MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Medical Policy

Interspinous Fixation (Fusion) Devices

Table of Contents

Policy Number: 436

BCBSA Reference Number: 7.01.138 (For Plan internal use only)
NCD/LCD: NA

Related Policies

Interspinous Distraction Devices (Spacers), #584

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Interspinous fixation (fusion) devices are **INVESTIGATIONAL** for any indication, including but not limited to use:

- In combination with interbody fusion, **OR**
- Alone for decompression in individuals with spinal stenosis.

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 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)
- SP-Link ™ System (Medical Designs LLC)
- ZIP ® MIS Interspinous Fusion System (Aurora Spine).

Interspinous fixation devices 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 FDA.

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

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is **not** a covered service.
Commercial PPO and Indemnity	This is **not** a covered service.
Medicare HMO Blue℠	This is **not** a covered service.
Medicare PPO Blue℠	This is **not** a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following HCPCS code is considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
C1821	Interspinous process distraction device (implantable)

Description

Contemporary models of interspinous fixation devices 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. Interspinous fixation devices are placed under direct visualization, while screw and rod systems may be placed 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.

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

Unlike interspinous fixation devices, 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 interspinous fixation devices are rigid. However, interspinous fixation devices might also be used to distract the spinous processes and decrease lordosis. Thus, interspinous fixation devices could be used off-label without interbody fusion as decompression (distraction) devices in patients with spinal stenosis. If interspinous fixation devices are used alone as a spacer, there is a risk of spinous process fracture.

Summary

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 are also being evaluated for stand-alone use in individuals with spinal stenosis and/or spondylolisthesis.

Summary of Evidence

For individuals who are undergoing spinal fusion who receive an interspinous fixation device 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. The randomized trials found comparable benefits for interspinous fixation devices 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 interspinous fixation devices compared with the established standard (pedicle screw with 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 interspinous fixation device alone, the evidence includes a small RCT and 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. Well-designed randomized controlled trials are needed that evaluate health outcomes following use of interspinous fixation devices as a stand-alone for decompression. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
6/2025	Policy updated with literature review through February 24, 2025; reference added. Policy statement unchanged.
6/2024	Annual policy review. References updated. Policy statements unchanged.

2/2024	Policy clarified to include a list of interspinous fixation devices cleared for marketing by the FDA.
6/2023	Annual policy review. Minor editorial refinement to policy statement; intent unchanged
2/2023	Clarified coding information.
6/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2021	Clarified coding information.
5/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
6/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
5/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
5/2018	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
5/2017	Annual policy review. New references added.
11/2015	Annual policy review. New references added.
4/2013	Annual policy review. New policy describing non-coverage. Effective 4/1/2013.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

1. Wu JC, Mummaneni PV. Using lumbar interspinous anchor with transforaminal lumbar interbody fixation. World Neurosurg. May 2010; 73(5): 471-2. 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. 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. May 2017; 9(2): 198-205. PMID 28544495
4. 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. Apr 2018; 12(2): 172-184. PMID 30276077
5. Baranidharan G, Bretherton B, Feltbower RG, et al. 24-Month Outcomes of Indirect Decompression Using a Minimally Invasive Interspinous Fixation Device versus Standard Open Direct Decompression for Lumbar Spinal Stenosis: A Prospective Comparison. J Pain Res. 2024; 17: 2079-2097. PMID 38894862
6. Sclafani JA, Liang K, Ohnmeiss DD, et al. Clinical outcomes of a polyaxial interspinous fusion system. Int J Spine Surg. 2014; 8. PMID 25694912
7. North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion. 2019; https://www.spine.org/Product-Details?productid=%7B7D67EEB8-4CC7-E411-9CA5-005056AF031E%7D. Accessed February 24, 2025.