Interspinous Fusion and Decompression Devices (for Ohio Only)

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➲ Instructions for Use

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Application

This Medical Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

Coverage Rationale

For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Interspinous Process Device with or without Open Decompression.

Click here to view the InterQual® criteria.

Interspinous fixation (fusion) devices are proven and medically necessary when performed according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions and all of the following criteria are met:

- Back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies
- No more than grade 1 spondylolisthesis
- Used with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1-S1)

Interspinous decompression and interlaminar stabilization systems (without fusion) for the treatment of spine pain or spinal stenosis are unproven and not medically necessary due to insufficient evidence of efficacy.

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the services requested.

The patient's medical record must contain documentation that fully supports the medical necessity for the requested services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request.

Definitions

Arthrodesis: A surgical procedure to eliminate motion in a joint by providing a bony fusion. The procedure is used for several specific purposes including: relief of pain, provide stability, overcome postural deformity resulting from neurologic deficit, and to halt advancing disease (Verywellhealth, 2022).

Interlaminar Lumbar Instrumented Fusion (ILIF): During the ILIF procedure, the surgeon makes an incision in the lower back and an opening is created through the ligaments. This allows access to the spinous processes. The bone, ligament or disc that is causing compression is removed to release pressure on the nerves. Allograft bone may be placed in the disc space. Autologous or allograft bone is placed between the spinous processes and on the remaining lamina. An implant is inserted to stabilize the spine and secure the spinous processes until the fusion takes place (The Centers for Advanced Orthopaedics, 2022).

Interlaminar Stabilization Device: An implantable interspinous process device intended to provide symptomatic relief of claudicatory lumbar spinal stenosis. An implantable titanium interspinous process device (IPD) intended to reduce the amount of lumbar spinal extension while preserving range of motion in flexion, axial rotation, and lateral bending. The U-shaped titanium device has two pair of serrated wings extending from the upper and lower long arms of the U. The device is inserted horizontally between two adjacent spinous processes (bones) in the back of the spine, and the wings are crimped over bone to hold the implant in place. The device is implanted after decompression of stenosis at the affected level(s) (Paradigm Spine, 2013).

Interspinous Fixation Devices: Devices i:ntended for attachment to the spinous processes for the purpose of achieving stabilization to promote fusion in patients with degenerative disc disease (The Centers for Advanced Orthopaedics, 2022).

Interspinous Process Decompression (IPD): Minimally invasive surgical procedure used to treat Lumbar Spinal Stenosis when conservative treatment measures have failed to relieve symptoms. IPD involves surgically implanting a spacer between one or two affected spinous processes of the lumbar spine. After implantation, the device is opened or expanded to distract (open) the neural foramen and decompress the nerves. Spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization following decompressive surgery. IPD is purported to block stenosis-related lumbar extension and, thus, relieve associated pain and allow resumption of normal posture (Healthcentral, 2019).

Lumbar Spinal Stenosis (LSS): Narrowing or constriction of the lumbar spinal canal that may result in painful compression of a nerve and/or blood vessel(s) supplying the nerve (Healthcentral, 2019).

Neurogenic Claudication: A common indicator of Lumbar Spinal Stenosis caused by an inflamed nerve coming from the spinal column. Symptoms include the sensation of pain in the buttock, thigh, or leg or weakness in the legs that is relieved with a change in position or leaning forward and improves with rest (Ammendolia, 2014).

Note: Neurogenic Claudication should be differentiated from vascular claudication.

Spinal Stabilization: These spinal devices are fixed in place using pedicle screws which are attached to the vertebral bodies adjacent to the intervertebral space being fused. Unlike standard frames, these devices are designed using flexible materials which purport to stabilize the joint while still providing some measure of flexibility (Healthcentral, 2019).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
22853	Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)
22854	Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
22859	Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
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)
22899	Unlisted procedure, spine [when specified as insertion of a non-pedicle interspinous process fixation device]

Description of Services

The lumbar spine is the lower back and contains five vertebrae which occupy the space between the bottom of the ribs and the pelvis. Lumbar spinal stenosis is the narrowing of the spinal canal in the lower back. Narrowing the canal can put pressure on the nerves that control muscle movement and sensation in the legs. This pressure can cause the nerves to become inflamed and cause pain in the back, buttocks, or legs. In rare cases, it may cause loss of movement in the legs, or loss of normal bowel or bladder function. Surgical treatment options include decompressive surgery with or without fusion, and fusion with or without instrumentation. Interspinous distraction has been developed as a less invasive approach to standard surgical treatments.

