Anthem

Medical Policy

Subject: Interspinous Process Fixation Devices
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Description/Scope

This document addresses interspinous, non-pedicle fixation devices attached to the *spinous process* to achieve *rigid* spinal fixation and accommodate bone graft material for spinal fusion.

Note: Interspinous process fixation devices in this document differ from interspinous process spacers and dynamic stabilization systems that are motion preserving devices. Please see the following related documents for additional information concerning these devices:

- SURG.00075 Intervertebral Stabilization Devices
- SURG.00092 Implanted Devices for Spinal Stenosis

Position Statement

Investigational and Not Medically Necessary:

Interspinous process fixation devices are considered **investigational and not medically necessary** for all indications.

Rationale

The standard surgical procedure for rigid spinal fixation involves the use of pedicle screws, rods and plates. Non-pedicle interspinous process fixation devices (with or without additional instrumentation) were developed as a minimally invasive rigid fixation alternative to standard rigid fixation instrumentation using pedicle screws and rods or interbody cages. According to the U.S. Food and Drug Administration (FDA) 510(k) clearance, interspinous process fixation devices are intended for use with bone graft material and are not intended for stand-alone use.

Available evidence comparing the Aspen® Spinous Process Fixation System (Zimmer Biomet Spine, Inc, Westminster, Colorado) to standard pedicle fixation includes two articles describing the biomechanical effect of the device on cadaver spines (Kaibara, 2012; Karahalios, 2010) and a small prospective study evaluating individuals with a primary diagnosis of lumbar spinal stenosis (with pain) treated with the Aspen device or an interspinous process spacer (Kim, 2012a). Of the 6 individuals implanted with the Aspen device (as a stand-alone procedure), 2 (33%) had postoperative spinous process fractures observed on computed tomography (CT). Limitations of this study include lack of randomization and small sample size leading to insufficient power to detect risk factors for fracture or differences in patient-centered outcomes.

Kim and colleagues (2012b) retrospectively compared 40 individuals who underwent single level spinal fusion with the CD HORIZON® SPIRE™ (Medtronic Sofamor Danek, Inc., U.S.A., Memphis, TN) interspinous fusion device (IFD) for lumbar spine disease (n=12, degenerative spondylolisthesis; n=2, intervertebral disc herniation; n=26, spinal stenosis) to 36 individuals with similar lumbar spinal disorders (n=10, degenerative spondylolisthesis; n=7, foraminal stenosis; n=1, intervertebral disc herniation; n=18, spinal stenosis) who underwent spinal fusion with pedicle screw fixation. All individuals in both groups underwent posterior lumbar interbody fusion with a polyetheretherketone cage or a titanium alloy cage. Both groups were evaluated using dynamic lateral radiographs, visual analogue scale (VAS), and a Korean version of the Oswestry Disability Index (K-ODI) scores. The mean follow-up period was 14.2 months in the IFD group and 18.3 months in pedicle screw group. At 1-year follow-up, there was an improvement in the mean preoperative to postoperative VAS scores from 7.16 (± 2.1) to 1.3 (± 2.9) and 8.03 (± 2.3) to 1.2 (± 3.2) ($p<0.05$) in the IFD and pedicle screw groups, respectively. The K-ODI was reduced significantly in an equal amount in both groups 1 year postoperatively ($p<0.05$); however, no statistical difference in clinical outcomes was noticed between the 2 groups. Postoperative radiographs in the IFD group showed less improvement of instability at the instrumented level compared with the pedicle screw group. A higher incidence of adjacent segmental degeneration was reported in the pedicle screw group (n=13, 36.1%) than in the IFD group (n=5, 12.5%; p=0.029). In the IFD group, 1 individual had sustained back pain, and lumbar CT revealed fusion failure and inferior articular process fracture. There were no major surgery-related complications such as deep infection, nerve root injury, and cerebral spinal fluid (CSF) leakage in the IFD group; however, in the pedicle screw group, 3 individuals developed deep infection, 2 individuals experienced CSF leakage, and 1 individual required re-operation for a postoperative epidural hematoma. Limitations of this study include the retrospective, nonrandomized design, the heterogeneous population of participants in terms of preoperative diagnoses, and a relatively short-term follow-up period.

