Interspinous Fusion and Decompression Devices (for Ohio Only)

Policy Number: CS363OH.B
Effective Date: April 1, 2024

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 bony 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:

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

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

Definitions

Arthrodesis: A surgical procedure to eliminate motion in a joint by providing a bony fusion. The procedure is used for several specific purposes: to relieve pain; to provide stability; to 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. Bone, either autograft and / or allograft, 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 titanium interspinous process device (IPD) that reduces the amount of lumbar spinal extension possible while preserving range of motion in flexion, axial rotation, and lateral bending. CoFlex® is a U-shaped device with 2 pair of serrated wings extending from the upper and lower long arms of the U. The U portion is inserted horizontally between 2 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 intended 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 (also known as pseudoclaudication): 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)

CPT 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)
22899	Unlisted procedure, spine [when specified as insertion of a non-pedicle interspinous process fixation device]

HCPCS Code	Description
C1821	Interspinous process distraction device (implantable)

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 of 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 distraction 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 patients 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.

ECRI (2022) performed 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 3 or more of the following: single-center focus, small sample size, retrospective design, and lack of randomization and independent controls. Two historical control and 2 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 Hayes report assessed the use of the CoFlex Interlaminar Stabilization device for the treatment of lumbar spinal stenosis in adults. An 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 8 years and compared with decompression alone for up to 2 years. Adverse events were similar between the CoFlex device and comparator groups, and 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 (Hayes, 2022).

Hayes (2020; Updated April 2023) performed a full-text review of clinical studies using Superion interspinous spacers (ISS) for the treatment of lumbar spinal stenosis and neurogenic claudication. 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 ISS on long-term net health outcomes is not currently known and requires further investigation.

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 patients with lumbar degenerative disease (LDD) on Visual Analogue Scale (VAS) scores, Oswestry Disability Index (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 patients had AEs (8 relapse and 3 dural sac rupture), the CoFlex device group had 4 AEs (2 dural sac rupture, 1 CoFlex device loosening, and 1 vertebral fracture), and the PLIF group had 14 AEs (3 relapse, 2 infection, 2 dural sac rupture, 1 venous thromboembolism, 2 intervention loosening, and 1 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 2-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 individuals 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 patient reported outcomes: the ODI scores, VAS back and neck pain scores and the Zürich Claudication Questionnaire. There were no significant differences in patient-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.

A systematic review and meta-analysis (Poetscher et al, 2018) was conducted to provide complete and reliable information regarding benefits and harms of interspinous process devices (IPDs) when compared to conservative treatment or decompression surgery and suggest directions for forthcoming RCTs. Overall quality of evidence was low. One trial compared IPDs to conservative treatment: IPDs presented better pain, functional status, quality of life outcomes, and higher complication risk. IPD implant presented a significantly higher risk of reoperation. We found low-quality evidence that IPDs resulted in similar outcomes when compared to standard decompression surgery. The review concluded that patients 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 5-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 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. 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. A systematic review by Machado et al. (2016) included three studies which compared interspinous process spacer devices to conventional decompression. The authors noted no studies directly compared spacers with decompression surgery but were based on indirect comparisons. A total of 355 individuals were included in studies for the CoFlex and X-stop devices. The authors concluded that while surgery using the interspinous spacer devices resulted in less blood loss and shorter hospital stays when compared to fusion, use of the devices did not lead to improved outcomes when compared to decompression. In addition, interspinous spacer devices were associated with higher reoperation rates.

Musacchio et al. (2016, included in the Hayes report above) completed a prospective, randomized, controlled trial that was conducted at 21 centers. The purpose of this study was to investigate 5-year outcomes associated with an interlaminar device. Results of this 5-year follow-up study demonstrate that decompression and interlaminar stabilization with CoFlex is a viable alternative to traditional decompression and fusion in the treatment of patients with moderate to severe stenosis at one or two lumbar levels. Additional randomized, controlled studies are needed to clearly outline the indications for their use.

