# Molina Clinical Policy
# Interspinous Process Fixation Devices for Spinal Fusion
# Policy No. 339

**Last Approval: 2/14/2024**
**Next Review Due By: February 2025**

## DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

## OVERVIEW

This policy addresses interspinous, non-pedicle fixation devices applied to the spinous process to achieve rigid spinal fixation and accommodate bone graft material for spinal fusion. Spinal fusion, which fuses two or more vertebral bodies together, is the most common surgery for chronic nonspecific low back pain with lumbar disc degenerative changes. The goal is to restrict spinal motion and remove the degenerated disc to relieve symptoms. A variety of fusion techniques are used, all of which involve the placement of a bone graft between the vertebrae. Fusion can be performed with or without supplemental hardware or instrumentation (e.g., pedicle rods, plates, screws, or cages) that acts as an internal splint while the bone graft heals. Fusion alters the normal mechanics of the spine and is associated with an increase in long-term degenerative changes in adjacent spine segments. The standard spinal fusion procedure for rigid spinal fixation involves the use of pedicle screws, rods, cages, and plates. Non-pedicle interspinous process fixation devices were developed as a minimally invasive rigid fixation alternative to standard rigid fixation instrumentation to aid in the stabilization of the spine. Interspinous fixation systems are less invasive and pose fewer risks than standard instrumentation; they are being evaluated as alternatives to pedicle screws, rods, cages, and plates in combination with interbody fusion. Interspinous fixation devices are also being evaluated for stand-alone use in patients with spinal stenosis (Chou 2021; Levin 2021).

### Regulatory

The Food and Drug Administration (FDA) has approved a number of interspinous process fixation devices and granted 510(k) clearance for use with bone graft material (FDA date unknown). Interspinous fixation devices are class II devices and assigned the product codes PEK (spinal interlaminal fixation orthosis), KWQ (spinal intervertebral body fixation orthosis), KWP (spinal interlaminal fixation orthosis), and NKB (thoracolumbosacral pedicle screw system).

## RELATED POLICIES

MCP-222: Interspinous Decompression Devices for Spinal Stenosis (includes X Stop, non-fusion Coflex)

**Interspinous process fixation devices for spinal fusion in this policy differ from interspinous decompression devices for spinal stenosis.*

## COVERAGE POLICY

Interspinous Process Fixation Devices for Spinal Fusion **are considered experimental, investigational, and unproven** for any indication due to insufficient clinical evidence of safety and efficacy in published peer-reviewed medical literature.

## SUMMARY OF MEDICAL EVIDENCE

Overall, there is a lack of evidence in the peer-reviewed published medical literature to support the long-term safety and effectiveness of interspinous process fixation devices when used in conjunction with interbody fusion or as a stand-alone procedure. Large, well-designed randomized controlled trials are required to demonstrate the clinical utility of interspinous process fixation devices in comparison to established standard surgical approaches involving fixation with lumbar fusion procedures (e.g., pedicle screws, rods, cages, or plates).

Poetscher et al. (2018) conducted a systematic review and meta-analysis to assess the benefits and risks of interspinous process devices (IPDs) versus conservative treatment or decompression surgery. The authors provide recommendations for forthcoming randomized control trials. Overall, the evidence was of poor quality. One study compared IPDs to conservative treatment and found that IPDs had superior pain, functional status, and quality of life outcomes, but a greater risk of complications. In five trials comparing IPDs to decompressive surgery, pain, functional status, and quality of life were comparable. IPD implants were associated with a significantly higher risk of reoperation. Low-quality evidence suggests that IPDs have similar outcomes when compared to standard decompression surgery. Primary and secondary outcomes were not measured in all studies, and they were frequently published in incomplete form. Analysis of subgroups were not feasible. Patients who received IPD implants had significantly higher rates of reoperation and lower cost-effectiveness; however, future trials should improve in terms of design quality and data reporting, with longer follow-up periods.

