



Louisiana

Vertebral Body Stapling and Vertebral Body Tethering for the Treatment of Scoliosis

Policy # 00769

Original Effective Date: 01/10/2022

Current Effective Date: 01/10/2022

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers vertebral body stapling and vertebral body tethering for the treatment of scoliosis to be **investigational**.*

Policy Guidelines

This policy does not address conventional surgery for scoliosis in patients with curve angles measuring 45° or more. Brace treatment for idiopathic scoliosis is usually recommended for juveniles and adolescents with curves measuring between 25° and 40° who have not completed spinal growth, with maturity defined as Risser grade 4, or 2 years after menarche for girls. Bracing may also be recommended for curves greater than 20° in a patient who has a rapidly progressing curve with more than 2 years of growth remaining.

- A rigid cervical-thoracic-lumbar-sacral orthosis is primarily prescribed for patients with thoracic apices above T7 for control of upper thoracic sagittal deformities and other spinal deformities not amenable to treatment with lower-profile designs.
- A low profile, rigid thoracic-lumbar-sacral orthosis worn full-time (18-23 hours per day) through skeletal maturity is used for most idiopathic curve patterns with a thoracic curve apex at or below T7 (most idiopathic curves).
- Nighttime bracing systems are more effective in patients with isolated flexible thoracolumbar and lumbar curves than in double curves; they may also be indicated in patients who are noncompliant with a full-time wear program, patients in whom other types of orthotic management have failed, and patients nearing skeletal maturity who may not require full-time wear.

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Background/Overview

Scoliosis

Scoliosis is an abnormal lateral and rotational curvature of the vertebral column. Adolescent idiopathic scoliosis is the most common form of idiopathic scoliosis, defined by the U.S. Preventive Services Task Force as “a lateral curvature of the spine with onset at ≥ 10 years of age, no underlying etiology, and risk for progression during puberty.” Progression of the curvature during periods of rapid growth can result in deformity, accompanied by cardiopulmonary complications. Diagnosis is made clinically and radiographically. The curve is measured by the Cobb angle, which is the angle formed between intersecting lines drawn perpendicular to the top of the vertebrae of the curve and the bottom vertebrae of the curve. Patients with adolescent idiopathic scoliosis are also assessed for skeletal maturity, using the Risser sign, which describes the level of ossification of the iliac apophysis.

The Risser sign measures remaining spinal growth by progressive anterolateral to posteromedial ossification. Risser sign ranges from 0 (no ossification) to 5 (full bony fusion of the apophysis). Immature patients will have 0% to 25% ossification (Risser grade 0 or 1), while 100% ossification (Risser grade 5) indicates maturity with no spinal growth remaining. Children may progress from a Risser grade 1 to grade 5 over a brief (eg, 2-year), period.

Treatment

Treatment of scoliosis currently depends on 3 factors: the cause of the condition (idiopathic, congenital, secondary), the severity of the condition (degrees of the curve), and the growth of the patient remaining at the time of presentation. Children who have vertebral curves measuring between 25° and 40° with at least 2 years of growth remaining are considered to be at high-risk of curve progression. Genetic markers to evaluate the risk of progression are also being evaluated. Because severe deformity may lead to compromised respiratory function and is associated with back pain in adulthood, surgical intervention with spinal fusion is typically recommended for curves that progress to 45° or more.

Bracing

Bracing is used to reduce the need for spinal fusion by slowing or preventing further progression of the curve during rapid growth. Commonly used brace designs include the Milwaukee, Wilmington, Boston, Charleston, and Providence orthoses. The longest clinical experience is with the Milwaukee

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cervical-thoracic-lumbar-sacral orthosis. Thoracic-lumbar-sacral orthoses, such as the Wilmington and Boston braces, are intended to improve tolerability and compliance for extended (>18-hour) wear and are composed of lighter weight plastics with a low profile (underarm) design. The design of the nighttime Charleston and Providence braces is based on the theory that increased corrective forces will reduce the needed wear time (ie, daytime), thereby lessening social anxiety and improving compliance. The smart brace consists of a standard rigid brace with a microcomputer system, a force transducer, and an air-bladder control system to control the interface pressure. Braces that are more flexible than thoracic-lumbar-sacral orthoses or nighttime braces, such as the SpineCor, are also being evaluated. The SpineCor is composed of a thermoplastic pelvic base with stabilizing and corrective bands across the upper body.