A 2015 meta-analysis by Hong et al. included 20 studies with 3,155 patients in the interspinous spacers group and 50,983 patients treated with open decompression. Results of this meta-analysis were similar to those obtained in the more selective analysis by Wu et al. There was no significant difference between the 2 procedures for improvement rate, Oswestry Disability Index (ODI), or visual analog scale (VAS) for back or leg pain. Although secondary outcomes such as operative and hospitalization time, perioperative blood loss, and postoperative complication rate were superior in the spacer group, reoperation rate was higher in that group (16.5% vs 8.7%). Because of the higher reoperation rate the authors concluded that, while the use of spacers may be a viable technique, they could not conclude that it had replaced open decompression surgery as the gold standard for treatment of lumbar spinal stenosis.

Patel et al. (2015, included in the ECRI and Hayes reports above) reported 3-year clinical outcomes from the randomized, controlled US Food and Drug Administration Investigational Device Exemption trial of the Superion® for the treatment of moderate degenerative lumbar spinal stenosis. The 3-year outcomes from this randomized controlled trial demonstrate durable clinical improvement consistently across all clinical outcomes for the Superion® in the treatment of patients with moderate degenerative lumbar spinal stenosis. Longer-term studies are in progress as part of FDA post-approval requirements.

Moojen et al. (2015) completed a randomized double-blind study in which interspinous process devices (IPDs) are implanted to treat patients with intermittent neurogenic claudication (INC) based on lumbar spinal stenosis. It is hypothesized that patients with lumbar spinal stenosis treated with IPD have a faster short-term recovery, an equal outcome after 2 years and less back pain compared with bony decompression. Five neurosurgical centers included participants. 211 participants were referred to the Leiden-The Hague Spine Prognostic Study Group. 159 participants with INC based on lumbar spinal stenosis at one or two levels with an indication for surgery were randomized into two groups. Patients and research nurses were blinded for the allocated treatment throughout the study period. 80 participants received an IPD, and 79 participants underwent spinal bony decompression. The primary outcome at long-term (2-year) follow-up was the score for the Zurich Claudication Questionnaire. Repeated measurement analyses were applied to compare outcomes over time. This double-blinded study could not confirm the advantage of IPD without bony decompression over conventional 'simple' decompression, two years after surgery. Moreover, in the IPD treatment arm,

the reoperation rate was higher and back pain was even slightly more intense compared to the decompression treatment arm. The use of interspinous implants did not result in a better outcome than conventional decompression, and the reoperation rate was significantly higher.

In 2014, Wu et al. conducted a meta-analysis of 2 RCTs and 3 non-randomized prospective comparative studies. There were 204 patients in the interspinous spacer group and 217 patients in the decompressive surgery group. Pooled analysis showed no significant difference at 12 and 24 months between the spacer and decompression groups for low back pain, leg pain, ODI, Roland Disability Questionnaire (RDQ) or complications. However, the traditional decompressive surgery group had a significantly lower incidence of reoperation, with 11 of 160 cases requiring reoperation compared to 31 of 161 cases in the interspinous spacer group. Several limitations to this meta-analysis were listed, with the primary concern being the small number of studies in the published literature comparing spacers and traditional decompression surgery. Although risk of bias was analyzed, no narrative critical appraisal of the included articles was provided. The authors noted the high reoperation rate associated with spacer use and stated that the indications, risks, and benefits of these devices required careful consideration before surgery.

Richter et al. (2014, included in the Hayes and ECRI reports above) also published 2-year follow-up results for 60 patients who underwent decompressive surgery with or without implantation of the CoFlex device. Though comparative, this study was not a randomized trial; treatment was allocated at the discretion of the surgeon. The authors reported no significant between-group differences in any outcome measures, and concluded that “additional placement of a CoFlex™ interspinous device does not improve the already good clinical outcomes after decompression surgery for LSS in this 24-month follow up interval.”

