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Interventions for Progressive Scoliosis Corporate Medical Policy

File Name: Interventions for Progressive Scoliosis
File Code: 2.01.VT83
Origination: 06/2018
Last Review: 08/2024
Next Review: 08/2025
Effective Date: 10/01/2024

Description/Summary

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

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive a conventional rigid brace, the evidence includes a systematic review, a high-quality nonrandomized controlled trial, and three retrospective studies. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Bracing has been considered the only option to prevent curve progression in juvenile or adolescent idiopathic scoliosis. The highest quality study on bracing is a sizable 2013 National Institutes of Health-sponsored trial that, using both randomized and observational arms, compared bracing with watchful waiting. This trial was stopped after interim analysis because of a significant benefit of bracing for the prevention of spinal fusion. Two retrospective studies with long-term follow-up (mean, 13 to 15 years) has also shown that curvature corrections with bracing were maintained. Another retrospective study demonstrated that nighttime bracing was more effective than a 24-hour brace for avoiding surgery and preventing curve progression, but investigators attributed this finding to likely noncompliance with the 24-hour brace. A systematic review and meta-analysis reported higher success with full-time and nighttime rigid braces compared to soft bracing or observation only. 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. 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 this 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. Relevant outcomes are changes in disease status, morbid events, quality of life, and treatment-related morbidity. A pilot randomized trial using a microcomputer-controlled brace reported improved outcomes compared to use of a standard rigid brace; however, the small number of included subjects limits the interpretation of these results. The evidence is insufficient to determine that this technology results in a net health outcome.

For individuals who have juvenile or adolescent idiopathic scoliosis at high risk of progression who receive a flexible brace, the evidence includes a randomized and a non-randomized comparative study. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. One RCT evaluating a flexible brace did not show equivalent outcomes compared to conventional brace designs. Another study has suggested that the flexible brace may improve outcomes compared to no treatment, but this study had design flaws limiting conclusions to be drawn. The evidence is insufficient to determine that this 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, 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 this 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 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. 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 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 this technology results in an improvement in the net health outcome.

OBJECTIVE

The objective of this evidence review is to evaluate the efficacy and to determine whether surgical and nonsurgical interventions for scoliosis improve the net health outcome for juveniles and adolescents who are at high-risk of spinal curve progression.

Policy

Coding Information

Click the links below for attachments, coding tables & instructions.
Attachment I – Code Table & Instructions

There is no specific CPT® code for the insertion of vertebral body staples or vertebral body tethering. The procedure would most likely be reported with the unlisted code 22899.

A rigid cervical-thoracic-lumbar-sacral or thoracic-lumbar-sacral orthosis may be considered **medically necessary** for the treatment of scoliosis in juvenile and adolescent patients at high risk of progression that meets the following criteria:

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

OR

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

When a service is considered investigational

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

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

Policy Guidelines

This policy does not address conventional surgery for scoliosis in patients with curve angles measuring 45° or more. Brace treatment for idiopathic scoliosis is recommended

for juveniles and adolescents with curves measuring between 25° and 40° who have not completed spinal growth, with maturity defined as Risser 4, or 2 years 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 for other spinal deformities not amenable to treatment with lower-profile designs.
- A low profile, rigid thoracic-lumbar-sacral orthosis worn full-time (18-23 hours per day) through skeletal maturity is used for most idiopathic curve patterns with a thoracic curve apex at or below T7 (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.

Reference Resources

1. Blue Cross and Blue Shield Association MPRM 2.01.83 - Interventions for Progressive Scoliosis. Updated 5/2024, Accessed 8/2024.
2. Crawford & Lenke, Growth Modulation by Means of Anterior Tethering Resulting in Progressive Correction of Juvenile Idiopathic Scoliosis: A Case Report, Journal of Bone & Joint Surgery 2010;92(1):202-9Braun, Comparison of Two Fusionless Scoliosis Surgery Methods in the Treatment of Progressive Adolescent Idiopathic Scoliosis: A Preliminary Study, Dartmouth Orthopedic Journal, 2014, Volume 1.
3. Newton PO. Spinal growth tethering: indications and limits. Ann Transl Med. 2020 Jan;8(2):27. doi: 10.21037/atm.2019.12.159. PMID: 32055618; PMCID: PMC6995909.
4. Karavidas N. Bracing In The Treatment Of Adolescent Idiopathic Scoliosis: Evidence To Date. Adolesc Health Med Ther. 2019 Oct 8;10:153-172. doi: 10.2147/AHMT.S190565. PMID: 31632169; PMCID: PMC6790111.

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non- compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

Incomplete authorization requests may result in a delay of decision pending submission of missing information. To be considered compete, see policy guidelines above.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm
benefits, please contact the customer service department at the member's health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

06/2018	New Policy adopted BCBSA MPRM 2.01.83. External feedback received. Corporate Policy Updated with additional references 31-32. Policy statement updated to include medical necessity criteria for Vertebral Body Tethering.
06/2019	Policy reviewed vertebral tethering for treatment for scoliosis is considered investigational.

