Interspinous Process Decompression System
(X-Stop®, Coflex®, Flexus™, et al)

Date of Origin: 09/2008  Last Review Date: 07/26/2017  Effective Date: 07/26/2017


Developed By: Medical Necessity Criteria Committee

I. 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. Initial randomized studies showed improvement with the X-STOP device with higher level of physical function. Later studies demonstrated design flaws in the initial study with control group and study group patients lost to follow-up and patient in both groups who went on to have laminectomies. Two of the primary authors in the initial study were noted to have a conflict of interest. Further studies demonstrated initial improvement but lacked long-term outcomes. Numerous additional interspinous devices have been marketed but most are not FDA approved and considered investigational.

The Coflex® Interlaminar 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. Several studies have shown initial
improvement however there is a lack of data on durability; well-designed studies with more subjects and longer follow-up are needed.

II. Criteria: CWQI HCS-0024
A. Moda Health considers interspinous distraction devices (i.e. X-STOP®) and interlaminar stabilization devices (i.e. Coflex®) investigational. Evidence based literature has not demonstrated that interspinous decompression devices or interlaminar stabilization systems provide significant advantage over surgical decompression and/or fusion.
B. Interspinous decompression devices and interlaminar stabilization devices include but are not limited to ALL of the following:
   a. Aperius™ - PercLID™ System
   b. Coflex® Interlaminar Stabilization Device
   c. DIAM™ Spine Stabilization System
   d. Falena® Interspinous Decompression Device
   e. FLEXUS™
   f. Helifix® Interspinous Spacer System
   g. In-Space
   h. NL-Prow™ Interspinous Spacer System
   i. Stenofix
   j. Superion® Interspinous Spacer System
   k. Wallis® System
   l. X-STOP® Interspinous Process Decompression (IPD®) System (discontinued in 2015)
   m. X-STOP® PEEK (Polyetheretherketone)

III. Information Submitted with the Prior Authorization Request:
   1. Chart notes for spine procedure requests should include any devices to be used

IV. CPT or HCPC codes NOT covered:

<table>
<thead>
<tr>
<th>Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0171T</td>
<td>Deleted code 1/1/17 - 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>Deleted code 1/1/17 - Each additional level (list separately in addition to primary procedure)</td>
</tr>
<tr>
<td>22867</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>22868</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>22869</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level</td>
</tr>
<tr>
<td>22870</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>C1821</td>
<td>Interspinous process distraction device (implantable)</td>
</tr>
<tr>
<td>22899</td>
<td>Unlisted procedure, spine</td>
</tr>
</tbody>
</table>

V. Annual Review History

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Revisions</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/2013</td>
<td>Annual Review: Added table with review date, revisions, and effective date.</td>
<td>04/24/2013</td>
</tr>
<tr>
<td>04/2014</td>
<td>Annual Review: No changes</td>
<td>04/30/2014</td>
</tr>
<tr>
<td>04/2015</td>
<td>Annual Review: Added Section II regarding Coflex considered E/I</td>
<td>04/25/2015</td>
</tr>
<tr>
<td>07/2016</td>
<td>Annual Review: X-STOP changed to investigational – combined interspinous distraction devices and interlaminar stabilization devices into one criteria. Added brand names of different devices.</td>
<td>10/1/2016</td>
</tr>
<tr>
<td>072017</td>
<td>Annual Review: Updated the codes, updated to new template</td>
<td>07/26/2017</td>
</tr>
</tbody>
</table>

VI. References


33. Orthopedic Spine Surgery Specialist
34. Physician Advisors
35. FDA U.S. Food and Drug Administration, coflex Interlaminar Technology – P110008, Summary of Safety and Effectiveness Data; Issued October 17,2012; Updated Nove meber 8, 2012
36. Coflex Interlaminar Stabilization, Your Back and Leg Pain, Paradigm Spine LLC
37. BCBS Guidelines
38. AETNA Criteria
40. BMJ 2013; 347 doi: http://dx.doi.org/10.1136/bmj.f6415, (Published 14 November 2013)

Appendix 1 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.
Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

<table>
<thead>
<tr>
<th>Jurisdiction(s): 5, 8</th>
<th>NCD/LCD Document (s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

**NCD/LCD Document (s):**

Medicare Part B Administrative Contractor (MAC) Jurisdictions

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
</tr>
</thead>
<tbody>
<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
</tbody>
</table>