Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

Policy #  00221
Original Effective Date: 02/21/2007
Current Effective Date: 11/01/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers interspinous distraction devices as a treatment of neurogenic intermittent claudication to be investigational.*

Based on review of available data, the Company considers the use of an interlaminar stabilization device following decompressive surgery to be investigational.*

Background/Overview
Interspinous and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension to reduce pain in patients 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 adjacent lamina and spinous processes to provide dynamic stabilization either following decompressive surgery or as an alternative to decompressive surgery.

Interspinous spacers are devices implanted between vertebral spinous processes. Interlaminar spacers are implanted between adjacent lamina and have 2 sets of wings that are placed around the inferior and superior spinous processes. These interspinous implants aim to restrict painful motion while otherwise enabling normal motion. The devices (spacers) distract the laminar space and/or spinous processes and restrict extension. This procedure theoretically, enlarges the neural foramen and decompresses the cauda equina in patients with spinal stenosis and neurogenic claudication. Other types of dynamic posterior stabilization devices are pedicle screw/rod-based devices and total facet replacement systems; these are not covered in this policy.

One type of interspinous implant is inserted between the spinous processes through a small (4–8cm) incision and acts as a spacer between the spinous processes, maintaining the flexion of that spinal interspace. The supraspinous ligament is maintained and assists in holding the implant in place. The surgery does not include any laminotomy, laminectomy, or foraminotomy at the time of insertion, thus reducing the risk of epidural scarring and cerebrospinal fluid leakage. Other interspinous spacers require removal of the interspinous ligament and are secured around the upper and lower spinous processes. Interlaminar implants are inserted between the adjacent lamina and spinous processes. These may be referred to as interlaminar implants or an interspinous U.
FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2005, the X-STOP® Interspinous Process Decompression (IPD®) System (Kyphon-now part of Medtronic Spine) was approved by the FDA through the premarket approval process for “treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis.” It is approved for patients with moderately impaired physical function who have had a regimen of at least 6 months of non-operative treatment and who have relief of their pain when in flexion. In 2015, Medtronic discontinued sales and distribution of the implant.

In 2015 the Superion® Interspinous Spacer (ISS VertiFlex) was approved by FDA through the premarket approval process. The Superion ISS, as stated in the premarket approval, is to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without grade 1 spondylolisthesis, confirmed by x-ray, magnetic resonance imaging, and/or computed tomography 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 2 adjacent lumbar levels in patients in whom treatment is indicated and at no more than 2 levels, from L1 to L5.

The Coflex® Interlaminar Technology implant (Paradigm Spine) was approved by the FDA in 2012 (P110008). It is a single-piece U-shaped titanium alloy dynamic stabilization device with pairs of wings that surround the superior and inferior spinous processes. This device was previously called the Interspinous U.

The Coflex is indicated for use in 1- or 2-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 6 months of non-operative treatment. The coflex is intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).

The FDA lists the following contraindications to use of the Coflex:

- Prior fusion or decompressive laminectomy at any index lumbar level.
- Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (e.g., compression fracture).
- Severe facet hypertrophy that requires extensive bone removal which would cause instability.
- Grade II or greater spondylolisthesis.
- Isthmic spondylolisthesis or spondyloysis (pars fracture).
- Degenerative lumbar scoliosis (Cobb angle of greater than 250 degrees).
- Osteoporosis.
- Back or leg pain of unknown etiology.
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- Axial back pain only, with no leg, buttock, or groin pain.
- Morbid obesity defined as a body mass index > 40.
- Active or chronic infection - systemic or local.
- Known allergy to titanium alloys or magnetic resonance imaging (MRI) contrast agents.
- Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction.

The FDA labeling also contains multiple precautions and the following warnings:

“Coflex Interlaminar Technology should only be used by surgeons who are experienced and have undergone hands-on training in the use of this device. Only surgeons who are familiar with the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with the coflex Interlaminar Technology should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events.

Data has demonstrated that spinous process fractures can occur with coflex implantation. Potential predictors for spinous process fractures include:
- Over-decompression during surgery leading to instability in the spine,
- Resection of the spinous process to ≤ 14 mm,
- Height of the spinous process ≤ 23 mm pre-operatively,
- Osteopenia or osteoporosis, and
- “Kissing” spinous processes.