For use in combination with fusion, it has been proposed that Interspinous Fixation Devices are less invasive and present fewer risks than pedicle or facet screws. While biomechanics studies have indicated that Interspinous Fixation Devices may be similar to pedicle screw-rod constructs in limiting the range of flexion and extension, they may be less effective than bilateral pedicle screw-rod fixation for limiting axial rotation and lateral bending. There is a potential for a negative impact on the interbody cage and bone graft due to focal kyphosis resulting from the Interspinous Fixation Device. There is also a potential for spinous process fracture.

Unlike Interspinous Fixation Devices, interspinous distraction devices (spacers) are used alone for decompression and are typically not fixed to the spinous process. In addition, Interspinous Fixation Devices have been designed for dynamic stabilization, whereas Interspinous Fixation Devices are rigid. However, Interspinous Fixation Devices might also be used to distract the spinous processes and decrease lordosis. Thus, Interspinous Fixation Devices could be used off-label without interbody fusion as decompression (distraction) devices in individuals with spinal stenosis. If Interspinous Fixation Devices are used alone as a spacer, there is a risk of spinous process fracture. (Veritas Health, 2022)

Clinical Evidence

Interspinous Decompression Devices (Without Fusion)

The quality of clinical evidence for interspinous decompression devices as an adjunct to spinal decompression is low and most of the existing studies are small or moderate in size. Additional large 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.

In a systematic review and meta-analysis, Ge et al. (2025) summarized the available data in the literature on nine different surgical approaches utilized to treat lumbar spinal stenosis (LSS). A total of 29 randomized controlled studies (RCTs) involving 4247 individuals were included. Nine intervention methods, including laminotomy, decompression, decompression plus fusion, endoscopic decompression, interspinous process spacer device (IPSD), laminectomy, minimally invasive decompression (MID), spinous process osteotomy, and lumbar interbody fusion were analyzed. Clinical outcomes were analyzed utilizing standardized questionnaires including the Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) scores. Based on the author's analysis, they concluded there was no significant difference in the efficacy of all intervention measures in relieving individual's leg pain (VAS score), endoscopic decompression was superior to the other interventions in relieving short-term pain and had the shortest hospital stay and IPSD was superior to other surgical interventions in relieving long-term pain, with the shortest surgical duration and the least intraoperative blood loss. However, the meta-analysis in this study showed that IPSD was more effective in reducing patients' short-term ODI scores, while decompression showed better effects in reducing patients' long-term ODI scores. There is no statistically significant difference in reducing leg VAS scores among the following six surgical approaches (laminectomy, IPSD, decompression, endoscopic decompression, laminotomy, and MID). Limitations include that there is currently no unified standard for the specific materials utilized in implants. Larger sample sized and extended follow-up periods are necessary for evaluating the clinical efficacy of IPSD.

Baranidharan et al. (2024) published the 24-month outcomes of indirect decompression utilizing a minimally invasive interspinous fixation device (IFD) versus standard open direct decompression for LSS. This two-year follow-up is a 24-month outcome report of a prospective, randomized control trial (RCT) with a total of five-year follow-up. Forty-eight participants were randomly assigned to IFD or decompression. Primary study endpoints included changes from baseline at eight-weeks, six, 12 and 24-months follow-up for leg and back pain VAS, ODI, LSS physical function (Zurich Claudication Questionnaire), distance walked in five minutes and number of repetitions of sitting-to-standing in one minute. Secondary study endpoints included participant and clinician global impression of change, adverse events, reoperations, operating parameters, and fusion rate. Both treatment groups identified statistically significant improvements in leg and back pain, ODI disability, LSS physical function, walking distance and sitting-to-standing repetitions compared to baseline at the 24-month follow-up. Mean reduction of ODI from baseline levels was between 35% and 56% for IFD ($p < 0.002$), and 49% to 55% for decompression ($p < 0.001$) for all follow-up time points. Mean reduction of IFD group leg pain was between 57% and 78% for all time points ($p < 0.001$), with 72% to 94% of participants having at least 30% reduction of leg pain from 8-weeks through 24-months. The authors conclude that at the 24-month follow-up period, clinically relevant improvements in leg and back pain, pain-related disability and LSS physical function were observed in both treatment groups. Mean improvements in walking distance and number of sitting-to-standing repetitions were larger for the IFD than the decompression group at all follow-up points. Limitations of the study include small sample size and at least two cases of nonadherence to treatment assignments which led to insufficient randomization. The study outcomes do not address the clinical impact of the technology on patient-centered outcomes, thus larger RCTs with longer-term outcomes are needed to establish the safety and efficacy of IDFs.

