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.

Clinical input has identified potential exceptions when 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. The following code might be used:

+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).

State or federal mandates (eg, Federal Employee Program) may dictate that certain U.S. Food and Drug Administration–approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only by their medical necessity.

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 as 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 has been proposed that IFDs are less invasive and present fewer risks than pedicle or facet screws. While biomechanics studies have indicated 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. 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 evidence review 7.01.107). 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 IFDs have been cleared for marketing by the U.S. Food and Drug Administration 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 Spine)
- Octave™ (Life Spine)
- Spire™ (Medtronic)
- SP-Fix™ (Globus)
- ZIP® MIS Interspinous Fusion System (Aurora Spine).

Food and Drug Administration product code: PEK.

IFDs are intended for use as an adjunct to interbody fusion. For example, the indication for the coflex-IF® implant is as:

“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.”

A number of interspinous plate systems have also been cleared for marketing by the Food and Drug Administration.
Use of an IFD for a stand-alone procedure is considered off-label.

RATIONALE

This evidence review was created in September 2012 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed though February 5, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical uses of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

INTERSPINOUS FIXATION DEVICE WITH FUSION

A systematic review by Lopez et al (2017) evaluated the literature on lumbar spinous process fixation and fusion devices. Reviewers included both interspinous plates and fixation devices, and excluded dynamic devices such as the X-Stop (see evidence review 7.01.107). Fifteen articles met 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) with 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 with pedicle screws. No study showed that IFDs reduced the hospital length of stay compared with pedicle screw implantation.

Included in the systematic review was a nonrandomized retrospective study by Kim et al (2012) that compared the SPIRE IFD with pedicle screw implantation in patients who underwent posterior lumbar interbody fusion. In this study, 40 patients underwent IFD with posterior lumbar interbody fusion and 36 underwent pedicle screw fixation with posterior lumbar interbody fusion 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 both 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 study by Vokshoor et al (2014), 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.

Section Summary: Interspinous Fixation Device With Fusion
The evidence for use of IFD with interbody fusion for those undergoing spinal fusion consists of a systematic review of nonrandomized comparative studies and case series. 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 with rod fixation).

IFD AS A STAND-ALONE
Sclafani et al (2014) reported on an industry-sponsored, retrospective series of 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, VAS, were 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) and spondylolisthesis (4.6, n=6, p=0.01), but not for patients with lumbar disc herniation (2.2, n=10, p>0.05).

Section Summary: IFD as a Stand-Alone
There is a lack of evidence (only a retrospective series) on the efficacy of IFDs as a stand-alone procedure for those who have spinal stenosis and/or spondylolisthesis. Randomized controlled trials are needed that evaluate health outcomes following use of IFDs as a stand-alone for decompression.

SUMMARY OF EVIDENCE
For individuals who are undergoing spinal fusion who receive an 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 with 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 as a stand-alone for decompression. The evidence is insufficient to determine the effects of the technology on health outcomes.
SUPPLEMENTAL INFORMATION

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. 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
The North American Spine Society issued a coverage position in 2004 on the use of interspinous devices with lumbar fusion. The Society noted 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
Not applicable.

MEDICARE NATIONAL COVERAGE
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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>
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<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td>NCT01455805a</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>
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<tr>
<td>Unpublished</td>
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<td>NCT01560273a</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>
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<td>NCT01016314a</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>39</td>
<td>Jan 2016 (completed)</td>
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<td>NCT01549366a</td>
<td>A Multi-Center Prospective Randomized Study Comparing Supplemental Posterior Instrumentation, Aspen™ Spinous Process System Versus Pedicle Screw Fixation, in Lateral Lumbar Interbody Fusion (LLIF) or Anterior Lumbar Interbody Fusion (ALIF)</td>
<td>64</td>
<td>Jan 2016 (completed)</td>
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NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

REFERENCES


CODES

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<td>CPT</td>
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<tr>
<td>ICD-10-CM</td>
<td>Investigational for all diagnoses</td>
</tr>
<tr>
<td>ICD-10-PCS</td>
<td>ICD-10-PCS codes are only used for inpatient services. There is no specific ICD-10-PCS code for this procedure.</td>
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Type of service: Surgery
Place of service: Inpatient

POLICY HISTORY

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<td>09/10/15</td>
<td>Replace policy</td>
<td>Policy updated with literature review through August 12, 2015; references 4-5 added. Policy statement unchanged.</td>
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<td>10/19/16</td>
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<td>Blue Cross of Idaho annual review; no change to policy.</td>
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<td>04/13/17</td>
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<td>Policy updated with literature review through February 23, 2017; references 2-3 added; one reference removed. Policy statement unchanged.</td>
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<tr>
<td>04/30/18</td>
<td>Replace policy</td>
<td>Blue Cross of Idaho adopted changes as noted. Policy updated with literature review through February 5, 2018; reference 6 updated. Policy statement unchanged</td>
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Original Policy Date: September 2012