Interspinous Fixation (Fusion) Devices

Number: 7.01.138
Effective Date: August 1, 2016
Revision Date(s): 07/12/16; 11/10/15; 11/10/14; 11/11/13
Replaces: N/A

Policy

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.

Related Policies

<table>
<thead>
<tr>
<th>Policy Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.01.107</td>
<td>Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)</td>
</tr>
<tr>
<td>7.01.130</td>
<td>Axial Lumbosacral Interbody Fusion</td>
</tr>
<tr>
<td>7.01.542</td>
<td>Lumbar Spinal Fusion</td>
</tr>
</tbody>
</table>

Policy Guidelines

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.

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>CPT</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>22840</td>
<td>Posterior non-segmental instrumentation (e.g., 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>
</tbody>
</table>
Add-on codes describe additional intra-service work associated with the primary procedure.

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

**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 are also being evaluated for stand-alone use in patients with spinal stenosis and/or spondylolisthesis.

**Background**

Contemporary models of interspinous fixation devices 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. Interspinous fixation devices are placed under direct visualization, while screw and rod systems may be placed either under direct visualization or percutaneously. Use of an interspinous fixation device in combination with a unilateral pedicle screw system has also been proposed. Interspinous fixation devices are not intended for stand-alone use.

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

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 interspinous fixation devices may be similar to pedicle screw-rod constructs in limiting the range of flexion-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 interspinous device. There is also a potential for spinous process fracture. Given these uncertainties, studies are needed that compare health outcomes between interspinous fixation devices and pedicle screw-rod fixation.

**Regulatory Status**

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

- Affix™ (NuVasive)
- Aileron™ (Life Spine)
- Aspen™ (Lanx, acquired by BioMet)
- Axle™ (X-Spine)
- BacFuse® (Pioneer Surgical)
- BridgePoint™ (Alphatec Spine)
- coflex-F® (Paradigm Spine)
- Inspan™ (Spine Frontier)
- Interbridge Interspinous Posterior Fixation System (LDR Spine)
- Minuteman™ (Spinal Simplicity)
- PrimaLOK™ (OsteoMed)
Interspinous fixation devices are intended to be used as an adjunct to interbody fusion. For example, the indication for use of the coflex-F 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.

Use of an interspinous fixation device for a stand-alone procedure would be considered off-label. FDA Product code: PEK

Scope

Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

Benefit Application

N/A

Rationale

This evidence review was created with a search of the literature through July 2012 and updated periodically using the MEDLINE database. The most recent update was performed though August 12, 2015.

Use of the Aspen interspinous fixation device as a stand-alone interspinous spacer was reported in a prospective series of 6 cases (an additional 32 patients received the X-stop interspinous distraction device). (2) The study population consisted of consecutive patients with a primary diagnosis of lumbar spinal stenosis with pain that was relieved by sitting or lumbar flexion. Of the 6 patients implanted with the Aspen device, 2 (33%) had spinous process fractures observable on computed tomography. Of the entire group of 38 patients, 55% of those with spondylolisthesis (n=20) had a fracture within 6 months of surgery. None of the 18 patients without spondylolisthesis experienced a fracture. In 2013, use of an interspinous fusion plate was reported in a series of 4 patients in conjunction with surgery for recurrent lumbar disc herniation. (3)

Vokshoor et al. reported a retrospective series of 86 patients who had a spinous process device implanted. (4) After adjusting for age and sex, there was a 3.6-point decrease in the visual analog scale for pain that was maintained over the 12-month follow-up. In the 50 patients who had computed tomography scans, interspinous process fusion was observed in 94%. Presence of an interbody cage did not affect the fusion rate. Two patients (2.3%) had the devices removed due to pain secondary to spinous process and/or lamina fracture.

In 2014, Sclafani et al. reported an industry-sponsored retrospective series on the polyaxial PrimaLOK interspinous fusion device. (5) Thirty four patients were implanted with the interspinous fusion device alone, 16
patients received the PrimaLOK together with an interbody cage, and 3 patients received the PrimaLOK together with pedicle screw instrumentation and an interbody cage. Evaluation at 6 weeks found no cases of fracture or migration of the device, although there were 4 cases of hardware removal and 2 cases of reoperation for adjacent level disease during the follow-up. At a mean 22 months after the index surgery, the average pain score had improved from 7.2 to 4.5 on a 10-point scale. There was a statistically significant improvement in pain score for patients with degenerative disc disease with lumbar stenosis (2.8, n=25, p<0.001) or spondylolisthesis (4.6, n=6, p=0.01), but not for patients with lumbar disc herniation (2.2, n=10, p>0.05).

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>
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<tbody>
<tr>
<td></td>
<td>Ongoing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01549366*</td>
<td>A Multi-Center Prospective Randomized Study Comparing Supplemental Posterior Instrumentation, Aspen™ Spine Process System Versus Pedicle Screw Fixation, in Lateral Lumbar Interbody Fusion (LLIF) or Anterior Lumbar Interbody Fusion (ALIF)</td>
<td>144</td>
<td>Dec 2015</td>
</tr>
<tr>
<td>NCT01016314*</td>
<td>A Multi-Center Prospective Randomized Study to Evaluate the Efficacy of the Aspen Spinous Process System for Use in Anterior Lumbar Interbody Fusion (ALIF)</td>
<td>156</td>
<td>Dec 2016</td>
</tr>
<tr>
<td>NCT01455805*</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>
<tr>
<td></td>
<td>Unpublished</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01019057*</td>
<td>A Prospective, Non-randomized, Multi-Center Evaluation of Interlaminar Lumbar Instrumented Fusion (ILIF™)</td>
<td>77</td>
<td>Completed Jun 2014</td>
</tr>
<tr>
<td>NCT01560273*</td>
<td>A Multi-Center Prospective Study Evaluation Aspen Spinous Process Fixation System for Use in Posterior Lumbar Fusion (PLF) in Patients With Spondylolisthesis</td>
<td>63</td>
<td>Suspended Sep 2015</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
* Denotes industry-sponsored or cosponsored trial.

Summary of Evidence
The evidence on interspinous fixation (fusion) devices in patients who are undergoing interbody fusion or who have spinal stenosis and/or spondylolisthesis includes a small prospective series and 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 interspinous fixation devices, both for use in combination with interbody fusion and for use as a stand-alone procedure. 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. Clinical trials are also needed to evaluate these devices 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 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 cases 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 (NASS)
The NASS issued a coverage position on the use of interspinous devices with lumbar fusion. (6) NASS recommends that interspinous fixation with fusion for stabilization is 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.

References


Appendix

N/A

History

<table>
<thead>
<tr>
<th>Date</th>
<th>Reason</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>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</td>
</tr>
</tbody>
</table>
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.

07/12/16 Annual review. Policy statement unchanged. No references added.
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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