Subject: Anterior Vertebral Body Tethering

Background: Scoliosis is a spinal deformity characterized by lateral and rotational curvature of the spine. The most common form of scoliosis is idiopathic scoliosis, which occurs in approximately 3 percent of individuals under age 16, most often in the early adolescent years. The majority of adolescents do not display progressive curves, but a subset of individuals with adolescent idiopathic scoliosis may exhibit a rapid progression of curvature. Prevention and/or correction of curve progression caused by idiopathic scoliosis includes non-operative (e.g. external bracing, scoliosis specific exercises) and surgical (e.g. spinal fusion, growing rods, anterior vertebral body tethering) options.

The primary goal of nonoperative treatment of adolescent idiopathic scoliosis (AIS) is to prevent curve progression. For AIS individuals with growth remaining and a curve magnitude between 25 and 45 degrees, conservative treatment with a rigid thoracolumbosacral orthosis (TLSO) is indicated. Brace wear for at least 13 hours per day is indicated until skeletal maturity to limit curve progression.

Vertebral body tethering (VBT) is a non-fusion surgical option for the treatment of idiopathic scoliosis. To date, the FDA has given humanitarian device exemption approval for one such device, The Tether™ - Vertebral Body Tethering System. Anchors and vertebral body screws are placed on the convex side of the spinal curve and the tether, a flexible tensioning cord made of synthetic polymer, is then secured along the convex side of the vertebrae. The tether provides tension across the convex side which partially straightens the spinal curvature. After surgery, the tether continues to correct the spinal curvature as the adolescent continues to grow.

Authorization: Prior authorization is required for vertebral body tethering procedures requested for members enrolled in commercial (HMO, POS, and PPO) products.

Policy and Coverage Criteria:
The Plan considers anterior vertebral body tethering as medically necessary when documentation confirms ALL of the following:

1. Idiopathic scoliosis of thoracic and/or lumbar spine
2. Radiographic imaging confirms the following:
   a. Major Cobb angle of 35 to 65 degrees and osseous structure is dimensionally adequate to accommodate screw fixation; and
   b. Cobb angle decreases in magnitude below 30 degrees on bending films
3. Progressive curvature that has not responded to one of the following conservative treatment options:
   a. Failed external bracing defined as curvature progression greater than 5 degrees despite external brace wear; or
   b. External bracing is not/no longer indicated secondary to skeletal maturity or severe scoliosis (greater than 45 degrees)
   c. Documentation of intolerance to external brace wear as prescribed despite reasonable efforts to improve brace fit, comfort, and brace wear compliance
4. Radiographic imaging confirms skeletal immaturity, defined as at least one of the following:
   a. Risser grade 0-2 and under; or
   b. Sanders Skeletal Maturation Stage (SMS) less than 5
5. Tethering device must be FDA approved; AND
6. Qualified orthopedic/spine specialist trained and with experience in VBT technique has completed in person evaluation and has documented member's suitability for VBT and the rationale for VBT procedure
7. Vertebral body tethering procedure will be performed by qualified orthopedic/spine specialist trained and with experience in VBT technique at a facility with appropriate experience and expertise in VBT procedure

**Exclusions:** The Plan considers vertebral body tethering as experimental and investigational for all other indications. In addition, The Plan does not cover:
- Skeletal maturity achieved with no spinal growth remaining
- Congenital scoliosis
- Hyperkyphosis (40-50 degrees)
- Kyphosis in the lumbar spine or at the thoracolumbar junction
- Vertebral or chest wall deformity malformation in addition to scoliosis (e.g., pectus excavatum, severe rib prominence defined as trunk rotation greater than 20 degrees as measured by a scoliometer)
- Previous surgery at the spinal levels where scoliotic curve(s) exist, unless related to prior tether correction
- Member is non-ambulatory
- Altered muscle function as a result of progressive neuromuscular disease

**Coding:**
Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Description</th>
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<tr>
<td>0656T</td>
<td>Vertebral body tethering, anterior; up to 7 vertebral segments</td>
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<tr>
<td>0657T</td>
<td>Vertebral body tethering, anterior; up to 8 or more vertebral segments</td>
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**Billing Guidelines:**
Member’s medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

**References:**
2. Joint SRS/POSNA Position Statement on Payor Coverage for Anterior Fusionless Scoliosis
3. Technologies for Immature Patients with Idiopathic Scoliosis


Summary of Changes:

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
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<tbody>
<tr>
<td>2/22</td>
<td>New Policy</td>
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Approved by Medical Policy Committee: 03/16/2022
Approved by Clinical Policy Operational Committee: 3/22
Policy Effective Date: 05/01/2022
Initiated: 2/2022