

Evidence Based Guideline

Interventions for Progressive Scoliosis

File Name: interventions_for_progressive_scoliosis
Origination: 7/2010
Last CAP Review: 2/2012
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Last Review: 2/2012

Description of Procedure or Service

Orthotic bracing attempts to slow curve progression and reduce the need for fusion surgery in patients with progressive scoliosis. Recently, fusionless surgical procedures (e.g., vertebral body stapling and implantation of vertical titanium growing rods) have been evaluated as alternatives to bracing to slow or correct curve progression in pediatric patients with scoliosis.

Background

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

Bracing is used in an attempt to reduce the need for spinal fusion by slowing or preventing further progression of the curve during rapid growth. Commonly used brace designs include the Milwaukee, Wilmington, Boston, Charleston, and Providence orthoses. The longest clinical experience is with the Milwaukee cervical-thoracic-lumbar-sacral orthosis (CTLSO). Thoracic-lumbar-sacral orthoses (TLSO), such as the Wilmington and Boston braces, are intended to improve tolerability and compliance for extended (over 18 hour) wear, and are composed of lighter-weight plastics with a low-profile (underarm) design. The nighttime Charleston and Providence braces are based on the theory that increased corrective forces will reduce the needed wear time (i.e., daytime), thereby lessening social anxiety and improving compliance. Braces that are more flexible than TLSOs or nighttime braces, such as the SpineCor, are also being evaluated. The SpineCor is composed of a thermoplastic pelvic base with stabilizing and corrective bands across the upper body.

Fusionless surgical procedures such as vertebral body stapling are being evaluated as an alternative to bracing. It is hoped that fusionless procedures may improve the curve as well as prevent its progression, maintain spine mobility following correction, and provide an effective treatment option for patients who are non-compliant or refuse to wear a brace. In the current stapling procedure, nickel-titanium alloy staples with shape memory are applied to the convex (outer) side of the curve. The shape memory allows the prongs to be straight when cooled and clamp down into the bone when the staple returns to body temperature. The goal of vertebral stapling is to unilaterally reduce the rate of spine growth, thus allowing the other side to “catch up”. The memory shape staple was tested in a goat model of scoliosis for safety and efficacy prior to its use in humans. A concern is that stapling spans the flexible discs, and the immobilized discs may be subject to degeneration. The vertical expandable prosthetic titanium rib (VEPTR) is also being explored for treatment of infantile and juvenile scoliosis that has advanced beyond

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45°. Use of the VEPTR requires expansion surgery every 4-6 months as growth occurs and may be replaced as needed. Anterolateral tethering and external fixation devices are also being evaluated.

Regulatory Status

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

Staples, using a shape memory nickel-titanium alloy, have 510(k) clearance from the FDA for a variety of indications for bone fixation. For example, Nitinol staples (Sofamor Danek, Memphis 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.

VEPTR has received approval from the FDA under a humanitarian device exemption (HDE). The FDA review noted that the device is indicated for the treatment of thoracic insufficiency syndrome (TIS) in skeletally immature patients. This review also indicated that the device should not be used in patients younger than 6 months.

Please also refer to the BCBSNC Medical Policy titled, “Orthotics”

*****Note: This Evidence Based Guideline is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

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A cervical-thoracic-lumbar-sacral or thoracic-lumbar-sacral orthosis may be appropriate for the treatment of scoliosis in juvenile and adolescent patients at high-risk of progression which meets the following criteria:

Idiopathic spinal curve angle between 25° and 40°; AND

Spinal growth has not been completed (Risser grade 0-3; no more than 1 year post-menarche in females)

OR

Idiopathic spinal curve angle greater than 20°; AND

There is documented increase in the curve angle; AND

At least 2 years growth remain (Risser grade 0 or 1; pre-menarche in females)

Medical Evidence regarding Interventions for Progressive Scoliosis indicates it is not recommended in the following situations

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

Vertebral body stapling for the treatment of scoliosis is not recommended.

Use of the vertical expandable titanium prosthetic rib (with or without expansion thoracoplasty) for the treatment of scoliosis in patients without thoracic insufficiency is not recommended.

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Benefits Application

This guideline relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Billing/Coding/Physician Documentation Information

This guideline may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: L1000-L1499

There is no specific CPT code for the insertion of vertebral body staples or vertical expandable titanium prosthetic ribs. The procedure would most likely be reported with the unlisted code 22899.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.83, 5/13/10

Senior Medical Director review 5/31/2010

Specialty Matched Consultant Advisory Panel 2/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.83, 5/12/11

Scoliosis Research Society. Adolescent Idiopathic Scoliosis 2011. Retrieved on June 2, 2011 from <http://www.srs.org/professionals/education/adolescent/idiopathic/treatment.php>.

American Academy of Orthopaedic Surgeons. Idiopathic Scoliosis in Children and Adolescents. Your Orthopaedic Connection 2010. Retrieved on June 2, 2011 from <http://orthoinfo.aaos.org/topic.cfm?topic=A00353>.

Specialty Matched Consultant Advisory Panel review 2/2012

Policy Implementation/Update Information

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| 7/6/10 | New Evidence Based Guideline. Cervical-thoracic-lumbar-sacral or thoracic-lumbar-sacral orthosis may be appropriate for the treatment of scoliosis in juvenile and adolescent patients at high-risk of progression. Vertebral Body Stapling and the Vertical Expandable Titanium Prosthetic Rib (with or without expansion thoracoplasty), are not recommended for treatment of Scoliosis. Senior Medical Director review 5/2010. (mco) |
| 3/15/11 | Specialty Matched Consultant Advisory Panel review 2/2011. References updated. (mco) |
| 7/19/11 | References updated. No changes to guideline. Added the following statement to the "Description" section: "Anterolateral tethering and external fixation devices are also being evaluated." (mco) |
| 3/20/12 | Specialty Matched Consultant Advisory Panel review 2/2012. No changes to guideline statements. (mco) |

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.