# Interspinous Fixation Devices



**Medical Policy #: 07.01.84**
**Original Effective Date:** January 2007
**Reviewed:** February 2022
**Revised:** February 2022

**NOTICE: This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.**

**Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.**

**This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.**

## DESCRIPTION

Back pain is a common symptom and, for some, can lead to disability. Devices that keep specific areas of the spine rigid are known as interspinous fixation devices. Surgeons attach these devices to the bones of the spine (vertebrae) to prevent the joints from bending and twisting as they normally would. The intent of the devices is to decrease pain. These devices are typically used as part of fusion surgery. The device holds the spine in place while the implanted bone material eventually fuses the vertebrae together. Occasionally the device might be used without fusion surgery to relieve pressure on the spinal cord or nerve.

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. 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. 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. Interspinous fixation devices are placed under direct visualization, while screw and rod systems may be placed either under direct visualization or percutaneously.

The interspinous fixation devices are being evaluated as alternatives to pedicle screw and rod constructs in combination with interbody fusion. 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. Both of the following fixation techniques support fusion when used with bone graft material.

- 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.

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

Interspinous fixation (fusion) devices are different from interspinous distraction devices (spacers), which are used alone for decompression and are typically not fixed to the spinous process (*See policy, Interspinous Distraction Devices*). In addition, interspinous distraction devices have been designed for 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 interspinous 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 devices 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. 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.

**Clinical Context and Therapy Purpose**

The purpose of interspinous fixation devices is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with spinal stenosis and/or spondylolisthesis and those who might undergo a spinal fusion.

The question addressed in this policy is: Does the use of interspinous fixation improve the net health outcome in patients who are undergoing spinal fusion?

The following PICO was used to select literature to inform this policy.

**Populations**
The relevant population of interest are the following individuals:

- Those who have spinal stenosis and/or spondylolisthesis.
- Those who are undergoing spinal fusion.

**Interventions**
The therapy being considered are the following:

- interspinous fixation device alone
- interspinous fixation devices with interbody fusion

**Comparators**
The following practice is currently being used to treat spinal stenosis and/or spondylolisthesis: decompression.

The following practice is currently being used for individuals who are undergoing spinal fusion: interspinous fixation devices with pedicle screw construct.

**Outcomes**
The general outcomes of interest include symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity.

**Review of Evidence**
(2019) Wei et al. 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 as a result of a post-operative complication; it 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.

(2018) Panchal et. al completed a multicenter, prospective, randomized, noninferiority controlled study on the anterior and lateral lumbar interbody fusion with supplemetal interspinous process fixation. All patients received single-level ALIF or LLIF with supplemental ISPF (n = 66) or pedicle screw fixation (PSF; n = 37) for degenerative disc disease and/or spondylolisthesis (grade ≤2). The randomization patient ratio was 2:1,

ISPF/PSF. Perioperative and follow-up outcomes were collected (6 weeks, 3 months, 6 months, and 12 months). The results noted for ISPF patients, mean posterior intraoperative outcomes were blood loss, 70.9 mL; operating time, 52.2 minutes; incision length, 5.5 cm; and fluoroscopic imaging time, 10.4 seconds. Statistically significant improvement in patient Oswestry Disability Index scores were achieved by just 6 weeks after operation ($P < .01$) and improved out to 12 months for the ISPF cohort. Patient-reported 36-Item Short Form Health Survey and Zurich Claudication Questionnaire scores were also significantly improved from baseline to 12 months in the ISPF cohort ($P < .01$). A total of 92.7% of ISPF patients exhibited interspinous fusion at 12 months. One ISPF patient (1.5%) required a secondary surgical intervention of possible relation to the posterior instrumentation/procedure. In conclusion, ISPF can be achieved quickly, with minimal tissue disruption and complication. In supplementing ALIF and LLIF, ISPF supported significant improvement in early postoperative (≤12 months) patient-reported outcomes, while facilitating robust posterior fusion. The authors acknowledge that heterogeneity in footprint size is a potential limitation; however, this remains an inherent limitation of any interbody fusion clinical study in which patient anatomy is variable. A perceived limitation of ISPF is that it cannot afford the same degree of lordotic correction as PSF and could potentially introduce local kyphosis by distracting the interspinous space. However, although PSF may provide greater mechanical leverage to induce lordosis, this may incur facet violation and again predispose to ASD. Although no definitive evidence exists differentiating PSF as a more effective posterior fixation modality with respect to sagittal balance maintenance, the diminished rates of ASD with ISPF provide compelling evidence that ISPF, despite the perceived limitations, can provide effective sagittal correction and preservation. Furthermore, the use of large anterior/lateral lordotic angled intervertebral cages can provide a source lordosis induction without necessitating significant induction via posterior manipulation. The authors do acknowledge that local kyphosis may occur if the ISPF device is oversized or inappropriately placed within the interspinous space; however, proper device trialing and placement mitigates this risk. The authors acknowledge that limitations did exist within this study, including the heterogeneity of PSF techniques. However, as emphasized, the use of a PSF control group significantly marginalizes any posterior technique selection bias. Accordingly, outcomes with ISPF should be considered within the context of what is clinically meaningful, with comparison to PSF outcomes contemplated only when appropriate. Heterogeneity also existed in the use of anterolateral plating; however, use of randomization and statistical controlling demonstrated a marginalized effect. Furthermore, standardization of concomitant medication(s) and intraoperative use of biologics were not performed; however, randomization of cohorts resulted in comparable distributions between cohorts that align with routine standard of care.

