Protocol

Interspinous and Interbody Fixation (Fusion) Devices

(701138)

(Formerly Interspinous Fixation [Fusion] Devices)

Medical Benefit		**Effective Date**: 05/01/20	**Next Review Date**: 11/20
Preauthorization	No	**Review Dates**: 01/13, 01/14, 11/14, 11/15, 11/16, 11/17, 11/18, 11/19, 05/20	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

Populations	Interventions	Comparators	Outcomes
Individuals: • Who are undergoing spinal fusion	Interventions of interest are: • Interspinous fixation device with interbody fusion	Comparators of interest are: • Interspinous fixation device with pedicle screw construct	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Resource utilization • Treatment-related morbidity
Individuals: • With spinal stenosis and/or spondylolisthesis	Interventions of interest are: • Interspinous fixation device alone	Comparators of interest are: • Decompression	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Resource utilization • Treatment-related morbidity

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 (IFDs) are also being evaluated for stand-alone use in patients with spinal stenosis and/or spondylolisthesis.

SUMMARY OF EVIDENCE

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. 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 the risks and benefits following use of IFDs compared with the established

standard (pedicle screw with 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. Randomized controlled trials are needed that evaluate health outcomes following use of IFDs as a stand-alone for decompression. The evidence is insufficient to determine the effects of the technology on health outcomes.

Interbody polyetheretherketone (PEEK) cages instrumentation such as plates, pedicle screws, or rods may be used to stabilize the spine during the months that fusion is taking place and to improve fusion success rates.

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.

Interbody PEEK cages instrumentation such as plates, pedicle screws, or rods are considered **medically necessary** when criteria for spinal fusion are met.

POLICY GUIDELINES

Potential exceptions exist where the devices might be considered medically necessary, such as patients with small pedicles where pedicle screws could not be safely placed.

BACKGROUND

Contemporary models of interspinous fixation devices (IFDs) 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 as an alternative to pedicle screw and rod constructs to aid in the stabilization of the spine with interbody fusion. IFDs are placed under direct visualization, while screw and rod systems may be placed under direct visualization or percutaneously. Use of an IFD in combination with a unilateral pedicle screw system has also been proposed. IFDs are not intended for stand-alone use.

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

Unlike IFDs, interspinous distraction devices (spacers) are used alone for decompression and are typically not fixed to the spinous process (see the Interspinous and Interlaminar Stabilization/Distraction Devices [Spacers] Protocol). In addition, interspinous distraction devices have been designed for dynamic stabilization, whereas IFDs 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.

REGULATORY STATUS

The following IFDs have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. This list may not be exhaustive.

- 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)
- ZIP® MIS Interspinous Fusion System (Aurora Spine).

Food and Drug Administration product code: PEK.

IFDs 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 Food and Drug Administration.

Use of an IFD for a stand-alone procedure is considered off-label.

RELATED PROTOCOL

Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services 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. May 2010;73(5):471-472. 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. 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. PMID 23133725
4. 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. PMID 25433267
5. Sclafani JA, Liang K, Ohnmeiss DD, et al. Clinical outcomes of a polyaxial interspinous fusion system. Int J Spine Surg. Feb 2014;8. PMID 25694912
6. North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion. 2004; https://www.spine.org/PolicyPractice/CoverageRecommendations/AboutCoverageRecommendations.aspx. Accessed March 6, 2017.
7. 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.
8. 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.
9. Chen Y, Wang X, Lu X, et al. Comparison of titanium and polyetheretherketone (PEEK) cages in the surgical treatment of multilevel cervical spondylotic myelopathy: a prospective, randomized, control study with over 7-year follow-up. Eur Spine J. Jul 2013;22(7):1539-1546.
10. Seaman S, Kerezoudis P, Bydon M, et al. Titanium vs. polyetheretherketone (PEEK) interbody fusion: Meta-analysis and review of the literature. J Clin Neurosci. Oct 2017;44:23-29.