Medical Coverage Policy

Effective Date 4/15/2024
Next Review Date 4/15/2025
Coverage Policy Number.....0448

Interspinous Process Spacer Devices

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Overview

This Coverage Policy (CP) addresses interspinous/interlaminar process spacers devices (e.g., coflex®, Superion®).

Note: Dynamic spine stabilization device systems and interspinous fixation/posterior non-pedicle supplemental fixation devices (e.g., coflex-F®) are addressed in CP 0303 titled Lumbar Fusion for Spinal Instability and Degenerative Disc Conditions, Including Sacroiliac Fusion.

Coverage Policy

Interspinous/interlaminar process spacer devices are considered experimental, investigational or unproven for all indications.

General Background

An interspinous/ interlaminar process spacer device may also be referred to as interspinous spacers (ISS), interspinous/ interlaminar stabilization/ distraction devices, and interspinous

process decompression (IPD) systems/devices. They are proposed for patients with lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least six months of non-operative treatment. The design of devices and the materials used in devices vary. The use of various devices has been proposed both as a minimally invasive surgical alternative to standard posterior lumbar decompression, with or without fusion procedures, and as an addition to decompressive surgery.

The American Academy of Orthopedic Surgeons estimates that spinal stenosis affects 8 to 11 percent of the population. Spinal stenosis is a narrowing of the vertebral canal that may lead to compression of the spinal nerves or nerve roots, especially in the lumbar vertebrae. Lumbar stenosis is commonly seen in an aging or degenerative spine. Neurogenic claudication is a combination of low back and leg pain, with numbness and motor weakness when standing or walking that is relieved by sitting or lying. Treatment for back pain may include pharmacological therapy (e.g., non-steroidal anti-inflammatory drugs [NSAIDs], analgesics, and muscle relaxants), exercise, spinal manipulation, acupuncture, cognitive-behavioral therapy, and physical therapy. Various interventional and surgical procedures may be considered if these measures are unsuccessful. Surgical options include decompressive procedures (e.g., laminectomy) alone, or decompression and fusion. Fusion is frequently performed with rigid implant fixation systems, including pedicle screws and interbody cages.

U.S. Food and Drug Administration (FDA)
The two current interspinous/interlaminar process spacers that are FDA approved and commercially available are the coflex® and Superion® devices. Coflex® is intended to be implanted after a decompression of the canal has been performed at the affected levels. Superion® is intended to "stand-alone" (does not requiring surgical decompression). It is delivered percutaneously as a single-piece through a cannula after dilators have opened the interspinous space. **coflex® Interlaminar Technology** (Paradigm Spine, LLC, New York, NY): The coflex® Interlaminar Technology received FDA approval through the PMA process on October 17, 2012. Since the original approval, there have been numerous supplemental approvals issued relating to the post-approval study. According to the FDA Summary of Safety and Effectiveness, the coflex Interlaminar Technology is an interlaminar stabilization device indicated for use in one or two level lumbar stenosis from L1-L5 in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least six months of non-operative treatment. The coflex is intended to be implanted midline between adjacent lamina of one or two contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s) (FDA, 2012).

Description: The coflex® device is a U-shaped implant manufactured from medical-grade titanium alloy designed to withstand a normal physiologic load in the spine. The device is a single-piece design with 2 pairs of serrated wings: 1 pair extending from the upper long arm and the other pair extending from the lower long arm of the U. This design allows a simple press-fit insertion of the device. The U portion is positioned horizontally between 2 adjacent spinous processes and pressed into place. The wings are crimped over bone to hold the implant in place. Implantation is performed after decompression of stenosis at the affected level(s).

Xtant Medical Holdings acquired the Coflex product portfolio from Surgalign Holdings in March 2023.

Superion™ Indirect Decompression System (IDS) (Boston Scientific Corporation) / Superion® InterSpinous Spacer (VertiFlex®, Inc., San Clemente, CA. Vertiflex was purchased by Boston Scientific in June 2019)**:** The Superion InterSpinous Spacer (ISS) received FDA approval through the PMA process on May 20, 2015 (P140004). Since the original approval, there have

been numerous supplemental approvals issued relating to the post-approval study. The ISS is indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, confirmed by X-ray, MRI and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. The Superion ISS is indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain, and who have undergone at least 6 months of non-operative treatment. The Superion ISS may be implanted at one or two adjacent lumbar levels in patients in whom treatment is indicated at no more than two levels, from L1 to L5 (FDA, 2015).

