheduled to undergo further spinal surgery for curve progression. It is unknown whether the young age at surgery, the severe preoperative curve, or the nature of the underlying scoliosis contributed to the high failure rate.

Betz et al (2010) reported on 29 patients with juvenile or adolescent idiopathic scoliosis(from a database of 93 patients) who met the study inclusion criteria (see Tables 5 and 6).[20] Selected

were patients with idiopathic scoliosis, a coronal curve magnitude of 20° to 45°, Risser grade 0 or 1, and staples with tines proportional to staple size (beginning in 2002). The average age at the time of stapling was 9.4 years (range, 4-13 years), with an average follow-up of 3.2 years (range 2-5.3 years). For thoracic curves greater than 35° at baseline, 75% progressed to greater than 50° (the threshold for recommending spinal fusion). For thoracic curves less than 35° at baseline, 6% of patients progressed to greater than 50° (the threshold for surgery).

**Table 4. Summary of Key Observational Study Characteristics for VBS**

| Study | Country | Study Design | N[a] | Participants | | | Minimum FU, y |
|---|---|---|---|---|---|---|---|
| | | | | ***Mean Age, y*** | ***Curve*** | ***Risser Grade*** | |
| Murray et al (2020)[29] | U.S. | Case series | 7 | 9.3 | 27.3° to 37.9° | NR | 6 |
| Cuddihy et al (2015)[18] | U.S. | Case control | 123 | 11 | 25° to 44° | 0 | 2 |
| Bumpass et al (2015)[14] | U.S. | Case series | 33 | 11 | 25° to 40° | 0 | 2 |
| Theologis et al (2013)[15] | U.S. | Case series | 12 | 8 | 30° to 39° | NR | 2 |
| Laituri et al (2012)[16] | U.S. | Case series | 7 | 9 | 25° to 41° | NR | 2 |
| O'Leary et al (2011)[17] | U.S. | Case series | 11 | 7 | 68° to 105° | 0 | 1 |
| Betz et al (2010)[19] | U.S. | Case series | 29 | 9 | 20° to 45° | 0 | 2 |

FU: follow-up; NR: not reported; VBS: vertebral body stapling.
[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 5. Summary of Key Observational Study Outcomes for VBS**

| Study | Tx | Change in Curve | | | | |
|---|---|---|---|---|---|---|
| | | ***>10° Progressed*** | ***Stable*** | ***>10° Improved*** | | |
| Murray et al (2020)[29] | VBS | 2 | 4 | 1 | | |
| | | ***>10° Progressed*** | ***Stable/Improved*** | ***p*** | **Progressed ≥50°** | **Subsequent Fusion** |
| Cuddihy et al (2015)[18] | VBS | Thoracic curves 25°-34°: (19)<br>Thoracic curves 35°-44°: (82)<br>Lumbar curves 25°-34°: (20)<br>Lumbar curves 35°-44°: (40) | Thoracic curves 25° to 34°: (81)<br>Thoracic curves 35° to 44°: (18)<br>Lumbar curves 25° to 34°: (80)<br>Lumbar curves 35° to 44°: (60) | >.05 for all comparisons of VBS vs. brace | NR | NR |

| | | | | | | |
|---|---|---|---|---|---|---|
| | Brace | Thoracic curves 25°-34°: (39)<br>Thoracic curves 35°-44°: (50)<br>Lumbar curves 25°-34°: (19)<br>Lumbar curves 35°-44°: (100) | Thoracic curves 25° to 34°: (61)<br>Thoracic curves 35° to 44°: (50)<br>Lumbar curves 25° to 34°: (81)<br>Lumbar curves 35° to 44°: (0) | | | |
| | | **>10° Progressed** | **Stable** | **>10° Corrected** | | |
| Bumpass et al (2015)[14] | VBS | 13 (39) | 14 (42) | 6 (18) | 9 (27) | 11 (31) |
| Theologis et al (2013)[15] | VBS | 0 (0) | 5 (42) | 7 (58) | 0 (0) | 0 (0) |
| Laituri et al (2012)[16] | VBS | 0 (0) | 2 (29) | 5 (71) | 0 (0) | 0 (0) |
| O'Leary et al (2011)[17] | VBS | 3 (27) | 6 (55) | 2 (18) | 0 (0) | 8 (73) |
| | | **Baseline Curve** | **>10° Progressed** | **Stable/Improved** | | |
| Betz et al (2010)[19] | VBS | <35°<br>≥35° | 4 (22)<br>6 (75) | 14 (78)<br>2 (25) | 1 (6)<br>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 have indicated that VBS might slow curve progression in children with thoracic curves less than 35° and is at least as effective as bracing but VBS appears to be less effective than bracing in patients with Cobb angles of 35° or more. Results from these studies are considered preliminary because few patients have been followed to skeletal maturity. Studies from other centers are consistent with results from those of the inventor of the procedure. Complications can include broken staples, staple dislodgement, curve overcorrection, congenital diaphragmatic hernia rupture, contralateral pleural effusion, pneumothoraces, and superior mesenteric artery syndrome. Investigators have commented that their approach is almost always to recommend bracing first and offer stapling only if the child or adolescent has difficulty wearing the brace. Notably, for patients with thoracic curves of 35° or greater, Cuddihy et al (2015) now perform vertebral body tethering (VBT; see next section) instead of VBS.

