Interspinous Process Spacer Devices

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Related Coverage Resources

- Intervertebral Disc (IVD) Prostheses
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- Minimally Invasive Intradiscal/Annular Procedures and Trigger Point Injections

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Coverage Policy

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

Overview

This Coverage Policy 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 Lumbar Fusion for Spinal Instability and Degenerative Disc Conditions, Including Sacroiliac Fusion.

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).

Superion® InterSpinous Spacer (VertiFlex®, Inc., San Clemente, CA): The Superion InterSpinous Spacer (ISS) received FDA approval through the PMA process on May 20, 2015. 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. The Superion Spacer is made of titanium alloy.

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) in an Orthopaedic & Rehabilitation Devices panel meeting in February 2016.

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

- Wallis® Posterior Dynamic Stabilization System (Zimmer Biomet, INC., Finland/Warsaw, IN, USA)
- APERIUS™ implant used in APERIUS™ PercLID™ System (Medtronics)
• HeliFix® Interspinous Spacer System (Alphatec Spine, Carlsbad, CA)

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 (ECADA) 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 Hayes Technology Brief, last updated September 21, 2018, gave a Hayes rating of C, for use of the coflex Interlaminar Stabilization device with decompression for the treatment of lumbar spinal stenosis in adult patients with and without spondylolisthesis. This Rating reflects a low-quality body of evidence suggesting that use of the coflex device with decompression surgery results in similar improvements in pain, disability, and function compared with decompression plus fusion or decompression alone and may have an advantage in operative time, estimated blood loss, and length of hospital stay. Substantial uncertainty remains due to a lack of definitive patient selection criteria and good- to fair-quality studies demonstrating a distinct benefit of the coflex device over traditional surgical intervention.
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.

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.

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.

A Hayes Clinical Research Response (May 2018) gave the following Hayes Viewpoint: There is insufficient evidence in the peer-reviewed medical literature to demonstrate the long-term safety, efficacy, and durability of the Superion ISS. There is also a lack of evidence comparing the Superion ISS to the established treatment for this condition, surgical decompression. Therefore, the impact of the Superion ISS on net health outcome is not currently known and requires further investigation.

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.

**Multiple Devices**

Machado et al. (2016) conducted a Cochrane database systematic review that included only randomized controlled trials investigating the efficacy and safety of surgery compared with no treatment, placebo or sham surgery, or with another surgical technique in patients with lumbar spinal stenosis. All included studies compared two or more surgical techniques. The authors judged all trials to be at high risk of bias for the blinding of care provider domain, and most of the trials failed to adequately conceal the randomization process, blind the participants or use intention-to-treat analysis.

- Three trials reported data of 355 participants comparing bony decompression (laminectomy or laminotomy) with the X-Stop or Coflex interspinous process spacer devices. These spacer devices resulted in similar reductions in pain and disability. The spacer devices required longer operation time and were associated with higher risk of reoperation, but no difference in perioperative blood loss was found.

- Two trials compared decompression plus fusion with the X-Stop or Coflex interspinous spacer devices and included a total of 382 participants. Although no difference in pain relief was found, the spacer devices revealed a small but significant effect in disability reduction. They were also superior to decompression plus fusion in terms of operation time and perioperative blood loss; however, there was no difference in rate of reoperation.

Overall, the authors found that patients who had decompression plus fusion fared no better than those who underwent decompression surgery alone. Decompression plus fusion resulted in more blood loss during surgery than decompression alone. Although the spinal spacers were slightly better than decompression plus fusion in terms of improvements on daily activities, there were no differences when they were compared with decompression alone. Finally, no difference between different forms of decompression was found.

Cai et al. (2016) conducted a meta-analysis of prospective studies to evaluate the safety and effectiveness of interspinous spacers versus posterior lumbar interbody fusion (PLIF) for degenerative lumbar spinal diseases.
Some of the terms used in the literature search included DIAM, coflex, X-STOP, and Wallis. Among the 177 titles and abstracts screened, ten studies satisfied the eligibility criteria. The ten studies including five RCTs and five prospective trials with 961 eligible cases were taken into the analysis (499 cases for interspinous spacers and 462 cases for PLIF). All but one included study evaluated coflex. Results were as follows: Complication rates, no significant differences; Post-operative VAS for pain, no significant differences; ODI score, no significant differences. The authors were unable to analyze re-operation trends in detail because the reasons were not described. The authors note that although clinical outcomes appear to be equivalent, more RCTs with larger sample size, longer follow-up, higher quality and more detailed outcomes are needed to confirm and update the meta-analysis findings.

