



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy:
Interspinous Fixation (Fusion) Devices

Policy #: 514
Category: Surgery

Latest Review Date: April 2021
Policy Grade: B

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **interspinous fixation (fusion) devices** as a **non-covered benefit** and as **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 Advantage 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 Advantage administers benefits based on the members' contract and 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.

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/Distraktion Devices (Spacers)” (Policy #282) for discussion and coverage of interspinous distraction devices.

KEY POINTS:

This policy was created and updated periodically using the MEDLINE database. The most recent update was performed through January 11, 2021.

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, and 2 small RCTs. 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 that the technology results in an improvement in the net health outcome.

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. RCTs are needed that evaluate health outcomes following use of interspinous fixation (fusion) devices when used alone for decompression. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

In 2019, the North American Spine Society issued a coverage position on the use of interspinous devices with lumbar fusion. The Society noted that although there is still limited evidence, interspinous fixation with fusion for stabilization may be considered when utilized in the context of lumbar fusion procedures for patients with diagnoses including stenosis, disc herniations, or synovial facet cysts in the lumbar spine, as an adjunct to cyst excision which involves removal of greater than 50 percent of the facet joint and when utilized in conjunction with a robust open laminar and/or facet decortication and fusion, and/or a robust autograft inter- and extraspinal process decortication and fusion, and/or an interbody fusion of the same motion segment. The Society also noted that "No literature supports the use of interspinous fixation without performing an open decortication and fusion of the posterior bony elements or interbody fusion."

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.

- Aerial™ Interspinous Fixation (Globus Medical Inc.)
- 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)
- SP-Link™ System (Medical Designs LLC)
- 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.

CURRENT CODING:

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

CPT Codes:

22899	Unlisted procedure, spine
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REFERENCES:

1. Huang WM, Yu XM, Xu XD, et al. Posterior Lumbar Interbody Fusion with Interspinous Fastener Provides Comparable Clinical Outcome and Fusion Rate to Pedicle Screws. *Orthop Surg*. 2017 May;9(2).
2. IOM (Institute of Medicine). 2011. *Clinical Practice Guidelines We Can Trust*. Washington, DC: The National Academies Press.
3. 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.
4. 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.
5. 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.
6. 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.
7. 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.
8. North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion. Revised December 2019. <https://www.spine.org/coverage>. Accessed February 19, 2020.
9. North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion. Revised December 2019. <https://www.spine.org/coverage>. Accessed March 15, 2021.

10. 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.
11. Panchal R, Denhaese R, Hill C, et al. Anterior and Lateral Lumbar Interbody Fusion With Supplemental Interspinous Process Fixation: Outcomes from a Multicenter, Prospective, Randomized, Controlled Study. *Int J Spine Surg*. 2018 Apr;12(2).
12. Sclafani JA, Liang K, Ohnmeiss DD, et al. Clinical outcomes of a polyaxial interspinous fusion system. *Int J Spine Surg*. 2014; 8.
13. 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.
14. Wu JC, Mummaneni PV. Using lumbar interspinous anchor with transforaminal lumbar interbody fixation. *World Neurosurg* 2010; 73(5):471-472.

POLICY HISTORY:

Adopted for Blue Advantage, October 2012

Available for comment October 24 through December 10, 2012

Medical Policy Group, September 2013

Medical Policy Group, September 2014

Medical Policy Group, October 2015

Medical Policy Group, December 2016

Medical Policy Group, April 2017

Medical Policy Group, June 2017

Medical Policy Group, May 2018

Medical Policy Group, May 2020

Medical Policy Group, April 2021

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.