GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

SCOPE
X Professional
X__ Facility

DESCRIPTION
Lumbar spinal stenosis (LSS) is a narrowing of the spinal canal that compresses the neural elements in the lower back. The resulting pain, weakness, and/or numbness in the legs is known as neurogenic intermittent claudication. Symptoms are relieved by postural flexion, such as by sitting, squatting, or lying with bent legs. Symptoms can range from mild to severe, and can affect patient mobility and quality of life. The incidence of LSS in the United States is approximately 10% of the population. LSS is mainly related to degenerative changes, and it is estimated that approximately 400,000 Americans, most aged 60 years or older, are afflicted. First-line treatment for symptomatic LSS includes conservative treatments such as rest, nonsteroidal anti-inflammatory drugs, muscle relaxants, corset use, physical therapy, and epidural steroid injections. If symptoms do not respond adequately to conservative treatments, open surgical treatments such as laminectomy or spinal fusion may be required, which can have serious complications and can be particularly risky for elderly patients.

Interspinous and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension to reduce pain in patients with lumbar spinal stenosis and neurogenic claudication.

- Interspinous spacers are small devices implanted between the vertebral spinous processes. After the implantation, the device is opened or expanded to distract (open) the neural foramina and decompress the nerves. Interspinous implants are intended to restrict painful motion while otherwise enabling normal motion.
- Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization either following decompression surgery or as an alternative to decompression surgery.

A number of Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers) have been approved by the U.S Food and Drug Administration (FDA)

Interspinous Fixation Devices (not an all-inclusive list)
- Affix II and Affix II Mini Spinous Process Plating System (NuVasive)
- Aileron Interspinous Fixation System (Life Spine)
- Aspen MIS Fusion System (Biomet)
- Aspen Spinous Process Fixation System (Lanx)
- Axle (X-Spine)
- BacFuse (Pioneer Surgical)
- Benefix Interspinous Fixation System
- Biomet Aspen fusion system
• BridgePoint (Alphatec)
• CD Horizon Spire Fixation System (Medtronic Sofamor Danek)
• Coflex-F (Paradigm Spine)
• Inspan (Spine Frontier)
• Minuteman Interspinous Interlaminar Fusion Device (Spinal Simplicity)
• PrimaLOK SP (OsteoMed)
• Octave (Life Spine)
• StabiLink MIS Interspinous Fixation Device (Southern Spine)
• SP-Fix Spinous Process Fixation System (Globus Medical)

Interspinous and Interlaminar Distraction Devices (not an all-inclusive list)
• Aperius PercLID System (Kyphon/ Medtronic Spine)
• Coflex Interlaminar Technology Implant (Paradigm Spine)
• CoRoent Extensure (Nuvasive)
• DIAM Spinal Stabilization System (Medtronic Sofamor Danek)
• Extensure (Nuvasive)
• FLEXUS (Globus Medical)
• Falena Interspinous Decompression Device (Mikai Spine)
• Helifix Interspinous Spacer System (Alphatec Spine)
• In-Space (Synthes)
• NL-Prow Interspinous Spacer (Non-Linear Technologies)
• Stenofix (Synthes)
• Superion ISS Interspinous Spacer System (Vertiflex)
• Wallis System (Abbott Spine/ Zimmer Spine)
• X-STOP Interspinous Process Decompression (IPD) System (Kyphon/ Medtronic Spine)
• X-STOP PEEK Interspinous Process Decompression (IPD) System (Kyphon/ Medtronic Spine)

POLICY

HMO, PPO, Individual Marketplace Effective 4/1/2021
Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers) (22867-22870, C1821) are non-covered. Current evidence is insufficient to permit conclusions about whether any beneficial effect from Interspinous process distraction or interlaminar stabilization spacers provides a significant advantage over surgical decompression, which is the current standard of care for surgical treatment of lumbar spinal stenosis.

Elite/ProMedica Medicare Plan Effective 4/1/2021
Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers) (22867-22870, C1821) are non-covered. There is no CMS National or Local Coverage Determination.

Advantage Effective 4/1/2021
Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers) (22867-22870, C1821) require a prior authorization.