Surgery

Fusionless surgical procedures, such as vertebral body stapling and vertebral body tethering, are being evaluated as alternatives to bracing. Both procedures use orthopedic devices off-label. The goal of these procedures is to reduce the rate of spine growth unilaterally, thus allowing the other side of the spine to “catch up.” The mechanism of action is believed to be down-regulation of the growth plate on the convex (outer) side by compression and stimulation of growth on the endplate of the concave side by distraction. In the current stapling procedure, nickel-titanium alloy staples with shape memory are applied to the convex side of the curve. The shape memory allows the prongs to be straight when cooled and clamp down into the bone when the staple returns to body temperature. Anterolateral tethering uses polyethylene ligaments that are attached to the convex side of the vertebral bodies by pedicle screws or staples. The ligament can be tightened to provide greater tension than the staple. The optimum degree of tension is not known. The polyethylene ligaments are more flexible than staples and are predicted to allow more spinal mobility. The goal of a fusionless growth modulating procedure is to reduce the curve and prevent progression, maintain spine mobility following correction, and provide an effective treatment option for patients who are noncompliant or who have a large curve but substantial growth is remaining.

Research Recommendations

The Scoliosis Research Society provided evidence-based recommendations in 2005, which were updated in 2015, for bracing studies to standardize inclusion criteria, methodologies, and outcome measures to facilitate comparison of brace trials. Janicki et al (2007) reported the first study to use the Scoliosis Research Society criteria concluded that a brace should prevent progression in 70% of patients to be considered effective. The Scoliosis Research Society evidence review and

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recommendations may also aid in the evaluation of fusionless surgical treatments for scoliosis progression in children.

The Scoliosis Research Society review of the natural history of scoliosis indicated that skeletally immature patients and patients with larger curves (between 20° and 29°) are significantly more likely to have more than 5° curve progression. Brace treatment for idiopathic scoliosis is usually recommended for juveniles and adolescents with curves measuring between 25° and 40° who have not completed spinal growth, with maturity defined as Risser grade 4, or at least 2 years after menarche for girls. Bracing may also be recommended for curves greater than 20° in a patient who has a rapidly progressing curve with more than 2 years of growth remaining.

Success from brace treatment is most frequently defined as progression of less than 5° before skeletal maturity, although alternative definitions may include progression of less than 10° before skeletal maturity or preventing the curve from reaching the threshold for surgical intervention. Surgery is usually recommended when the curve magnitude exceeds 45° to 50° (before or at skeletal maturity), although many patients will not undergo surgery at this point. Based on this information, Scoliosis Research Society provided the following recommendations for brace studies on adolescent idiopathic scoliosis:

- “Optimal inclusion criteria for brace studies consist of: age is 10 years or older when the brace is prescribed, Risser [grade] 0-2, curve 25°–40°, and no prior treatment.”
- Outcomes of brace effectiveness should include all of the following:
 - “The percentage of patients with 5° or less curve progression and the percentage of patients who have 6° or more progression at skeletal maturity.”
 - The number of patients at the start and end of treatment exceeding 10°, 30°, and 50° Cobb angles, as these risk thresholds have potential health consequences in adulthood, such as back pain and curve progression.
 - "A minimum of 2-year follow-up beyond skeletal maturity for each patient who was ‘successfully’ treated with a brace to determine the percentage who subsequently required or had surgery recommended. The surgical indications must be documented."
 - Clinically significant outcomes such as aesthetics, deformity progression, disability, pain, and quality of life.

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- “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.”

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Staples, using a shape memory nickel-titanium alloy, have been cleared for marketing by the FDA through the 510(k) process for various bone fixation indications. For example, nitinol staples (Sofamor Danek) are indicated for fixation with spinal systems. Other memory shape staples cleared for marketing by the FDA through the 510(k) process for bone fixation include the OSStaple™‡ (BioMedical Enterprises) and the reVERTO™‡ Dynamic Compression Device. FDA product code: JDR. Vertebral body stapling in scoliosis is considered off-label use.

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

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 "skeletal immature patients that require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, with a major Cobb angle of 30 to 65 degrees whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. Patients should have failed bracing and/or be intolerant to brace wear."

Several of the cleared devices are described in Table 1.

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Table 1. Scoliosis Bracing Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Coronet Soft Tissue Fixation System	CoNextions Medical	3/4/2020	K200028	Off Label Use for Scoliosis support
Superelastic Staple	Neosteo	2/28/2020	K192447	Off Label Use for Scoliosis support
Mactafix CI Fixation Button With Continuous Loop	Medacta International SA	2/10/2020	K193165	Off Label Use for Scoliosis support
Motoband Cp Implant System	CrossRoads Extremity Systems, LLC	1/10/2020	K193452	Off Label Use for Scoliosis support
Trimax Implant System	CrossRoads Extremity Systems, LLC	8/16/2019	K190772	Off Label Use for Scoliosis support
Colink Plating System, Fracture and Correction System, Rts Implant System, Neospan Compression Staple System	In2Bones USA, LLC	8/8/2019	K190385	Off Label Use for Scoliosis support
Trimed Nitinol Staple System	TriMed, Inc.	7/1/2019	K190166	Off Label Use for Scoliosis support
Vertex Nitinol Staple System	Nvision Biomedical Technologies, LLC	4/4/2019	K182943	Off Label Use for Scoliosis support

