Description:
The X-STOP Interspinous Process Decompression System is a minimally invasive surgical procedure designed to alleviate painful symptoms of lumbar spinal stenosis. It is a titanium implant that fits between the spinous processes of the vertebrae in the lumbar spine. The X-STOP is designed to remain permanently in place without attaching to the bone or ligaments in the back. It consists of two parts: a spacer assembly that fits between the spinous processes and a wing assembly that is designed to prevent the implant from moving. The X-STOP is designed to reduce extension of the spine in the affected area and thereby prevent motions that induce back pain.

The Coflex® Interlaminal Technology implant (Paradigm Spine) was approved by the FDA in 2012 (P110008). It is a single-piece U-shaped titanium alloy dynamic stabilization device with pairs of wings that surround the superior and inferior spinous processes. This device was previously called the Interspinous U. The Coflex® is indicated for use in 1- or 2-level lumbar stenosis from L1-L5 in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 6 months of non-operative treatment. The Coflex® is intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s). Data has demonstrated that spinous process fractures can occur with Coflex® implantation. ExtendSure and CoRoent (both from NuVasive) were launched in Europe in 2005 and 2006. The NL-Prow™ (Non-Linear Technologies), Aperius® (Medtronic Spine), and Falena® (Mikai) devices are in trials in Europe.

Criteria: CWQI HCS-0041A

I. Moda Health will cover X-STOP to plan limitations when all of the following criteria are met:
A. The member is age 50 or older; and
B. Presence of neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis at no more than two levels (x-ray, CT or MRI is required); and
C. Member has no more than grade I spondylolisthesis or up to 20º of scoliosis; and
D. Member experiences moderately impaired physical function with relief of symptoms of leg, buttock or groin pain (with or without back pain) with spinal flexion or sitting; and
E. Member has failed 6 months of non-operative conservative treatment (e.g. nonsteroidal anti-inflammatory drugs (NSAIDS), muscle relaxants, physical therapy, epidural steroid injections); and
F. The X-STOP is planned for one or two lumbar levels in patients in whom operative treatment is indicated at no more than two levels.

II. CoFlex®, an interspinous distraction device is NOT covered as it is considered investigational as a treatment for ALL of the following:
   i. Neurogenic intermittent claudication.
   ii. As a stabilization device following decompressive surgery

Limitations:

I. X-STOP is contraindicated and will not be covered if any of the following conditions apply:
   A. Allergy to titanium or titanium alloy
   B. Spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable such as:
      1. Significant instability of the lumbar spine such as spondylolisthesis greater than grade 1.0; or
      2. An ankylosed segment at the affected level(s); or
      3. Acute fracture of the spinous process or pars interarticularis; or
      4. Significant scoliosis (greater than 20º)
   C. Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction
   D. Severe osteoporosis, as defined by a bone mineral density in the spine or hip greater than 2.5 SD, with evidence of fragility fracture(s)
   E. Active systemic infection or infection localized to the site of implantation
   F. L5/S1 stenosis (the S1 spinous process is too small)

II. The FDA lists the following contraindications to use of the CoFlex®:
   a. Prior fusion or decompressive laminectomy at any index lumbar level.
   b. Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (e.g., compression fracture).
   c. Severe facet hypertrophy that requires extensive bone removal which would cause instability.
   d. Grade II or greater spondylolisthesis.
   e. Isthmic spondylolisthesis or spondylolysis (pars fracture).
   f. Degenerative lumbar scoliosis (Cobb angle of greater than 250 degrees).
   g. Osteoporosis.
   h. Back or leg pain of unknown etiology.
   i. Axial back pain only, with no leg, buttock, or groin pain.
   j. Morbid obesity defined as a body mass index >40.
   k. Active or chronic infection - systemic or local.
I. Known allergy to titanium alloys or magnetic resonance imaging (MRI) contrast agents.

m. Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction.

