Title: Interspinous Fixation (Fusion) Devices

See Also: Lumbar Spine Fusion

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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.

OBJECTIVE
The objective of this policy is to determine whether an interspinous fixation device improves health outcomes when used alone or in combination with interbody fusion to stabilize the spinal segment.

BACKGROUND
Contemporary models of interspinous fixation devices 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. 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.

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. There is a potential for a negative impact on the interbody cage and bone graft due to focal kyphosis resulting from the interspinous fixation 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. 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.

REGULATORY STATUS
The following interspinous fixation devices (IFDs) 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 Spine)
• Octave™ (Life Spine)
• Spire™ (Medtronic)
• SP-Fix™ (Globus)
• 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-F® implant:

“is a posterior, nonpedicle 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 is considered off-label.
POLICY
A. Interspinous fixation (fusion) devices are considered experimental / investigational for any indication, including, but not limited to, use:

1. in combination with interbody fusion, OR

2. alone for decompression in patients with spinal stenosis.

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.

RATIONALE
This policy 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 February 23, 2017.

A 2016 systematic review by Lopez et al evaluated the literature on lumbar spinous process fixation and fusion devices. They included both interspinous plates and fixation devices, and excluded dynamic devices such as the X-Stop (see evidence review 7.01.107). A total of 15 articles met the inclusion and exclusion criteria, including 4 comparative studies (level III evidence), 2 case series (level IV evidence), and 9 in vitro biomechanics studies (level V evidence). Two of the nonrandomized studies compared interspinous fixation devices (IFDs) to pedicle screws in patients undergoing interbody fusion and 2 included IFD alone or pedicle screws plus an IFD in patients undergoing interbody fusion. Use of an IFD decreased surgical time and blood loss compared to pedicle screws. No study showed that IFDs reduced the length of stay compared to pedicle screw implantation.

Included in the systematic review was a 2012 nonrandomized retrospective study by Kim et al that compared the SPIRE IFD to pedicle screw implantation in patients who underwent posterior lumbar interbody fusion (PLIF). In this study, 40 patients underwent IFD with PLIF and 36 underwent pedicle screw fixation with PLIF during the same time period. The 2 groups were comparable at baseline, but the treatment selection criteria were not described. At a minimum 1-year follow-up, scores on the visual analog scale (VAS) for pain and on the Korean version of the Oswestry Disability Index improved to a similar extent in the 2 groups. For example, VAS scores in the IFD group improved from 7.16 to 1.3 while VAS scores in the pedicle screw group improved from 8.03 to 1.2. Range of motion at the adjacent segment was increased in the pedicle screw group but not in the IFD group, and adjacent segment degeneration was more prevalent in the pedicle screw group (36.1%) than in the IFD group (12.5%; p=0.029). Other adverse events, such as deep infection and cerebrospinal fluid leakage, were higher in the pedicle screw group.

A 2014 study by Vokshoor et al (also included in the systematic review) reported on a retrospective series of 86 patients who had a spinous process device implanted. Some patients received IFD with interbody fusion and some received an IFD plus pedicle screws and interbody fusion. After adjusting for age and sex, there was a 3.6-point decrease in VAS scores 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 (2.3%) patients had devices removed due to pain secondary to spinous process and/or lamina fracture.

In 2014, Sclafani et al reported on an industry-sponsored, retrospective series on the polyaxial PrimaLOK interspinous fusion device. Thirty-four patients were implanted with the IFD alone, 16 patients received the PrimaLOK plus an interbody cage, and 3 patients received the PrimaLOK plus pedicle screw instrumentation and an interbody cage. Evaluation at 6 weeks found no cases of fracture or device migration, although there were 4 cases of hardware removal and 2 cases of reoperation for adjacent-level disease during 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 (method of collection, eg, visual analog scale, not specified). 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).

**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-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 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

The North American Spine Society (NASS) issued a coverage position on the use of interspinous devices with lumbar fusion. 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

Not applicable.

Ongoing and Unpublished Clinical Trials

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

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<th>Table 1. Summary of Key Trials</th>
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NCT: national clinical trial.

Denotes industry-sponsored or cosponsored trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

22840 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)

22853 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)
22854    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)

22859    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)

Diagnoses
Experimental / Investigational for all diagnoses related to this medical policy.

REVISAIONS

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<td>01-01-2017</td>
<td>▪ Added CPT codes: 22853, 22854, 22859 (New codes, effective January 1, 2017).</td>
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REFERENCES