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

Last Approval: 4/13/2022
Next Review Due By: April 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

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 in order 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.

The X-Stop Interspinous Spacer device (Medtronic Inc.) was approved by the FDA in 2005 for treatment of patients 50 years or older with confirmed lumbar spinal stenosis (LSS) and moderate symptoms that have not responded adequately to at least 6 months of non-operative treatment (FDA, 2005). Medtronic has discontinued the distribution of the X-Stop system.

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, relief from 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.

COVERAGE POLICY

Interspinous decompression devices (e.g., X-STOP, 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.

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

X-STOP

The clinical evidence of interspinous decompression devices (e.g., X-STOP) for the treatment of lumbar spinal stenosis consists of several randomized controlled trials (RCTs), retrospective comparative studies, prospective studies, and retrospective case series. The study sample sizes ranged from 30 to 285 patients, and follow-up times ranged from 6 months to 4 years. The RCTs compared the efficacy and safety of the device with conservative treatment, decompression, spinal fusion, or with another interspinous spacer. The quality of the overall body of evidence is low and most of the existing studies are small or moderate in size. Additional well-designed, long-term clinical trials are needed to further evaluate the efficacy and safety of interspinous decompression devices and to compare these with standard treatment and other alternatives. A summary of the relevant RCTs is provided below.

One of the earliest RCTs conducted by Zucherman, et al. (2004) compared the efficacy and safety of the X Stop with conservative treatment. Results of longer follow-up were reported in a second publication (Zucherman, et al., 2005). Participants included 200 patients who had experienced back pain for an average of 4.1 years and who had neurogenic intermittent claudication secondary to LSS. The patients were treated with implantation of 1 or 2 X Stop devices (X Stop group; n=100; mean age 69.9 years) or conservative management with 1 or more epidural steroid injections (Control group; n=91; mean age 68.6 years). Some Control group patients received NSAIDs, analgesics, and/or physical therapy. At 2 years, mean Zurich Claudication Questionnaire (ZCQ) symptom severity scores had improved 45% for the X Stop group versus 7% for the Control group. At 1- and 2-year follow-up, there were no significant differences between the 2 groups in any of 8 spinal radiographic measurements. During the 2-year follow-up period, 6% of patients in the X Stop group and 30% in the Control group underwent laminectomy for unresolved symptoms.

Another RCT conducted by Azzazi, et al. (2010) compared the efficacy and safety of the X Stop with fusion and transpedicular screw fixation in 60 patients with LSS. There were 30 patients in the X Stop group (mean age 57 years, range 28 to 78; mean duration of symptoms 5.4 years), and 30 patients in the spinal fusion group (mean age 56.3 years, range 27 to 79; mean duration of symptoms 5.2 years). Outcomes included pain and disability assessed by the Visual Analog Scale (VAS) (100-point scale) and the (Oswestry Disability Index) ODI. Patients were followed for 24 months. The source of funding or support for this study was not mentioned. At 24 months, leg pain had decreased significantly from a mean of 82.5 millimeters (mm) preoperatively to 25.5 mm in the X Stop group, and from 80.5 to 35.5 mm in the Spinal Fusion group ($P<0.01$). Back pain improved significantly from 52 mm preoperatively to 29.5 mm in the X Stop group, and from 54 to 37.5 mm in the Spinal Fusion group ($P<0.01$). The ODI score improved significantly from a mean of 53 preoperatively to 26.5 in the X Stop group, and a mean of 55 to 34.5 in the Spinal Fusion group ($P<0.01$ for outcomes in each group).

Miller and Block (2012) conducted an RCT that compared the efficacy and safety of the X Stop spacer with the Superion Interspinous Spacer, an investigational device at the time. The X Stop group had 86 patients and the Superion group had 80 patients (mean age 67 years in each group). Data from the first 6 months of assessment were available for 30 patients in the X Stop group and 36 patients in the Superion group. By 6 months, ZCQ symptom severity scores improved by 25% and 30%, and physical function scores improved by 27% and 32% in the X Stop and Superion groups, respectively ($P<0.001$ for all analyses). The proportion of patients who had ZCQ clinical success was 53% and

75% for symptom severity, 63% and 64% for physical function, and 93% and 78% for patient satisfaction in the X Stop and Superion groups, respectively. By 6 months, axial pain improved by 64% and 70%, and extremity pain improved by 81% and 93% in the X Stop and Superion groups, respectively (P<0.001). Clinical success for axial pain was achieved by 50% and 60%, and clinical success for extremity pain by 60% and 74% in the X Stop and Superion groups, respectively. By 6 months, back function improved by a median of 38% and 48%, and back function clinical success was achieved by 37% and 47% in the X Stop and Superion groups, respectively (P<0.001 for all analyses). The authors reported on significant improvements in pain and disability within each treatment group but did not systematically compare outcomes for patients treated with the X Stop and the Superion devices.

