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

Last Approval: 12/11/2024
Next Review Due By: December 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

Lumbar spinal stenosis, most commonly caused by spondylosis, results from the narrowing of either the intraspinal canal, lateral recess, or the neural foramen. Pain, sensory loss, and lower limb weakness are the predominant symptoms of lumbar spinal stenosis, which are thought to be caused by the mechanical compression and ischemia of nerve roots in the spine. Often the neurological symptoms accompanying lumbar spinal stenosis are exacerbated by activity, such as walking and standing for long periods of time, which leads to a lower quality of life in those affected. Conservative treatment consists of physical therapy, pharmacotherapy, and possibly epidural injections. If conservative treatment fails, surgical treatment is explored ([1-2]Levin 2024).

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 (Chou 2023; [1-2]Levin 2024).

Interspinous, non-pedicle fixation devices were developed as a minimally invasive rigid fixation alternative to standard rigid fixation instrumentation to aid in the stabilization of the spine. These devices are applied to the spinous process to achieve rigid spinal fixation and accommodate bone graft material for spinal fusion. Interspinous fixation systems are proposed to be less invasive and pose fewer risks than standard instrumentation and 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 2023; [1-2]Levin 2024).

Regulatory Status

The Food and Drug Administration (FDA) has approved several 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), and KWP (spinal interlaminal fixation orthosis).

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.*

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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).

Systematic Reviews

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.

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.

Randomized Controlled Trials

Barandiharan et al. (2024) is conducting an early-stage, multi-center, prospective, randomized controlled trial comparing outcomes of indirect decompression using a minimally invasive interspinous fixation device versus standard open decompression. The trial is currently ongoing, with a projected five year follow up. The study design ensures all participants have a diagnosis of lumbar spinal stenosis confirmed with imaging, leg pain, and had failed at least 6 months of conservative treatment. Primary end point is clinical efficacy as assessed by the following measures: pain assessment via visual analogue scores (VAS), pain related disability via the Oswestry Disability Index (ODI) scores, and physical functioning via walking distance and Zurich Claudication Questionnaire (ZCQ) scores. Success is defined as ≥30% improvement in leg pain (VAS), ≥30% improvement in back pain (VAS), ≥30% improvement in pain-related disability (ODI) and ≥0.5-point improvement in physical function (ZCQ). This publication discussed the two-year results. Forty-eight participants were enrolled and randomized 1:1; however, only 43 participants underwent a procedure, therefore the final group numbers were 18 in the interspinous fixation group and 25 in the decompression group. After a few participants were either lost to follow up or withdrew consent, the two-year results consist of 15 in the interspinous fixation group and 19 in the decompression group. The 24-month results revealed that four participants had unfavorable outcomes (3 decompression, 1 interspinous fixation), and five participants demonstrated a loss of clinical

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benefit (2 decompression, 3 interspinous fixation). The mean reduction of leg pain at all post operative time points varied between 59-7-% for the decompression group versus 57 – 78% for the interspinous fixation group. ODI scores for the decompression group were 56% for the interspinous fixation group versus 80% for the decompression group. Composite clinical success rates 50% (9 of 18) for the interspinous fixation group versus 72% (18 of 25) for the decompression group. It is repeatedly noted that baseline scores for the interspinous group were significantly higher on the pain and disability scales than the decompression group, rendering the results not directly comparable. The limitations of this study are high risk of performance and detection bias, and small sample size.

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 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." 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, ≤ 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 **American Society of Pain and Neuroscience (ASPN)** published *Best Practices for Minimally Invasive Lumbar Spinal Stenosis Treatment 2.0 (MIST): Consensus Guidance from the American Society of Pain and Neuroscience* (Deer et al. 2022), which stated "The MIST recommends consideration of ISF [interspinous fixation] in patients with lumbar degenerative spine disease, in the presence of degenerative disc disease, with symptomatic mild-to-moderate LSS, with or without instability, with a grade 2 spondylolisthesis or less. Grade C; Level of certainty moderate; Level of evidence I-C".

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

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

12/11/2024	Policy reviewed. No changes to coverage criteria.
02/14/2024	Policy reviewed. No changes to criteria. Updated references. IRO Peer Reviewed on January 10, 2024, by a practicing physician board certified in orthopedic surgery.
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.

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