Description: The Superion Interspinous Spacer is a 1-piece, fully assembled implant designed to fit between the spinous processes of the lumbar spine. It consists of the titanium alloy body with 2 Cam lobes (" wings") superior and inferior to the main body that secure the device in place. Once the implant is in place, an actuation mechanism opens the implant to provide distraction and minimize flexion in the targeted spinal region. Superion is delivered through a single small incision (12-15 millimeters [mm]) in the patient's back utilizing proprietary manual instrumentation. The device may be implanted at 1 or 2 adjacent levels from L1 to L5 to expand the space between the vertebral spinous processes. The Superion Interspinous Spacer System includes a set of single-use stainless steel instruments necessary to deliver the implant, including a dilator, cannula, reamer, interspinous gauge, inserter, and driver. The procedure can be performed on an outpatient basis under local anesthesia using fluoroscopic guidance. However, in the Investigating Superion™ In Spinal Stenosis randomized controlled trial (Patel, et al., 2015a), 82% of patients had general anesthesia, 13.2% had conscious sedation, and only 7.4% had local anesthesia. Although the Vertiflex Procedure is noted in some resources as percutaneous, in the same study only 46.8% had a percutaneous placement and 53.2% had a "miniopen" procedure.

X-STOP® Interspinous Process Decompression (IPD) System (Medtronics, Minneapolis, Minnesota): The X-Stop device received FDA premarket approval in 2005, with promising results in the short-term, but further research demonstrated minimal benefit with longer-term follow-up, along with relatively high complication rates including spinous process fracture. PMA withdrawal date was 04/30/2015. Medtronic discontinued the distribution of the X-Stop system in 2015.

DIAM® Spinal Stabilization System: The FDA recommended against approval for the DIAM system (Medtronics, P140007) in an Orthopaedic & Rehabilitation Devices panel meeting in February 2016.

Other devices undergoing study but not currently FDA-approved include:

- Wallis® Posterior Dynamic Stabilizsation System (Zimmer Biomet, INC., Finland/Warsaw, IN, USA)
- APERIUS™ implant used in APERIUS™ PercLID™ System (Medtronics)
- HeliFix® Interspinous Spacer System (Alphatec Spine, Carlsbad, CA)
- In-space (Depuy Synthes, MA, USA)
- the Lobster (Techlamed, Italy)

Literature Review

coflex® Interlaminar Technology: FDA approval of the coflex was based on an Investigational Device Exemption (IDE) randomized, multicenter trial conducted by Davis et al. (2013a). A total of 322 patients who met the following criteria were included: ages of 40 and 80, at least moderate lumbar stenosis, which narrows the central spinal canal at one or two contiguous levels from L1–L5 that require surgical decompression, and BMI not > 40. Patients were followed for two years. Patients received laminectomy and coflex insertion (n=215) or posterolateral spinal fusion with pedicle screw (PS) instrumentation (n=107). The proportion of patients with spondylolisthesis was

similar (coflex: 99/215 = 46.0%; PS [control]: 51/107 = 47.7%). Composite Clinical Success (CCS) criteria included some of the following: device survives 24 months, no epidural injections in 24 months, Oswestry Disability Index (ODI) improvement from baseline to month 24 visit of at least 15 points, no persistent new or worsening sensory or motor deficit, and no major device-related complications. Five year results were reported, with a five year follow-up rate of 91% (Musacchio, et al. 2016).

- Based on composite for overall success, 66.2% of coflex and 57.7% of PS succeeded (p= 0.999), thus demonstrating non-inferiority at 24 months. At 5-year follow-up, 50.3% of coflex patients met the success criteria compared with 44% of PS patients (p>0.35; not significant). Of note, patients who underwent additional surgery or injections after the study surgery were classified outcome failures in the composite assessment of success, and excluded from the analyses of individual outcome assessments such as Visual Analogue Scale (VAS) and Zurich Claudication Questionnaire (ZCQ).
- ODI (percent achieving a 15-point reduction in ODI): At 2 years, coflex 85.8%, PS 76.7%; at 5 years coflex 80.6%; PS 73.2%.
- VAS back and leg pain: Both groups showed significant improvement from baseline in both back and leg pain at all time points out to 5 years.
- ZCQ: At 5 years, the ZCQ symptom severity improvement of at least 0.5 was assessed per patient where 79.8% of coflex and 72.7% of PS met that criteria. The ZCQ physical function improvement of at least 0.5 was assessed per patient where 78.2% of coflex and 70.9% of PS patients met the criteria. The third component of patient satisfaction was consistent from Week 6 to Month 60 in both groups (percentage of patients meeting criteria was not provided).
- Narcotic usage: There was no significant difference between the two groups at Month 60 but both groups were significantly improved from their preoperative status.
- Reoperation rates Reoperation rate at 24 months was coflex 23/215 (10.7%) and PS 8/107 (7.5%) (p= 0.426). At 5-year, cumulative total occurrences of reoperations/revisions were coflex group 35/215 (16.3%) and PS group 19/107 (17.8%).

