

Corporate Medical Policy

Interspinous Fixation (Fusion) Devices

File Name: interspinous_fixation_(fusion)_devices
Origination: 11/2012
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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.

Interspinous fixation (fusion) devices contrast with interspinous distraction devices (spacers), which are used alone for decompression and are typically not fixed to the spinous process (See policy, Interspinous and Interlaminar Stabilization/Distracton Devices (Spacers)). In addition, whereas interspinous distraction devices may use dynamic stabilization, interspinous fixation devices are rigid. However, the fixation devices might also be used to distract the spinous processes and decrease lordosis. Thus, the fixation devices might be used off-label without interbody fusion as decompression (distraction) devices in patients with spinal stenosis. If fixation devices are used alone as a spacer, there is a risk of spinous process fracture.

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 device. There is also a potential for spinous process fracture.

Regulatory Status

The following interspinous fixation devices have received clearance to market by the U.S. Food and Drug Administration (FDA). This may not be an exhaustive list.

- Aerial™ Interspinous Fixation (Globus Medical Inc.)
- Affix™ (NuVasive)
- Aileron™ (Life Spine)

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- Aspen™ (Lanx, acquired by BioMet)
- Axle™ (X-Spine)
- BacFuse® (Pioneer Surgical)
- BridgePoint™ (Alphatec)
- coflex-IF® (Paradigm Spine)
- Inspan™ (Spine Frontier)
- Interbridge Interspinous Posterior Fixation System (LDR Spine)
- Minuteman™ (Spinal Simplicity)
- PrimaLOK™ (OsteoMed)
- Octave™ (Life Spine)
- 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-IF 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 the FDA.

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

Related Policies:

Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)
Lumbar Spine Fusion Surgery

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

Interspinous Fixation (Fusion) Devices are considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Interspinous Fixation (Fusion) Devices are covered

Not applicable.

When Interspinous Fixation (Fusion) Devices are not covered

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.

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Policy Guidelines

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, and two small randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. The randomized trials found comparable benefits for IFD with interbody fusion for those undergoing spinal fusion compared with interbody fusion with pedicle screws, but the comparative safety was less clear. One risk is spinous process fracture, while a potential benefit is a reduction in adjacent segment degeneration. Additionally, the RCTs had important methodological and relevancy weaknesses that limited their interpretation. 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. RCTs 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbssc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: None

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.138, 9/13/2012

Senior Medical Director – 10/2012

Specialty Matched Consultant Advisory Panel – 5/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.138, 9/12/2013

Specialty Matched Consultant Advisory Panel – 5/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.138, 9/11/2014

Specialty Matched Consultant Advisory Panel – 5/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.138, 9/10/2015

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Specialty Matched Consultant Advisory Panel – 5/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.138, 4/13/2017

Specialty Matched Consultant Advisory Panel – 5/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.138, 4/12/2018

Specialty Matched Consultant Advisory Panel – 5/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.138, 4/8/2019

Specialty Matched Consultant Advisory Panel – 5/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.138, 4/16/2020

Specialty Matched Consultant Advisory Panel – 5/2020

Policy Implementation/Update Information

- 11/27/12 New policy. “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.” (btw)
- 7/1/13 Specialty Matched Consultant Advisory Panel review 5/15/2013. No change to policy. (btw)
- 10/29/13 Reference added. (btw)
- 6/10/14 Specialty Matched Consultant Advisory Panel review 5/27/2014. No change to policy. (btw)
- 11/25/14 Reference added. Related policy added. (sk)
- 7/1/15 Specialty Matched Consultant Advisory Panel review 5/26/2015. (sk)
- 10/30/15 Reference added. (sk)
- 7/1/16 Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/25/2016. (sk)
- 12/30/16 Codes 22853, 22854, and 22859 added to Billing/Coding section. (sk)
- 2/3/17 Codes 22853, 22854, and 22859 removed from Billing/Coding section. (sk)
- 6/30/17 Reference added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/31/2017. (sk)
- 6/29/18 Reference added. Specialty Matched Consultant Advisory Panel review 5/23/2018. (sk)
- 6/11/19 Reference added. Specialty Matched Consultant Advisory Panel review 5/15/2019. (sk)

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6/9/20 Reference added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/20/2020. (bb)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.