Molina Clinical Policy
Interspinous Decompression Devices for Spinal Stenosis: Policy No. 222

Last Approval: 04/09/2025
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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

Spinal stenosis is a narrowing of the spinal canal that causes pressure on the spinal cord and nerve roots, resulting in symptoms such as low back pain, neurogenic claudication (a combination of low back and leg pain, with numbness and motor weakness when standing or walking), and reduced capacity for physical activity. Severity of symptoms ranges from mild to severe and can affect patient mobility and quality of life.

Interspinous decompression devices are intended to be used in patients with lumbar spinal stenosis who have at least moderately impaired physical function, have failed conservative management, and experience relief in flexion from their symptoms of leg/buttock/groin/back pain. The devices, also known as spacers, are implanted between spinous processes of the vertebrae to distract the spinous processes and restrict extension, thus creating more space in the spinal canal for the spinal cord and nerves. The goal is to provide symptomatic relief of pain, maintain spinal motion, and reduce spine hypermobility and degeneration of adjacent segments levels. There are two types of interspinous devices that include static (e.g., X-STOP implant) and dynamic (e.g., non-fusion Coflex®). Dynamic devices are intended to be used in conjunction with laminectomy to reduce the amount of lumbar spinal extension possible while preserving range of motion in flexion, axial rotation, and lateral bending. Static devices are used to provide indirect decompression by reducing spinal extension to prevent motions that induce back pain.

Regulatory Information

The Coflex® Interlaminar Stabilization device (Surgalign Spine Technologies Inc.) is regulated by the FDA as a spinous process spacer/plate prosthesis and received approval via the premarket approval (PMA) process for treatment of 1- or 2-level LSS from L1-L5 in skeletally mature patients with at least moderately impaired function, buttock/groin/leg pain when in flexion, and 6 months of non-operative treatment (FDA, 2012). The Coflex® device is to be used as a minimally invasive adjunct to decompression surgery rather than a stand-alone spacer.

Boston Scientific's Superion® interspinous spacer system received FDA premarket approval in May 2015 for the treatment of moderate stenosis. The device is indicated to treat skeletally mature patients suffering from neurogenic intermittent claudication due to moderate degenerative LSS with or without grade 1 spondylolisthesis, who have undergone at least 6 months of non-operative treatment (FDA, 2015). Unlike the Coflex device, which is placed following decompression, the Superion® device is inserted percutaneously via a cannula in between adjacent spinous process and then deployed. The device is intended to be used at 1 or 2 contiguous levels of the lumbar vertebrae.

The X-Stop Interspinous Spacer device (Medtronic Inc.) was approved by the FDA in 2005; however, due to adverse events related to the disassembly of the device Medtronic withdrew the system from the market in 2015.

COVERAGE POLICY

Interspinous decompression devices (e.g., Coflex, Superion, and any other devices) 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

Systematic Reviews and Meta-Analyses

Han et al. (2024) conducted a systematic review and meta-analysis of five RCTs totaling 555 patients analyzing the safety and efficacy data of interspinous process devices in the treatment of lumbar spinal stenosis (LSS). The studies were analyzed to reveal no significant differences in Visual Analogue Scale (VAS) leg pain (SMD - 0.08, 95% CI - 0.32 to 0.15) and back pain (SMD 0.09, 95%CI-0.27 to 0.45), Oswestry Disability Index (ODI) scores (MD 1.08, 95% CI - 11.23 to 13.39) and Zurich Claudication Questionnaire (ZCQ) physical function (MD-0.09, 95% CI-0.22 to 0.05) for interspinous process devices compared with decompression surgery. In terms of ZCQ symptom severity (MD - 0.22, 95% CI - 0.27 to - 016), decompression surgery showed superior to the interspinous process devices. As for complications (RR 1.08, 95% CI 0.36 to 3.27), the interspinous process devices had no advantages compared to decompression surgery and was inferior to it in reoperation rate (RR 2.58, 95% CI 1.67 to 3.96). The authors concluded there was no superiority in the clinical outcome for interspinous process devices compared with decompression surgery, and urged more clinical studies are warranted to determine the efficacy and safety of interspinous process devices.