Abjornson et al. (2018) reported a Davis/Musacchio sub-study on the cohort treated with decompression plus coflex at 1 or 2 levels and who did not present with spondylolisthesis preoperatively (n=116, 65 in the 1-level coflex group and 51 in the 2-level coflex group).

- CCS was achieved in 48.3% of 1 level and 60.9% of 2 level at 5 years.
- ODI: There was 15-point improvement in 81.6% of 1-level and 90.3% of 2-level patients at 5 years.
- VAS: 94.7% of 1 level and 100% of 2 level achieved at least a 20-mm improvement, at 5 years.
- ZCQ: Improvement of ≥ 0.5 as compared to preoperative score is calculated as improvement. In the symptom severity component, 81.6% of 1-level and 83.9% of 2-level patients reported improvement at 5 years. In the physical function component, 76.3% of 1 level and 83.9% of 2 level patients reported improvement at 5 years.
- No secondary surgery or epidural injections: 1 level (69.2%); 2 level (70.6%); at 5 years. Of the 16 patients that required a secondary surgery over the course of the study, 8 were not related, 2 unlikely, 4 possibly, and 2 definitely related to the device.

A limitation of this study is the lack of comparison with non-spondylolisthesis patients from the 'fusion with pedicle screw' cohort.

Davis et al. (2013b) reported a Davis/Musacchio sub-study on the cohort of patients with low grade (grade 1) degenerative spondylolisthesis with spinal stenosis (coflex =99, PS=51). Two years results include:

- Overall success (as described above) was similar with 59 coflex patients meeting success (62.8%), and 30 PS patients (62.5%) meeting success at 24 months.
- ODI: The percentage of patients that achieved a 15-point reduction in ODI at 2 years from

baseline was 86.1% for coflex and 81.0% for PS.
- VAS back and leg pain: no significant differences noted at baseline or at 24 months.
- ZCQ: both groups improved similarly from baseline in physical function and symptom severity scores, but the coflex cohort performed significantly better than PS controls with respect to ZCQ patient satisfaction at 24 months (p = 0.05).
- Reoperation: The overall reoperation rate was 14.1% (14 of 99) and 5.9% (3 of 51) for the coflex and PS controls, respectively (p = 0.18, not statistically significant).

Simon et al. (2018) reported a Davis/Musacchio sub-study on the cohort of 116 patients who required surgical treatment at two levels. The decompression and interlaminar stabilization with coflex group consisted of 77 patients, and the posterolateral spinal fusion with pedicle screw instrumentation (PS) group consisted of 39 patients.
- CCS: the percentage of patients who achieved CCS, coflex 55.1%, PS 36.4% at 5 years.
- ODI: Of those assessed, 86.7% of coflex patients (39/45) and 92.9% of PS patients (13/14) saw an improvement of ≥15 points in the ODI at month 60 compared to baseline
- VAS: At 60 months, the mean VAS back pain scores decrease of 59.8 points for the ILS group was similar to the fusion group with 58.9 points.
- ZCQ: There was no significant difference between groups for Symptom Severity, Physical Function or Satisfaction score, at 60 months.

- No secondary surgery or epidural injections: The number of patients in the coflex group who did not receive a reoperation or epidural injection was 53/77 (68.8%) compared to 20/39 (51.3%) PS patients.The European Study of Coflex And Decompression Alone (ESCADA) trial (Schmidt, et al., 2018) is a randomized controlled trial with modified intent-to-treat analysis. The trial included 230 patients seen at seven sites in Germany. Schmidt et al. compared open microsurgical decompression followed by interlaminar stabilization with coflex (D+ILS) to decompression alone (DA).
  - Inclusion criteria included age > 40 years, VAS back pain score of ≥ 50 mm, at least moderate degenerative spinal stenosis, with constriction of the central spinal canal in 1 or 2 adjacent segments from L-3 to L-5 with the need for decompression. In addition, the following was allowed but not required: hypertrophy of the facet joints and subarticular recess stenosis in the relevant segment or stenosis of the foramen in the relevant segment, and/or spondylolisthesis (anterolisthesis or retrolisthesis) up to grade I.
  - Exclusions were translational instability in the main segment as well as in adjacent segments (dynamic translational instability ≤ 3 mm), previous surgery at index level, and/or vertebral or pars fracture.

