Medical Policy
Interventions for Progressive Scoliosis

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Policy Number: 550
BCBSA Reference Number: 2.01.83
NCD/LCD: N/A

Related Policies
• Vertical Expandable Prosthetic Titanium Rib, #305
• DNA-Based Testing for Adolescent Idiopathic Scoliosis, #545

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members

A 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 which meets the following criteria:
• Idiopathic spinal curve angle between 25 and 40 degrees; 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 degrees; 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).

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.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Service</th>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>No</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>No</td>
</tr>
<tr>
<td>Medicare HMO BlueSM</td>
<td>No</td>
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<tr>
<td>Medicare PPO BlueSM</td>
<td>No</td>
</tr>
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</table>

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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</thead>
<tbody>
<tr>
<td>L1000</td>
<td>Cervical-thoracic-lumbar-sacral orthotic (CTLSO) (Milwaukee), inclusive of furnishing initial orthotic, including model</td>
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<tr>
<td>L1001</td>
<td>Cervical-thoracic-lumbar-sacral orthotic (CTLSO), immobilizer, infant size, prefabricated, includes fitting and adjustment</td>
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<tr>
<td>L1200</td>
<td>Thoracic-lumbar-sacral orthotic (TLSO), inclusive of furnishing initial orthotic only</td>
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<tr>
<td>L1300</td>
<td>Other scoliosis procedure, body jacket molded to patient model</td>
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<tr>
<td>L1310</td>
<td>Other scoliosis procedure, postoperative body jacket</td>
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Description

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 degrees 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 degrees 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 (more than 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 (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. All cervical-thoracic-lumbar-sacral or thoracic-lumbar-sacral orthosis are considered investigational regardless of the commercial name, the
manufacturer or FDA approval status except when used for the medically necessary indications that are consistent with the policy statement.

Fusionless surgical procedures, such as vertebral body stapling, are being evaluated as an alternative to bracing. It is hoped that fusionless procedures 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.

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 Tenn.) 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. All vertebral body stapling systems are considered investigational regardless of the commercial name, the manufacturer or FDA approval status.

Summary
Orthotic bracing attempts to slow curve progression and reduce the need for fusion surgery in patients with progressive scoliosis. 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.

Bracing has been considered the only available option to prevent curve progression in juvenile or adolescent idiopathic scoliosis, although efficacy has not been consistently demonstrated when compared with watchful waiting. The highest quality study on bracing is a large National Institute of Health-sponsored trial from 2013 that has both randomized and observational arms comparing bracing versus watchful waiting. This study 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 may be considered medically necessary 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.

There is a small body of published evidence on surgical interventions for preventing curve progression in juvenile and adolescent scoliosis. Vertebral stapling with memory shape staples has been investigated for patients with curves between 20° and 35°. The evidence to date, which consists of 6 publications with limited follow-up from a single center that developed the technique, and 2 small case series from other institutions, is insufficient to conclude that vertebral stapling maintains or improves the curve, or that stapling reduces the rate of subsequent spinal fusion. Vertebral body tethering, which was developed by the same investigators as the vertebral stapling technique, has been evaluated for thoracic curves greater than 35°. There is very limited evidence to date on this technique, with case series reporting 1-year follow-up in 32 patients and 2-year follow-up in 11 patients. Additional studies from other centers, with a larger number of total subjects and longer follow-up, are needed to evaluate the safety and efficacy of these surgical procedures.

Policy History

<table>
<thead>
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<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>12/2016</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>10/2015</td>
<td>BCBSA National medical policy review.</td>
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6/2013 New references from BCBSA National medical policy.
5/1/12 New policy describing ongoing coverage and non-coverage.

Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References