Machado et al. (2016) conducted a Cochrane review to show a paucity of evidence regarding the efficacy of surgery for lumbar spinal stenosis. Twenty-four randomized controlled trials included 2352 participants with lumbar spinal stenosis and symptoms of neurogenic claudication. Three trials compared the effects of interspinous process spacer devices to conventional bony decompression; the spacer devices resulted in similar reductions in pain and disability, but they required longer operation time and were associated with a higher risk of reoperation. Two trials compared interspinous spacer devices to decompression plus fusion. While there was no difference in pain relief, the spacer devices showed a small but significant effect in disability reduction and were superior to decompression plus fusion in terms of operation time and perioperative blood loss. When several types of surgical decompression techniques were compared, there were no differences in the primary or secondary outcomes. Placebo-controlled trials in surgery are both feasible and required in the field of lumbar spinal stenosis. The findings show that decompression plus fusion and interspinous process spacers are not superior to conventional decompression alone; therefore, methodologically rigorous studies are required.

Lopez et al. (2017) conducted a systematic review of the literature on lumbar spinous process fixation and fusion devices through a systematic review of 15 articles (excluding dynamic fixation and spinous process spacer devices). Two non-randomized studies compared interspinous process fixation devices to pedicle screws in patients undergoing interbody fusion; two additional studies compared interspinous process fixation devices alone or pedicle screws plus an interspinous process fixation device in patients undergoing interbody fusion. The 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 one year, rates of device failure, bony fracture, and complications. There are no comparative studies that compare the complication rates of interspinous process fixation devices to other treatment modalities or the length of hospital stay for interspinous process fixation devices to pedicle screw implantation procedures.

### National and Specialty Organizations

The **North American Spine Society (NASS)** (2019) published *Coverage Policy Recommendations: Interspinous Fixation with Fusion.* It was noted that despite limited evidence, the procedure may be considered when used for patients with diagnoses such as stenosis, disc herniations, or synovial facet cysts in the lumbar spine. The NASS recommends stabilization with an interspinous device without fusion in conjunction with laminectomy as an alternative to lumbar fusion for degenerative lumbar stenosis (with or without low-grade spondylolisthesis, $\leq$ 3 mm of anterolisthesis on a lateral radiograph) when the following criteria are met:

- Patient presents with significant mechanical back pain (as well as symptoms related to neural compression), and pain is unlikely to improve with decompression alone. Evidence of back pain at rest and/or with movement

while standing should be present as well as pain that lacks neurogenic claudication characteristics.
- Lumbar fusion is indicated post-decompression for a diagnosis of lumbar stenosis with a Grade 1 degenerative spondylolisthesis.

The NASS also stated that "no literature supports the use of interspinous fixation without performing an open decortication and fusion of the posterior bony elements or interbody fusion."

Guidelines published by the **American Association of Neurological Surgeons (AANS)** (Eck et al. 2014) included the following recommendations:
- Lumbar fusion or a comprehensive rehabilitation program incorporating cognitive therapy as treatment alternatives for those with chronic, refractory low-back pain to traditional conservative treatment (e.g., physical therapy), and pain is cause by one-or-two level degenerative disc disease without stenosis or spondylolisthesis.
- Lumbar fusion should be performed for those with refractory low-back pain to conservative treatment (e.g., physical therapy or other nonoperative measures) and is due to one-or-two-level degenerative disc disease without stenosis or spondylolisthesis.

## CODING & BILLING INFORMATION

**CPT (Current Procedural Terminology) Code**

| Code | Description |
|---|---|
| **22899** | Unlisted procedure, spine (when specified as insertion of a non-pedicle interspinous process fixation device) |

**CODING DISCLAIMER.** Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

## APPROVAL HISTORY

**02/14/2024** Policy reviewed. No changes to criteria. Updated references.
**02/08/2023** Policy reviewed. No changes to coverage position. Added 'Related Policies' section. Updated references.
**02/09/2022** Policy reviewed, no changes to criteria, updated references.
**02/08/2021** Policy reviewed, no changes.
**04/23/2020** Policy reviewed, no changes.
**03/11/2019** New policy. IRO Peer Review. Policy reviewed by a practicing, board-certified physician in orthopedic surgery on January 14, 2019.

## REFERENCES

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