  At 24 months, with an overall 91% follow up rate, results demonstrated no significant differences between the groups in the patient reported outcomes: ODI scores, ZCQ, and VAS back and neck pain scores (p > 0.05). The CCS was calculated using 1) ODI success with improvement > 15 points; 2) survivorship with no SSIs or lumbar injections; 3) neurological maintenance or improvement without worsening; and; 4) no device- or procedure-related severe adverse events. The DA arm had 228% more lumbar injections (p = 0.0065) than the D+ILS arm (epidural steroid injections for D+ILS, 5/110 [4.5%]; for DA, 17/115 [14.8%]). When this measurement was included in the CCS, the result became significant. Authors conclude the use of coflex extends the durability and sustainability of a decompression procedure.

  A randomized controlled double-blind 'FELIX' trial (Moojen, et al., 2013) was conducted at five neurosurgical centers in the Netherlands to assess whether interspinous process device implantation is more effective in the short term than conventional surgical decompression for patients age 40 and 85 years with NIC due to lumbar spinal stenosis. Patients with lumbar spinal stenosis at one or two levels with an indication for surgery were randomized to treatment with coflex device (no bony decompression was done) (n=80) or surgical decompression (n=79). The difference in ZCQ scores coflex group and the standard decompression group at eight weeks (63% vs. 72%, p=0.44) or one year (66% vs. 69%, p=0.77) is not significant. However, the repeat

surgery rate in the coflex was significantly higher than in the standard decompression group, at 29% vs. 8% ($p<0.001$). The authors stated "the number of reoperations in the interspinous process device treatment arm is very worrisome, especially because reoperations do not reach the success rate of primary surgeries; use of interspinous process devices might even prevent recovery in 20% of patients".

Richter et al. (2014) conducted a prospective, controlled study to assess the outcome of symptomatic lumbar spinal stenosis (LSS) treated with decompressive surgery alone (n=31) compared to decompressive surgery with implantation of the coflex interspinous device (n-31). Included patients had signs, symptoms and MRI findings of lumbar spinal stenosis and a minimum of three months of conservative treatment, were age 45-80 with one or two level stenosis, and had not undergone previous surgery of the lumbar spine. There was no formal randomization procedure. There was a significant improvement in both groups ($p>0.001$) in the clinical outcome assessed in the ODI, the Roland-Morris Disability Questionnaire, the VAS, and the pain-free walking distance at all time of assessment compared to baseline. Up to two years after surgery, there were no significant differences between the two groups in all measured parameters, including patient satisfaction and subjective operation decision. In the coflex group, three revisions with pedicle screw fusion of the segment were necessary. In surgery only group, two patients had to be instrumented and fused. The authors concluded that the additional placement of a coflex interspinous device does not improve the already good clinical outcome after decompressive surgery for lumbar spinal stenosis in the 24-month follow-up interval. In a prospective study, Kumar et al. (2014) compared decompression plus coflex (n=22) to decompression alone (n=24). The included 46 patients were 40–74 years old with symptomatic lumbar spinal stenosis. The mean ODI score for both the coflex and the comparison group showed significant improvement at six months, one year, and two years as compared to the preoperative score. The mean improvement in ODI scores of patients in the coflex group was significantly greater than the comparison group ($p<0.001$). The incidence of complications in the two groups was not significantly different ($p=0.35$). The authors support the implantation of coflex after spinal decompression.

Li et al. (2019) reported on a retrospective study including 99 patients with degenerative lumbar disease (DLD) at L3–L5. A total of 45 patients underwent 'Topping off' surgery or 'hybrid' surgery (L4–5 posterior lumbar interbody fusion [PLIF] + L3–4 Coflex) and 54 patients underwent PLIF = L3–5 PLIF. Patients were excluded if they had degenerative lumbar scoliosis or kyphosis, lumbar spine fracture, spondylolisthesis at L3–L4 of grade II and above, severe osteoporosis, and history of lumbar spine surgery. The primary study outcome was to assess the efficacy of preventing adjacent segment degeneration (ASD).

