Interspinous Decompression and Interlaminar Stabilization Devices
(Spacers)

Date of Origin: 09/2008  
Last Review Date: 04/22/2021  
Effective Date: 05/01/2021


Developed By: Medical Necessity Criteria Committee

I. Description

Lumbar spinal stenosis (LSS) results in narrowing of the spinal canal, which may lead to compression of the thecal sac and neural elements. The LSS is the most common cause of lumbar neurogenic claudication, a syndrome that may be characterized by radiating pain down one or both legs during ambulation. Investigators have sought less invasive ways to stabilize the spine and reduce the pressure on affected nerve roots, including interspinous and interlaminar implants (spacers). Lumbar interspinous process decompression (IPD), also known as interspinous distraction or posterior spinal distraction, and interlaminar stabilization have been proposed as minimally invasive alternatives to laminectomy and fusion.

The Interspinous process decompression is a minimally invasive surgical procedure designed to alleviate painful symptoms of lumbar spinal stenosis in those patients who do not respond to conservative, nonsurgical treatment. The procedure involves placing interspinous process decompression spacers between the spinous processes of the symptomatic lumbar disc levels. The spacers can be implanted at one or two lumbar levels and are designed to remain in place without being permanently affixed to the bone or ligamentous structures of the spine. Numerous interspinous devices have been marketed but most are not FDA approved and considered investigational.

Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization following decompressive surgery or as an alternative to decompression surgery. The spacers have two sets of wings that are placed around the inferior and superior spinous processes (they may also be referred to as interlaminar implants). They aim to restrict painful motion while otherwise enabling normal motion.

Overall, the spacer devices stabilize or distract the adjacent lamina and/or spinous processes and restrict extension in patients with lumbar spinal stenosis and neurogenic claudication.
II. Criteria: CWQI HCS-0041A

A. Moda Health considers interspinous distraction devices and interlaminar stabilization devices 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 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) (withdrawn from market)

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>
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<th>Codes</th>
<th>Description</th>
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<tbody>
<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>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>
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<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>
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<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>
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<tr>
<td>C1821</td>
<td>Interspinous process distraction device (implantable)</td>
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<td>22899</td>
<td>Unlisted procedure, spine</td>
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V. Annual Review History

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Revisions</th>
<th>Effective Date</th>
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<tbody>
<tr>
<td>04/2013</td>
<td>Annual Review: Added table with review date, revisions, and effective date.</td>
<td>04/24/2013</td>
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<td>04/2014</td>
<td>Annual Review: No changes</td>
<td>04/30/2014</td>
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<tr>
<td>04/2015</td>
<td>Annual Review: Added Section II regarding Coflex considered E/I</td>
<td>04/25/2015</td>
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<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>
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<td>07/2017</td>
<td>Annual Review: Updated the codes, updated to new template</td>
<td>07/26/2017</td>
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<tr>
<td>04/2019</td>
<td>Annual Review: Updated the title, background information</td>
<td>05/01/2019</td>
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<td>04/2020</td>
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<td>05/01/2020</td>
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<tr>
<td>04/2021</td>
<td>Annual Review: No changes</td>
<td>05/01/2021</td>
</tr>
</tbody>
</table>

VI. References


17. Physician Advisors

18. 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

19. Coflex Interlaminar Stabilization, Your Back and Leg Pain, Paradigm Spine LLC


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>
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<tr>
<th>Jurisdiction(s): 5, 8</th>
<th>NCD/LCD Document (s):</th>
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NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions

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<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
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