If a spinous process fracture occurs during the surgical procedure, the surgeon should assess if sufficient bone stock exists for coflex implantation.”

Continued FDA approval of the coflex is contingent on annual reports of 2 post-approval studies to provide longer-term device performance and device performance under general conditions of use. One study will provide 5-year follow-up of the cohort in the pivotal investigational device exemption (IDE) trial. The second will be a multi-center trial with 230 patients with follow-up at 5 years that compares decompression alone versus decompression plus Coflex. FDA product code: NQO.

The Wallis™ System (originally from Abbott Spine; currently from Zimmer Spine) was introduced in Europe in 1986. The first generation Wallis implant was a titanium block; the second generation device is composed of a plastic-like polymer that is inserted between adjacent processes and held in place with a flat cord that is wrapped around the upper and lower spinous processes. The Wallis System is currently being tested in an FDA-regulated clinical trial. Also in a FDA-regulated clinical trial is the DIAM™ Spinal Stabilization System (Medtronic Sofamor Danek), which is a soft interspinous spacer with a silicone core. The DIAM system requires removal of the interspinous ligament and is secured with laces around the upper and lower spinous processes. Other clinical trials underway at U.S. centers are studying the In-Space (Synthes), Superion™ (Vertiflex), and FLEXUS™ (Globus Medical) devices; the comparator in these trials is the X-STOP device.
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ExtendSure and CoRoent (both from NuVasive) were launched in Europe in 2005 and 2006. The NL-Prow™ (Non-Linear Technologies), Aperius™ (Medtronic Spine), and Falena™ (Mikai) devices are in trials in Europe.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source
Literature searches have been dominated by reports from non-U.S. centers evaluating devices not approved by FDA, though a number of them are in trials at U.S. centers. As of April 2016, only the X-STOP, Coflex and Superion ISS devices have FDA approval for use in the U.S., and the Superion is under FDA review. Manufacturing of the X-STOP ended in 2015. This policy focuses on devices approved for use in the United States. Following is a summary of the key literature to date.

Interspinous or Interlaminar Spacer as a Stand-Alone Treatment for Lumbar Spinal Stenosis
Two meta-analyses compared use of interspinous distraction devices versus traditional decompressive surgery for lumbar spinal stenosis (LSS). In 2014, Wu et al conducted a meta-analysis of 2 randomized controlled trials (RCTs) and 3 nonrandomized prospective comparative studies. There were 204 patients in the interspinous spacer group and 217 patients in the decompressive surgery group. The interspinous spacers that were studied were the X-STOP, Aperius, coflex, DIAM, and distraXion. Pooled analysis showed no significant difference between the spacer and decompression groups for low back pain, leg pain, Oswestry Disability Index (ODI), Roland-Morris Disability Questionnaire (RMDQ), or complications. However, the traditional decompressive surgery group had a significantly lower incidence of reoperation, with 11 of 160 cases requiring reoperation compared with 31 of 161 cases in the interspinous spacer group (relative risk, 3.34; 95% confidence interval [CI], 1.77 to 6.31).

A 2015 meta-analysis by Hong et al included 20 studies with 3155 patients in the interspinous spacers group and 50,983 patients treated with open decompression. Devices studied were the X-STOP, DIAM, Aperius, coflex, Wallis, and SPIRE. Results of this meta-analysis were similar to those obtained in the more selective analysis by Wu. There was no significant difference between the 2 types of procedures for improvement rate, ODI, or visual analog scale (VAS) for back or leg pain. Although postoperative complication rate, perioperative blood loss, hospitalization time, and operation time were lower/shorter in the interspinous spacer group, the reoperation rate was higher (16.5% vs 8.7%).