- Outcomes showed both two groups had a significant improvement in VAS and ODI scores for lower back/leg pain at 3 years after surgery than before ($p< 0.05$). But there was no significant difference in the pairwise comparison ($p> 0.05$).
- The two groups had no significant difference in intervertebral mobility (L2–L3) before surgery ($p> 0.05$). After surgery, it was lower in the Topping-off group than in the PLIF group ($p< 0.05$). At 3 years after surgery, general adjacent segment mobility (GASM) (L2–4) was not significantly different between the two groups ($p> 0.05$).
- At 3 years after surgery, the modified Pfirrmann grade of disc was increased by 1 grade in 2 cases of the Topping-off group (4.44%). In contrast, disc degeneration was more severe in the PLIF group, with increased Pfirrmann grade in 14 cases (25.93%) (including 2 cases with intervertebral mobility > 10°). Among them, 11 cases had an increase by 1 grade, 2 cases 2 grade, and 1 case 3 grade (this patient received a revision surgery). The difference was of statistical significance between the groups ($p< 0.05$).

In the Topping-off group, one case had intraspinal hematoma after surgery; in the PLIF group, one case had subcutaneous incision infection and another case intraspinal hematoma. The clinical efficacy and the incidence of adjacent segment degeneration (ASD) of Topping-off surgery for degenerative lumbar disease (DLD) remain to be verified by trials with a larger sample size and

longer follow-up.

In a long term retrospective study, patients receiving coflex implant were followed for a minimum of 8 years (Du, et al., 2020). A total of 56 patients who underwent single segment interlaminar decompression and coflex implantation were followed for 107.6 ± 13.3 months. Results showed ROM of adjacent segments increased at 6 months and at the last follow-up compared with that before surgery ($P > 0.05$). At 6 months after surgery, intervertebral space height (ISH) and intervertebral foramen height (IFH) of implanted segment was significantly higher than that before surgery ($P < 0.05$). At the last follow-up, there was a decrease in ISH and IFH ($P > 0.05$). During the follow-up period, a total of 11 patients (19.6%) experienced complications and 6 patients (10.7%) underwent secondary surgery.

Two small retrospective studies report greater than five year results. A small retrospective study reported at least five year results on 87 patients (Yuan, et al., 2017) with a total of 42 patients who underwent decompression and coflex interspinous stabilization. A total of 45 patients had decompression and posterior lumbar interbody fusion (PLIF). The mean ODI and VAS scores in the coflex group were significantly lower compared with the PLIF group initially. However, at final follow-up, the mean ODI scores between the two groups had no significant difference. At final follow-up, the index level ROM was significantly higher in the coflex group. At the final follow-up, two (4.8%) patients in the coflex group required revision surgery for ASD, five (11.1%) patients in the PLIF group underwent a revision surgery for ASD (did not reach statistical significance; $p = 0.277$). Errico et al. (2009) reported retrospective results from one orthopedic spine surgeon who followed 127 patients for a mean of 6.3 years. A patient satisfaction query demonstrated that 7% were unsatisfied, 46% were satisfied, and 46% were very satisfied with their clinical outcome. Based on the follow-up radiographs, 92 of patients had no device related issues and 8% had device-related issues. Both studies are limited by their small, retrospective design.

A small, retrospective cohort of adults with lumbar stenosis and grade 1 stable spondylolisthesis (n=83) were evaluated to compare postoperative outcomes following single-level decompression and implantation of coflex (n=46) and single-level laminectomy alone (n=37). Mean follow-up was 516 to 677 days. Patients who received coflex were older, had a higher anesthesia grade but similar comorbidities. Results demonstrated the coflex cohort had higher estimated blood loss ($p = 0.004$), longer operative time ($p = 0.001$), and longer length of stay ($p = 0.001$). Total perioperative complications (21.7% vs 5.4%, $p = 0.035$) and instrumentation related complication was higher in the coflex cohort (10.9% vs 0% laminectomy group, $p = 0.039$). Similar post-op complications, revision, and neurologic complication rates were seen between the two cohorts at last follow up (Zhong, et al., 2020).

coflex® Literature Review Summary: Studies in the published peer reviewed scientific literature include small populations, especially considering the prevalence of lumbar stenosis. One trial demonstrated a significantly higher reoperation rate that may actually prevent a better recovery owing to the lower recovery rate after a second operation. Published studies do not demonstrate any long-term health outcome advantage with the additional use of coflex**.** Large population sufficiently powered randomized controlled trials that demonstrate long-term health outcome advantages with the addition of coflex are needed.