Liang et al. (2022) published a systematic review and network meta-analysis that compared 20 RCTs that contained at least two of the following surgical procedures: (a) bilateral decompression via the unilateral approach, (b) decompression with conventional laminectomy, (c) decompression with fusion, (d) endoscopic decompression, (e) interspinous process devices only, (f) decompression with interlaminar stabilization, (g) decompression with lumbar spinal process-splitting laminectomy, and (h) minimally invasive tubular decompression. A total of 2201 patients were included in the meta-analysis. The primary outcomes of the meta-analysis were the ODI score, and secondary outcomes included VAS, SF-36, operation time, duration of hospital stay, reoperation, complications, and blood loss. Lower ODI scores were considered superior. The results of the meta-analysis found that decompression with interlaminar stabilization was significantly superior compared to bilateral decompression via the unilateral approach when comparing ODI scores. In terms of VAS scores, decompression with lumbar spinal process-splitting laminectomy was superior to decompression with conventional laminectomy, interspinous process devices, and unknown decompression (the procedure was uncertain or involved multiple options). The operation time of interspinous process devices was significantly shorter than all other options. However, interspinous process devices had a much higher rate of reoperation than other surgical methods of decompression. The most promising routine surgical option for most patients with LSS was the minimally invasive tubular decompression.

Tram et al. (2020) conducted a systematic review of decompression surgery versus interspinous devices for LSS. Twenty-five decompression-exclusive clinical trials totaling 3,386 patients and a mean age of 68.7 years, reported a 2.2% incidence rate of dural tears and a 2.6% incidence rate of postoperative infections. Eight interspinous devices exclusive clinical trials totaling 1,496 patients and a mean age of 65.1, reported a 5.3% incidence rate of postoperative leg pain and a 3.7% incidence rate of spinous process fractures. Seven studies that compared interspinous devices and decompression totaling 624 patients, found a reoperation rate of 8.3% in interspinous devices patients vs. 3.9% in decompression patients and dural tears in 0.32% of interspinous devices patients vs. 5.2% in decompression patients. Utilizing a random-effects model the difference between preoperative and the 1-2-year postoperative VAS scores between interspinous device surgery and lumbar decompression was analyzed to reveal no difference between the groups. The authors concluded that decompression and interspinous devices are unique surgical interventions with different therapeutic efficacies and complications. The collected studies do not consistently demonstrate superiority of either procedure over the other.

Coflex

Systematic Reviews and Meta-Analyses

Fan and Zhu (2020) conducted a network meta-analysis of studies comparing decompression alone versus fusion and Coflex in the treatment of lumbar degenerative disease. A total of 10 randomized controlled trials were included totaling

946 patients. Compared with decompression alone group, there were no significant differences of ODI in Coflex and lumbar interbody fusion groups after surgery. Coflex and posterior lumbar interbody fusion were better in decreasing VAS score compared with decompression alone. In addition, Coflex have a less complication incidence rate. A total analysis of the data led the authors to conclude that while the effectiveness and safety of the fusion and Coflex techniques are still not clear, Coflex and lumbar interbody fusion had the similar effectiveness in improving lumbar function and quality of life, with the added benefit of increase in pain relief reporting and a lower complication incidence rate.

Non-Randomized Studies, Retrospective Reviews and Other Evidence

Hayes (2024) published an update to the Health Technology Assessment report on the use of the CoFlex Interlaminar Stabilization device for the treatment of lumbar spinal stenosis in adults. The available evidence, although of low quality, indicates that outcomes for the CoFlex device combined with decompression are comparable to decompression with fusion over an 8-year period, and to decompression alone over a 2-year period. Adverse event rates appeared to be similar across groups using the CoFlex device and its comparators. Additionally, the CoFlex device may offer advantages in terms of reduced operative time and shorter hospital stays. Hayes emphasized that the uncertainty surrounding the evidence is largely due to the fact that all studies reviewed were of low quality, providing limited insight into the long-term benefits of the CoFlex device compared to traditional surgical approaches. Additionally, the absence of clear criteria for patient selection further contributes to this uncertainty.

Davis et al. (2013a) compared the efficacy and safety of spinal decompression plus Coflex with decompression plus fusion in 322 patients with LSS, and in a subset of 150 patients with grade I spondylolisthesis. Both treatments led to significant improvement at 24 months in mean scores on the VAS for back pain and leg pain, ODI, SF-12 physical component, and ZCQ symptom severity and physical function, compared with baseline values. At 24 months, mean scores for the SF-12 physical component and ZCQ symptom severity, physical function, and patient satisfaction were significantly better for the Coflex than for fusion; however, mean VAS and ODI scores were similar for the 2 approaches in the entire cohort. In the entire cohort and the in the subset with spondylolisthesis, the mean SF-12 mental component score did not change appreciably and was similar between the Coflex and Fusion groups at all evaluation times. At 24 months, radiographic results revealed changes in ROM in patients who had fusion (rotation and translation decreased at the treated lumbar level(s) and increased at the level above and the level below the treated level(s)). In contrast, ROM was fairly well preserved (rotation and translation changed by < 1.0° or < 1.0 mm, respectively, at treated and adjacent levels) in the Coflex group.