X-STOP Device vs Medical Therapy
Multiple reports have been published from a single prospective randomized trial, conducted for FDA approval, which compared the X-STOP device with medical therapy. This study randomized 191 patients from 9 clinical centers in the United States to implantation of the X-STOP device or medical therapy. Inclusion criteria were neurogenic intermittent claudication caused by LSS, age at least 50 years or older, and able to walk at least 50 feet. The primary outcome measure was the Zurich Claudication Questionnaire (ZCQ), which consists of a physical function domain, a symptom severity domain, and a patient satisfaction
domain. Outcomes were assessed at 6 weeks, 6 months, 1 year and 2 years. Using the entire study population of 191 patients in this multicenter trial, Zucherman et al reported an improvement of 45% over the mean baseline Symptom Severity Score in the treated patients at 2 years compared with 7% improvement in the control group, which had medical (nonoperative) therapy including epidural injection. In a separate paper, Anderson et al, reporting on a subset of 75 randomized patients who had spondylolisthesis (of total 191 patients with 1- or 2-level LLS), found a success rate of 63% in treated patients compared with 13% in controls. Four-year follow-up was reported for 18 of the treated patients in the study. Hsu et al reported quality-of-life data (36-item Short-Form Health Survey [SF-36]) from the same trial. The patients, who had to meet a number of inclusion/exclusion criteria, were assessed at baseline and at 6 weeks, 6 months, 1 year, and 2 years following the initial treatment. The X-STOP group showed improvements (by single-factor ANOVA or t test) in both physical and mental component scores compared with both baseline and control subjects. There was a large loss to follow-up (42%) in the medical treatment group; 6% of the experimental and 26% of the control subjects underwent laminectomy.

Puzzilli et al reported a multicenter controlled trial of X-STOP versus nonsurgical management in 2014. A total of 542 patients with LSS and intermittent claudication relieved on flexion were enrolled. All patients had failed a 6-month trial of conservative therapy (medical and/or physical). Initially patients were randomized, but randomization to conservative management was terminated after the first 120 patients due to poor outcomes. These patients were followed for a minimum of 3 years. By 3 years, the overall failure rate was 12.3% of X-STOP patients compared with 50% of patients with continued nonsurgical management.

Several large case series of patients implanted with X-STOP devices have been reported. A series of 175 patients were treated at a German center between February 2003 and June 2007. Improvements in VAS and ODI scores were maintained through the 2-year evaluation. No complications were associated with use of the device. Eight patients required device removal and microsurgical decompression because of unsatisfactory outcome. In 2010, Rolfe et al evaluated outcomes for a series of 179 patients with and without scoliosis to test a contraindication limiting X-STOP use to patients with a maximum scoliosis of 25°.

Case series from other institutions have reported good outcomes in only about a third of patients treated with the X-STOP. Others have focused on device complications. Barbagallo et al found 4 X-STOP dislocations and 4 spinous process fractures in a series of 69 (11.5%) patients.14 In a small series (N=13) reported by Bowers et al, the overall complication rate was 38%, including 3 spinous process fractures and 2 instances of new-onset radiculopathy. Eleven of the 13 patients required additional spinal surgery. Kim et al reported a prospective observational study that found a high rate of spinous process fractures (28.9%) after implantation of the X-STOP titanium (n=34), X-STOP PEEK (n=8), or Aspen (n=8) devices.

**X-STOP Versus Decompressive Surgery**

Two randomized trials have compared implantation with X-STOP versus decompression. A randomized noninferiority trial of the X-STOP compared with decompressive surgery was published by Stromqvist et al in 2013. One hundred patients with symptomatic 1- or 2-level LLS and neurogenic claudication relieved on flexion were included in the study. Blinding of patients and evaluators was not described. There was a decrease in surgical time (62 vs 98 minutes) and blood loss (54 vs 262) with insertion of the X-STOP.
although statistical analysis was not reported. Both intention-to-treat analysis and as-treated analysis at 6, 12, and 24 months found no significant differences between the groups on the patient-reported ZCQ, VAS for leg and back pain, or SF-36. Thirteen patients (26%) in the X-STOP group had additional surgery (typically decompression) compared with 3 patients (6%) in the decompression group, and there was 1 spinous process fracture. The X-STOP patients who later underwent decompression were not considered to be treatment failures. In 2015, Lonne et al reported a trial of X-STOP versus minimally invasive decompression in 96 patients with symptoms of neurogenic intermittent claudication relieved on flexion. Intention-to-treat analysis showed no significant differences between the groups in primary and secondary outcome measures at up to 2-year follow-up. However, the number of patients having secondary surgery due to persistent or recurrent symptoms was significantly higher in the X-STOP group (25% vs 5%; odds ratio, 6.5). In addition, 2 patients had fracture of the spinous process and 1 had dislocation of the implant. Three patients in the decompression group had secondary surgery during the first hospital stay due to hematoma. Mean days of rehabilitation were 66 for X-STOP and 48 for surgical decompression. The study was terminated after planned mid-term analysis due to the higher reoperation rate with X-STOP.