## Vertebral Body Tethering

### Clinical Context and Therapy Purpose

The purpose of vertebral body tethering (VBT) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as observation, in patients with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

The following **PICO** was used to select literature to inform this review.

**Populations**
The relevant population of interest are individuals with juvenile or adolescent idiopathic scoliosis at high-risk of progression.

**Interventions**
The therapy being considered is VBT.
This is a fusionless surgical procedure intended to replace the use of traditional braces.

**Comparators**
Comparators of interest include observation conducted by orthopedists and primary care providers in an outpatient clinical setting. Self-treatment includes physical exercise and stretching.

**Outcomes**
The general outcomes of interest are change in disease status, morbid events, QOL, and treatment-related morbidity.

**Study Selection Criteria**
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

**Review of Evidence**

**Systematic Reviews**
Zhu et al (2022) published a systematic review and meta-analysis of 26 studies representing 1045 subjects (mean age range, 11.1 to 14.9 years) treated with vertebral body tethering (VBT) for scoliosis, finding that the Cobb angle of the major curve was significantly corrected from 40.0° to 59.0° at baseline to 15.9° to 38.0° immediately post-surgery and 10° to 38° at final follow-up.30 The overall clinical success rate was 73.02% (95% CI, 68.31% to 78.05%). The pooled overall unplanned reoperation rate after VBT was 8.66% (95% CI, 5.53% to 13.31%; 23 studies). The top 3 reinterventions were conversion to posterior spinal fusion (3.51%; 95% CI, 2.45% to 5.01%), tether removal (2.3%; 95% CI, 1.47% to 3.58%), and tether replacement (1.09%; 95% CI, 0.57% to 2.08%). The overall complication incidence rate was 36.8% (95% CI, 23.9% to 49.7%; 24 studies). Most common complications included curve progression with tether breakage (16.79%; 95% CI, 7.43% to 26.15%), pulmonary complications (6%; 95% CI, 4.66% to 7.68%), and overcorrections (4.55%; 95% CI, 3.4% to 6.06%). A subgroup analysis of patients with more than 36 months follow-up time indicated that these patients had increased clinical success (73.88% vs. 65.93%), unplanned reoperation (15.8% vs. 4.55%), and complication rates (52.17% vs. 23.79%) compared to those with less than 36 months follow-up, respectively. Thus, based on the increased reoperation and complication rates observed with longer follow-up, the authors concluded that further improvements to the implant and refinement of patient selection criteria are warranted and should be assessed in the context of high-quality randomized controlled trials. Study

demographics and outcomes based on race, ethnicity, and sex were not reported, potentially limiting the generalizability of these findings.

**Observational Studies**

As noted in a 2015 review article, the devices used for VBT are under development, and the optimum tension for VBT is currently unknown.[20]

Other studies not included in the Zhu et al (2022) systematic review [30] are discussed below.

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 for idiopathic scoliosis.[21,22] 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, 20 and 11 consecutive patients had 2-year follow-up.[22] 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) 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 FDA approval of the procedure.

Pehlivanoglu et al (2021) conducted a prospective cohort study of 13 skeletally immature patients (mean age, 11.8 years)who underwent vertebral body tethering with the Dynesys system for adolescent idiopathic scoliosis with double curves. [31] At baseline, the mean thoracic/thoracolumbar and lumbar curve magnitudes were 48.2° and 45.3°,respectively. An average of 11.8 levels of tethering were undertaken. Postoperatively, mean thoracic/thoracolumbar curve magnitudes were 14.3° to 17.3°. At the last follow-up (mean, 36.4 months), the mean thoracic/thoracolumbar curve magnitudes were 8.2° to 9.7°. No major complications were reported.