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Geo Staple System	Gramercy Extremity Orthopedics LLC	1/11/2019	K182212	Off Label Use for Scoliosis support
DynaClip™ Bone Staple	MedShape Inc.	11/5/2018	K181781	Off Label Use for Scoliosis support
DynaBridge	Fusion Orthopedics LLC	10/15/2018	K181815	Off Label Use for Scoliosis support
MotoCLIP/HiMAX Step Staple Implant System	CrossRoads Extremity Systems LLC	8/9/2018	K181866	Off Label Use for Scoliosis support
DePuy Synthes Static Staples	Synthes (USA) Products LLC	7/24/2018	K180544	Off Label Use for Scoliosis support
MotoCLIP/HiMAX Implant System	CrossRoads Extremity Systems LLC	6/29/2018	K181410	Off Label Use for Scoliosis support
Clench Compression Staple	F & A Foundation LLC d.b.a. Reign Medical	4/6/2018	K173775	Off Label Use for Scoliosis support
Orbitum Bone Staple Implant X and VI	Orthovestments LLC	2/23/2018	K173693	Off Label Use for Scoliosis support
ExoToe Staple	ExoToe LLC	1/11/2018	K172205	Off Label Use for Scoliosis support

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ToggleLoc System	Biomet Inc.	1/5/2018	K173278	Off Label Use for Scoliosis support
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Rationale/Source

Description

Orthotic bracing attempts to slow spinal curve progression and reduce the need for fusion surgery in patients with juvenile or adolescent idiopathic scoliosis who are at high-risk of progression. Vertebral body stapling and vertebral body tethering, both fusionless surgical procedures, have been evaluated to determine whether the procedures could be used as alternatives to traditional orthotic bracing. This review does not address patients who are not at high-risk of progression or conventional fusion surgery for scoliosis, such as patients with Cobb angles measuring 45° or more.

Vertebral Body Tethering

There is limited published evidence on vertebral body tethering. The Tether is the only vertebral body tethering device that the FDA has approved for marking based on an 6/4/19 Humanitarian Device Exemption. Available evidence for The Tether is limited to a small, single-center, uncontrolled, unpublished retrospective cohort study of 57 pediatric patients. Although reported Cobb angle corrections are promising, serious adverse events occurred, data are lacking on other important health outcomes, and there are important study design limitations, including lack of a control group. Additional early reports of a correction in Cobb angle from published reports on the Dynesys system are also promising, but little is known about longer-term outcomes with this procedure. Larger, controlled studies are needed to verify these findings.

Vertebral Body Stapling

Evidence on the use of VBS for patients with idiopathic scoliosis consists of a nonrandomized comparative study, a case-control study, and several small case series. Results from the nonrandomized comparative study and case-control study have indicated that VBS might slow curve progression in children with thoracic curves less than 35° and is at least as effective as bracing, but VBS appears to be less effective than bracing in patients with Cobb angles of 35° or more. Results from these studies are considered preliminary because few patients have been followed to skeletal maturity. Studies from other centers are consistent with results from those of the inventor of the procedure. Complications can include broken staples, staple dislodgement, curve overcorrection,

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congenital diaphragmatic hernia rupture, contralateral pleural effusion, pneumothoraces, and superior mesenteric artery syndrome. Investigators have commented that their approach is almost always to recommend bracing first and offer stapling only if the child or adolescent has difficulty wearing the brace. Notably, for patients with thoracic curves of 35° or greater, Cuddihy et al (2015) now perform vertebral body tethering (see next section) instead of VBS.

Summary of Evidence

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

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive vertebral body tethering, the evidence includes case series. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Vertebral body tethering has been evaluated for thoracic curves at high-risk of progression. Currently, there is very limited evidence on this technique, with published case series on the Dynesys system reporting 1-year follow-up in 32 patients, 2-year follow-up in 11 patients, and an additional prospective study reporting approximately 2-year follow-up in 21 patients. Available evidence for The Tether is limited to a small, single-center, uncontrolled, unpublished retrospective cohort study of 57 pediatric patients. Although reported Cobb angle corrections are promising, serious adverse events occurred, data is lacking on other important health outcomes, and there are important study design limitations including lack of a control group. Additional studies, with a larger number of total subjects and longer follow-up, are needed to evaluate the safety and efficacy of this surgical procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Society on Scoliosis Orthopaedic and Rehabilitation Treatment

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

Scoliosis Research Society

The Scoliosis Research Society has indicated that the treatment of adolescent idiopathic scoliosis falls into 3 main categories (observation, bracing, surgery) and is based on the risk of curve progression. In general, adolescent idiopathic scoliosis curves progress in 2 ways: first, during the rapid growth period of the patient and, second, into adulthood if the curves are relatively large. Because scoliosis gets larger during rapid growth, the potential for growth is evaluated taking into consideration the patient's age, the status of whether females have had their first menstrual period, as well as radiographic parameters. The Risser grading system rates a child's skeletal maturity on a scale of 0 to 5. Patients who are Risser grade 0 and 1 are growing rapidly, while patients who are 4 and 5 have stopped growing. The Society made the following recommendations:

- “Observation is generally for patients whose curves are less than 25° who are still growing, or for curves less than 50° in patients who have completed their growth.”