Superion ISS Device vs X-STOP Device
In 2015, results were published from an FDA-regulated, multicenter randomized, IDE, noninferiority trial comparing the ISS with the X-STOP. A total of 391 patients with intermittent neurogenic claudication despite 6 months of nonsurgical management were enrolled, randomized, and implanted with either Superion or X-STOP spacers, and followed for 2 years. The primary end point was a composite of clinically significant improvement in at least 2 of 3 ZCQ domain scores compared with baseline, freedom from reoperation, revision, removal, or supplemental fixation at the index level, freedom from epidural steroid injection or nerve block within 12 weeks of the 2-year visit, freedom from rhizotomy or spinal cord stimulator at any level, and freedom from major implant or procedure-related complications. The primary noninferiority end point was met, with a Bayesian posterior probability of 0.993. However, 111 patients (28%; 54 Superion, 57 XSTOP) were withdrawn from the study during follow-up due to a protocol-defined secondary intervention. Modified intention-to-treat analysis showed clinical success (improvement, ≥20 mm/100) for leg pain in 76% to 77% of patients and for back pain in 67% to 68% of patients, with no significant differences between groups. At 2 years, ODI success was achieved in 63% of Superion patients and 67% of XSTOP patients (p=0.061). Rates of complications and reoperations (44 [23.2%] Superion, 38 [18.9%] XSTOP) were similar between groups. Spinous process fractures, reportedly asymptomatic, occurred in 16.4% of Superion patients and 8.5% of XSTOP patients.

At 3-year follow-up, 120 patients in the Superion ISS group and 129 in the X-STOP group remained (64% [249/391]). Of these, composite clinical success was obtained in 52.5% of patients in the Superion ISS group and 38.0% of the X-STOP group (p=0.023). The 36-month clinical outcomes were reported for 82 patients in the Superion ISS group and 76 patients in the X-STOP group (40% [158/391]). It is not clear from the report whether the remaining patients were lost to follow-up or were considered treatment failures and censored from the results. In addition, study interpretation is limited by questions about the efficacy of the comparator and lack of a control group treated with surgical decompression.
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coflex Device
An industry-sponsored, European, multicenter, randomized, double-blind trial (Foraminal Enlargement Lumbar Interspinous distraction: FELIX) compared implantation of coflex (without bony decompression) to bony decompression in 159 patients with intermittent neurogenic claudication due to LSS. Functional outcomes measured by the ZCQ and Modified RMDQ, and pain measured by VAS and the McGill Pain Questionnaire, were similar in the 2 groups at 1-year follow-up: surgery times were shorter, but reoperation rates due to absence of recovery were higher in the coflex group (29%) than in the bony decompression group (8%; p<0.001). For patients with 2-level surgery, the reoperation rate was 38% for coflex versus 6% for bony decompression (p<0.05). At 2 years, reoperations due to absence of recovery had been performed in 33% of the coflex group and 8% of the bony decompression group. VAS back pain score at final follow-up was also higher in the coflex group (36 mm vs 28 mm; on 100-point scale).

Section Summary: Interspinous or Interlaminar Spacer as Stand-Alone Treatment for Lumbar Spinal Stenosis
Overall, use of interspinous or interlaminar distraction devices (spacers) used as a stand-alone treatment for LSS has shown high failure and complication rates.

The X-STOP device has been compared with nonsurgical therapy and decompressive surgery in RCTs. RCTs and case series have shown high rates of persistent symptoms and complications, including spinous fractures. In 2015, sales and distribution of the X-STOP were discontinued.