Scalfani and colleagues (2014) retrospectively reviewed medical records to evaluate postoperative clinical outcomes in 53 individuals who were implanted with a second generation polyaxial PrimaLOK™ SP Interspinous Fusion System (OsteoMed, Addison, TX). All subjects reached the 1-year postoperative time point. Subjects had a mean age of 60 years (range, 34-89 years) at the time of surgery. The most common primary surgical indications were degenerative disc disease with stenosis (45.3%), herniated disc (18.9%) and spondylolisthesis (11.3%). A total of 34 subjects were implanted with the PrimaLOK SP device, 16 subjects received both a polyetheretherketone interbody cage and the PrimaLOK SP device, and 3 subjects received pedicle screw instrumentation, a polyetheretherketone interbody cage and the PrimaLOK SP device. Complications included intraoperative dural tear (n=1) and readmission for intractable pain after a post-discharge mechanical fall (n=1). There were no cases of fracture or migration of the device observed at the 6-week postoperative time point; however, there were 4 cases of hardware removal and 2 cases of re-operation for adjacent level disease during the follow-up period. The pain index score improved from 7.17 ± 1.68 to 4.48 ± 2.8 ($p=0.0001$, 22 months average follow-up) for the overall study group. There was no difference in Macnab classification score between different primary surgical indication groups (χ^2 $p>0.05$). Limitations of this review include the retrospective study design and lack of data collection on preoperative VAS scores of low back and leg pain and validated quality of life of life data to distinguish if the postoperative improvement was predominantly in axial low back pain, radicular lower extremity pain or neurogenic claudication.

Lopez and colleagues (2017) systematically evaluated the literature on lumbar spinous process fixation and fusion devices (excluding dynamic fixation and spinous process spacer devices). A total of 15 articles met the inclusion and exclusion criteria, including 4

comparative studies (level III evidence), 2 case series (level IV evidence), and 9 in vitro biomechanics studies (level V evidence). Two of the nonrandomized studies compared interspinous process fixation devices to pedicle screws in individuals undergoing interbody fusion and two other studies included interspinous process fixation devices alone or pedicle screws plus an interspinous process fixation device in individuals undergoing interbody fusion. Use of an interspinous process fixation device was associated with decreased surgical time and blood loss compared to pedicle screw implantation procedures., Lopez et al. report that flawed study designs may have inadequately controlled for biases when reporting outcomes of reduced spinal instability at 1 year, rates of device failure, bony fracture, and complications. No comparative studies exist that report either complication rates of interspinous process fixation devices to other treatment modalities or length of hospital stay for interspinous process fixation devices compared to pedicle screw implantation procedures.

In 2019, Wei and colleagues published the results of a retrospective study that included 95 subjects with lumbar disc herniation (LDH). The subjects were treated with inter-spinal distraction fusion (ISDF) using the BacFuse® Spinous Process Fusion Plate (RTI Surgical, Inc., Marquette, MI). Symptoms and imaging were evaluated prior to surgery, immediately following surgery, 6 months post-op, and a single final visit (average was 15.4 ± 3.4 months). Follow-up assessment reported improvements from baseline in VAS from 6.7 ± 1.3 to 2.1 ± 1.4 ($p<0.001$) at final follow-up, and ODI of 33.3 ± 6.2 to 12.5 ± 5.7 ($p<0.001$) at final follow-up. Imaging showed the anterior disc height was not statistically different at the post-operative follow-up ($p=0.502$). The imaging results showed initial improvement in imaging for both posterior disc height (18.3%) and foramina height (9.7%), only to have decreases of 2.4% and 5.1% respectively, at the final follow-up. Only 1 subject suffered a spinous process fracture but this did not cause significant back discomfort and was treated non-operatively. Long-term studies with a robust sample size are needed to show the product is durable and subjects experience long-term improvement with use of the BacFuse implant for LDH.