Superion® InterSpinous Spacer
Patel et al. (2015a) conducted a prospective, multicenter, randomized controlled investigational device exemption trial to compare two year outcomes in patients with NIC secondary to moderate lumbar spinal stenosis (LSS) who were treated with the Superion spacer or a control spacer (X-STOP). Eligible patients were at least 45 years of age and reported symptoms of NIC secondary to a confirmed diagnosis of LSS at one or two contiguous levels from L1 to L5, despite at least six months of nonsurgical management. A total of 391 randomized patients were implanted with Superion (n = 190) or X-STOP (n = 201) spacers at 29 sites in the United States. At study end,

participation was 280, Superion (n = 136) or X-STOP (n = 144) spacers. A total of 28% were lost in follow-up: 111 withdrawn due to a protocol-defined secondary intervention, including device explant, revision surgery at the index level without explant, rhizotomy, rehospitalization for deep infection, or lumbar injection at the index level. The primary endpoint of this study was a composite treatment success outcome at the two year follow-up visit, defined as: (1) clinically significant improvement in at least 2 of 3 ZCQ domain scores compared with baseline (2) freedom from reoperation, revision, removal, or supplemental fixation at the index level, (3) freedom from epidural steroid injection or nerve block at the index level within 12 weeks of the 2-year visit, (4) freedom from rhizotomy or spinal cord stimulator at any level, and (5) freedom from major implant or procedure-related complications.

At two years follow up, the authors stated that the primary composite endpoint of this study was met, which demonstrated that the Superion spacer was non-inferior to the X-Stop spacer. Leg pain, the predominant patient complaint, decreased in severity by 70% during 2 years in each group. Most (77%) patients achieved leg pain clinical success (improvement ≥ 20 mm) at 2 years. Back pain clinical success (improvement ≥ 20 mm) was 68%, with no differences between groups. Oswestry Disability Index clinical success (≥ 15% point improvement) was achieved in 65% of patients. There were a total of 44 (23.2%) reoperations or revisions in the Superion group compared with 38 (18.9%) in the X-STOP (control) group (p= 0.32). The authors noted that the long-term durability of interspinous process spacers is currently unknown and requires further investigation.

- Lauryssen et al. (2015) performed a qualitative comparison of the published two-year clinical findings from Patel et al. (2015a) with historical laminectomy literature, (19 studies) for similar outcome measurements associated with decompressive laminectomy (N=1045). The 19 studies included retrospective, prospective, and randomized trials. Back and leg pain, ODI, and ZCQ values were compared. Following treatment with either spacer or laminectomy, patients attained clinically substantial gains across all outcome measures at 12 months with durable improvement through 24 months, postoperatively. The authors of this literature review that included retrospective studies concluded that both treatments provide effective and durable symptom relief of claudicant symptoms.
- Patel et al. (2015b) reported three year outcomes. All outcomes were reported using a modified intention-to-treat population. At year three, 36.4% are lost in follow up (Superion = 120 or X-STOP = 129). The 'primary composite endpoint' was individual patient success based on four components: improvement in two of three domains of the Zurich Claudication Questionnaire, no reoperations at the index level, no major implant/ procedure-related complications, and no clinically significant confounding treatments. The proportion of subjects achieving the 'primary composite endpoint' was greater for Superion (63/120, 52.5%) than for X-STOP (49/129, 38.0%) (p=0.023). Comparing the 24-month data with the 36-month data, there was a higher increase in X-STOP reoperations, revisions, and removals (n=15 out of 44 total) compared to the Superion device (n=11 out of 49 total).

Nunley et al. (2017) reported five year outcomes on the Superion arm of the Patel et al. (2015a) trial. Of the original 190 patients randomly assigned to receive treatment with Superion, 88 were free from reoperation or steroid injection at 5-year follow-up and able to provide complete clinical outcome evaluations (46.3%). Authors' report 74 of 88 patients (84%) demonstrated clinical success on at least 2 of 3 ZCQ domains (symptom severity, physical function, and patient satisfaction). A limitation of this study is the loss of participation at five year follow-up (88 of 190 = 46.3%).

- In a quality of life sub-study, Nunley et al. (2018a) reported that of 189 patients initially randomized to Superion treatment, SF-12 questionnaire responses were captured in 68 study subjects at 5 years. Physical component summary and mental component summary (PCS, MCS) scores were computed preoperatively and the percentage improvement in PCS

and MCS at the 5-year follow-up interval compared to preoperative values was computed. The mean PCS score improved from 29.4 ± 8.1 preoperatively to 43.8 ± 11.6 at 5 years, representing average percentage improvements of 49%, ($p<0.001$). 87% (59 of 68) of subjects who provided 5-year SF-12 responses continued to maintain or improve their PCS score. The mean MCS score improved from 50.0 ± 12.7 preoperatively to 54.7 ± 8.6 at 5 years, representing a 9% improvement ($p >0.10$ for both comparisons). At 5 years, 57% (39 of 68) of subjects showed maintenance or improvement in PCS scores.

