MEDICAL POLICY – 7.01.138
Interspinous Fixation (Fusion) Devices

Introduction

Back pain is a common symptom and, for some, can lead to disability. Devices that keep specific areas of the spine rigid are known as interspinous fixation devices. Surgeons attach these devices to the bones of the spine (vertebrae) to prevent the joints from bending and twisting as they normally would. The intent of the devices is to decrease pain. These devices are typically used as part of fusion surgery. The device holds the spine in place while the implanted bone material eventually fuses the vertebrae together. Occasionally the device might be used without fusion surgery in order to relieve pressure on the spinal cord or nerve. Interspinous fixation devices are considered unproven. There is not enough evidence to show whether these devices are effective when used during a fusion surgery or on their own. The health plan considers these devices investigational.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
# Devices

## Interspinous fixation (fusion) devices

Interspinous fixation (fusion) devices 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

**Note:** Investigational devices include, but are not limited to the following:

Affix™ (NuVasive), Aileron™ (Life Spine), Aspen™ (Lanx, acquired by BioMet), Axle™ (X-Spine), BacFuse® (Pioneer Surgical), BridgePoint™ (Alphatec Spine), coflex-IF® (Paradigm Spine), Inspan™ (Spine Frontier), InterBRIDGE® Interspinous Posterior Fixation System (LDR Spine), Minuteman™ (Spinal Simplicity), PrimaLOK™ (OsteoMed), Octave™ (Life Spine), Spire™ (Medtronic), SP-Fix™ (Globus), ZIP® MIS Interspinous Fusion System (Aurora Spine)

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## Coding

There are no specific CPT codes for insertion of these devices (see Regulatory Status). The following add on codes might be used, but should not be reported as stand-alone services:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>22840</td>
<td>Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>22853</td>
<td>Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>22854</td>
<td>Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>22859</td>
<td>Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

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**Notes:** Clinical input has identified potential exceptions where the devices might be considered medically necessary, such as patients with small pedicles where pedicle screws could not be safely placed.

The name of the specific fixation device used for the procedure should be included in the clinical documentation.

**Related Information**

N/A

**Evidence Review**

**Description**

Interspinous fixation (fusion) devices are being developed to aid in the stabilization of the spine. They are evaluated as alternatives to pedicle screw and rod constructs in combination with interbody fusion. Interspinous fixation devices (IFDs) are also being evaluated for stand-alone use in patients with spinal stenosis and/or spondylolisthesis.
Background

Contemporary models of interspinous fixation devices (IFDs) have evolved from spinous process wiring with bone blocks and early device designs (eg, Wilson plate, Meurig-Williams system, Daab plate). The newer devices range from paired plates with teeth to U-shaped devices with wings that are attached to the spinous process. They are intended to be an alternative to pedicle screw and rod constructs to aid in the stabilization of the spine with interbody fusion. IFDs are placed under direct visualization, while screw and rod systems may be placed under direct visualization or percutaneously. Use of an IFD in combination with a unilateral pedicle screw system has also been proposed. IFDs are not intended for stand-alone use.

For use in combination with fusion, it is proposed that IFDs are less invasive and present fewer risks than pedicle or facet screws. While biomechanical studies indicate that IFDs may be similar to pedicle screw-rod constructs in limiting the range of flexion and extension, they may be less effective than bilateral pedicle screw-rod fixation for limiting axial rotation and lateral bending.\(^1\) There is a potential for a negative impact on the interbody cage and bone graft due to focal kyphosis resulting from the IFD. There is also a potential for spinous process fracture.

Unlike IFDs, interspinous distraction devices (spacers) are used alone for decompression and are typically not fixed to the spinous process (see Related Policies). In addition, interspinous distraction devices have been designed for dynamic stabilization, whereas IFDs are rigid. However, IFDs might also be used to distract the spinous processes and decrease lordosis. Thus, IFDs could be used off-label without interbody fusion as decompression (distraction) devices in patients with spinal stenosis. If IFDs are used alone as a spacer, there is a risk of spinous process fracture.

Summary of Evidence

For individuals who are undergoing spinal fusion who receive IFD with interbody fusion, the evidence includes a systematic review of nonrandomized comparative studies and case series and 2 small randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. The randomized trials found comparable benefits for interspinous fixation devices with interbody fusion for those undergoing spinal fusion compared with interbody fusion with pedicle screws, but the comparative safety was less clear. One risk is spinous process fracture, while a potential benefit is a reduction in adjacent segment degeneration. Additionally, the RCTs had important methodological and relevancy weaknesses that limited their interpretation. Randomized trials with longer follow-up are needed to evaluate the risks and benefits following use of IFDs.
compared with the established standard (pedicle screw and rod fixation). The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with spinal stenosis and/or spondylolisthesis who receive an IFD alone, the evidence includes a retrospective series. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. There is a lack of evidence on the efficacy of IFDs as a stand-alone procedure. RCTs are needed that evaluate health outcomes following use of IFDs as a stand-alone for decompression. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this evidence review are listed in Table 1.

### Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01455805(^a)</td>
<td>Efficacy and Quality of Life Following Treatment of Lumbar Spinal Stenosis, Spondylolisthesis or Degenerative Disc Disease With the Minuteman Interspinous Interlaminar Fusion Implant Versus Surgical Decompression</td>
<td>50</td>
<td>Mar 2024</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01560273(^a)</td>
<td>A Multi-Center Prospective Study Evaluation Aspen Spinous Process Fixation System for Use in Posterolateral Fusion (PLF) in Patients With Spondylolisthesis</td>
<td>25</td>
<td>Sep 2015 (terminated)</td>
</tr>
<tr>
<td>NCT01549366(^a)</td>
<td>System Versus Pedicle Screw Fixation, in Lateral Lumbar Interbody Fusion (LLIF) or Anterior Lumbar Interbody Fusion (ALIF)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NCT: national clinical trial

\(^a\) Denotes industry-sponsored or cosponsored trial
Clinical Input Received From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 3 physician specialty societies (2 reviewers) and 2 academic medical centers while this policy was under review in 2012. The input was mixed. Some indications where the devices might be medically necessary were noted, such as patients with small pedicles where pedicle screws could not be safely placed.

Practice Guidelines and Position Statements

North American Spine Society

In 2019, the North American Spine Society issued a coverage position on the use of interspinous devices with lumbar fusion. The North American Spine Society noted that although there is still limited evidence, interspinous fixation with fusion for stabilization may be considered when utilized in the context of lumbar fusion procedures for patients with diagnoses including stenosis, disc herniations, or synovial facet cysts in the lumbar spine, as an adjunct to cyst excision which involves removal of greater than 50 percent of the facet joint and when utilized in conjunction with a robust open laminar and/or facet decortication and fusion, and/or a robust autograft inter-and extra-spinous process decortication and fusion, and/or an interbody fusion of the same motion segment. The North American Spine Society also noted that “No literature supports the use of interspinous fixation without performing an open decortication and fusion of the posterior bony elements or interbody fusion.”

Medicare National Coverage

There is no national coverage determination.
Regulatory Status

The following interspinous fixation devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. This list may not be exhaustive.

- Aerial™ Interspinous Fixation (Globus Medical Inc.)
- Affix™ (NuVasive)
- Aileron™ (Life Spine)
- Aspen™ (Lanx, acquired by BioMet)
- Axle™ (X-Spine)
- BacFuse® (Pioneer Surgical)
- BridgePoint™ (Alphatec Spine)
- coflex-IF® (Paradigm Spine)
- Inspan™ (Spine Frontier)
- InterBRIDGE® Interspinous Posterior Fixation System (LDR Spine)
- Minuteman™ (Spinal Simplicity)
- PrimaLOK™ (OsteoMed)
- Octave™ (Life Spine)
- Spire™ (Medtronic)
- SP-Fix™ (Globus)
- SP-Link™ System (Medical Designs LLC)
- ZIP® MIS Interspinous Fusion System (Aurora Spine)

FDA product code: PEK.

Interspinous fixation devices are intended to be used as an adjunct to interbody fusion. For example, the indication for use of the coflex-IF® implant is as:

A posterior, non-pedicle supplemental fixation device intended for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1-S1). It is intended for
attachment to the spinous processes for the purpose of achieving stabilization to promote fusion in patients with degenerative disc disease — defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies — with up to Grade 1 spondylolisthesis.

A number of interspinous plate systems have also been cleared for marketing by the FDA.

Use of an interspinous fixation device for a stand-alone procedure would be considered off-label.

References


History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/13/12</td>
<td>New policy. Policy created with literature search through July 2012; considered investigational.</td>
</tr>
<tr>
<td>01/29/13</td>
<td>Update Related Policies, add 7.01.130.</td>
</tr>
<tr>
<td>12/04/13</td>
<td>Replace policy. Policy updated with literature review through July 30, 2013; policy statement unchanged.</td>
</tr>
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<td>Date</td>
<td>Comments</td>
</tr>
<tr>
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</tr>
<tr>
<td>04/20/15</td>
<td>Update Related Policies. Edit title to 7.01.542.</td>
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<tr>
<td>11/10/15</td>
<td>Annual Review. Added clarification to the Policy Guidelines that the codes in this policy describe additional intra-service work associated with the primary procedure and would not be reported as stand-alone services. Added a note to state the name of the device used in the procedure should be included in the clinical documentation. Policy updated with literature review through August 12, 2015; references 4-5 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>08/01/16</td>
<td>Annual review approved July 12, 2016. Policy statement unchanged. No references added.</td>
</tr>
<tr>
<td>10/11/16</td>
<td>Policy moved into new format; no change to policy statements.</td>
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<tr>
<td>01/01/17</td>
<td>Coding update, added new CPT codes 22853, 22854, and 22859 with effective date of 01/01/17.</td>
</tr>
<tr>
<td>01/13/17</td>
<td>Clarified and corrected coding update. Note was added that CPT code 22851 was deleted as of 01/01/17 and replaced with three new CPT codes (22853, 22854, and 22859) effective 01/01/17.</td>
</tr>
<tr>
<td>01/01/18</td>
<td>Coding update, removed CPT code 22851 as it was terminated 1/1/17.</td>
</tr>
<tr>
<td>07/01/18</td>
<td>Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; reference 6 updated. Policy statement unchanged. Removed CPT code 22851 as it was deleted and replaced with 3 other codes on 1/1/17.</td>
</tr>
<tr>
<td>07/01/19</td>
<td>Annual Review, approved June 20, 2019. Policy updated with literature review through February 2019; references 7 and 8 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>04/01/20</td>
<td>Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.</td>
</tr>
<tr>
<td>06/10/20</td>
<td>Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review
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Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at

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