The evidence for the Superion ISS for LSS includes an FDA-regulated pivotal trial. This trial compared the Superion ISS with the X-STOP, but did not include comparison groups for conservative care or standard surgery. The trial reported significantly better outcomes on some measures. For example, the percentage of patients experiencing improvement in outcomes was reported as over 80%. However, this percentage was based on 40% of the original dataset. Interpretation of this study is limited by questions about number of patients used to calculate success rates, the lack of efficacy of the comparator, and the lack of an appropriate control group treated by surgical decompression. The evidence is insufficient to determine the effects of the technology on health outcomes.

The coflex interlaminar implant was compared with decompression in the multicenter, double-blind trial FELIX trial. Functional outcomes and pain were similar in both groups at 1-year follow-up, but reoperation rates due to lack of recovery were substantially higher with the coflex implant (29%) compared with bony decompression (8%). It is not clear whether patients with reoperations were included in pain and function assessments; if they were, this would have decreased assessment scores at 1 year. For patients with 2-level surgery, the reoperation rate was 38% for coflex versus 6% for bony decompression. At 2 years, reoperations due to absence of recovery had been performed in 33% of the coflex group compared with 8% of the bony decompression group.

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Interlaminar Stabilization Devices Used With Spinal Decompression Surgery
coflex Device

The pivotal IDE trial for coflex Interlaminar Technology was a nonblinded, randomized, multicenter trial of decompression plus coflex compared to decompression plus posterolateral fusion and pedicle screw fixation in patients with low-grade spondylolisthesis. Four-year follow-up was reported in 2015 and 5 year follow-up in 2016. A total of 344 patients were randomized in a 2:1 ratio (215 coflex, 107 fusion controls, with 22 protocol violators). This trial was conducted in a restricted population with numerous exclusion criteria. Compared with fusion, implantation of the coflex device required less operative time (98.0 minutes vs 153.2 minutes), resulted in less blood loss (109.7 mL vs 348.6 mL), and required a shorter hospital stay (1.9 days vs 3.2 days).

Composite clinical success (a combination of a minimum 15-point improvement in ODI score, no reoperations, no device-related complications, and no epidural steroid injections in the lumbar spine) at 24 months showed coflex (66.2%) was noninferior to posterolateral fusion (57.7%). Secondary effectiveness criteria, which included ZCQ score, VAS scores for leg and back pain, SF-12 score, time to recovery, patient satisfaction, and several radiographic end points, tended to favor the coflex group using Bayesian analysis. (In this analysis, nonoverlapping CIs imply statistically reliable group differences.) For example, ZCQ composite success was achieved in 78.3% of coflex patients (95% CI, 71.9% to 84.7%) compared with 67.4% of control patients (95% CI, 57.5% to 77.3%). The percentage of device-related adverse events was the same for the 2 groups (5.6% coflex, 5.6% control), and similar percentages of asymptomatic spinous process fractures were observed. In the subset of patients with grade I spondylolisthesis, the coflex and fusion groups had similar outcomes in ODI, VAS, and ZCQ scores, but the reoperation rate trended higher in the coflex cohort (14.1% vs 5.9%, p=0.18).28 FDA considered the data in this nonblinded trial to support reasonable assurance of safety and effectiveness for device approval, but approval was conditioned on 2 additional studies that will provide longer term follow-up (in the IDE cohort) and evaluate device performance under actual conditions of use (decompression alone vs decompression with coflex; see Table 1).

The reported follow-up rates at 5 years ranged from 40% to 100%, depending on the outcome measured. For example, the ODI scores at 6 months were reported for 56% of patients, while major device-related complications and composite clinical success were reported for 100% of patients. Interpretation of the 5-year results is limited by the variable loss to follow-up in outcomes.

In 2015, Roder et al reported a cross registry study that compared lumbar decompression plus coflex (SWISS spine registry) to lumbar decompression alone (Spine Tango registry) in 50 pairs matched by a multifactorial propensity score. SWISS spine is a governmentally mandated registry from Switzerland for coverage with evidence development. Spine Tango is a voluntary registry from the Spine Society of Europe. Both registries use the numeric rating scale (NRS) for back and leg pain and the Core Outcome Measures Index (COMI) as the patient-based outcome instrument. The COMI consists of 7 questions to evaluate pain, function, well-being, quality of life, and disability. At 7- to 9-month follow-up, the coflex group had greater reductions in NRS back pain score (3.8 vs 2.5, p=0.014), NRS leg pain score (4.3 vs 2.5, p<0.001), NRS maximum pain score (4.1 vs 2.3, p=0.002), and greater improvement in COMI score (3.7 vs 2.5; p=0.029).
In 2010, Richter et al reported a prospective case-control study of the coflex device in 60 patients who underwent decompression surgery. Two-year follow-up was published in 2014. The surgeon determined whether the midline structures were preserved or resected and whether the coflex device was implanted (1 or 2 levels). The indications for the 2 groups were identical, and use of the device was considered incidental to the surgery. At 1- and 2-year follow-up, placement of a coflex device did not significantly improve the clinical outcome compared to decompression surgery alone.

