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Subject: Interspinous and Interlaminar Stabilization/Distract (Spacers) and Fixation (Fusion) Devices

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Update			

DESCRIPTION:

Interspinous and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension to reduce pain in those with lumbar spinal stenosis and neurogenic claudication. Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract (open) the neural foramen and decompress the nerves. Interlaminar spacers are implanted midline between the adjacent lamina and spinous processes to provide dynamic stabilization either following decompression surgery or as an alternative to decompression surgery.

Interspinous fixation (fusion) devices are being developed to aid in the stabilization of the spine. They are evaluated as alternatives to pedicle screw and rod constructs in combination with interbody fusion. Interspinous fixation devices (IFDs) are also being evaluated for stand-alone use in individuals with spinal stenosis and/or spondylolisthesis.

Summary and Analysis of Evidence: Xin et al (2023) conducted a systematic review and meta-analysis of RCTs comparing interspinous spacer devices (ISDs) to decompressive surgery for patients with lumbar spinal stenosis. Eight RCTs including patients (N=852) with lumbar spinal stenosis who received either ISD or decompressive surgery were included. Follow-up duration of trials ranged from 6 to 40 months. The pooled data indicated that patients in the ISD group experienced shorter operation time (p=.003) and otherwise similar hospital stay time and dural violation compared to decompressive surgery. After initial ISD or decompressive surgery, there was a significantly higher rate of reoperation after ISD compared to decompression (odds ratio [OR], 3.21; 95% confidence interval. In terms of clinical efficacy

endpoints, there was no significant difference in mean visual analog scale leg and back pain scores, Oswestry Disability Index (ODI) scores, or Zurich Claudication Questionnaire symptom severity subscores between groups. There was a significantly lower Zurich Claudication Questionnaire physical function subscore with ISD compared to decompression, but the clinical significance is unknown. The studies included X-STOP ISD devices or other, non-FDA approved ISD devices, which contributed to heterogeneity. Also, there was no discussion or stratification of patients based on severity of lumbar spinal stenosis.

Hagedorn et al (2022) conducted a retrospective study to determine the incidence of lumbar decompression surgery following minimally invasive lumbar decompression or treatment with the Superion interspinous spacer. Of the 199 patients included in the final analysis, 57 patients underwent minimally invasive lumbar decompression only, 124 patients underwent treatment with the Superion interspinous spacer only, and 18 patients underwent minimally invasive lumbar decompression followed by treatment with the Superion interspinous spacer. After 2 years of follow-up, subsequent spine surgery was received by 3 patients who initially underwent minimally invasive lumbar decompression and 1 patient who initially underwent treatment with the Superion interspinous spacer. All patients who underwent subsequent surgery were noted to have severe lumbar spine stenosis.

Whang et al (2023) conducted a retrospective, comparative claims analysis using Medicare claims data to compare rates of subsequent interventions between patients with lumbar spinal stenosis treated initially with ISD and open surgery (such as decompression or fusion). Patients were included in the analysis if they were at least 50 years of age with lumbar spinal stenosis and a qualifying procedure during 2017 to 2021 in the Medicare database. Once identified, patients were reviewed from the qualifying procedure until the end of data availability, up to a 3-year follow-up period. Claims data reflected inpatient hospital, outpatient hospital, skilled nursing facility, or home health encounters for Medicare beneficiaries, but not medication coverage. A total of 400,685 patients (mean age, 71.5 years; 50.7% male) received a qualifying procedure (4183 [10%] treated with ISD; 211,014 [52.7%] with decompression alone; 76,935 [19.2%] with decompression + fusion; and 108,553 [27.1%] with fusion alone) and were included in the analysis. Patients who received ISD were older at baseline compared to open surgery group and had increased prevalence of comorbidities, including hypertension, osteoarthritis, diabetes, obesity, chronic obstructive pulmonary disease, atrial fibrillation, osteoporosis, and congestive heart failure.