- Nunley et al. (2018b) reported an opioid-medication analysis of the Superion arm of the Patel et al. (2015a) trial. At baseline, almost 50% (94 of 190) of subjects were using opioid medication. Thereafter, there was a sharp decrease in opioid-medication prevalence from 25.2% (41 of 163) at 12 months to 13.3% (20 of 150) at 24 months to 7.5% (8 of 107) at 60 months. A similar pattern was also observed among subjects with a history of opiates prior to entering the trial.

Tekmyster et al. (2019) reported on a prospective registry of 445 patients at multiple US sites. The objective was to report 12 month outcomes of pain severity data and patient satisfaction after interspinous process decompression (IPD) with a stand-alone interspinous spacer (Superion). The maximum number of patients providing pain severity data was 2,090, 759, 1,553 and 445 at baseline, 3 weeks, 6 and 12 months, respectively.
For patient satisfaction and treatment approval, the maximum number of patients providing follow-up data was 751, 1,542 and 443 at 3 weeks, 6 and 12 months, respectively.

- Mean leg pain severity decreased from 76.6 ± 22.4 mm preoperatively to 33.0 ± 29.9 mm at 3 weeks, 33.1 ± 34.0 mm at 6 months, and 30.4 ± 34.6 mm at 12 months, reflecting an overall 60% improvement.
- Back pain severity improved from 76.8 ± 22.2 mm preoperatively to 37.5 ± 29.6 mm at 3 weeks, 41.9 ± 32.5 mm at 6 months, and 39.9 ± 32.3 mm at 12 months (48% improvement).
- For patient satisfaction at 3 weeks, 6 and 12months, 89%, 80%, and 80%were satisfied or somewhat satisfied with their treatment and 90%, 75%, and 75% would definitely or probably undergo the same treatment again.
- In the phone survey, the rate of revision was 3.6% (51 of 1,426).

In a retrospective study, Welton, et al. (2021) reported short-term (30 days) adverse outcomes from 189 Superion patients in the Vertiflex-provided database. The Superion patients were compared to 378 matched controls in the American College of Surgeons National Surgical Quality Improvement Program (ACSNSQIP) Database, who had undergone primary lumbar spine laminectomy or laminotomy. Complications analyzed included rates of wound infection, pulmonary embolism, deep venous thrombosis, urinary tract infection, sepsis, septic shock, cardiac arrest, death, and reoperation within 30 days of index surgery. There was no significant difference in rates of complications between groups noted at 30 days.

In a prospective study, Bini et al. (2011) observed 121 patients following insertion of the Superion device. Patients had a diagnosis of moderate lumbar spinal stenosis, failed 3 months conservative treatment, and persistent pain relieved by lumbar flexion, A total of 22 (18%) of the patient's patients presented with concomitant grade I spondylolisthesis. A total of 52 were observed at 12 months. ODI improved 64% ($p<0.001$) through 12 months and clinical success was 92%. Extremity and axial pain improved 53% and 49% (both $p<0.001$), respectively, through 12 months with clinical success of 76% for axial pain and 86% for extremity pain. The follow-up period in the current study extends only through 12 months so no direct comparison of complication and revision rates can be made with certainty.

Superion® Literature Review Summary: There is a lack of large well-designed studies in the peer review scientific literature comparing stand alone use of Superion device to established surgical decompression. Published studies do not demonstrate any long-term health outcome

advantage with the use of Superion as an alternative to standard surgical treatment. Large population sufficiently powered randomized controlled trials that demonstrate long-term health outcome advantages are needed.

Professional Societies/Organizations

American Academy of Orthopaedic Surgeons (AAOS): At this time, there are no AAOS Clinical Practice Guidelines or AAOS Appropriate Use Criteria addressing the use of interspinous/interlaminar spacer devices.

North American Spine Society (NASS):
Lumbar Interspinous Device without Fusion and Decompression Coverage Policy Recommendations (May 2018) apply to interspinous process (ISP) devices that are intended to be used in conjunction with a direct decompressive procedure and include: Stabilization with an ISP 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.
- previous decompression has been performed at the intended operative segment.