Information to be Submitted with Pre-Authorization Request:

- Medical records from the treating physician including subjective and objective findings
- Imaging reports
- Conservative treatment attempts
- Prior history of spine surgery or other treatment

Applicable CPT Codes: Not covered

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<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0171T</td>
<td>Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar: single level</td>
</tr>
<tr>
<td>0172T</td>
<td>Each additional level (list separately in addition to primary procedure)</td>
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<tr>
<td>C1821</td>
<td>Interspinous process distraction device (implantable)</td>
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Applicable ICD-9 Codes:

<table>
<thead>
<tr>
<th>ICD-9 Code</th>
<th>Diagnosis</th>
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<tbody>
<tr>
<td>344.60</td>
<td>Cauda equina syndrome</td>
</tr>
<tr>
<td>344.61</td>
<td>Cauda equina syndrome with neurogenic bladder</td>
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<tr>
<td>733.00</td>
<td>OSTEOPOROSIS UNSPECIFIED</td>
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<tr>
<td>733.01</td>
<td>SENILE OSTEOPOROSIS</td>
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<td>733.02</td>
<td>IDIOPATHIC OSTEOPOROSIS</td>
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<td>733.03</td>
<td>DISUSE OSTEOPOROSIS</td>
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<td>733.09</td>
<td>OTHER OSTEOPOROSIS</td>
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<td>737.30</td>
<td>Scoliosis [and kyphoscoliosis], idiopathic</td>
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<td>737.31</td>
<td>Resolving infantile idiopathic scoliosis</td>
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<td>737.32</td>
<td>Progressive infantile idiopathic scoliosis</td>
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<td>737.33</td>
<td>Scoliosis due to radiation</td>
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<td>737.34</td>
<td>Thoracogenic scoliosis</td>
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<td>737.39</td>
<td>Other kyphoscoliosis and scoliosis</td>
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<td>738.4</td>
<td>Acquired Spondylolisthesis</td>
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<tr>
<td>754.2</td>
<td>Congenital musculoskeletal deformity of spine</td>
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<td>756.10</td>
<td>Congenital anomaly of spine, unspecified</td>
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<td>756.12</td>
<td>Congenital spondylolisthesis</td>
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Applicable ICD-10 Codes:

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<th>ICD-10 Code</th>
<th>Diagnosis</th>
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<tr>
<td>G83.4</td>
<td>Cauda equina syndrome</td>
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<td>M41.00</td>
<td>Infantile idiopathic scoliosis, site unspecified</td>
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<td>M41.20</td>
<td>Other idiopathic scoliosis, site unspecified</td>
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<td>M41.30</td>
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<td>M41.80</td>
<td>Other forms of scoliosis, site unspecified</td>
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<td>M41.9</td>
<td>Scoliosis, unspecified</td>
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<td>M43.00</td>
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<td>M43.10</td>
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<td>M81.0</td>
<td>Age-related osteoporosis without current pathological fracture</td>
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<td>M81.8</td>
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<td>M96.5</td>
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<td>Q76.3</td>
<td>Congenital scoliosis due to congenital bony malformation</td>
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<td>Q76.425</td>
<td>Congenital lordosis, thoracolumbar region</td>
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<td>Q76.426</td>
<td>Congenital lordosis, lumbar region</td>
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<td>Q76.427</td>
<td>Congenital lordosis, lumbosacral region</td>
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<td>Q76.428</td>
<td>Congenital lordosis, sacral and sacrococcygeal region</td>
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</tbody>
</table>

Review Date | Revisions                                                                 | Effective Date |
-------------|---------------------------------------------------------------------------|----------------|
04/2013       | Annual Review: Added table with review date, revisions, and effective date. | 04/24/2013     |
04/2014       | Annual Review: No changes                                                 | 04/30/2014     |
04/2015       | Annual Review: Added Section II regarding Coflex considered E/I           | 04/25/2015     |
07/2015       | Added ICD-9 and ICD-10 codes                                               | 7/2015         |

References:

- Asgarzadie F, Khoo LT. Minimally invasive operative management for lumbar spinal


Moda Health
Medical Necessity Criteria

Subject: Interspinous Process Decompression System (e.g. X-STOP)

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Origination Date: 9/08

Revision Date(s): 7/10, 7/11, 6/12, 04/13, 04/14, 04/15

Developed By: Medical Criteria Committee

- Orthopedic Spine Surgery Specialist
- Physician Advisors
- FDA U.S. Food and Drug Administration, coflex Interlaminar Technology – P110008, Summary of Safety and Effectiveness Data; Issued October 17, 2012; Updated November 8, 2012
- Coflex Interlaminar Stabilization, Your Back and Leg Pain, Paradigm Spine LLC
- BCBS Guidelines
- AETNA Criteria
- Stephen H. Hochschuler, M.D., Spine-health, Interspinous Process Spacers; Published 03/26/2007
- BMJ 2013; 347 doi: http://dx.doi.org/10.1136/bmj.f6415, (Published 14 November 2013)