Rosner et al (2024) also conducted a retrospective Medicare claims analysis to determine rates of subsequent spinal procedures between individuals receiving ISD alone versus minimally invasive lumbar decompression (MILD) during 2017 to 2021. Patients receiving ISD and MILD were matched 1:1 using propensity score matching based on demographics and clinical characteristics. A total of 3614 patients from each group were included after matching (mean age, 74 years; mean follow-up, 20 months). At 20 months of follow-up, the ISD cohort showed lower rates of any subsequent surgical intervention and lumbar spinal stenosis surgical intervention compared to the MILD cohort. There were no significant differences in safety endpoints between the cohorts, including postoperative complications or life-threatening complications. Authors concluded that the safety was comparable between procedures, with a lower re-operation rate at 20 months after ISD compared to MILD. Limitations are similar to the other claims analysis, since the study did not examine changes in symptoms, functionality, or pain. Because the enrollment criteria was the same as that in Whang et al (2023), there may have been patients included in both analyses. Patients were also not randomized to treatment groups and MILD

and ISD do not always have identical clinical indications, which could increase the risk of implicit bias in patient selection.

A European, multicenter, randomized, double-blind trial (Foraminal Enlargement Lumbar Interspinous distraXion; FELIX) assessed the superiority of coflex (without bony decompression) over bony decompression in 159 patients who had intermittent neurogenic claudication due to lumbar spinal stenosis (Moojen et al, 2013). The primary outcome at 8-week and 1-year follow-ups was the Zurich Claudication Questionnaire score. The score increases with increasing disability. At 8 and 52 weeks, the primary outcome efficacy measure in the coflex arm was not superior to that for standard decompression. In addition, more coflex recipients required reoperation than the standard decompression patients at the 1- and 2-year follow-ups. Given the substantially higher frequency of reoperation in the absence of statistically significant improvements in the efficacy outcome, further summarization of study limitations was not done for this trial.

The FDA approved coflex on the basis of an open-label, randomized, multicenter, noninferiority trial (-10% noninferiority margin) that compared coflex plus decompression to decompression plus posterolateral fusion in patients who had stenosis, significant back pain, and either no spondylolisthesis or grade 1 spondylolisthesis (Davis, Errico et al, 2013; Davis, Auerbach et al, 2013; FDA, Summary of Safety and Effectiveness Data (SSED): coflex Interlaminar Technology, 2012). The control group was treated with pedicle screw and rod fixation with autograft but without an interbody (intervertebral) cage or bone morphogenetic protein. A total of 398 patients were randomized, of whom 322 were included in the per-protocol analysis. Composite clinical success (a minimum 15-point improvement in Oswestry Disability Index score, no reoperations, no device-related complications, no epidural steroid injections in the lumbar spine, and no persistent new or worsening sensory or motor deficit) at 24 months showed that coflex was noninferior to screw and rod fixation (-10% noninferiority margin). Secondary effectiveness criteria, which included Zurich Claudication Questionnaire score, visual analog scale scores for leg and back pain, SF-12 scores, time to recovery, patient satisfaction, and several radiographic endpoints, tended to favor the coflex group. The percentages of device-related adverse events (5.6%) did not differ statistically between the 2 groups. Wound problems were more frequent in the coflex group (14% vs. 6.5%) but all of these were resolved by 3 months. There was a 14% incidence of spinous process fractures in the coflex arm, which were reported to be mostly asymptomatic. The reported follow-up rates through 5 years were at least 85% (Bae et al, 2016). At 2 years, overall success was similar for patients treated with the coflex device at 1 or 2 levels (68.9% and 69.4%, respectively). At 60 months, the composite clinical success was achieved in 48.3% of 1 level and 60.9% of 2 level patients (Abjornson et al, 2018).