Bae et al. (2016) performed a three-year follow-up analysis of the Davis (2013a) RCT. At 36 months, 91% (195/215) of the Coflex group and 88% (94/107) of the fusion group were included in the analysis. The initial efficacy endpoints (composite scores) were modified for use at 36 months. At 36 months, 62.2% of the individuals in the Coflex group compared to 48.9% of the individuals in the 94-group reported composite clinical success scores (difference = 13.3%, 95% confidence interval [CI]; 1.1%-25.5%, p=0.03). There are several limitations in this study including the limited follow-up period and the heterogeneous mix of individuals including those without spondylolisthesis for which fusion/stabilization is an unproven procedure

Davis et al. (2013b) reported on the outcomes of a subset of 150 patients with Meyerding grade I spondylolisthesis (≤ 25% sagittal plane translation on flexion-extension radiographs) who were included in the randomized FDA IDE trial in the Coflex group (n=99; mean age 63.1 years, range not reported; 41% men; 2-level procedures required in 64.2%; mean ODI 59.4; mean VAS for back pain 80.3; mean VAS for worse leg pain 77.9) or the Fusion group (n=51; mean age 65.0 years, range not reported; 19% men; 2-level procedures required in 63.6%; mean ODI 60.0; mean VAS for back pain 78.6; mean VAS for worse leg pain 79.1). Follow-up findings were reported only for the 24-month evaluation, at which time data were available in 94.9% of the Coflex group and 94.1% of the Fusion group. Both groups demonstrated significant improvement in mean scores for ODI (−38.3 and −37.1 points, respectively), VAS for back pain (−54.9 and −58.0 mm), VAS for worse leg pain (−58.9 and −56.2 points), SF-12 physical component (16.4 and 14.8 points), ZCQ symptom severity (−1.64 and −1.40 points), and ZCQ physical function (−1.24 and −1.10 points) The rate of composite clinical success was similar in the Coflex and Fusion groups (62.8%and 62.5%, respectively).

Superion

Randomized Controlled Trials

Nunley et al. (2017a) reported five-year clinical outcomes of a randomized controlled U.S. FDA noninferiority trial in individuals with moderate lumbar spinal stenosis. While the original trial compared the Superion to the X STOP device,

the analysis was restricted to the Superion trial arm. A total of 73% (88/121) of the living individuals who received the spacer device participated in the 5-year clinical outcomes assessment. Outcomes were assessed using the ZCQ, leg and back pain severity by VAS, and the ODI. The authors reported success rates in all areas of assessment, 84% reported clinical success in at least two of the three ZCQ domains, 80% leg pain VAS scores, 65% back pain VAS scores and 65% for ODI scores. There remains a lack of studies which compare interspinous spacers to standard treatments, such as decompression surgery.

Non-Randomized Studies, Retrospective Reviews and Other Evidence

Hayes (2024) published an update to the Evolving Evidence Review on the Superion interspinous spacer (ISS). The review evaluated clinical studies, systematic reviews (none of which met inclusion criteria), and guidelines for the treatment of lumbar spinal stenosis and neurogenic claudication using the Superion device. The assessed studies were determined to be of very poor or poor quality , and no comparative research was identified. Hayes concluded that there is no evidence to suggest that the Superion ISS offers advantages over other treatment options, such as fusion surgery or existing commercial alternatives. An analysis of guidelines and position statements revealed inconsistent support for the Superion ISS, specifically in its role in addressing lumbar spinal stenosis with neurogenic claudication. While some guidelines deemed the evidence sufficient to endorse its use, others found the evidence insufficient. Consequently, the long-term health outcomes associated with the Superion ISS remain uncertain, underscoring the need for further investigation.

Hagedorn et al. (2022) conducted a retrospective study to assess the rate of lumbar decompression surgery following minimally invasive procedures, specifically the MILD (Minimally Invasive Lumbar Decompression) procedure and the placement of the Superion Indirect Decompression device. The study included patients with lumbar spinal stenosis (LSS) who underwent MILD and/or Superion between January 2011 and July 2019. Eligible participants had a follow-up of at least two years, pre-procedural MRI findings, and surgical records. The final analysis comprised 199 patients: 28.6% underwent only MILD, 62.3% underwent only Superion, and 9.0% received MILD followed by Superion. Notably, two patients underwent the MILD procedure twice at the same spinal level. Over the two-year follow-up period, 2.0% of patients (four individuals) required subsequent lumbar surgery, with rates of 5.3% for MILD and 0.8% for Superion. The study acknowledged that some patients might not have been candidates for surgery, which could have influenced the results. The authors concluded that minimally invasive decompression treatments for LSS are associated with low rates of follow-up surgeries, potentially resulting in cost savings and a reduction in severe adverse events (AEs). The low surgical rates may be attributed to symptom improvement, patient preferences to avoid surgery, or the patients being deemed unsuitable for surgical intervention. It should be noted that the lead author is a consultant for Boston Scientific (device manufacturer) and disclosed this conflict of interest.