Gazzeri et al. (2015) conducted a retrospective, European multicenter study consisting of 1108 patients to evaluate implant survival and failure modes after the implantation of 8 different interspinous process devices (IPD). Preoperative and postoperative clinical assessments in the patients were based on the visual analog scale. A minimum of 3 years after IPD placement, information on long-term outcomes was obtained from additional follow-up or from patient medical and radiological records. The number of patients per device type was as follows: DIAM 193, coflex 15, Wallis 27, Viking 185, X-Stop 422, Ellipse 58, BacJac 141, and Aperius 67. The complication rate was 7.8%. There were 27 fractures of the spinous process and 23 dura mater tears with CSF leakage. The ultimate failure rate requiring additional surgery was 9.6%. The reasons for revision, which always involved removal of the original implant, were acute worsening of low-back pain or lack of improvement (45 cases), recurrence of symptoms after an initial good outcome (42 cases), and implant dislocation (20 cases). The authors concluded that overdistraction, poor bone density, and poor patient selection may all be factors in the development of complications.

Wu et al. (2014) conducted a meta-analysis to compare the clinical outcomes of interspinous spacer use to traditional decompressive surgery. Some of the terms used in the literature search included DIAM, Coflex, X-Stop, and Wallis. Two RCTs and three non-randomized prospective studies were included, with 204 patients in the interspinous spacer (IS) group and 217 patients in the traditional decompressive surgery (TDS) group. Pooled analysis showed no significant difference between the IS and TDS groups for low back pain, leg pain, ODI, Roland disability questionnaire, or complications. The reoperation rate was significantly higher in the IS group (37/161; 23.0%) compared to the TDS group (11/160, 6.9%). The authors concluded that because of the high reoperation rate associated with interspinous spacer use, the indications, risks, and benefits of using an interspinous process device should be carefully considered before surgery.

Kim et al. (2012) conducted a risk factor analysis for early spinous process fracture associated with interspinous process spacer (IPS) surgery in a prospective study including 38 patients (50 levels). Consecutive patients with a primary diagnosis of lumbar spinal stenosis affecting one or two lumbar spinal levels between L1 and L5 underwent implant of 34 titanium X-STOP, 8 PEEK X-STOP, and 8 Aspen (Lanx, Broomfield, CO, USA) devices. Pre- and post-operative CT scans were performed. One year follow-up demonstrated 11 spinous process fractures were identified by CT in 11 patients (22.0% of levels). No fractures were apparent on plain radiographs. The rate of spondylolisthesis observed on preoperative radiographs was 100% (11 of 11) among patients with fractures compared with 33.3% (9 of 27) of patients without fracture (p=.0001). Overall, 21 of 39 patients in this series had spondylolisthesis, and the rate of fracture in this group was 52%. Among patients without spondylolisthesis, the fracture rate was 0%. The authors concluded that degenerative spondylolisthesis appears strongly associated with the occurrence of spinous process fracture after IPS surgery.

**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.

On the AAOS website, under Disease & Conditions, under Lumbar Spinal Stenosis, the AAOS states: Interspinous process devices, or spacers, are inserted between the spinous processes in the back of the spine. These devices spread the vertebrae apart and keep the space for the nerves open and functioning. This procedure is a minimally invasive surgical option for lumbar spinal stenosis. Interspinous process spacers were approved in 2005. Many procedures have been performed since then. In some studies, success rates are greater than 80 percent. Numerous spacer devices are currently being evaluated. They may be a safe alternative.
to an open laminectomy for some patients. Limited bone (lamina) is removed with this procedure, and it may be performed under local anesthesia. The key to success with this procedure is appropriate selection of the patients. The appropriate candidate must have relief of buttock and leg pain when sitting or bending forward. The pain returns upon standing. (AAOS, 2013).