A retrospective review of prospectively collected data was collected by Chua et al. (2024) of 94 individuals with symptomatic LSS who underwent spinal decompression with or without interlaminar device (ILD) to assess and compare five-year radiologic outcomes. Radiological indices were assessed preoperatively, immediate post-operative, two years, and five years postoperatively. A total of 94 individuals with 55 in the decompression alone (DA) group and 39 in the decompression plus ILD (D + ILD) group. All individuals had follow-up at least to the two-year mark with similar loss to follow-up rates between both groups. Radiological indices were categorized into three groups: sagittal balance, lumbar lordosis, and intervertebral height. Additionally, the VAS and short form-36 (SF-36) were standardized questionnaires administered to measure clinical outcome scores during specified time periods during the study. The authors concluded that in the DA group, the mean pre-operative VAS were 5.9. At post-operative follow-up, the mean VAS score improved to 1.9, 1.4 and 1.1 across the five-year follow-up with significant improvement at all time points ($p < 0.01$). In the D + ILD group, the mean pre-operative VAS were 6.0. At post-operative follow-up, the mean VAS improved to 1.5, 1.4 and 1.0 across the 5-year follow-up with significant improvement at all time points ($p < 0.01$). When comparing the groups, there was no significant difference in VAS ($p = 0.83$). Additionally, the authors found that the use of an ILD as an adjunct to decompression surgery resulted in significant improvement in anterior disc, posterior disc and foraminal height with expected focal kyphosis at the level of intervention without a change in sagittal balance at the five-year follow-up. Limitations included limited long-term outcomes, a small sample size. Additional research involving randomization of individuals in the two groups with longer-term outcomes is needed to establish ILD utilization with decompression alone surgery to address the clinical impact of the technology on patient-centered outcomes.

Han et al. (2024) conducted a systematic review and meta-analysis of randomized controlled trials (RCT) to evaluate the efficacy and safety of interspinous process devices (IPD) as an alternative treatment between conservative therapy and decompression surgery in individuals with degenerative LSS. Five RCTs with 555 individuals were included. For efficacy evaluation, the VAS and the ODI were analyzed, as well as the Zurich Claudication Questionnaire. Complication and

reoperation rates were utilized for the assessment of safety. The authors concluded there were no significant differences in VAS leg and back pain or ODI scores for IPD compared to decompression surgery. This systematic review and meta-analysis indicated no superiority in the clinical utility for IPD compared with decompression surgery. Limitations include a limited quantity of previous high-quality studies assessing the clinical utility and long-term safety of this technology in treating individuals with degenerative (LSS).

In a systematic review and meta-analysis, Pennington et al. (2024) summarized the available data in the literature on the use of interspinous devices (ISDs) and interlaminar devices (ILDs) as alternatives to conventional decompression surgery for degenerative lumbar conditions. Twenty-nine studies were included in the final analysis. Outcomes were analyzed at < six weeks, three-months, one-year, two-years and "last follow-up." ILD/ISD showed greater leg pain improvement at three months [mean difference, −1.43; 95% confidence interval, (−1.78, −1.07); $p < 0.001$], six months [−0.89; (−1.55, −0.24); $p = 0.008$], and 12 months [−0.97; (−1.25, −0.68); $p < 0.001$], but not two years ($p = 0.22$) or last follow-up ($p = 0.09$). Back pain improvement was observed after ISD/ILD only at one year [−0.87; (−1.62, −0.13); $p = 0.02$]. The authors conclude that individual-reported outcomes are similar between the decompression surgery alone and ILD/ISD group. This study does not address the clinical impact of the technology on patient-centered outcomes. Additionally, the study is limited by the need for larger studies to further assess the clinical utility and evaluate the long-term clinical impact and safety of this technology over conventional decompression surgery.