**Section Summary: Interlaminar Stabilization Devices With Spinal Decompression Surgery**

Use of the coflex interlaminar implant as a stabilizer after surgical decompression has been studied in 2 different situations: as an alternative to spinal fusion after decompression or as an adjunct to decompression compared to decompression alone. The pivotal RCT, conducted in a very selective patient population, showed that stabilization of a decompression with the coflex implant was noninferior to decompression with spinal fusion. However, 2 non-RCTs have mixed results on whether use of the implant in combination with decompression improves outcomes compared with decompression alone. The different comparators used in these trials and the very selective patient population in the pivotal trial limit conclusions about the generalizability of these results. Greater certainty about the net health benefit of this device may be obtained when results of a recently completed and moderately sized RCT on decompression with and without the coflex implant are published.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this policy are listed in Table 1.

### Table 1. Summary of Key Active Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td>NCT02555280</td>
<td>A 2 and 5 Year Comparative Evaluation of Clinical Outcomes in the Treatment of Degenerative Spinal Stenosis With Concomitant Low Back Pain by Decompression With and Without Additional Stabilization Using the Coflex Interlaminar Technology for FDA Real Conditions of Use Study (Post-Approval ‘Real Conditions of Use’ Study)</td>
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<td>Jun 2022</td>
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<td>NCT00517751</td>
<td>Treatment of Lumbar Spinal Stenosis with X-STOP PEEK Spacer in Moderately Symptomatic Patients – Condition of Approval Study (COAST)</td>
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<td>NCT02457468</td>
<td>The Coflex COMMUNITY Study: An Observational Study of Coflex Interlaminar Technology</td>
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<td>NCT01316211</td>
<td>Comparative Evaluation of Clinical Outcome in the Treatment of Degenerative Spinal Stenosis With Concomitant Low Back Pain by Decompression With and Without Additional Stabilization Using the Coflex Interlaminar Technology</td>
<td>245</td>
<td>Mar 2016</td>
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NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.
Clinical Input Received through Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2011 Input
In response to requests, input was received from 2 physician specialty societies and 2 academic medical centers while this policy was under review in 2011. Two of those providing input agreed this technology is investigational due to the limited high-quality data on long-term outcomes (including durability). Two reviewers did not consider this investigational, stating the technology has a role in the treatment of selected patients with neurogenic intermittent claudication.

2009 Input
In response to requests, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2009. Differing input was received; several reviewers indicated data were sufficient to demonstrate improved outcomes.