Patel et al. (2015b) published a report on 3-year durability of results of the pivotal trial. At 36 months, the overall treatment success (primary composite endpoint) remained stable in the Superion group (52.5% of 120 participants available for follow-up at 36 months versus 52.7% at 24 months). In the X-Stop group, the composite endpoint of overall treatment success was 38.0% of 129 participants available for follow-up at 36 months, reduced from 50.2% at 24 months. The difference between groups was statistically significant (P=0.023). A total of 26 (14%) participants in the Superion group required surgical decompression within 3 years. Most patients in the Superion group experienced significant improvements in individual outcome measures, including back pain as measured by a ≥ 20 mm decrease in VAS (76.8%), VAS leg pain (84.1%), ZCQ physical function (80.5%), ZCQ symptom severity (82.9%), ODI (≥ 15-point decrease) (69.5%), and ZCQ patient satisfaction (91.5%) at 36 months. Between-group differences in most individual outcome measures were not statistically significant, except for VAS leg pain. A total of 69.7% of patients in the X-Stop group had durable improvement in leg pain at 36 months, compared with 84.1% of the Superion group (P=0.037).

National and Specialty Organizations

The **North American Spine Society** (2025) published coverage policy recommendations for lumbar interspinous devices with decompression. These recommendations pertain to all interspinous process devices intended for placement during the same surgery as direct decompression procedures. Interspinous distraction devices without fusion may be considered appropriate for degenerative lumbar stenosis, provided specific criteria are met. These criteria include the presence of neurogenic claudication that improves with lumbar flexion, patients being over 50 years old, a failure of nonoperative treatment, no more than 25° of degenerative scoliosis, and no greater than a Grade I degenerative spondylolisthesis.

The **International Society for the Advancement of Spinal Surgery** views interlaminar stabilization following direct decompression as a nonfusion alternative that could offer greater stability than decompression alone (Guyer et al., 2016). They regard the evidence from studies comparing decompression alone to decompression combined with interlaminar stabilization using the Coflex device as persuasive in supporting this treatment for carefully selected patients. Eligible patients for decompression with interlaminar stabilization include radiographically confirmed moderate lumbar spinal stenosis (LSS) at levels L1 to L5 requiring decompression, no instability at the index or adjacent spinal levels, pain relief with lumbar flexion (with or without associated back pain), and at least 12 weeks of attempted conservative management.

The **National Institute for Health and Clinical Excellence** (NICE) (2010) issued guidance on interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication in 2010 which state that current evidence shows the procedures are, "efficacious for carefully selected patients in the short and medium term, although failure may occur, and further surgery may be needed. There are no major safety concerns; these procedures may be used provided that normal arrangements are in place for clinical governance, consent, and audit."

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level
22870	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
C1821	Interspinous process distraction device (implantable)

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

04/09/2025	Policy reviewed. No changes to coverage criteria. Updated Summary of Medical Evidence and References.
04/10/2024	Policy reviewed, no changes to coverage criteria. IRO Peer Review on February 27, 2024, by a practicing physician board certified in Orthopedic Surgery.
04/13/2023	Policy reviewed, no changes to coverage statement. Updated references and Summary of Evidence. Added topping-off procedure to Overview.
04/13/2022	Policy reviewed, no changes to coverage statement. Updated references and Summary of Evidence.
04/05/2021	Policy reviewed, no changes. A review of clinical studies and guidelines suggests minimal support for using interspinous spacers for the treatment of lumbar spinal stenosis with neurogenic claudication.
04/23/2020	Policy reviewed, no changes.
06/19/2019	Policy reviewed, no changes, updated professional society guidelines and references.
07/10/2018	Policy reviewed, no changes to coverage. Added new device (Vertiflex's Superion® interspinous spacer system), updated Summary of Medical Evidence, references, and coding. IRO reviewed on March 27, 2018, by a practicing, board-certified physician in Orthopedic Surgery.

06/22/2017	Policy reviewed, no changes.
09/15/2016	Policy reviewed, no changes.
12/16/2015	Policy reviewed, no changes.
03/16/2015	New policy.

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