The use of interspinous process devices (IPD) continues to be debated that it had a higher reoperation rate compared to traditional decompression when used as a surgical treatment in individuals with LSS. (Zhu and Xiao, 2020) conducted a systematic review and meta-analysis to evaluate the effectiveness and safety of IPD treatment in comparison to traditional surgical decompression. Thirteen studies, including five RCTs and eight retrospective studies were included and consisted of a total of 954 individuals diagnosed with LSS. The authors utilized data including ODI score, VAS pain score in addition to operative time, bleeding loss, reoperation rates and complications. The authors reported that their meta-analysis results demonstrated IPD treatment had no significant difference for ODI and the results of studies showed high heterogeneity. Additionally, their pooled data analysis demonstrated that there was no significant difference in operation time, bleeding loss, complication rate and reoperation rate between IPD treatment and traditional decompression treatment. In conclusion, the author's current evidence indicated no superiority for patient-reported outcomes for IPD treatment compared with alone decompression treatment. Most of the included studies were retrospective studies which are considered a study limitation and short follow-up durations in some studies. Larger sample size studies and longer follow-up intervals are necessary to assess the clinical effectiveness and utility of IPD treatment for LSS.

ECRI (2023) performed clinical evidence assessment review of Minuteman® Fixation Devices for Spinal Fusion Procedures. The review identified the two different studies: A prospective case series that reported on fusion success and adverse events in participants with degenerative spine diseases, as well as a multicenter retrospective case series that reviewed data from the medical records of 191 patients who underwent posterior lateral spinal arthrodesis. The case series was at high risk of bias and reported only fusion data and is insufficient to determine how well Minuteman® fixation devices work compared with alternative treatments for spinal stabilization and fusion. Additionally, limitations included no control groups, no randomization or blinding. Furthermore, longer follow-up intervals are needed to further evaluate the clinical impact of the technology on patient-centered outcomes and to evaluate the safety and efficacy of the health technology.

In 2024, Hayes updated their 2021 Evolving Evidence Review of the Superion® Interspinous Spacer System (Vertiflex) for Treatment of Neurogenic Claudication Caused by Spinal Stenosis. The studies were of very poor or poor quality and no comparative studies were identified. According to Hayes, clinical studies do not demonstrate equal or superior benefits or advantages over commercially available alternatives or fusion surgery. Based on a review of guidelines and position statements, guidance appears to confer no support or unclear support for the Superion® Interspinous Spacer, specifically, for the treatment of lumbar spinal stenosis with neurogenic claudication. Recommendations from guidelines are mixed for the use of interspinous spacers, with some determining evidence to be sufficient to support use, while others determined evidence is insufficient to support use. Therefore, the impact of the Superion® Interspinous Spacer System on long-term health outcomes is not currently known and requires further investigation.

ECRI (2022) performed a clinical evidence review of Superion® Indirect Decompression System. The case series, historical control studies, and before-and-after studies are at high risk of bias due to three or more of the following: single-center focus, small sample size, retrospective design, and lack of randomization and independent controls. Two historical control and two before-and-after studies assessed the same group of Superion-treated patients; thus, independent RCTs comparing Superion® with other devices and laminectomy are needed to validate findings. Independent RCTs comparing Superion® with other devices are required to validate long-term health outcomes.

A (2021, updated 2024) Hayes Health Technology Assessment assessed the use of the Coflex® Interlaminar Stabilization Device for the treatment of lumbar spinal stenosis in adults. No newly published studied meeting inclusion criteria were identified since the original technology assessment. Additionally, the annual review is based on a review of study abstracts only. The overall low-quality body of evidence suggests that the Coflex® device plus decompression may result in similar outcomes compared with decompression with fusion for up to eight years and compared with decompression alone for up to two years. Adverse events were similar between the Coflex® device and comparator groups. The Coflex® device may have an advantage in operative time and hospital length of stay. According to Hayes, the uncertainty associated with this body of evidence is due to the limited number of good to fair quality studies showing a distinct benefit of the Coflex® device over traditional surgical interventions over the long term and a lack of definitive patient selection criteria. A review of the studies containing new evidence is required to confirm the clinical impact of the technology on patient-centered outcomes.

