DRAFT Medical Coverage Policy | Interspinous Fixation (Fusion) Devices

EFFECTIVE DATE: 01|01|2027
POLICY LAST REVIEWED: 09|02|2026

OVERVIEW

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.

MEDICAL CRITERIA

N/A

PRIOR AUTHORIZATION

N/A

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Interspinous fixation (fusion) devices* for any indication, including but not limited to the applicable uses below, are considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine the effects of the technology on health outcomes:

- 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).

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COVERAGE

Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered surgery benefits/coverage.

BACKGROUND

The purpose of interspinous fixation devices is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals who are undergoing spinal fusion or individuals 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 (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. 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.

Regulatory Status

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- SP-Fix™ (Globus)
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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.

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 2small 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 2 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.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code(s) are considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

22899 Unlisted procedure, spine

RELATED POLICIES

Device Intensive Procedure Edit
Unlisted Procedures

PUBLISHED

Provider Update, November 2026

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