Summary
The evidence for an interspinous or interlaminar spacer as a stand-alone procedure in individuals who have spinal stenosis includes RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Overall, use of interspinous or distraction devices (spacers) used as an alternative to spinal decompression have shown a high failure and complication rates. Three devices are considered: X-STOP and Superion ISS and the coflex interlaminar implant. RCTs that compared the X-STOP device with nonoperative therapy have reported greater short-term improvements in symptoms and functional status for the device groups. While this establishes that the use of this interspinous spacer can lead to better short-term symptom relief than continued conservative therapy, trials comparing this device with standard decompressive surgery have reported higher reoperation rates for the devices than for decompressive surgery. In addition, case series suggest high complication rates, thereby creating uncertainty around the risk-benefit ratio. In 2015, sales and distribution of the device were discontinued. A pivotal trial regulated by U.S. FDA compared the Superion ISS to the X-STOP, without conservative care or standard surgery comparators. The study reported significantly better outcomes on some outcome measures. For example, the percentage of patients experiencing improvement was reported as over 80%. Interpretation of this study is limited by questions about the number of patients used to calculate success rates, the lack of efficacy of the comparator, and the lack of an appropriate control group treated by surgical decompression. The coflex interlaminar implant (also called the interspinous U) was compared with decompression in the multicenter, double-blind trial FELIX trial. Functional outcomes and pain were similar in the 2 groups at 1-year follow-up, but reoperation rates due to absence of recovery were substantially higher with the coflex implant (29%) than with bony decompression (8%). For patients with 2-level surgery, the reoperation rate was 38% for coflex and 6% for bony decompression. At 2 years, reoperations due to absence of recovery had been performed in 33% of the coflex group and 8% of the bony decompression group. The evidence is insufficient to determine the effects of the technology on health outcomes.
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The evidence for interlaminar spacers in individuals who have spinal decompression surgery for spinal stenosis includes RCTs and nonrandomized comparative studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Use of the coflex interlaminar implant as a stabilizer after surgical decompression has been studied in 2 different situations, as an alternative to spinal fusion after decompression or as an adjunct to decompression compared to decompression alone. The pivotal RCT, conducted in a very selective patient population, showed that outcomes following stabilization of a decompression with the coflex implant did not differ from decompression with spinal fusion. This study was not blinded and had a high rate of missing data for patient-reported measures. There are also 2 non-RCTs, and they reported mixed results on whether use of the implant in combination with decompression improves outcomes compared with decompression alone. The different comparators used in these trials and the very selective patient population in the pivotal trial limit conclusions about the generalizability of these results. Greater certainty about the net health benefit of this device may be obtained when a recently completed and moderately sized RCT on decompression includes RCTs and nonrandomized comparative studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Use of the coflex interlaminar implant as a stabilizer after surgical decompression has been studied in 2 different situations, as an alternative to spinal fusion after decompression or as an adjunct to decompression compared to decompression alone. The pivotal RCT, conducted in a very selective patient population, showed that outcomes following stabilization of a decompression with the coflex implant did not differ from decompression with spinal fusion. This study was not blinded and had a high rate of missing data for patient-reported measures. There are also 2 non-RCTs, and they reported mixed results on whether use of the implant in combination with decompression improves outcomes compared with decompression alone. The different comparators used in these trials and the very selective patient population in the pivotal trial limit conclusions about the generalizability of these results. Greater certainty about the net health benefit of this device may be obtained when a recently completed and moderately sized RCT on decompression with and without the coflex implant is published. The evidence is insufficient to determine the effects of the technology on health outcomes.

References

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Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

Policy # 00221

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Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

Policy # 00221
Original Effective Date: 02/21/2007
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Policy History
Original Effective Date: 02/21/2007
Current Effective Date: 11/01/2017
02/07/2007 Medical Director review
02/21/2007 Medical Policy Committee approval.
02/04/2009 Medical Director review
02/19/2009 Medical Policy Committee approval. No change to coverage.
02/04/2010 Medical Policy Committee review
02/17/2010 Medical Policy Implementation Committee approval. No change to coverage.
02/03/2011 Medical Policy Committee review
02/16/2011 Medical Policy Implementation Committee approval. No change to coverage.
02/02/2012 Medical Policy Committee review
02/15/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/06/2013 Medical Policy Committee review
06/25/2013 Medical Policy Implementation Committee approval. Title changed from “Interspinous Distraction Devices (Spacers)” to “Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)”. Removed “secondary to lumbar stenosis” from the first investigational statement. Added that the use of an interlaminar device following decompressive surgery is considered to be investigational. Updated FDA section with new approval for Coflex.
06/05/2014 Medical Policy Committee review
06/18/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015 Medical Policy Committee review
09/08/2016 Medical Policy Committee review
09/21/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes and CPT coding update
02/01/2017 Coding adjustment
07/06/2017 Medical Policy Committee review

Next Scheduled Review Date: 07/2018

Coding
The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2016 by the American Medical Association (AMA).

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
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<th>Code Type</th>
<th>Code</th>
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| CPT       | Codes deleted eff 1/1/17: 0171T, 0172T  
New codes eff 1/1/17: 22867, 22868, 22869, 22870 |
| HCPCS     | C1821 |
| ICD-10 Diagnosis | All related diagnoses |

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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