BlueCross BlueShield of Alabama

Name of Policy:
Interspinous Fixation (Fusion) Devices

Policy #: 514
Category: Surgery

Latest Review Date: May 2018
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

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.

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.

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, interspinous fixation devices 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.

For use in combination with fusion, it has been proposed that interspinous fixation systems are less invasive and present fewer risks than pedicle or facet screws. While biomechanical studies have indicated 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 IFD. There is also a potential for spinous process fracture.

See "Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)" (Policy #282) for discussion and coverage of interspinous distraction devices.

Policy:

Interspinous fixation (fusion) devices do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and 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.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

This policy was created and updated periodically using the MEDLINE database. The most recent update was performed through 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 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. 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 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 patients (2.3%) had the 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).

Interspinous Fixation Device as a Stand-Alone
In 2014, Sclafani et al reported an industry-sponsored retrospective series on the polyaxial PrimaLOK interspinous fusion device. Thirty four patients were implanted with the interspinous fusion device alone, 16 patients received the PrimaLOK together with an interbody cage, and three patients received the PrimaLOK together with pedicle screw instrumentation and an interbody cage. Evaluation at six weeks found no cases of fracture or migration of the device, although there were four cases of hardware removal and two 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).

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 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 risks and benefits following use of interspinous fixation (fusion) devices in comparison with the established standard of 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 interspinous fixation devices as a stand-alone procedure. Randomized controlled trials are needed that evaluate health outcomes following use of interspinous fixation (fusion) devices when used alone for decompression. The evidence is insufficient to determine the effects of the technology on health outcomes.

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. 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
Not applicable.

Key Words:
Interspinous fixation devices, interspinous fusion devices, Affix™, Aileron™, Aspen™, Axle™, BacFuse®, BridgePoint, coflex-F®, PrimaLok™, Spire™, SP-Fix™, spondylolisthesis, ZIP® MIS, InterBridge®, Inspan™, Minuteman™, Octave™

Approved by Governing Bodies:

The following interspinous fixation devices have been cleared for marketing 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)
- coflex-F® (Paradigm Spine)
- Inspan™ (Spine Frontier)
- InterBRIDGE Interspinous Posterior Fixation System (LDR Spine)
- Minuteman™ (Spinal Simplicity)
- Octave™ (Life Span)
- PrimaLok™ (OsteoMed)
- 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-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."

A number of interspinous plate systems have also been cleared for marketing by FDA.

Use of an interspinous fixation device for a stand-alone procedure would be considered off-label.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

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

22899 Unlisted procedure, spine

Previous Coding:

22851 Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure) **(Deleted 12/31/16)**

References:

1. Kim DH, Shanti N, Tantorski ME et al. Association between degenerative spondylolisthesis and spinous process fracture after interspinous process spacer surgery. Spine J 2012; 12(6):466-472.
2. 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.
3. 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.
4. North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion. www.spine.org/Documents/PolicyPractice/CoverageRecommendations/InterspinousFixationWithFusion.pdf.
5. Oppenheim JS, Mills J. Recurrent lumbar disc herniation treated with interspinous fusion and instrumentation: a case series. Surg Technol Int. Sep 2013; 23:269-272.
6. Sclafani JA, Liang K, Ohnmeiss DD, et al. Clinical outcomes of a polyaxial interspinous fusion system. Int J Spine Surg. 2014; 8.
7. 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.
8. Wu JC, Mummaneni PV. Using lumbar interspinous anchor with transforaminal lumbar interbody fixation. World Neurosurg 2010; 73(5):471-472.

Policy History:

Medical Policy Panel, September 2012
Medical Policy Group, September 2012 **(2):** New policy. Non-covered/investigational statement
Medical Policy Administration Committee, October 2012
Available for comment October 24 through December 10, 2012
Medical Policy Panel, September 2013
Medical Policy Group, September 2013 **(4):** Key Points updated. No change in policy statement at this time.

Medical Policy Panel, September 2014
Medical Policy Group, September 2014 **(3):** 2014 Updates to Key Points, Governing Bodies & References; no change in policy statement.
Medical Policy Panel, September 2015
Medical Policy Group, October 2015 **(2):** 2015 Updates to Description, Key Points, Approved by Governing Bodies, and References, no change in policy statement.
Medical Policy Group, December 2016: Annual Coding Update. Added CPT codes 22853, 22854, and 22859. Created Previous Coding section and moved deleted code 22851 to this new section.
Medical Policy Panel, April 2017
Medical Policy Group, April 2017 **(7):** 2017 Updates to Description, Key Points, Key Words, Approved by Governing Bodies & References; no change in policy statement.
Medical Policy Group, June 2017 **(7)**: Removed CPT codes 22840, 22853, 22854, 22859 from Coding section as there are no specific codes for these devices; added CPT 22899.
Medical Policy Panel, May 2018
Medical Policy Group, May 2018 **(7):** 2018 Updates to Key Points and References. No change in Policy Statement.
