MEDICAL POLICY – 7.01.138
Interspinous Fixation (Fusion) Devices

BCBSA Ref. Policy: 7.01.138

Effective Date: July 1, 2017
Last Revised: Jan. 1, 2018
Replaces: N/A

RELATED MEDICAL POLICIES:
7.01.107  Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)
7.01.130  Axial Lumbosacral Interbody Fusion
7.01.542  Lumbar Spinal Fusion

Select a hyperlink below to be directed to that section.

POLICY CRITERIA  |  CODING  |  RELATED INFORMATION
EVIDENCE REVIEW  |  REFERENCES  |  HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Back pain is a common symptom and leads to pain and disability in some people. Despite extensive knowledge of the bones, nerves, muscles, tendons and structures of the spine, it is still very difficult to identify a specific source of pain for many people. 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. In this case, 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 and unproven, and does not pay for them.

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.
Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Devices</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interspinous fixation (fusion) devices</td>
<td>Interspinous fixation (fusion) devices are considered investigational for any indication, including but not limited to use:</td>
</tr>
<tr>
<td></td>
<td>• In combination with interbody fusion OR</td>
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<td></td>
<td>• Alone for decompression in patients with spinal stenosis</td>
</tr>
<tr>
<td></td>
<td>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.</td>
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<tr>
<td></td>
<td>The name of the specific fixation device used for the procedure should be included in the clinical documentation.</td>
</tr>
</tbody>
</table>

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>CPT</td>
<td></td>
</tr>
<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>22851</td>
<td>Application of intervertebral biomechanical device(s) (eg, synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure) (code deleted as of 1/1/17, replaced with three new codes – 22853, 22854, and 22859)</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</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>-------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>integral anterior instrumentation for device anchoring (e.g., 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>22859</td>
<td>Insertion of intervertebral biomechanical device(s) (e.g., 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>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

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**Related Information**

N/A

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**Evidence Review**

**Description**

Interspinous fixation (fusion) devices are being developed to aid in the stabilization of the spine. They are being 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 (e.g., 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 either 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 interspinous fixation systems are less invasive and present fewer risks than pedicle or facet screws. However, while biomechanical studies indicate that IFDs may be similar to pedicle screw and rod constructs in limiting the range of flexion-extension, they may be less effective than bilateral pedicle screw and rod fixation for limiting axial rotation and lateral bending. There is a potential for a negative impact on the interbody cage and bone graft due to focal kyphosis resulting from the interspinous device. 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.

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>
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<tr>
<td>NCT01549366a</td>
<td>A Multi-Center Prospective Randomized Study Comparing Supplemental Posterior Instrumentation, Aspen™ Spinal Process System Versus Pedicle Screw Fixation, in Lateral Lumbar Interbody Fusion (LLIF) or Anterior Lumbar Interbody Fusion (ALIF)</td>
<td>144</td>
<td>Dec 2017</td>
</tr>
<tr>
<td>NCT01016314a</td>
<td>A Multi-Center Prospective Randomized Study to Evaluate the Efficacy of the Aspen Spinal Process System for Use in</td>
<td>156</td>
<td>Dec 2016 (ongoing)</td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
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<tr>
<td>---------</td>
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<tr>
<td></td>
<td>Anterior Lumbar Interbody Fusion (ALIF)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01455805&lt;sup&gt;a&lt;/sup&gt;</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>Dec 2020</td>
</tr>
</tbody>
</table>

**Unpublished**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
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<tbody>
<tr>
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</tr>
<tr>
<td>NCT01019057&lt;sup&gt;a&lt;/sup&gt;</td>
<td>A Prospective, Non-randomized, Multi-Center Evaluation of Interlaminar Lumbar Instrumented Fusion (ILIF™)</td>
<td>77</td>
<td>Completed June 2014</td>
</tr>
<tr>
<td>NCT01560273&lt;sup&gt;a&lt;/sup&gt;</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>
</tbody>
</table>

NCT: national clinical trial

<sup>a</sup> Denotes industry-sponsored or cosponsored trial

**Summary of Evidence**

For individuals who are undergoing spinal fusion who receive an interspinous fixation device (IFD) with interbody fusion, the evidence includes a systematic review of nonrandomized comparative studies and case 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 in combination with interbody fusion. One risk is spinous process fracture, while a potential benefit is a reduction in adjacent segment degeneration. 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 who have 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. Randomized controlled trials are needed that evaluate health outcomes following use of IFDs when used alone for decompression. The evidence is insufficient to determine the effects of the technology on health outcomes.
Clinical Input Received From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, 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 cases were noted where the devices might be medically necessary, such as patients with small pedicles where pedicle screws could not be safely placed.

Practice Guidelines and Position Statements

North American Spine Society (NASS)

The NASS issued a coverage position in 2004 on the use of interspinous devices with lumbar fusion. NASS recommended that interspinous fixation with fusion for stabilization was currently not indicated as an alternative to pedicle screw fixation with lumbar fusion procedures.

U.S. Preventive Services Task Force Recommendations

Use of interspinous fixation devices is not a preventive service.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.
**Regulatory Status**

The following interspinous fixation devices have received clearance to market by the U.S. Food and Drug Administration (FDA) through the 510(k) process. This list may not be exhaustive.

- 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)

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 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.

FDA Product code: PEK

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>
<tr>
<td>04/20/15</td>
<td>Update Related Policies. Edit title to 7.01.542.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
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</tr>
<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>
</tr>
<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>
</tbody>
</table>

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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)

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