A secondary (unplanned) analysis of patients with grade 1 spondylolisthesis (99 coflex patients and 51 fusion patients) showed a decrease in operative time and blood loss. There were no statistically significant differences between the coflex and fusion groups in Oswestry Disability Index, visual analog scale, and Zurich Claudication Questionnaire scores after 2 years (Davis, Auerbach, et al, 2013). In that analysis, 62.8% coflex patients and 62.5 fusion patients met the criteria for operative success. Fusion was obtained in 71% of the control group, leaving nearly a third of patients with pseudoarthrosis. The authors reported no significant differences in Oswestry Disability Index or visual analog scale between the patients with pseudoarthrosis or solid fusion, but Zurich Claudication Questionnaire scores were not reported. There were 18% spinous process fractures in the coflex group, of which 7 had healed by the 2-

year follow-up. Reoperation rates were 6% in the fusion group ($p=.18$) and 14% in the coflex group, including 8% of coflex cases that required conversion to fusion. Another post-hoc analysis of the pivotal RCT evaluated the use of the device in patients 65 years or older (Grinberg et al, 2020). Clinical outcomes (eg, Oswestry Disability Index, visual analog score, Zurich Claudication Questionnaire, epidural injections) were measured out to 60 months. Patients age 65 years or older who received the interlaminar implant with decompression ($n=84$) had clinical outcomes that were not significantly different to patients 65 years or older who received decompression and fusion ($n=57$), and to patients younger than 65 who received the interlaminar implant with decompression ($n=131$). In contrast, perioperative outcomes such as operative time, blood loss, and hospital stay were improved with the interlaminar implant compared to posterolateral fusion. A limitation in the study is that other published evidence about the use of coflex as an alternative to fusion is sparse. The results of a single randomized trial do not always correspond with the rates of treatment response, complications, and reoperations in actual practice. Although thousands of coflex operations have been performed in the U.S. and elsewhere, there are few data on the performance of coflex plus decompression surgery other than in randomized trials.

Zheng et al (2021) retrospectively compared the long-term outcomes of coflex plus decompression to decompression plus fusion for lumbar degenerative disease. The coflex group was comprised of 39 patients and the decompression plus posterior lumbar interbody fusion group (PLIF) was comprised of 43 patients. Both groups had a mean follow-up period of 104 months. Both the Oswestry disability index and visual analog scale leg and back pain scores of both groups significantly improved compared to the baseline, with no difference detected between groups. Compared to the PLIF group, the coflex group displayed preserved mobility, shorter duration of surgery, decreased amount of blood loss, and shorter hospital stay.

Schmidt et al (2018) reported on results of an RCT in patients with moderate-to-severe lumbar spinal stenosis and back pain with or without spondylolisthesis randomized to open microsurgical decompression with interlaminar stabilization using the coflex device ($n=110$), or open microsurgical decompression alone ($n=115$). The proportion of patients who met the criteria for composite clinical success at 24 months was statistically significantly higher in the coflex arm (58.4%) than in the decompression alone arm (41.7%), with a treatment difference of 16.7%. This result was driven primarily by the lower proportion of patients who received an epidural steroid injection in the coflex arm (4.5%) versus the decompression alone arm (14.8%) at 24 months.

Zhong et al (2021) evaluated perioperative outcomes in a comparative study of 83 patients. Patients who had the coflex interlaminar implant in combination with laminectomy ($n=46$) had higher estimated blood loss, longer operative time, and longer length of stay compared to laminectomy alone ($n=37$). Total perioperative complications (21.7% vs. 5.4%) and instrumentation-related complications (10.9% vs. 0%) were also higher in the interlaminar implant cohort.

Gilbert et al (2022) retrospectively evaluated interlaminar stabilization with coflex following decompressive laminectomy in 20 patients with lumbar stenosis without instability or spondylolisthesis. The average visual analog scale score for low back pain preoperatively was 8.8, which improved postoperatively to 4.0, 3.7, and 3.9 at 2 months, 6 months, and 1 year, respectively. The average visual analog scale score for lower extremity pain preoperatively was 9.0, which improved postoperatively to 2.7, 2.5, and 2.5 at 2 months, 6 months, and 1 year, respectively. Furthermore, the average Oswestry

Disability Index scores significantly improved from 66.6 preoperatively to 23.8, 23.3, and 24.5 at 2 months, 6 months, and 1 year postoperatively, respectively. The difference in visual analog scale or Oswestry Disability Index scores between 2 months, 6 months, and 1 year did not reach statistical significance. The retrospective nature of the study and short follow-up period after surgery limit conclusions on the role of coflex interlaminar stabilization.

