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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
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Next Review: 07/2021
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Description/Summary

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

For individuals who have juvenile or adolescent idiopathic scoliosis at high risk of progression who receive a conventional rigid brace, the evidence includes a high - quality randomized controlled trial (RCT). Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Bracing has been considered the only option to prevent curve progression in juvenile or adolescent idiopathic scoliosis. The highest quality study on bracing is a 2013 large National Institutes of Health–sponsored trial that, using both randomized and observational arms, compared bracing to watchful waiting. This trial was stopped after interim analysis because of a significant benefit of bracing for the prevention of spinal fusion. Based on evidence of efficacy, lack of alternative treatment options, professional society recommendations, and potential to prevent the need for a more invasive procedure, bracing with a conventional rigid brace is considered an option for the treatment of scoliosis in patients with a high risk of curve progression.

Curves have a high risk of progression when they measure 25° or more and spinal growth has not been completed, or when a 20° curve is progressively worsening and at least 2 years of growth remain. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have juvenile or adolescent idiopathic scoliosis at high risk of

progression who receive a microcomputer-controlled brace, the evidence includes a pilot RCT. Relevant outcomes are 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 the effects of the technology on health outcomes.

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

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive vertebral body stapling, 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. 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 study with larger sample sizes and longer follow-up is needed to evaluate the safety and efficacy of this procedure. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive vertebral body tethering, the evidence includes case series. The relevant outcomes are change in disease status, morbid events, QOL, 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 case series reporting 1-year follow-up in 32 patients and 2-year follow-up in 11 patients. Additional studies, with a larger number of total subjects and longer follow-up, are needed to evaluate the safety and efficacy of this surgical procedure. The evidence is insufficient to determine the effects of the technology on health outcomes.

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. Interventions for Progressive Scoliosis, MPRM #2.01.83, May 2020. Reviewed: July 2020.
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):202-9
3. Braun, Comparison of Two Fusionless Scoliosis Surgery Methods in the Treatment of Progressive Adolescent Idiopathic Scoliosis: A Preliminary Study, Dartmouth Orthopedic Journal, 2014, Volume 1.
4. 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.
5. 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.

Eligible providers

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

Approved by BCBSVT Medical Directors Date Approved

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Chief Medical Officer

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FAAP Senior Medical Director

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	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
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
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
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®	22899	Unlisted procedure, spine There is no specific code for the insertion of vertebral staples or vertebral tethering	Will suspend for Medical Review