Another RCT conducted by Strömqvist, et al. (2013) compared the efficacy and safety of the X Stop with standard decompressive surgery in 100 patients with LSS. There were 50 patients in the X Stop group (mean age 67 years, range 49 to 89) and 50 patients in the Decompression group (mean age 71 years, range 57 to 84); all patients had symptoms of neurogenic claudication for at least 6 months. Outcomes included pain and disability assessed by the VAS, ZCQ, ODI, SF-36, and European Quality of Life 5-dimension questionnaire (EQ-5D; EuroQol Group). Patients were evaluated at 6 months, 12 months, and 2 years. Symptom severity and physical function according to ZCQ were significantly improved by 6 months in both groups. The SF-36 physical component score improved from 25 and 28 points preoperatively to 40 and 38 points at 2 years postoperatively, for the X Stop and Decompression groups, respectively. As measured by VAS, mean back pain improved from 58 and 60 points preoperatively to 34 and 23 points at 2 years postoperatively, for the X Stop and Decompression groups, respectively. Mean left leg pain improved from 57 and 58 points preoperatively to 25 and 19 points at 2 years postoperatively and mean right leg pain improved from 60 and 53 points preoperatively to 21 and 21 points postoperatively, respectively. The changes in pain from baseline were significant in both groups (P<0.001); however, there were no significant differences between groups.

Coflex

The clinical evidence of interspinous decompression devices as an adjunct to spinal decompression (e.g., Coflex) for the treatment of lumbar spinal stenosis consists of RCTs, prospective nonrandomized comparative studies, retrospective comparative studies, and retrospective case series. The study sample sizes ranged from 20 to 344 patients, and mean follow-up ranged from 1 to 8 years. Outcomes included pain levels and function assessed by a VAS or other scale for pain, narcotics use, ROM, and/or neurological examination. The quality of the overall body of evidence is low and most of the existing studies are small or moderate in size. Additional well-designed, long-term clinical trials are needed to further evaluate the efficacy and safety of interspinous decompression devices and to compare these with standard treatment and other alternatives. A summary of the relevant RCTs is provided below.

A moderate size RCT (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.

In a secondary analysis of this RCT, 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).

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.

Musacchio et al. (2016) compared decompression and interlaminar stabilization with decompression and fusion for the treatment of lumbar spinal stenosis in a 5-year follow-up of a prospective multicenter RTC. Patients with moderate to severe LSS were randomized (2:1) to a decompression plus interlaminar stabilization (D+ILS; n=215) using the Coflex device or decompression and fusion with pedicle screws (D+PS; n=107). Composite success scores were based on meeting four criteria: 1) >15-point improvement in (ODI) score; 2) no reoperation, revision, removal, or supplemental fixation; 3) no major device-related complication; and 4) no epidural steroid injection after surgery. At 5 years, 50.3% of D+ILS vs. 44% of D+PS patients (p>0.35) met the composite success criteria. Reoperation rates at 5-year follow up were similar between the groups (16.3% for D+ILS and 17.8% for D+PS). One noted limitation of this study is the lack of blinding following the procedure, which may have contributed to expectation bias. Also, data from subjects who underwent reoperation, revision, removal or supplemental fixation procedures during the 5-year timeframe was not included in the calculation of clinical outcome measurements such as the ODI, VAS and ZCQ.

A multicenter RCT conducted by Schmidt et al. (2018) compared decompression with interlaminar stabilization (D+ILS) using the Coflex device vs. decompression alone (DA). A total of 230 patients were randomized (1:1) to the Coflex group or the decompression-only group and outcomes were evaluated up to 2 years postoperatively, including ODI scores, need for secondary surgery or lumbar injection, neurological status, and the presence of adverse events. The composite clinical success (CCS) was calculated by combining these outcomes. At 24 months there were no significant differences in isolated patient-reported outcomes (p>0.05) (VAS, ODI, and ZCQ), however the composite score was statistically superior for the D+ILS group.

Superion

Published reports of the Superion Interspinous Spacer include a randomized controlled trial and prospective case series. Although the randomized device trials report short-term improvements in symptoms and functional status when compared to non-operative therapy, a number of questions remain. Overall, high-quality comparative data is limited and there is a lack of evidence to support that interspinous spacer devices are as safe and effective as the gold standard of decompression. In addition, there are concerns that the devices may not be as effective as surgical decompression and lead to higher rates of reoperation.

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. A majority of patients in the Superion group experienced significant improvements in individual outcome measures, including back pain as measured by a ≥ 20 mm decrease in visual analog scale (VAS) (76.8%), VAS leg pain (84.1%), ZCQ physical function (80.5%), ZCQ symptom severity (82.9%), Oswestry Disability Index (≥ 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, with the exception of 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).

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 Zurich Claudication Questionnaire (ZCQ), leg and back pain severity by visual analog scale (VAS), and the Oswestry Disability Index (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.

National and Specialty Organizations

The **North American Spine Society** (Ghiselli & Kreiner, 2018) published coverage policy recommendations for lumbar interspinous devices used as an adjunct to decompression, stating, "Stabilization with an interspinous device without fusion in conjunction with laminectomy may be indicated as an alternative to lumbar fusion for degenerative lumbar stenosis with or without low-grade spondylolisthesis (less than or equal to 3 mm of anterolisthesis on a lateral radiograph) with qualifying criteria when appropriate." The **International Society for the Advancement of Spinal Surgery** published similar recommendations/coverage criteria in 2016 (Guyer et al., 2016).

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."

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	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 Code

HCPCS	Description
C1821	Interspinous process distraction device (implantable) [valid for Medicare on claims for hospital outpatient department services and procedures]

ICD-10 Codes

ICD-10	Description
M48.06-M48.07	Spinal stenosis

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

04/13/2022	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.
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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Government Agencies

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Other Evidence Based Reviews and Publications

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2. Hayes. Evolving Evidence Review. Superion interspinous spacer system (Vertiflex) for treatment of neurogenic claudication caused by spinal stenosis. Available from Hayes. Published October 6, 2020. Updated September 17, 2021. http
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Evidence Based Reviews and Publications

X-Stop

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Coflex
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APPENDIX

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