**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)”.

**International Society for the Advancement of Spine Surgery (ISASS):** The ISASS Policy Statement Decompression with Interlaminar Stabilization (Guyer, et al., 2016) states that patients who have all of the following criteria may be eligible for decompression with interlaminar stabilization:

1. Radiographic confirmation of at least moderate lumbar stenosis, which narrows the central spinal canal at 1 or 2 contiguous levels from L-1 to L-5 that require surgical decompression. Moderate stenosis is defined as > 25% reduction of the anteroposterior dimension compared with the next adjacent normal
level, with nerve root crowding compared with the normal level, as determined by the surgeon on CT scanning or MRI.

2. Radiographic confirmation of the absence of gross angular or translatory instability of the spine at index or adjacent levels (instability as defined by White and Panjabi: sagittal plane translation >4.0 mm or 15% or local sagittal plane rotation > 15° at L1–2, L2–3, and L3–4; >20° at L4–5 based on standing flexion-extension radiographs). Improved imaging technologies are able to better refine/detect previously undetected instability and as these technologies become more established, surgeons should expect to refine with specificity and clear delineation of appropriate surgical candidates requiring stabilization.

3. Patients who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 12 weeks of non-operative treatment consisting of non-steroidal anti-inflammatory drugs and at least one of the following: rest, restriction of activities of daily living, physical therapy, or steroid injections.

The American Board of Internal Medicine's (ABIM) Foundation Choosing Wisely® Initiative
No relevant information.

Centers for Medicare & Medicaid Services (CMS)

- National Coverage Determinations (NCD): No applicable NCD found.
- Local Coverage Determinations (LCDs): First Coast Service Options, Inc. Interspinous Process Decompression (IPD®) (L34006). Revision Effective Date: For services performed on or after 10/01/2017 (Fla, Puerto Rico, Virgin Islands):

**Indications**
IPD® will be considered medically reasonable and necessary for patients who meet **ALL** of the following criteria:

- Aged 50 or older suffering from (intermittent neurogenic claudication) secondary to a confirmed diagnosis of lumbar spinal stenosis, with moderately impaired physical function who experience relief in flexion from their symptoms of leg/buttock/groin pain, with or without back pain; and
- Patients who have undergone at least 6 months of non operative treatment

**Limitations**
IPD® will not be considered medically reasonable and necessary with **ANY** of the following conditions:

- Allergic to titanium or titanium alloy
- Spinal anatomy or disease that would prevent implant of the device or cause the device to be unstable in situ, such as significant instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1.0 (on a scale of 1 to 4); an ankylosed segment at the affected level(s); acute fracture of the spinous process or pars interarticularis
- Significant scoliosis (Cobb angle greater than 25 degrees)
- Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction
- Diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA scan or some comparable study) in the spine or hip that is more than 2.5 SD below the mean of adult normals in the presence of one or more fragility fractures;
- Active systemic infection or infection localized at the site of implantation
- Body mass index (BMI) > 40kg/m²

**Use Outside the U.S.**
National Institute for Health and Clinical Excellence (NICE) (United Kingdom)
NICE issued guidance in November 2010 (updated January 2012) on Interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication. The revised guidance states that current evidence shows that these procedures are efficacious for carefully selected patients in the short and medium term, although failure may occur and further surgery may be needed. The guidance states that here are no major safety concerns, and that these procedures may be used provided that normal arrangements are in place for clinical governance, consent and audit. The guidance also states that patient selection should be carried out by specialist spinal surgeons who are able to offer patients a range of surgical treatment options.
Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
   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:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>22867</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level</td>
</tr>
<tr>
<td>22868</td>
<td>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)</td>
</tr>
<tr>
<td>22869</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level</td>
</tr>
<tr>
<td>22870</td>
<td>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)</td>
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<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>C1821</td>
<td>Interspinous process distraction device (implantable)</td>
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</tbody>
</table>


References


20. Local Coverage Determinations (LCD) First Coast Service Options, Inc. Interspinous Process Decompression (IPD®) (L34006). Revision Effective Date: for services performed on or after 10/01/2017 (Fla, Puerto Rico, Virgin Islands). Accessed Feb 2019. Available at URL address:https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34006&ver=12&SearchType=Advanced&CovetageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=All&


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