(2017) Huang et al. completed a randomized controlled trial to investigate the clinical feasibility and validity of interspinous fastener (ISF) for lumbar degenerative diseases. From October 2013 to March 2014, a total of 46 patients suffering from lumbar degenerative diseases underwent posterior lumbar interbody fusion (PLIF) randomly augmented by ISF or pedicle screws. The clinical outcome was primarily measured by Oswestry Disability Index (ODI) score. The minimal clinical important difference

(MCID) was defined as an eight-point decrease in ODI. The second clinical outcome measurement was Japanese Orthopedic Association (JOA) score. Interbody fusion rates were evaluated by lumbar plain radiograph and computed tomography (CT) scan. Complications were also compared between groups. Statistical analyses were performed by SPSS version 13.0. Sample size calculation was performed before the study. The type I error $\alpha$ was set at 0.05 and the type II error $\beta$ at 0.1. Based on these assumptions and adding 10% for possible dropouts, sample size calculations indicated that a total of 46 patients were required for the study. Parametric data was compared by independent t-test and categorical variables were compared using $\chi 2$ -tests or Fisher exact tests depending on the sample size. A P-value of less than 0.05 was considered significantly statistically different. Fleiss kappa coefficients were calculated for intra-observer and inter-observer reliability. The results noted a total of 43 patients completed the follow-up, with 22 cases in the ISF group and 21 patients in the pedicle screws group, respectively. Less intraoperative blood loss and shorter operation time were observed in the ISF group. The mean ODI significantly declined in both groups, with the ISF group's decreasing from preoperative 43.3 ± 8.2 to 21.4 ± 3.5 at 24-month follow-up and the pedicle screws group's decreasing from preoperative 42.9 ± 7.9 to 22.5 ±3.8 at 24-month follow-up, respectively. The ODI changes between groups had no statistical difference ($P > 0.05$). Of the 43 patients, 33 patients achieved an MCID. The bone fusion rate was 77.3% according to X-rays and 68.2% according to CT scans in the ISF group, and 81.0% according to X-rays and 76.2% according to CT scans in the pedicle screws group at the final follow-up. The intra-observer and inter-observer reliability assessed by the kappa value were 0.93 and 0.89, respectively. One patient in the pedicle screws group demonstrated screw loosening at the 6-month follow-up but was asymptomatic. One patient with spondylolisthesis in the ISF group demonstrated cage subsidence during the follow-up but also without related symptoms. In conclusion, the less invasive ISF combined with PLIF provided comparable clinical outcome and a similar bone fusion rate to pedicle screws. The ISF could potentially serve as a new alternative for lumbar degenerative diseases. Several limitations should be noted. First, despite no statistical difference, heterogeneity in baseline characteristics, including diagnosis, smoking and index levels, do exist between groups and may potentially generate bias. Second, it is well established that the most accurate standard to determine fusion is surgical exploration. Despite improvement in CT scans in fusion assessment, neither radiographs nor CT scans can demonstrate the same accuracy as surgical exploration. The third potential weakness of the study is the relatively short follow-up period.

(2017) Lopez et al. 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 decreased

surgical time and blood loss compared to pedicle screw implantation procedures, however, study designs were methodologically flawed and biased 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.

(2014) Sclafani et al. 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 ($\chi 2$ $p>0.05$). 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.

(2012b) Kim et al. 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.

(Kaibara, 2012; Kim, 2012a and Karahalios, 2010 et al.) The available evidence in the peer-reviewed published medical literature 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 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. Of the 6 individuals implanted with the Aspen device (as a stand-alone procedure), 2 (33%) had postoperative spinous process fractures observable on computed tomography (CT). Limitations of this study include the small sample size, heterogeneous population, and lack of outcome measures reporting a change in Oswestry Disability Index (ODI) or a reduction in pain medication usage.

**Summary of Evidence**

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. 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 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 interspinous fixation devices compared with the established standard (pedicle screw-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 interspinous fixation device 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 interspinous fixation devices as a stand-alone procedure. Randomized controlled trials are needed that evaluate health outcomes following use of interspinous fixation devices when used alone

for decompression. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Practice Guidelines and Position Statements**
**The North American Spine Society (NASS)**
(2019) The North American Spine Society issued a coverage position statement on the use of interspinous devices with lumbar fusion:

- It noted 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.
- They 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."
- Current evidence is insufficient to permit conclusions about whether any beneficial effect from interspinous process distraction or interlaminar stabilization spacers provides a significant advantage over surgical decompression, which is the current standard of care for surgical treatment of lumbar spinal stenosis. In addition, the complication rates and reoperation rates for these spacers compared with those of decompression surgery is unknown.