07/2020	Reference List removed as Policy based upon references in BCBSA Policy. References 4 and 5 added. References reviewed and updated. No change in policy statement.
07/2021	Adaptive Maintenance: Effective 07/01/2021 codes 0656T & 0657T added as investigational.
07/2021	Policy reviewed. Minor changes to align with MPRM policy. Minor formatting changes. No change to Policy Statement.
08/2022	Policy reviewed, updated references. No changes to policy statement.
08/2023	Policy reviewed. Minor grammatical changes. Updated summary section to reflect most up to date medical literature. Updated references. No changes to policy statement.
12/2023	Adaptive Maintenance Effective 01/01/2024 added codes 22836, 22837, 22838 as investigational.
08/2024	Policy reviewed. No changes to policy statement. References updated.

Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by BCBSVT Medical Directors

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Attachment I
Code Table & Instructions

Code Type	Number	Description	Policy Instructions
The following codes are considered medically necessary when applicable criteria have been met.			
HCPCS	L1000	Cervical-thoracic-lumbar-sacral orthosis (CTLSO) (Milwaukee), inclusive of furnishing initial orthosis, including model	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1001	Cervical thoracic lumbar sacral orthosis, immobilizer, infant size, prefabricated, includes fitting and adjustment	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1005	Tension based scoliosis orthosis and accessory pads, includes fitting and adjustment	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1006	Scoliosis orthosis, sagittal-coronal control provided by a rigid lateral frame, extends from axilla to trochanter, includes all accessory pads, straps and interface, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1010	Addition to cervical-thoracic-lumbar-sacral orthosis (CTLSO) or scoliosis orthosis, axilla sling	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1020	Addition to CTLSO or scoliosis orthosis, kyphosis pad	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1025	Addition to CTLSO or scoliosis orthosis, kyphosis pad, floating	Prior Approval is Required if purchase price is greater than dollar threshold

Code Type	Number	Description	Policy Instructions
HCPCS	L1030	Addition to CTLSO or scoliosis orthosis, lumbar bolster pad	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1040	Addition to CTLSO or scoliosis orthosis, lumbar or lumbar rib pad	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1050	Addition to CTLSO or scoliosis orthosis, sternal pad	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1060	Addition to CTLSO or scoliosis orthosis, thoracic pad	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1070	Addition to CTLSO or scoliosis orthosis, trapezius sling	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1080	Addition to CTLSO or scoliosis orthosis, outrigger	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1085	Addition to CTLSO or scoliosis orthosis, outrigger, bilateral with vertical extensions	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1090	Addition to CTLSO or scoliosis orthosis, lumbar sling	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1100	Addition to CTLSO or scoliosis orthosis, ring flange, plastic or leather	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1110	Addition to CTLSO or scoliosis orthosis, ring flange, plastic or leather, molded to patient model	Prior Approval is Required if purchase price is greater than dollar threshold

Code Type	Number	Description	Policy Instructions
HCPCS	L1120	Addition to CTLSO, scoliosis orthosis, cover for upright, each	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1200	Thoracic-lumbar-sacral-orthosis (TLSO), inclusive of furnishing initial orthosis only	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1210	Addition to TLSO, (low profile), lateral thoracic extension	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1220	Addition to TLSO, (low profile), anterior thoracic extension	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1230	Addition to TLSO, (low profile), Milwaukee type superstructure	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1240	Addition to TLSO, (low profile), lumbar derotation pad	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1250	Addition to TLSO, (low profile), anterior ASIS pad	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1260	Addition to TLSO, (low profile), anterior thoracic derotation pad	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1270	Addition to TLSO, (low profile), abdominal pad	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1280	Addition to TLSO, (low profile), rib gusset (elastic), each	Prior Approval is Required if purchase price is greater than dollar threshold

Code Type	Number	Description	Policy Instructions
HCPCS	L1290	Addition to TLSO, (low profile), lateral trochanteric pad	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1300	Other scoliosis procedure, body jacket molded to patient model	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1310	Other scoliosis procedure, postoperative body jacket	Prior Approval is Required if purchase price is greater than dollar threshold
HCPCS	L1499	Spinal orthosis, not otherwise specified	Prior Approval is Required
CPT®	0656T	Vertebral body tethering, anterior; up to 7 vertebral segments	Investigational
CPT®	0657T	Vertebral body tethering, anterior; up to 8 or more vertebral segments	Investigational
CPT®	22836	Vertebral body tethering; up to 7 vertebral segments	Investigational
CPT®	28837	Vertebral body tethering; 8 or more vertebral segments	Investigational
CPT®	22838	Revision, replacement, or removal of vertebral body tethering	Investigational
CPT®	22899	Unlisted procedure, spine There is no specific code for the insertion of vertebral staples or vertebral tethering	Will suspend for Medical Review