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

Last Approval: 2/9/2022
Next Review Due By: February 2023

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 attached to the spinous process to achieve rigid spinal fixation and accommodate bone graft material for spinal fusion. The most common surgery for chronic nonspecific low back pain with lumbar disc degenerative changes is spinal fusion, a procedure that fuses two or more vertebral bodies together. The goal is to restrict spinal motion and remove the degenerated disc (the presumed cause of pain) in order to relieve symptoms. A variety of fusion techniques are used – all 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 function 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 present fewer risks than standard instrumentation – these are being evaluated as alternatives to pedicle screw, rod, 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).

A number of interspinous process fixation devices have been approved by the Food and Drug Administration (FDA) and received 510(k) clearance for use as an adjunct to interbody fusion. (The use of a device for a stand-alone procedure would be considered an off-label use). Examples of include: Affix™ II and Affix II Mini Spinous Process Plate System (Nuvasive®), Aileron® Posterior Fusion System (Life Spine®) Surgery M-SUR172 3, Aspen® Spinous Process Fixation System (BioMet) , Axle™ Interspinous Fusion System (X-Spine), BacFus® Spinous Process Fusion Plate (RTI Surgical™, BridgePoint™ Spinous Process Fixation System (Alphatec Spine®), coflex-F® Implant Systems (Paradigm Spine), Inspan™ Spinous Process Plate System (SpineFrontier®), InterBRIDGE Interspinous Posterior Fixation System (LDR Spine), Minuteman® Interspinous Interlaminar Fusion Device (percutaneous spinal fusion) (Spinal Simplicity), Octave™ Posterior Fusion System (Life Spine®), PrimaLOK™ SP Interspinous Fusion System (OsteoMed Spine), SP-Fix™ Spinous Process Fixation System (Globus Medical), Spire™ Stabilization System (Medtronic Sofamor Danek), ZIP™ MIS Interspinous Fusion System (Aurora Spine).

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. (AMR, 2019).

NOTE: Interspinous process fixation devices for spinal fusion in this MCP differ from interspinous decompression devices for spinal stenosis. Please refer to *MCP-222: Interspinous Decompression Devices for Spinal Stenosis* (includes X Stop, non-fusion Coflex).

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Overall, there is a paucity 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 combination with interbody fusion or as a stand-alone procedure. Large well designed randomized controlled trials are needed to demonstrate the clinical utility of interspinous process fixation devices compared with 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 analyze the benefits and harms of interspinous process devices (IPDs) when compared to conservative treatment or decompression surgery. The authors suggest directions for forthcoming randomized control trials. Overall, quality of evidence was low. One trial compared IPDs to conservative treatment and found that IPDs presented better pain, functional status, quality of life outcomes, and higher complication risk. Five trials compared IPDs to decompressive surgery; pain, functional status, and quality of life had similar outcomes. IPD implants presented a significantly higher risk of reoperation. Low-quality evidence suggests that IPDs result in similar outcomes when compared to standard decompression surgery. Primary and secondary outcomes were not measured in all studies and were often published in incomplete form. Subgroup analysis was not feasible. In conclusion, patients submitted to IPD implants had significantly higher rates of reoperation, with lower cost-effectiveness however, future trials should improve in 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 investigated the effects of interspinous process spacer devices compared with conventional bony decompression; these spacer devices resulted in similar reductions in pain and disability, but the spacer devices required longer operation time and were associated with higher risk of reoperation. Two trials compared interspinous spacer devices with decompression plus fusion; the data found no difference in pain relief the spacer devices revealed a small but significant effect in disability reduction and were also superior to decompression plus fusion in terms of operation time and perioperative blood loss. (There was no difference in rate of reoperation). Overall, there were no differences for the primary or secondary outcomes when different types of surgical decompression techniques were compared. The quality of evidence varied from very low quality to high quality. Placebo-controlled trials in surgery are feasible and needed in the field of lumbar spinal stenosis. Results demonstrate that decompression plus fusion and interspinous process spacers have not been shown to be superior to conventional decompression alone. More methodologically rigorous studies are needed.

Lopez et al. (2017) conducted a systematic review of 15 articles that evaluated the literature on lumbar spinous process fixation and fusion devices (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 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 one 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.

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, ≤ 3 mm of anterolisthesis on a lateral radiograph) when the following 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.

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.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Code

CPT	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

2/9/2022	Policy reviewed, no changes to criteria, updated references.
2/8/2021	Policy reviewed, no changes.
4/23/2020	Policy reviewed, no changes.
3/11/2019	New policy.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Available from CMS. Accessed January 25, 2022.
2. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). Premarket approval (PMA) database (search: product codes KWP, KWQ, MNH, MNI, and PEK). Available from FDA. Accessed January 25, 2022.

National and Specialty Organizations

1. North American Spine Society (NASS). Coverage policy recommendations: Interspinous fixation with fusion. Available from NASS. Published December 1, 2019 Accessed January 25, 2022.
2. Eck JC, Sharan A, Ghogawala Z, Resnick DK, Watters WC, Mummaneni PV, et al. Guideline update for the performance of fusion procedure for degenerative disease of the lumbar spine. Part 7: Lumbar fusion for intractable low-back pain without stenosis or spondylolisthesis. J Neurosurg Spine. 2014 Jul;21(1):42-7. doi: 10.3171/2014.4.SPINE14270. Accessed January 25, 2022.

Evidence Based Reviews and Publications

1. Chou R. Subacute and chronic low back pain: Surgical treatment. Available from UpToDate. Updated June 11, 2021. Accessed January 25, 2022. Registration and login required.
2. Levin K. Lumbar spinal stenosis: Treatment and prognosis. Available from UpToDate. Updated February 1, 2021. Accessed January 25, 2022. Registration and login required.
3. Advanced Medical Reviews (AMR) Peer Review. Policy reviewed on January 14, 2019 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the area of Orthopedic Surgery.

Peer Reviewed Publications

1. Lopez AJ, Scheer JK, Dahdaleh NS, Patel AA, Smith ZA. Lumbar spinous process fixation and fusion: A systematic review and critical analysis of an emerging spinal technology. Clin Spine Surg. 2017 Nov;30(9):E1279-E1288. doi: 10.1097/BSD.0000000000000411. Accessed January 25, 2022.
2. Machado GC, Ferreira PH, Yoo RI, Harris IA, Pinheiro MB, Koes BW, et al. Surgical options for lumbar spinal stenosis. Cochrane Database Syst Rev. 2016 Nov 1;11(11):CD012421. doi: 10.1002/14651858.CD012421. Accessed January 25, 2022.
3. Poetscher AW, Gentil AF, Ferretti M, Lenza M. Interspinous process devices for treatment of degenerative lumbar spine stenosis: A systematic review and meta-analysis. PLoS One. 2018 Jul 6;13(7):e0199623. doi: 10.1371/journal.pone.0199623. Accessed Jan. 25, 2022.

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*