(*Accessed February 2022*)

**Regulatory Status**
The following *interspinous fixation devices* have received clearance to market by the U.S. Food and Drug Administration (FDA). *This is not intended to be an all-inclusive list.*

- Aerial™ Interspinous Fixation (Globus Medical Inc.)
- Affix™ (NuVasive)
- Affix II (NuVasive)
- Aileron™ (Life Spine)
- Aspen™ (Lanx, acquired by BioMet)
- Axle™ (X-Spine)
- BacFuse® (Pioneer Surgical)
- Benefix Interspinous Fixation System
- BridgePoint™ (Alphatec)
- CD HORIZON™ Spinal Fixation System (Medtronic Sofamor Danek)
- Coflex-F® (Paradigm Spine)
- Inspan™ (Spine Frontier)
- InterBRIDGE® Interspinous Posterior Fixation System (LDR Spine)
- Minuteman™ G3 Interspinous Interlaminar Fusion Device (Spinal Simplicity)
- Octave™ Posterior Fusion System (Life Spine)
- PrimaLOK™ SP Interspinous Fusion System (OsteoMed)
- SP-Link™ System (Medical Designs LLC)

- SP-Fix™ Spinous Process Fixation Plate (Globus)
- Spire™ (Medtronic)
- StabiLink® MIS Interspinous Fixation System
- Zip Mis Interspinous Fusion System

# PRIOR APPROVAL

Not applicable.

# POLICY

**Related Medical Policies**:

- 07.01.35 Interspinous Distraction Devices

Interspinous fixation devices are considered **investigational** for all indications to include but not limited to when they are used:

- alone for decompression in individuals with spinal stenosis and/or spondylolisthesis; **or**
- in combination with interbody fusion

To include, but not limited to, the following devices:

- Aerial™ Interspinous Fixation
- Affix™
- Aileron™
- Aspen™
- Axle™
- BacFuse®
- Benefix Interspinous Fixation System
- BridgePoint™
- CD HORIZON™ Spinal Fixation System
- Coflex-F®
- Inspan™
- InterBRIDGE® Interspinous Posterior Fixation System
- Minuteman™ G3 Interspinous Interlaminar Fusion Device
- Octave™ Posterior Fusion System
- PrimaLOK™ SP Interspinous Fusion System
- SP-Link™ System
- SP-Fix™ Spinous Process Fixation Plate
- Spire™
- StabiLink® MIS Interspinous Fixation System
- Zip Mis Interspinous Fusion System

These procedures allow for a period of relief before the canal has to be opened and can delay the day when a more invasive operation is needed. It does not prevent the procedures from being needed later. It is the longer-term performance which remains the

principle unanswered question. Randomized controlled trials are needed that evaluate health outcomes following use of interspinous fixation (fusion) devices in comparison with the established standard of pedicle screw-rod fixation. There is a need for longer term (>2 years) outcome data on the durability of symptom relief, the need for repeat procedures, and implant survival. Based on review of the current peer reviewed literature the evidence is insufficient to determine the technology improves net health outcomes.

**Policy Guidelines**

- Interspinous fixation devices are intended for use as an adjunct to interbody fusion. For example, the indication for the coflex-F® 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."
  - Use of an interspinous fixation device for a stand-alone procedure is considered off-label.

# PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 22899 Unlisted procedure, spine [*when specified as insertion of an interspinous process fixation device*]

# SELECTED REFERENCES


- North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion (Draft for comment only). 2019
- Australian Government Medical Services Advisory Committee, Public Summary Document No. 1422. Minimally invasive, lumbar decompression and dynamic stabilisation using an interlaminar device, with no rigid fixation to the vertebral pedicles, of one or two lumbar motions.
- North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion. Revised December 2019.
- North American Spine Society (NASS). NASS Coverage Policy Recommendations. Interspinous fixation with fusion. May 2014
- 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

- 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.
- 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.
- 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.
- 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.
- 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.
- Sclafani JA, Liang K, Ohnmeiss DD, Gordon C. Clinical outcomes of a polyaxial interspinous fusion system. Int J Spine Surg. 2014; 8:35. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4325480/.
- 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.
- 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.
- U.S. National Institutes of Health. ClinicalTrials.gov.
- 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. May 2017; 9(2): 198-205. PMID 28544495
- 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. Apr 2018; 12(2): 172-184. PMID 30276077


# POLICY HISTORY

| Date | Reason | Action |
|---|---|---|
| February 2022 | Annual Review | Policy Revision, New Policy Created |

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst

PO Box 9232
Des Moines, IA 50306-9232

*CPT® is a registered trademark of the American Medical Association.