- ISP 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 2 or higher.
  - degenerative scoliosis or other signs of coronal instability.
  - dynamic instability as detected on flexion-extension views demonstrating at least 3 mm of change in translation.
  - iatrogenic instability or destabilization of the motion segment.
  - a fusion is otherwise not indicated for a Grade 1 degenerative spondylolisthesis and stenosis as per the NASS Coverage Recommendations for Lumbar Fusion.
  - a laminectomy for spinal stenosis is otherwise not indicated as per the NASS Coverage Recommendations for Lumbar Laminectomy.

The NASS Evidence-Based Clinical Guideline Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis (Kreiner, et al., 2013) states "There is insufficient evidence at this time to make a recommendation for or against the placement of an interspinous process spacing device in patients with lumbar spinal stenosis".

The NASS Evidence-Based Clinical Guideline Diagnosis and Treatment of Degenerative Lumbar Spondylolisthesis (Matz, et al., 2016) states "There is insufficient and conflicting evidence to make a recommendation for or against the efficacy of interspinous spacers versus medical/interventional treatment in the management of degenerative lumbar spondylolisthesis patients. Grade of Recommendation: I (Insufficient Evidence)".

These NASS publications do not address Coflex, Superion or X-STOP:

- Coverage Policy Recommendations Lumbar Decompression: Laminectomy, Laminotomy & Foraminotomy (Jan 2022)
- Clinical Guideline Diagnosis & Treatment of Low Back Pain (Kreiner, et al., 2020; last updated 1/27/2021 and endorsed by the American Academy of Physical Medicine and Rehabilitation and American Association of Neurological Surgeons and Congress of Neurological Surgeons)
- Coverage Policy Recommendation Interspinous Fixation with Fusion Coverage Policy Recommendations (December 2019)
- Coverage Policy Recommendation Lumbar Fusion (June 2021)

- Coverage Policy Recommendation Minimally Invasive Sacroiliac Joint Fusion (September 2021) **The American Society of Pain and Neuroscience (ASPN):** The ASPN Evidence-Based Clinical Guideline of Interventional Treatments for Low Back Pain (Sayed, et al., 2022) Back Consensus Group Recommendations for Interspinous Spacers, Indirect Decompression is "Stand-alone interspinous spacers for indirect decompression are safe and effective for the treatment of mild to moderate lumbar spinal stenosis if no contraindications exist" (Grade A: The ASPN Back Group recommends the service. There is high certainty that the net benefit is substantial).

  The ASPN states that standalone lumbar interspinous spacers are indicated to treat skeletally mature patients suffering from painful walking, numbness, and/or cramping in the legs (neurogenic claudication) secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, as confirmed by advanced radiographic imaging. They are indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain, and who have undergone at least 6 months of non-operative treatment. Interspinous spacers may be implanted at one or two adjacent lumbar levels in patients in whom treatment is indicated at no more than two levels, from L1 to L5.

  For this intended use, moderate degenerative lumbar spinal stenosis is defined as follows:

  - 25% to 50% reduction in the central canal and/or nerve root canal (subarticular, neuroforaminal) compared to the adjacent levels on radiographic studies, with radiographic confirmation of any one of the following:
    - Evidence of thecal sac and/or cauda equina compression,
    - Evidence of nerve root impingement (displacement or compression) by either osseous or non-osseous elements,
    - Evidence of hypertrophic facets with canal encroachment.
  - And associated with the following clinical signs:
    - Presents with moderately impaired physical function defined as a score of ≥2.0 on the Zurich Claudication Questionnaire (ZCQ),
    - Ability to sit for 50 min without pain and to walk 50 feet or more.

  The interspinous spacers may be contraindicated in the following situations:
  - Severe spinal stenosis with neurological deficits
  - Multilevel (more than 2 levels of spinal stenosis)
  - Spinal instability (>3mm of translation)
  - Osteoporosis (high risk for spinous process fracture)
  - Scoliosis (Cobb angle >17 degrees)
  - Baastrup's disease
  - Greater than grade I spondylolisthesis
  - Previous lumbar surgery at the affected level
  - Symptoms not relieved with forward flexion (Sayed, et al., 2022).

US Department of Health and Human Services (HHS): The US Department of Health and Human Services published a document titled "Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations" in 2019. It states "Research has shown that interspinous process spacer devices can provide relief for patients with lumbar spinal stenosis with neuroclaudication" and cites Nunley et al. (2017/2018).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No Determination found	
LCD		No Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Experimental/Investigational/Unproven:

CPT®* Codes	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 Codes	Description
C1821	Interspinous process distraction device (implantable)

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	No policy statement changes.	4/15/2024