Fan and Zhu (2020) conducted a systematic review and network meta-analysis investigating whether the Coflex® device, decompression, or fusion resulted in better outcomes for LSS when compared with each other. Ten RCTs were eligible for inclusion in this analysis, but only six included the Coflex® device as an intervention. Included studies were required to be RCTs, to be published in the English or Chinese language, and to report clinical outcomes for participants with lumbar degenerative disease (LDD) on VAS scores, ODI scores, or complications. Exclusion criteria included lower-quality study designs or studies that had incomplete data. All studies were assessed using the Cochrane risk of bias tool. Nine studies reported ODI outcomes, and, after pooling results, no significant difference in postoperative mean differences were observed between the Coflex® device and fusion groups. However, for VAS pain outcomes, a significant postoperative difference was observed, with a mean difference of –0.42 in the Coflex® device group and –0.37 in the fusion group compared with decompression alone. According to the authors, subgroup analyses to determine consistency of the effect showed good convergence efficiency. The authors summed the number of adverse events (AEs) reported across the trials and found that in the decompression alone group, 13 participants had AEs (eight relapse and three dural sac rupture), the Coflex® device group had four AEs (two dural sac rupture, one Coflex® device loosening, and one vertebral fracture), and the PLIF group had 14 AEs (three relapse, two infection, two dural sac rupture, one venous thromboembolism, two intervention loosening, and one vertebral fracture). No statistical comparison between groups was reported for complications, and the authors did not provide an overall grade of the evidence.

ECRI (2019) conducted an evidence review of the Coflex® interlaminar stabilization device for treating lumbar spinal stenosis. The health technology assessment literature search identified two systematic reviews, two randomized controlled trials, four non-randomized controlled trials and three cost analysis studies. The two systematic reviews addressed the safety and efficacy of the Coflex® device as compared to decompression and/or fusion. The evidence from the literature review suggests the Coflex® device may be effective at reducing pain and improving patient functionality along with quality of life than decompression alone. Limitations of the evidence included risk of bias in four of the studies due to lack of randomization, small sample sizes and lack of long-term outcomes.

In a prospective, randomized multicenter study, Schmidt et al. (2018, included in ECRI report above) reported on the two-year results of a study comparing treatment with decompression with interlaminar stabilization with the Coflex® device to decompression alone in individuals with moderate to severe lumbar spinal stenosis at one or two adjacent levels. A total of 115 participants were randomized to each arm. A composite clinical success (CCS) measure consisting of four components: ODI improvement > 15 points, survivorship with no secondary surgeries or lumbar injections, maintenance or improvement of neurological symptoms, and no device- or procedure-related severe AEs. At 24 months, there were no significant differences between the groups in the participant reported outcomes: the ODI scores, VAS back and neck pain scores and the Zürich Claudication Questionnaire. There were no significant differences in participant-reported outcomes between the groups. There were no significant differences in the primary outcome measures between the groups. However, when the secondary measure outcome of subsequent epidural injections (4.5% in the D+ILS group versus 14.8% in the DA group) was included in the CCS, the result became significant. NASS (2018) reviewed this study and noted: Overall, the results of this study on a strict evidence-based medicine level can be summarized as not finding a significant difference in the primary outcome measure(s). However, when considering the significant difference in subsequent epidural injections, which is a secondary outcome measure, the composite clinical success score becomes different.

In a systematic review and meta-analysis, Poetscher et al. (2018) evaluated the benefits and risks of interspinous process devices (IPDs) compared to conservative treatment or decompression surgery and suggest directions for forthcoming RCTs. The overall quality of evidence was low. One trial compared IPDs to conservative treatment: IPDs presented better pain, functional status, quality of life outcomes, but a higher complication risk. IPD implant presented a significantly higher risk of reoperation. The authors found low-quality evidence that IPDs resulted in similar outcomes when compared to standard decompression surgery. The review concluded that individuals submitted to IPD implants had significantly higher

rates of reoperation, with lower cost effectiveness. Future trials should improve in design quality and data reporting, with longer follow-up periods.

Nunley et al. (2017, included in the ECRI and Hayes reports above) 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% of the living individuals who received the spacer device participated in the five-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. Overall, 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 appears to be some concerns that the devices are not as effective as surgical decompression and lead to higher rates of reoperation.