In summary, there is insufficient evidence in the peer-reviewed published medical literature to support the long-term clinical benefit of interspinous process fixation devices. Randomized controlled trials are needed to demonstrate the clinical utility of interspinous process fixation devices compared with established standard surgical approaches involving pedicle screw-rod fixation with lumbar fusion procedures.

Other Considerations

In 2014, the North American Spine Society (NASS) issued coverage policy recommendations for the clinical indications for interspinous process fixation devices marketed as an alternative to pedicle screw fixation for lumbar fusion, which was revised in 2019 as follows:

> NASS noted that although there is still limited evidence, interspinous fixation with fusion for stabilization may be considered when utilized in the context of lumbar fusion procedures for patients with diagnoses including stenosis, disc herniations, or synovial facet cysts in the lumbar spine, as an adjunct to cyst excision which involves removal of greater than 50 percent of the facet joint and when utilized in conjunction with a robust open laminar and/or facet decortication and fusion, and/or a robust autograft inter- and extra-spinous process decortication and fusion, and/or an interbody fusion of the same motion segment. NASS also noted that no literature supports the use of interspinous fixation without performing an open decortication and fusion of the posterior bony elements or interbody fusion.

Background/Overview

Vertebral Anatomy and Interspinous Process Fixation Devices

The pedicle is a small area of bone that is the first to extend out from both sides of the back of the vertebral body and joins with broad flat plates of bone (laminae) to form a hollow archway that protects the spinal cord. One type of fixation involves pedicle screws that are inserted as anchors for rods that provide fixation. Another type of fixation is the interbody cage placed in the disc space. Both of these fixation devices support fusion when used with bone graft material.

Interspinous process fixation devices attach to a vertebral spinous process and are intended for use as an adjunct to instrumented vertebral fixation procedures, as well as a compartment for bone graft material for fusion. Interspinous process fixation devices have been proposed for use after failed spinal fusion procedures and for treatment of degenerative disc disease, pseudoarthrosis, spondylolisthesis, trauma (dislocation or fracture), and tumors.

Definitions

Lamina: Part of the vertebra located behind the vertebral body. A flat area of bone between the superior process forming the facet joint and the spinous process, helping to form the central canal through which the spinal cord passes.

Pedicles: Two short, rounded processes made of thick cortical bone that extend posteriorly from the lateral margin of the dorsal surface of the vertebral body.

Spinal fusion: A surgical procedure to stabilize the spine by fusing together two or more vertebrae.

Spinous process: The small, bony protuberances located along the back of the spinal column that act as attachment sites for muscles and ligaments.

Spondylolisthesis: A condition that occurs when one vertebra slips out of the proper position onto the bone below it.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

22899	Unlisted procedure, spine [when specified as insertion of a non-pedicle interspinous process fixation device]

ICD-10 Procedure

	For the following procedures **when specified as insertion of a non-pedicle interspinous process fixation device**:
0RH40BZ	Insertion of interspinous process spinal stabilization device into cervicothoracic vertebral joint, open approach
0RH60BZ	Insertion of interspinous process spinal stabilization device into thoracic vertebral joint, open approach
0SH00BZ	Insertion of interspinous process spinal stabilization device into lumbar vertebral joint, open approach
0SH30BZ	Insertion of interspinous process spinal stabilization device into lumbosacral joint, open approach
ICD-10 Diagnosis	All diagnoses

References

Peer Reviewed Publications:

1. 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. 2017; 9(2):198-205.
2. Kaibara T, Karahalios DG, Porter RW, et al. Biomechanics of a lumbar interspinous anchor with transforaminal lumbar interbody fixation. World Neurosurg. 2010; 73(5):572-577.
3. Karahalios DG, Kaibara T, Porter RW, et al. Biomechanics of a lumbar interspinous anchor with anterior lumbar interbody fusion. J Neurosurg Spine. 2010; 12(4):372-380.
4. Kim DH, Shanti N, Tantorski ME, et al. Association between degenerative spondylolisthesis and spinous process fracture after interspinous process spacer surgery. Spine J. 2012a; 12(6):466-472.
5. 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. 2012b; 52(4):359-364.
6. 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. 2017; 30(9):E1279-E1288.
7. Moojen WA, Arts MP, Bartels RH, et al. Effectiveness of interspinous implant surgery in patients with intermittent neurogenic claudication: a systematic review and meta-analysis. Eur Spine J. 2011; 20(10):1596-1606.
8. 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. 2018; 12(2):172-184.
9. Sclafani JA, Liang K, Ohnmeiss DD, Gordon C. Clinical outcomes of a polyaxial interspinous fusion system. Int J Spine Surg. 2014; 8:35.
10. Tram J, Srinivas S, Wali AR, et al. Decompression surgery versus interspinous devices for lumbar spinal stenosis: A systematic review of the literature. Asian Spine J. 2020; 14(4):526-542.
11. Wei H, Tang H, Zhang T, et al. Preliminary efficacy of inter-spinal distraction fusion which is a new technique for lumbar disc herniation. Int Orthop. 2019; 43(4):899-907.

Government Agency, Medical Society, and Other Authoritative Publications:

1. North American Spine Society (NASS). NASS Coverage Policy Recommendations. Interspinous Fixation with Fusion. December 2019. For additional information, visit the NASS website: https://www.spine.org/PolicyPractice/CoverageRecommendations/AboutCoverageRecommendations. Accessed on May 15, 2023.
2. U.S. Food and Drug Administration. 510(k) Premarket Notification Database. Product Codes: KWP, KWQ, MNH, MNI, and PEK. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. Accessed on May 15, 2023.
3. U.S. National Institutes of Health. ClinicalTrials.gov. Available at:https://clinicaltrials.gov/ct2/home. Accessed on May 15, 2023.

Websites for Additional Information

1. U.S. National Library of Medicine. Medline Plus. Medical Encyclopedia. Spinal fusion. Last Reviewed July 2019. Available at: https://medlineplus.gov/ency/article/002968.htm. Accessed on May 15, 2023.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References section.
Reviewed	05/12/2022	MPTAC review. The Rationale and References sections were updated.
Reviewed	05/13/2021	MPTAC review. Updated Rationale, References, Websites, and Index sections.
Reviewed	05/14/2020	MPTAC review. Updated Rationale, References and Websites sections.
Reviewed	06/06/2019	MPTAC review. Updated Rationale, References and Websites for Additional Information sections.
Reviewed	07/26/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale, References, Websites for Additional Information, and Index sections.
Reviewed	08/03/2017	MPTAC review. Updated Rationale, References, and Websites for Additional Information sections.
Reviewed	08/04/2016	MPTAC review. Updated Rationale, References, Websites for Additional Information, and Index sections. Removed ICD-9 codes from Coding section.
Reviewed	08/06/2015	MPTAC review. Updated Rationale, References, Websites for Additional Information, and Index sections.
Revised	02/05/2015	MPTAC review. Revised Subject and investigational and not medically necessary statement, clarifying content to address the use of interspinous “process” fixation devices. Updated Description, Rationale, Background, and References sections.
Reviewed	08/14/2014	MPTAC review. Updated Description, Rationale, Background, Definitions, References, Index and Websites for Additional Information sections.
Reviewed	08/08/2013	MPTAC review. Updated Description, Rationale, and Background sections. Index updated with the StabiLink MIS Spinal Fixation System and VertiFlex Spinous Process Fixation Plate devices.
	04/19/2013	Updated Index section with the Aileron Interspinous Fixation System.
	12/11/2012	Updated Index section with the coflex-F implant device.
New	08/09/2012	MPTAC review. Initial document development.

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