The evidence for use of an interspinous fixation device with interbody fusion for those undergoing spinal fusion consists of a systematic review of nonrandomized comparative studies (Lopez et al, 2017) and 2 small RCTs (Panchal et al, 2018; Huang et al, 2017). The randomized trials found comparable benefits for interspinous fixation devices with interbody fusion for those undergoing spinal fusion compared with interbody fusion with pedicle screws, but the comparative safety was less clear. One risk is spinous process fracture, while a potential benefit is a reduction in adjacent segment degeneration. Additionally, the RCTs had important methodological and relevancy weaknesses that limited their interpretation. Randomized trials with longer follow-up are needed to evaluate the risks and benefits following use of interspinous fixation devices compared with the established standard (pedicle screw with rod fixation).

There is a lack of evidence (only a retrospective series) on the efficacy of interspinous fixation devices as a stand-alone procedure for those who have spinal stenosis and/or spondylolisthesis. RCTs that evaluate health outcomes following use of interspinous fixation devices as a stand-alone for decompression are needed. Sclafani et al (2014) reported on an industry-sponsored, retrospective series of the polyaxial PrimaLOK interspinous fusion device. Thirty-four patients were implanted with interspinous fixation devices alone, 16 patients received the PrimaLOK plus an interbody cage, and 3 patients received the PrimaLOK plus pedicle screw instrumentation and an interbody cage. Evaluation at 6 weeks found no cases of fracture or device migration, although there were 4 cases of hardware removal and 2 cases of reoperation for adjacent-level disease during follow-up. At a mean 22 months after the index surgery, the average pain score had improved from 7.2 to 4.5 on a 10-point scale (method(s) of pain score collection were not specified). There was a statistically significant improvement in pain score for patients with degenerative disc disease with lumbar stenosis (2.8; n=25) and spondylolisthesis (4.6; n = 6), but not for patients with lumbar disc herniation (2.2; n=10).

POSITION STATEMENT:

Interspinous and interlaminar distraction devices are considered **experimental or investigational** for all indications, including as treatment of spinal stenosis.

Interlaminar stabilization devices used alone, or following decompressive surgery is considered **experimental or investigational**.

Interspinous fixation (fusion) devices are considered **experimental or investigational** for any indication, including but not limited to use in combination with interbody fusion, or used alone for decompression to treat spinal stenosis.

There is insufficient clinical evidence in the peer reviewed literature demonstrating the safety and efficacy of these procedures, or demonstrating the effects of these procedures on long-term health outcomes.

BILLING/CODING INFORMATION:

The following codes may be used to describe distraction devices:

CPT Coding

22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level (Investigational)
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) (Investigational)
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level (Investigational)
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) (Investigational)

HCPCS Coding

C1821	Interspinous process distraction device (implantable) (Investigational)
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There are no specific CPT codes for insertion of interspinous fixation (fusion) devices.

REIMBURSEMENT INFORMATION:

Refer to sections entitled [POSITION STATEMENT](#) and [PROGRAM EXCEPTIONS](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

DEFINITIONS:

Neural foramen: the passage formed by the inferior and superior notches on the pedicles of adjacent vertebrae; it transmits a spinal nerve and vessels.

Neurogenic claudication: a type of claudication that is accompanied by pain and paresthesias in the back, buttocks, and lower limbs and is relieved by stooping or sitting. The usual cause is a mechanical disturbance due to posture, and a rare cause is ischemia of the cauda equina.

Spinal stenosis: narrowing of the vertebral canal, nerve root canals, or intervertebral foramina of the lumbar spine caused by encroachment of bone upon the space; symptoms are caused by compression of

the cauda equina and include pain, paresthesias, and neurogenic claudication. The condition may be either congenital or due to spinal degeneration.

