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Medical Policy Manual

Topic: Interspinous Fixation (Fusion) Devices

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Section: Surgery

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Policy No: 172

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

The spinous process fixation orthosis is marketed as a minimally invasive alternative to pedicle screw instrumentation in spinal interbody fusion. The device is inserted through a small incision over the spinal level being fused. It includes an enclosure in which bone graft material is placed.

This device may also be referred to as an interspinous anchor, spinous fixation system, or spinal interlaminal fixation orthosis. It differs from interspinous process spacers (e.g., X-STOP) and dynamic stabilization systems in that it is intended for fixation/fusion rather than as motion preserving devices.

Regulatory Status

There are a number of spinous process fixation orthoses under investigation, some of which have received approval for marketing from the U.S. Food and Drug Administration (FDA) for single-level fixation with bone graft material for achieving supplemental fusion. **These devices are not approved for stand-alone use**:

Device name	Manufacturer	FDA Approved?
Affix™ II and Affix II Mini Spinous Process Plate System	Nuvasive®	Yes
Aileron® Posterior Fusion System	Life Spine®	Yes
Aspen® Spinous Process Fixation System	Lanx®	Yes
Axle™ Interspinous Fusion System	X-Spine	Yes

BacFus® Spinous Process Fusion Plate	RTI Surgical™ (formerly Pioneer® Surgical)	Yes
BridgePoint™ Spinous Process Fixation System	Alphatec Spine®	Yes
coflex-F® Implant Systems*	Paradigm Spine	Yes
Inspan™ Spinous Process Plate System	SpineFrontier®	Yes
Minuteman® Interspinous Interlaminar Fusion Device (percutaneous spinal fusion)	Spinal Simplicity	No
Octave™ Posterior Fusion System	Life Spine®	Yes
PrimaLOK™ SP Interspinous Fusion System	OsteoMed Spine	Yes
SP-Fix™ Spinous Process Fixation System	Globus Medical	Yes
Spire™ Stabilization System	Medtronic Sofamor Danek	Yes

*For the non-fusion coflex® Interlaminar Implant, see Medical Policy Surgery No. 155.

MEDICAL POLICY CRITERIA

Implantation of spinous process fixation orthoses is considered **investigational** for all indications.

SCIENTIFIC EVIDENCE

Evaluating the safety and effectiveness of spinous process fixation orthoses requires randomized comparisons with spinal fusion using conventional devices (e.g., pedicle screws). These comparisons are necessary to determine whether the benefits of spinous process fixation orthoses outweigh any risks and whether they offer advantages over conventional devices with respect to the following:

- Pain and functioning
- Durability of treatment effects (the benefits of spinal surgery are known to diminish over time; therefore, it cannot be assumed that any early benefits will remain stable in the long term)
- Adverse events (e.g., vertebral fracture)
- Device failure/replacement
- Impact on future surgical options in the same or adjacent spinal levels.

Literature Appraisal

There is no clinical trial evidence published for spinous process fixation orthoses used in combination with spinal fusion. The current evidence for this indication consists of two articles describing a single ex vivo biomechanical study on cadaver spines.[1,2] Conclusions from cadaver studies cannot be used to determine the outcomes of device implantation in living human subjects.

Spinous process fixation devices are not approved by the U.S. Food and Drug Administration (FDA) for stand-alone use; therefore, this indication is considered off-label. Current clinical trial evidence for stand-alone procedures is limited to a single case series of 6 patients which does not permit conclusions about the safety and effectiveness of these devices due to significant methodological limitations such as small sample size, lack of a control group for comparison, and lack of randomized treatment allocation.[3]

Clinical Practice Guidelines

There are no clinical practice guidelines from U.S. professional societies that address the use of spinous process fixation devices.

Summary

Due to the lack of evidence from well-designed clinical trials, conclusions cannot be reached about the long-term benefits and risks of spinous process fixation orthoses. Therefore, use of these devices is considered investigational for all indications.

REFERENCES

1. Karahalios, DG, Kaibara, T, Porter, RW, et al. Biomechanics of a lumbar interspinous anchor with anterior lumbar interbody fusion. *J Neurosurg Spine*. 2010 Apr;12(4):372-80. PMID: 20367372
2. Kaibara, T, Karahalios, DG, Porter, RW, et al. Biomechanics of a lumbar interspinous anchor with transforaminal lumbar interbody fixation. *World Neurosurg*. 2010 May;73(5):572-7. PMID: 20920945
3. Kim, DH, Shanti, N, Tantorski, ME, et al. Association between degenerative spondylolisthesis and spinous process fracture after interspinous process spacer surgery. *Spine J*. 2012;12:466-72. PMID: 22622239

CROSS REFERENCES

Dynamic Stabilization of the Spine, Surgery, Policy No. 143

Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers), Surgery, Policy No. 155

Percutaneous Axial Anterior Lumbar Fusion, Surgery, Policy No. 157

Total Facet Arthroplasty, Surgery, Policy No. 171

Image-Guided Minimally Invasive Spinal Decompression (IG-MSD) for Spinal Stenosis, Surgery, Policy No. 176

Lumbar Spinal Fusion, Surgery, Policy No. 187

CODES	NUMBER	DESCRIPTION
There are no specific codes for spinal instrumentation using the spinous process fixation orthoses. The appropriate code for reporting this procedure is 22899; it is inappropriate to use the posterior pedicle fixation CPT codes 22840-22844 or interspace instrumentation code 22851. It is also inappropriate to use the CPT codes for conventional spinal fusion 22610-22632 because the procedure for insertion of this device is significantly different than conventional fusion techniques (eg. pedicle screw fixation).		
CPT	22899	Unlisted procedure, spine

CODES	NUMBER	DESCRIPTION
HCPCS	None	