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

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

Scoliosis Research Society/Pediatric Orthopaedic Society of North America

A joint Scoliosis Research Society/Pediatric Orthopaedic Society of North America position statement (2020) on payor coverage for anterior fusionless scoliosis technologies for immature patients with idiopathic scoliosis drew the following conclusions after a review of scientific evidence on anterior vertebral growth modulation:

- "...payors should provide coverage for any FDA approved devices under FDA stated clinical indications and requirements (limited to surgeons with active IRB approval) at the same level as traditional spinal instrumentation/fusion and growing rod procedures for management of skeletally immature patients (Risser ≤ 2 or Sanders ≤ 5) with idiopathic scoliosis (as defined above, 30 to 65 degrees Cobb angle)."
- "For those patients who meet criteria for use of The Tether or other similarly FDA approved growth modulation systems, the decision for fusion versus growth modulation is best made between the patient, guardians, and treating physician - accounting for individual needs, values, and perspectives."
- "The SRS and POSNA do not support the use or reimbursement for anterior nonfusion instrumentation in skeletally mature individuals for the management of scoliosis or other spinal deformities."

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American Academy of Orthopaedic Surgeons

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

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

Vertebral body stapling and vertebral body tethering are not addressed on the Society's website.

National Institute of Arthritis and Musculoskeletal and Skin Diseases

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

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

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

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

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U.S. Preventive Services Task Force Recommendations

The U.S. Preventative Services Task Force (USPSTF) has published recommendations for idiopathic scoliosis screening. The USPSTF (2004) recommended against the routine screening of asymptomatic adolescents for idiopathic scoliosis (grade D recommendation). The USPSTF (2018) updated their recommendation to state that there is insufficient evidence to assess screening of adolescents for idiopathic scoliosis (grade I recommendation). Review conclusions for scoliosis treatments are listed below:

“The USPSTF found inadequate evidence on treatment with exercise and surgery. It found adequate evidence that treatment with bracing may slow curvature progression in adolescents with mild or moderate curvature severity (Cobb angle <40° to 50°); however, evidence on the association between reduction in spinal curvature in adolescence and long-term health outcomes in adulthood is inadequate. The USPSTF found inadequate evidence on the harms of treatment.”

Medicare National Coverage

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

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02589106	Safety and Efficacy of Anisotropic Textile Braces for Adolescent Idiopathic Scoliosis	15	Dec 2024
NCT01761305	CONTRAIS: CONservative TRreatment for Adolescent Idiopathic Scoliosis. A Randomised Controlled Trial	135	Dec 2023

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NCT02897453 ^a	Retrospective Review With Prospective Surveillance of Safety and Efficacy in a Clinical Series of Spinal Tethering Patients	55	Oct 2022
NCT04296903	Post-approval Registry Study to Evaluate the Continued Safety and Probable Benefit of the MID-C System for 5 Years Post-Implantation in Adolescent Idiopathic Scoliosis (AIS)	200	May 2028
NCT04116723	Trial of Personalized Flexible Bracing Treatment of Adolescents Idiopathic Scoliosis	100	Dec 2023
NCT03802656	Safety and Feasibility of a Vertebral Body Tethering Technique for Pediatric Idiopathic Scoliosis	40	Feb 2025
NCT03506334	Prospective Pilot Study of Anterior Vertebral Body Tethering Using Zimmer Biomet Tether System or Dynesys System Components to Treat Pediatric Scoliosis	80	Jul 2027
NCT04590807	Posterior Spinal Fusion With Pedicle Screws vs. Anterior Vertebral Body Tethering in Adolescent Idiopathic Scoliosis	70	Dec 2025
NCT04505579	The Tether™ - Vertebral Body Tethering System Post Approval Study	200	Dec 2027

^a Denotes industry-sponsored or cosponsored trial.

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12/02/2021 Medical Policy Committee review

12/08/2021 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 12/2022

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0656T, 0657T, 22899
HCPCS	No codes
ICD-10 Diagnosis	M41.0-M41.9

***Investigational** – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

****Medically Necessary** (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;

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- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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