In a multicenter, randomized controlled manufacturer-funded Food and Drug Administration (FDA) Investigational Device Exemption (IDE) trial conducted in the United States, compared outcomes between decompression followed by CoFlex implantation and decompression followed by instrumented posterolateral spinal fusion in 322 patients (215 CoFlex and 107 fusions). Patients were stratified by site and number of vertebral levels to be treated and were randomized to treatment with the CoFlex, or spinal fusion group. The primary objective was to evaluate the safety and efficacy of CoFlex interlaminar stabilization compared with posterior spinal fusion in the treatment of 1- and 2-level spinal stenosis and degenerative spondylolisthesis. Patient follow-up at minimum 2 years was 95.3% and 97.2% in the CoFlex and fusion control groups, respectively. Patients taking CoFlex experienced significantly shorter operative times, blood loss, and length of stay. There was a trend toward greater improvement in mean Oswestry Disability Index scores in the CoFlex cohort. Both groups demonstrated significant improvement from baseline in all visual analogue scale back and leg parameters. The overall adverse event rate was similar between the groups, but CoFlex had a higher reoperation rate. At 2 years, fusions exhibited increased angulation and a trend toward increased translation at the superior adjacent level, whereas CoFlex maintained normal operative and adjacent level motion. While the changes with fusion were expected, longer follow-up is needed to determine whether motion preservation with CoFlex leads to lower reoperation rates, compared with fusion, for adjacent level disease (Davis et al. 2013, included in the Hayes report above).

Bae and colleagues (2016, included in the Hayes report above) performed a 3-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. There are several limitations in this study including the limited follow-up period and the heterogeneous mix of individuals. The authors noted that an RCT comparing decompression and stabilization with CoFlex device to decompression alone will be underway in the near future. Four-year follow-up was reported in 2015- and 5-year follow-up was reported in 2016. The reported rate of follow-up at 5 years ranged from 40% to 100%, depending on the outcome measured. For example, the ODI at 6 months was reported for 56% of patients, while major device-related complications and composite clinical success were reported for 100% of patients. Interpretation of the 5-year results is limited by the variable loss to follow-up in outcomes.

Clinical Practice Guidelines

North American Spine Society (NASS)

Interspinous Fusion Devices (With Fusion)

In 2019, the North American Spine Society issued a coverage position on the use of interspinous devices with lumbar fusion. The North American Spine Society noted that although there is still limited evidence, interspinous fixation with fusion for 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 Decompression Devices (Without Fusion)

The North American Spine Society (NASS; 2018) published specific coverage policy recommendations on the lumbar interspinous device without fusion and with decompression., NASS recommended that: "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:

- Significant mechanical back pain is present (in addition to those symptoms associated with neural compression) that is felt unlikely to improve with decompression alone. Documentation should indicate that this type of back pain is present at rest and/or with movement while standing and does not have characteristics consistent with neurogenic claudication.
- A lumbar fusion is indicated post-decompression for a diagnosis of lumbar stenosis with a Grade 1 degenerative spondylolisthesis as recommended in the NASS Coverage Recommendations for Lumbar Fusion.
- A lumbar laminectomy is indicated as recommended in the NASS Coverage Recommendations for Lumbar Laminectomy.
- Previous lumbar fusion has not been performed at an adjacent segment.

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 for interspinous fusion 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. (Accessed October 24, 2023)

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Policy History/Revision Information

Date	Summary of Changes
11/01/2024	**Template Update** • Modified font and InterQual® reference link styles; no change to policy content

04/01/2024	**Coverage Rationale**
	• Removed language indicating:
	  ○ Spinal procedures for the treatment of spine pain are proven and medically necessary
	  ○ Interspinous bony fusion devices used for stand-alone procedures are considered off-label and not medically necessary
	• Revised language pertaining to medical necessity clinical coverage criteria; removed reference to the InterQual® CP: Procedures:
	  ○ Decompression +/- Fusion, Cervical
	  ○ Decompression +/- Fusion, Lumbar
	  ○ Decompression +/- Fusion, Thoracic
	  ○ Fusion, Cervical Spine
	  ○ Fusion, Lumbar Spine
	  ○ Fusion, Thoracic Spine

Date	Summary of Changes
	Applicable Codes • Revised description for CPT code 22899 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS363OH.A

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.