7.01.138	Interspinous Fixation (Fusion) Devices		
Original Policy Date:	January 30, 2015	**Effective Date:**	July 1, 2019
Section:	7.0 Surgery	**Page:**	Page 1 of 8

Policy Statement

Interspinous fixation (fusion) devices are considered **investigational** for any indication, including but not limited to use in **either** of the following:

- Alone for decompression in patients with spinal stenosis
- In combination with interbody fusion

Policy Guidelines

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.

Coding

There are no specific CPT codes for insertion of these devices. The following code might be used:

- **22840**: 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)

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.

Related Policies

- Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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

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 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.[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 Blue Shield of California Medical Policy: Interspinous and Interlaminar Stabilization/Distraction Devices [Spacers]). 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.

Literature Review
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 function¾including 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.

Clinical Context and Therapy Purpose
The purpose of interspinous fixation devices is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does interspinous fixation improve the net health outcome in patients who are undergoing spinal fusion or who have spinal stenosis and/or spondylolisthesis?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population(s) of interest are patients who are undergoing spinal fusion or who have spinal stenosis and/or spondylolisthesis.

Interventions
The therapy being considered is interspinous fixation (fusion) devices.

Comparators
The following therapies/tools/rules/practices are currently being used to make decisions about interspinous fixation (fusion) devices.

For individuals who are undergoing spinal fusion, comparators of interest are interspinous fixation devices with pedicle screw construct.

For individuals with spinal stenosis and/or spondylolisthesis, the comparator of interest is decompression.

Outcomes
The general outcomes of interest include symptoms, functional outcomes , quality of life , resource utilization, and treatment-related morbidity.

Interspinous Fixation Device With Fusion

A systematic review by Lopez et al (2017) evaluated the literature on lumbar spinous process fixation and fusion devices.[2] 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.[3] 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.[4] 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.[5] 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, e.g., 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, from Blue Cross Blue Shield Association, input was received from 3 physician specialty societies (2 reviewers) and 2 academic medical centers 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 (NASS) issued a coverage position in 2004 on the use of interspinous devices with lumbar fusion.[6] 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. NASS updated their coverage position in 2014 and the recommendation did not change,[7] A 2019 draft update of the recommendation is currently posted for public comment.[8]

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

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01455805[a]	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	50	Dec 2023
Unpublished			
NCT01560273[a]	A Multi-Center Prospective Study Evaluation Aspen Spinous Process Fixation System for Use in Posterolateral Fusion (PLF) in Patients With Spondylolisthesis	25	Sep 2015 (terminated)
NCT01549366[a]	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)	64	Jan 2016 (completed)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

References

1. Wu JC, Mummaneni PV. Using lumbar interspinous anchor with transforaminal lumbar interbody fixation. World Neurosurg. May 2010;73(5):471-472. PMID 20920928
2. Lopez AJ, Scheer JK, Dahdaleh NS, et al. Lumbar spinous process fixation and fusion: a systematic review and critical analysis of an emerging spinal technology. Clin Spine Surg. Nov 2017;30(9):E1279-E1288. PMID 27438402
3. Kim HJ, Bak KH, Chun HJ, et al. Posterior interspinous fusion device for one-level fusion in degenerative lumbar spine disease : comparison with pedicle screw fixation - preliminary report of at least one year follow up. J Korean Neurosurg Soc. Oct 2012;52(4):359-364. PMID 23133725
4. Vokshoor A, Khurana S, Wilson D, et al. Clinical and radiographic outcomes after spinous process fixation and posterior fusion in an elderly cohort. Surg Technol Int. Nov 2014;25:271-276. PMID 25433267
5. Sclafani JA, Liang K, Ohnmeiss DD, et al. Clinical outcomes of a polyaxial interspinous fusion system. Int J Spine Surg. Feb 2014;8. PMID 25694912
6. North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion. 2004; https://www.spine.org/PolicyPractice/CoverageRecommendations/AboutCoverageRecommendations.aspx. Accessed March 6, 2017.
7. North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion. 2014; https://www.spine.org/ProductDetails?productid={7D67EEB8-4CC7-E411-9CA5-005056AF031E}. Accessed March 15, 2019.
8. North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion (Draft for comment only). 2019; https://www.spine.org/Portals/0/Documents/PolicyPractice/CoverageRecommendations/InterspinousFixationFusionDRAFT.pdf. Accessed March 15, 2019.
9. Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 7.01.138 (April 2019).

Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

IE
The following services may be considered investigational.

Type	Code	Description
CPT®	22840	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)
HCPCS	None	
ICD-10 Procedure	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
01/30/2015	BCBSA Medical Policy adoption	Medical Policy Committee
12/30/2016	Policy revision without position change	Medical Policy Committee
06/01/2017	Policy revision without position change	Medical Policy Committee
06/01/2018	Policy revision without position change	Medical Policy Committee
07/01/2019	Policy revision without position change	Medical Policy Committee

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an

authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.