

(701138)

Medical Benefit		Effective Date: 04/01/13	Next Review Date: 01/15
Preauthorization	No	Review Dates: 01/13, 01/14	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but is recommended if despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

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 are also being evaluated for stand-alone use in patients with spinal stenosis.

Background

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. 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. (1) 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. Given these uncertainties, studies are needed that compare health outcomes between interspinous fixation devices and pedicle screw-rod fixation.

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.

- Affix™ (NuVasive)
- Aileron™ (Life Spine)
- Aspen™ (Lanx)
- Axle™ (X-Spine)
- BacFuse® (Pioneer Surgical)
- BridgePoint™ (Alphatec)
- coflex-F® (Paradigm Spine)
- Inspan™ (Spine Frontier)
- PrimaLOK™ (OsteoMed)
- Octave™ (Life Spine)
- Spire™ (Medtronic)
- SP-Fix™ (Globus)

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

Related Protocol

Interspinous Distraction Devices (Spacers)

Policy (Formerly Corporate Medical Guideline)

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.

Policy Guideline

Clinical input has identified potential exceptions where the devices might be considered **medically necessary**, such as patients with small pedicles where pedicle screws could not be safely placed.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced

procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Wu JC, Mummaneni PV. Using lumbar interspinous anchor with transforaminal lumbar interbody fixation. *World Neurosurg* 2010; 73(5):471-2.
2. 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):466-72.