Meyers et al (2022) performed a retrospective review of adolescent scoliosis patients (N=49; 74% female) treated with VBT via the Dynesys system after reaching peak height velocity (Risser stage 3-5).[32] Mean patient age was 15 ±- 1.9 years with mean follow-up duration 32.5 ± 9.1 months. In patients with thoracic major curvatures (n=24), the Cobb angle improved from 51.1 ± 6.9° to 27.2 ± 8.1° (47.7% correction; p<.01). In those with thoracolumbar major curves, curvature improved from 37.2 ± 10.7° to 18.8 ± 9.4° (49.5% correction; p<.01). Improvements in major curve inclinometer measurements and SRS-22 domains improved significantly (p≤.05), except for the SRS-22 activity domain. Overall, 37/49 (76%) of patients were deemed clinically successful with residual major curves ≤30°. At final follow-up, 2 major complications were reported. At 3.1 years after VBT, 1 patient required posterior fusion of the thoracic curve due to curve progression and revision of the thoracolumbar tether due to tether breakage. A second patient developed late onset superior mesenteric artery syndrome (SMAS) 1 year postoperatively which required Ladd's derotation surgery. Overall, 20 (41%) patients experienced tether breakage. However, only 4 of 19 (21%) patients with broken tethers failed

to meet criteria for clinical success which was comparable to the 7 of 29 (24%) patients with intact tethers. Thus, treatment success in subjects with limited remaining skeletal growth was feasible. While treatment success was not impacted by age or Risser stage, patients with treatment failures reported slightly larger major Cobb angles at baseline.

**Section Summary: Vertebral Body Tethering**
There is limited published evidence on vertebral body tethering (VBT). The Tether is the only vertebral body tethering device that the FDA has approved for marketing based on an 6/4/19 Humanitarian Device Exemption. Available evidence for The Tether is limited to a small, single-center, uncontrolled, unpublished retrospective cohort study of 57 pediatric patients. Although reported Cobb angle corrections are promising, serious adverse events occurred, data are lacking on other important health outcomes, and there are important study design limitations, including lack of a control group. Additional early reports of a correction in Cobb angle from published reports on the Dynesys system are also promising, but little is known about longer-term outcomes with this procedure. A meta-analysis of vertebral body tethering studies with more than 36 months follow-up reported a 74% clinical success rate, a 52% complication rate, and a 16% unplanned reoperation rate. Most commonly reported complications were tether breakages, pulmonary complications, and overcorrections. Larger, controlled studies are needed to verify these findings.

## SUMMARY OF EVIDENCE

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

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive a microcomputer-controlled brace, the evidence includes a pilot RCT. The relevant outcomes are change in disease status, morbid events, QOL, and treatment-related morbidity. A pilot randomized trial using a microcomputer-controlled brace reported improved outcomes compared with the use of a standard rigid brace; however, the low number of individuals included in the trial ultimately limited the interpretation of these results. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive a flexible brace, the evidence includes a randomized and a nonrandomized comparative study. The relevant outcomes are change in disease status, morbid events, QOL,

and treatment-related morbidity. One RCT evaluating a flexible brace did not show equivalent outcomes compared with conventional brace designs. Another study has suggested the flexible brace might improve outcomes compared with no treatment but this study had design flaws, which interfered with drawing significant conclusions from the study. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive vertebral body stapling, the evidence includes a comparative cohort study and case series. The relevant outcomes are change in disease status, morbid events, QOL, and treatment-related morbidity. There is a small body of published evidence on surgical interventions for preventing curve progression in juvenile and adolescent idiopathic scoliosis. VBS with memory shape staples may control some thoracic curves between 20° and 35° but it is less effective than bracing for larger curves. The evidence is composed primarily from a center that developed the technique, along with a few case series from other institutions. Additional study with larger sample sizes and longer follow-up is needed to evaluate the safety and efficacy of this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive vertebral body tethering (VBT), the evidence includes case series and a systematic review and meta-analysis of 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 published case series on the Tether and on off-label use of the Dynesys system. Available evidence for The Tether is limited to a small, single-center, uncontrolled, unpublished retrospective cohort study of 57 pediatric patients. A meta-analysis of vertebral body tethering studies with more than 36 months follow-up reported a 74% clinical success rate, a 52% complication rate, and a 16% unplanned reoperation rate. Most commonly reported complications were tether breakages, pulmonary complications, and overcorrections. Although reported Cobb angle corrections are promising, serious adverse events occurred, data is lacking on other important health outcomes, and there are important study design limitations including lack of a control group. Additional studies, with a larger number of total subjects and longer follow-up, are needed to evaluate the safety and efficacy of this surgical procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome

## Ongoing and Unpublished Clinical Trials

Some ongoing trials that might influence this policy are listed in Table 6.