RELATED GUIDELINES:

[Total Facet Arthroplasty, 02-20000-37](#)

OTHER:

Index terms:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

- Affix™ Next Gen Spinous Process Plate System
- Affix II and Affix II Mini Spinous Process Plating System
- Aileron™ Interspinous Fixation System
- Aperius® PercLID System
- Aspen™ MIS Fusion System
- Aspen Spinous Process Fixation System
- Aurora Spine ZIP™ MIS Interspinous Fusion System
- Axle™ Interspinous Fusion System
- BacFuse® Spinous Process Fusion Plate
- Benefix Interspinous Fixation System
- BioFlex intervertebral stabilization device
- Biomet Aspen fusion system
- BridgePoint™ Spinous Process Fixation System
- CD HORIZON SPIRE Z Spinal System or plate
- CD Horizon Agile Dynamic Stabilization Device
- coflex® Interlaminar Technology implant
- coflex-F® Implant System
- CoRoent Extensure
- DIAM™ Spinal Stabilization System
- DSS Dynamic Soft Stabilization System
- Dynabolt Dynamic Stabilization System
- Dynesys Spinal System
- ExtenSure
- Falena® Interspinous Decompression Device
- FLEXUS™
- Helifix Interspinous Spacer System

- In-Space
- Inspan™
- Interbridge Interspinous Posterior Fixation System
- Isobar Spinal System
- Minuteman™ Interspinous Interlaminar Fusion Device
- NFix®
- NL-Prow™ Interspinous Spacer
- PrimaLOK™ SP, SP-Fix Interspinous Fusion System
- Octave™
- Satellite Spinal System
- Spire™ MIS Spinal Fixation System
- Stabilimax NZ Dynamic Spine Stabilization System
- Stabilink MIS Interspinous Fixation Device
- Stenofix
- Superior™ ISS Interspinous Spacer
- SP-Fix™ Spinous Process Fixation Plate
- VertiFlex®
- X-STOP® Interspinous Process Decompression System (IPD®)
- X-STOP® PEEK Interspinous Process Decompression (IPD®)
- Wallis® System
- Zip Mis Interspinous Fusion System
- Zodiac DynaMo System

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/26/24.

GUIDELINE UPDATE INFORMATION:

07/15/08	New Medical Coverage Guideline.
04/15/09	HCPCS code C1821 deleted from policy.
06/15/09	Scheduled review; no change in position statement. Update references.
04/15/10	Annual review; added investigational statement for dynamic spinal stabilization to position statement; description of dynamic spinal stabilization devices added to description section; references updated; and guideline title revised.
12/15/11	Scheduled review; no change in position statement. Updated description section and references.
11/15/12	Scheduled review; position statement maintained. Revised description and Medicare Advantage program exception (added utilization guidelines). Updated references.
07/15/13	Revision; updated description section (coflex® Interlaminar Technology implant language). Revised Program Exceptions section and index terms. Updated references.
11/15/13	Scheduled review. Revised MCG title and description section. Maintained position statement. Revised index terms. Updated references.
01/01/15	Scheduled review. Position statement maintained. Revised description section and index terms. Updated references.
10/15/15	Scheduled review. Revised description section and index terms. Updated references.
01/01/17	Annual CPT/HCPCS update. Added 22867, 22868, 22869, 22870. Deleted 0171T, 0172T.
02/15/17	Scheduled review. Maintained Position Statement section. Updated references.
06/15/18	Unscheduled review. Maintained Position Statement section. Revised index terms. Updated references.

06/15/20	Scheduled review. Revised description. Maintained position statement and updated references.
07/01/20	Added code C1821.
03/15/22	Scheduled review. Maintained position statement and updated references.
08/15/22	Unscheduled review. Updated references and maintained position statement.
06/15/23	Unscheduled review. Updated references and maintained position statement.
01/01/24	Position statements maintained.
03/15/24	Revision. Updated references and maintained position statement.
10/15/24	Scheduled review. Revised description. Maintained position statement and updated references.