COVERAGE CRITERIA:

HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan
Interspinous Distraction Devices
Interspinous distraction devices (including but not limited to Coflex® Interlaminar Technology Implant/Coflex Intralaminar Stabilization Devices, X-STOP® Interspinous Process Decompression (IPD®) System Vertiflex interspinous decompression spacer/Superion InterSpinous Spacer) are considered investigational.
There is insufficient evidence in the peer-reviewed medical literature to demonstrate the long-term safety and efficacy of interspinous distraction devices and the durability of the devices. The impact of this technology on net health outcome is not known. There is a need for longer-term outcome data on symptom relief, the need for repeat procedures, and implant survival.

**Interspinous Fixation Devices**
Interspinous fixation devices (including but not limited to: Affix™, Axle™, BacFuse®, Coflex-F®, Inspan™, Screwless Fusion Devise, Spire™, Lanx® SFS, TOPS™ (Total Posterior – element System) Spinal System) are considered investigational for any indication, including but not limited to use:
- In combination with interbody fusion, or
- Alone for decompression in patients with spinal stenosis and or spondylolisthesis

These procedures allow for a period of relief before the canal has to be opened and can delay the day when a more invasive operation is needed. It does not prevent the procedures from being needed later. It is the longer-term performance that remains the principle unanswered question. Randomized controlled trials are needed that evaluate health outcomes following use of interspinous fixation (fusion) devices in comparison with the established standard of pedicle screw-rod fixation. There is a need for longer term (>2 years) outcome data on the durability of symptom relief, the need for repeat procedures, and implant survival.

**Advantage**
While there is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of an Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers), they may be covered with a prior authorization. The Ohio Department of Medicaid requires this procedure be reviewed for medical necessity. Therefore, it may be covered with a prior authorization for Advantage members.

**Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers) Treatment reviewed for indications Include:**
- A complete history and physical, including neurologic exam, documenting spinal stenosis clinically, and radiologically (diagnostic image(s))
- Significant mechanical back pain is present (in addition to those symptoms associated with neural compression) at rest and/or with movements while standing and does not have characteristics consistent with neurogenic claudication
- Failed conservative treatment with no improvement in symptoms after 12 weeks:
  - Oral medication, steroids and non-steroidal anti-inflammatory drugs (NSAIDs)
  - Epidural steroid injections
  - Physical therapy, spinal manipulation therapy, cognitive behavioral therapy (CBT) or other interventions based on the individual’s specific presentation
  - Modification of activities of daily life
- Continued worsening of symptoms
  - Functional impairment that is interfering with activities of daily living (meals, walking, getting dressed, driving)

**CODING/BILLING INFORMATION**
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>CPT CODES</th>
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<tbody>
<tr>
<td>22867</td>
</tr>
<tr>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level</td>
</tr>
</tbody>
</table>
22868  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)

22869  Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level

22870  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)

22899  Unlisted procedure, spine [when specified as insertion of a non-pedicle interspinous process fixation device]

HCPCS CODE
C1821  Interspinous process distraction device (implantable)

REVISION HISTORY EXPLANATION
ORIGINAL EFFECTIVE DATE: 03/01/2009

<table>
<thead>
<tr>
<th>Date</th>
<th>Explanation &amp; Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/15/10</td>
<td>• Updated references</td>
</tr>
<tr>
<td>05/01/11</td>
<td>• No changes</td>
</tr>
<tr>
<td>01/22/16</td>
<td>• Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).</td>
</tr>
<tr>
<td>04/22/16</td>
<td>• Per Medical Director’s review of CMS A52693, the Coflex® Interlaminar Stabilization Device is non-covered. Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).</td>
</tr>
<tr>
<td>01/27/17</td>
<td>• Codes 0171T &amp; 0172T deleted effective 12/31/16. New effective 01/01/17 codes added 22867-22870 as covered for Elite and Advantage only with prior authorization. Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).</td>
</tr>
<tr>
<td>01/25/18</td>
<td>• Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).</td>
</tr>
<tr>
<td>12/16/2020</td>
<td>• Medical policy placed on the new Paramount Medical Policy Format</td>
</tr>
<tr>
<td>02/01/2021</td>
<td>• Medical policy name changed from Interspinous Process Decompression Devices, to Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers) Policy updated to reflect the most current Industry Standards</td>
</tr>
<tr>
<td></td>
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</tr>
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<td></td>
<td>• Criteria established for Advantage medical necessity review</td>
</tr>
</tbody>
</table>

REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services

Ohio Department of Medicaid

American Medical Association, Current Procedural Terminology (CPT®) and associated publications and
Services

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets

Hayes, Inc.

Industry Standard Review