**Table 6. Summary of Key Trials**

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| **NCT No.** | **Trial Name** | **Planned Enrollment** | **Completion Date** |
| *Ongoing* | | | |

| | | | |
|---|---|---|---|
| NCT04889339 | Validation of a New Generation of Orthopedic Brace for Treating Adolescent Idiopathic Scoliosis by Using Growth Modulation | 58 | Jan 2024 |
| NCT04992845[a] | Fusionless Treatment of Idiopathic Scoliosis With the SCOLI- TETHER System During The Growth Period | 51 | May 2025 |
| NCT05001568 | Validation of a New Optimized Nighttime Providence Brace for Personalized Treatment of Adolescent Idiopathic Scoliosis | 58 | Jan 2025 |
| NCT04805437 | 3D Designed Boston Brace Versus Standard Boston Brace in Halting Progression in Idiopathic Scoliosis: a Randomized Controlled Trial (PRISCOPRO) | 170 | Apr 2037 |
| NCT01761305 | CONTRAIS: CONservative TReatment for Adolescent Idiopathic Scoliosis. A Randomised Controlled Trial | 135 | Dec 2023 |
| NCT02897453[a] | Retrospective Review With Prospective Surveillance of Safety and Efficacy in a Clinical Series of Spinal Tethering Patients | 56 | Oct 2022 (unknown) |
| NCT04296903[a] | Post-approval Registry Study to Evaluate the Continued Safety and Probable Benefit of the MID-C System for 5 Years Post-Implantation in Adolescent Idiopathic Scoliosis (AIS) | 200 | May 2028 |
| NCT04116723 | Trial of Personalized Flexible Bracing Treatment of Adolescents Idiopathic Scoliosis | 100 | Dec 2024 |
| NCT03802656 | Safety and Feasibility of a Vertebral Body Tethering Technique for Pediatric Idiopathic Scoliosis | 40 | Feb 2025 |
| NCT03506334 | Prospective Pilot Study of Anterior Vertebral Body Tethering Using Zimmer Biomet Tether System or Dynesys System Components to Treat Pediatric Scoliosis | 57 | Apr 2023 |
| NCT04590807 | Posterior Spinal Fusion With Pedicle Screws vs. Anterior Vertebral Body Tethering in Adolescent Idiopathic Scoliosis | 70 | Dec 2025 |

| | | | |
|---|---|---|---|
| NCT04505579[a] | The Tether™ - Vertebral Body Tethering System Post Approval Study | 200 | Dec 2027 |
| NCT04914507 | A Prospective Analysis of Long-Term Clinical Outcomes and 3D Spine Growth in Anterior Vertebral Body Tethering | 106 | Sep 2029 |

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

## SUPPLEMENTAL INFORMATION

### PRACTICE GUIDELINES AND POSITION STATEMENTS

#### Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT)

The guidelines from the Society on Scoliosis Orthopaedic and Rehabilitation Treatment (2016) included recommendations on the following conservative treatments for idiopathic scoliosis[23]: assessment, bracing, physiotherapy, physiotherapeutic scoliosis-specific exercises and other conservative treatments for idiopathic scoliosis, exercises, special inpatient rehabilitation, and bracing (nighttime rigid bracing, soft bracing, part-time rigid bracing, full-time bracing). The guidelines did not address vertebral body stapling (VBS) or vertebral body tethering (VBT). Treatment decisions should be individualized based on the probability of progression, curve magnitude, skeletal maturity, patient age, and sexual maturity. The following is a summary of the 20 recommendations in the guidelines specific to bracing:

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

#### Scoliosis Research Society (SRS)

SRS states that the treatment of scoliosis falls into three main categories (observation, bracing, surgery) and is based on the risk of curve progression.[25] In general, curves progress in two 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° who are still growing, or for curves <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 >45° while still growing or >50° when growth has stopped. The goal 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 one bone.
- Alternative treatments to prevent curve progression or prevent further curve progression, such as chiropractic medicine, physical therapy, yoga, etc., have not demonstrated any scientific value in the treatment of scoliosis.