Clinical Practice Guidelines

North American Spine Society (NASS)

Interspinous Fusion Devices (With Fusion)

In 2025, The North American Spine Society revised their 2019 coverage recommendations for the use of interspinous devices with lumbar fusion. Interspinous devices which affix to the spinous processes for the purposes of stabilization may be considered when utilized in the context of lumber fusion procedures for patients with diagnoses including stenosis, disc herniations, or synovial facet cysts in the lumbar spine, as an adjunct to cyst excision which involves removal of greater than 50 percent of the facet joint. They also noted that this is when utilized in conjunction with a robust open laminar and/or facet decortication and fusion, and/or a robust autograft inter-and extra-spinous process decortication and fusion, and/or an interbody fusion of the same motion segment. The North American Spine Society also noted that "No literature supports the use of interspinous fixation without performing an open decortication and fusion of the posterior bony elements or interbody fusion."

"Interspinous devices which affix to the spinous processes for purposes of stabilization should not be utilized/are not indicated in the following scenarios:

- Spondylolisthesis greater than Grade I
- Bilateral isthmic spondylolysis
- Significant dynamic instability (e.g., as detected on flexion-extension views)
- Scoliosis, or signs of coronal or rotatory instability
- Fusion is indicated at more than one level of the lumbar spine
- ISPD is generally not indicated for procedures at L5-S1 given mechanical limitations of fixation to small S1 spinous processes, but special consideration may be given if the anatomy is favorable
- Complete resection of the facet (unless accompanied by an interbody fusion)
- Disc herniations: as an adjunct to primary excision of a central or posterolateral disc herniation at any level in the absence of instability or spondylolisthesis
- Stenosis: as an adjunct to primary decompression of central and/or lateral recess stenosis in the absence of instability, foraminal stenosis, spondylolisthesis
- Discogenic low back pain
- A fusion is otherwise not indicated as per the NASS Coverage Recommendation for Lumbar Fusion"

Interspinous Decompression Devices (Without Fusion & Without Decompression)

In 2025, The North American Spine Society updated their 2018 Coverage Recommendations for the use of static (nonflexible or noncompressible) devices and dynamic implants. Static devices are used to provide indirect decompression of the neural elements. Dynamic devices, according to their FDA labeling, are intended to be used in conjunction with a direct decompression (e.g., laminectomy). The following coverage recommendations apply only to static devices that are intended to be used instead of a direct decompressive procedure.

"Based on a review of the current evidence-base, interspinous distraction devices without fusion may be indicated for the following diagnoses with qualifying criteria, when appropriate:
Clinically symptomatic degenerative lumbar stenosis:

- Associated with neurogenic claudication that is relieved by lumbar flexion
- Sitting for at least 50 minutes without pain
- Can walk at least 50 feet

- Mild to moderate stenosis as assessed on advanced imaging (ct or mri) defined as 25-50% reduction in lateral/Central foraminal diameter compared to adjacent levels
- Failure of 6 months nonoperative treatment
- No more than 25° of degenerative scoliosis
- No more than a grade i degenerative spondylolisthesis
- Open surgery (e.g., laminectomy) is not a medically safe treatment option because of comorbidities"

"Interspinous distraction devices are NOT indicated in cases that do not fall within the above parameters. In particular, they are not indicated in the following scenarios and conditions:

- Degenerative spondylolisthesis of Grade II or higher
- Degenerative scoliosis greater than 25°
- Dynamic instability at the operative level
- Symptoms are not relieved by flexion
- Patient is medically suitable for a direct decompressive procedure (e.g., laminectomy)
- Patient has primarily axial back pain that is unrelated to activity
- BMI > = 40
- Fixed motor deficit
- Prior lumbar surgery at the intended level"

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

A variety of products have received marketing clearance through the FDA's 510(k) process and decompression. Refer to the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

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Policy History/Revision Information

Date	Summary of Changes

02/01/2026	**Medical Records Documentation Used for Reviews**
	• Added language to indicate:
	  ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service
	  ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested
	  ○ The patient's medical record must contain documentation that fully supports the medical necessity for the requested services
	  ○ This documentation includes but is not limited to relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures
	  ○ Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request
	Definitions
	• Updated definition of:
	  ○ Arthrodesis
	  ○ Interlaminar Lumbar Instrumented Fusion (ILIF)
	  ○ Interlaminar Stabilization Device
	  ○ Neurogenic Claudication

Date	Summary of Changes
	Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS363OH.C

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]) or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC) or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC) or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC) or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Ohio Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.