VBS was not addressed on the Society's website.

**American Academy of Orthopaedic Surgeons (AAOS)**

Information updated on the AAOS Info website indicates that the type of treatment required for idiopathic scoliosis in children and adolescents depends on the kind and degree of the curve, child's age, and the number of remaining growth years until the child reaches skeletal maturity.[24]

- Observation is appropriate when the curve is mild (<25°) or if the child is near skeletal maturity.
- The goal of bracing is to prevent scoliotic curves from worsening. Bracing can be effective if the child is still growing and has a spinal curvature between 25° and 45°.
- Surgery may be recommended if the curve is >45°- 50° or if bracing did not stop the curve from reaching this point. An implant made up of rods, hooks, screws, and/or wires is used to straighten the spine.

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

**National Institute of Arthritis and Musculoskeletal and Skin Diseases**

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) has an educational website page on scoliosis in children and adolescents (last reviewed, December 2019). [27] When treatment is needed, an orthopedic spine specialist should suggest the best treatment for each patient based on the patient's age, how much more he or she is likely to grow, the degree and pattern of the curve, and the type of scoliosis.

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

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

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

**National Institute for Health and Care Excellence**
In 2022, the National Institute for Health and Care Excellence (NICE) published an interventional procedures guidance on vertebral body tethering for idiopathic scoliosis in children and young people.[33] Recommendations stated that "evidence on the safety of vertebral body tethering for idiopathic scoliosis in children and young people is limited but raises concerns of serious complications. Evidence on its efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research."

**U.S. Preventive Services Task Force Recommendations**
The U.S. Preventive Services Task Force (USPSTF) published recommendations for idiopathic scoliosis screening in 2004.[25] USPSTF recommends 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).[27] 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."

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## Government Regulations

### National:
There is no national coverage determination (NCD)

### Local:
There is no local coverage determination (LCD)

*(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)*

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## Related Policies

- Growing Rods for Scoliosis (e.g., MAGEC Spinal Bracing and Distraction System)
- Vertical Expandable Prosthetic Titanium Rib

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*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through July 31, 2023, the date the research was completed.*

**Joint BCBSM/BCN Medical Policy History**

| Policy Effective Date | BCBSM Signature Date | BCN Signature Date | Comments |
|---|---|---|---|
| 1/1/17 | 10/11/16 | 10/11/16 | Joint policy established |
| 1/1/18 | 10/19/17 | 10/19/17 | Updated rationale section, added references 16 and 17. No change in policy status. |
| 1/1/19 | 10/16/18 | 10/16/18 | Routine policy maintenance, deleted MDHHS section. No change in policy status. |
| 1/1/20 | 10/15/19 | | Rationale reformatted, reference #9 added, reference #26 removed. No change in policy status. |
| 1/1/21 | 10/20/20 | | Routine policy maintenance. No change in policy status. |
| 1/1/22 | 10/19/21 | | Routine policy maintenance. No change in policy status. Per code update information: 7/1/21: new codes to added: 0656T and 0657T |
| 1/1/23 | 10/18/22 | | Routine policy maintenance. No change in policy status. (ky) |
| 1/1/24 | 10/17/23 | | Routine policy maintenance. No change in policy status. Vendor: TP policy #1020 Surgery for spinal deformity. (ky) |
| 5/1/24 | 2/20/24 | | This policy is coming early as code update – informational to add codes 22836, 22837, 22838, and 0790T eff 1/1/24 per code update as E/I. Codes 0656T and 0657T are revised eff 1/1/24 to clarify their use for vertebral body tethering limited to the lumbar or thoracolumbar spine. This policy will go back to its original date of October, 2024 JUMP.<br>Vendor: TP (ky) |

Next Review Date: 4th Qtr. 2024

## Pre-Consolidation Medical Policy History

| Original Policy Date | Comments |
|---|---|
| BCN: | Revised: |
| BCBSM: | Revised: |

# BLUE CARE NETWORK BENEFIT COVERAGE
# POLICY: VERTEBRAL BODY TETHERING AND/OR STAPLING FOR SCOLIOSIS

## I. Coverage Determination:

| | |
|---|---|
| **Commercial HMO (includes Self-Funded groups unless otherwise specified)** | Not covered |
| **BCNA (Medicare Advantage)** | See government section. |
| **BCN65 (Medicare Complementary)** | Coinsurance covered if primary Medicare covers the service. |

## II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.