I. Policy

Interspinous Distraction Devices are considered investigational as a treatment of neurogenic intermittent claudication as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Use of an interlaminar stabilization device following decompressive surgery is considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Dynamic stabilization devices including, but not limited to the Dynesys® Spinal System are considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:
MP-1.093 Artificial Intervertebral Disc (Lumbar and Cervical)
MP-1.123 Automated Percutaneous Discectomy and Endoscopic Discectomy
MP-1.125 Decompression of the Intervertebral Disc Using Laser Energy Discectomy or Radiofrequency Coblacion Nucleoplasty
MP-1.021 Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis and Discography
MP-1.124 Percutaneous Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty
II. PRODUCT VARIATIONS

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO*

*Refer to FEP Medical Policy Manual MP-7.01.107 Interspinous Distraction Devices (Spacers). The FEP Medical Policy manual can be found at: www.fepblue.org

III. DESCRIPTION/BACKGROUND

Interspinous implants aim to restrict painful motion while otherwise enabling normal motion. The interspinous distraction devices (spacers) distract the spinous processes and restrict extension. This theoretically enlarges the neural foramen in patients with 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 following 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 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 (4–8 cm) 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 following decompressive surgery.

Regulatory Status

In November 2005, the X-STOP® Interspinous Process Decompression (IPD®) System (Kyphon-now part of Medtronic Spine LLC) was approved by the U.S. Food and Drug Administration (FDA) 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. The device is approved for implantation at 1 or 2 lumbar levels in patients whose condition warrants surgery at no more than 2 levels. The X-STOP PEEK (polyetheretherketone) received approval in 2006 and is a modified version of the X-STOP that includes a PEEK spacer and additional 16-mm spacer size. The indications are the same as for the X-STOP titanium model.

The FDA lists the following contraindications to use of the X-STOP:

- an allergy to titanium or titanium alloy;
- spinal anatomy or disease that would prevent implantation 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 1-4);
  - an ankylosed segment at the affected level(s);
  - acute fracture of the spinous process or pars interarticularis;
  - significant scoliosis (Cobb angle greater than 25);
- cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction;
- diagnosis of severe osteoporosis, defined as bone mineral density (from dual energy x-ray absorptiometry) 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 1 or more fragility fractures;
- active systemic infection or infection localized to the site of implantation.

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 spondylolysis (pars fracture).
- Degenerative lumbar scoliosis (Cobb angle of greater than 25 degrees).
- Osteoporosis.
- Back or leg pain of unknown etiology.
- 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®.

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.

In February 2015, the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee of FDA recommended approval for the Superion® Interspinous Spacer device sponsored by VertiFlex. The proposed indication for use of the Superion Interspinous Spacer device, as stated in the premarket approval, is for treating skeletally mature patients suffering from pain, numbness, and/or cramping of the legs secondary to a diagnosis of moderate lumbar spinal stenosis (Docket No. FDA-2015-N-0001; February 20, 2015).

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. Dynamic stabilization devices such as the Dynesys use flexible material to stabilize the spine and alter load transmission without the purpose of fusing the segment. These non-rigid spinal stabilization devices are surgically implanted at the affected level of the spine to support the spinal motion segment without fusion, preserving a fuller range of motion. Other terms used to describe non-rigid implants are soft, dynamic and flexible. Dynamic stabilization has been proposed as an adjunct or alternative to fusion.

IV. RATIONALE

The most recent literature review was performed through February 22, 2016.

The literature is dominated by reports from non-U.S. centers evaluating devices not approved by the U.S. Food and Drug Administration (FDA), though a number of them are in trials at U.S. centers. As of April 2016, only the X-STOP, coflex, and Superion Interspinous Spacer (ISS) devices have FDA approval for use in the United States, and the Superion is under FDA review. Manufacturing of the X-STOP ended in 2015. This review 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 interspinous distraction devices and 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.1 There were 204 patients in the interspinous spacer group and 217 patients in the decompressive surgery group. The spacers 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) score, Roland-Morris Disability Questionnaire (RMDQ) score, 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 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.2 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 procedures for improvement rate, ODI score, or visual analog scale (VAS) scores for back or leg pain. Although postoperative complication rate,
perioperative blood loss, hospitalization time, and surgery time were lower or 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, comparing the X-STOP device to 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 of at least 50 years, and ability to walk at least 50 feet. The primary outcome measure was the Zurich Claudication Questionnaire (ZCQ), which consists of physical function, symptom severity, and patient satisfaction domains. Outcomes were assessed at 6 weeks, 6 months, 1 year and 2 years. Using the entire study population of 191 patients, Zucherman et al reported an improvement of 45% over the mean baseline Symptom Severity Score in the device group at 2 years compared with 7% improvement in the control group, which had medical (nonoperative) therapy including epidural injection.³ Separately, Anderson et al, reporting on a subset of 75 randomized patients who had spondylolisthesis (of the 191 patients with 1- or 2-level lumbar spinal stenosis), found a success rate of 63% in treated patients compared with 13% in controls.⁴ Four-year follow-up was reported for 18 of the treated patients in the study.⁵ Hsu et al reported quality-of-life data (36-Item Short-Form Health Survey [SF-36]) from the same trial.⁶ The patients, after meeting inclusion and 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 SF-36 Physical and Mental Component Summary scores compared to both baseline and control subjects. There was a large loss to follow-up (42%) in the device treatment group; 6% of the X-STOP and 26% of the control subjects underwent laminectomy.

Puzzilli et al reported a multicenter controlled trial of X-STOP versus nonsurgical management in 2014.⁷ A total of 542 patients with LSS and intermittent claudication relieved by flexion were enrolled. All patients had failed a 6-month trial of conservative therapy (medical and/or physical). Initially patients were randomized, but assignment 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 patients who received X-STOP 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 2007.⁸ 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. 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 Device vs Decompressive Surgery

Two randomized trials have compared implantation with X-STOP to 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 lumbar spinal stenosis and neurogenic claudication relieved by flexion were included in the study. Blinding of patients and evaluators was not described. There was a decrease in surgical time (62 minutes vs 98 minutes) and blood loss (54 mL vs 262 mL) with insertion of the X-STOP, although statistical analyses were 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 score, VAS scores for leg and back pain, or SF-36 score. Thirteen (26%) patients in the X-STOP group had additional surgery (typically decompression) compared with 3 (6%) patients in the decompression group, and there was 1 spinous process fracture. 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 by flexion. Intention-to-treat analysis showed no significant differences between 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. Mean days of rehabilitation were 66 for X-STOP patients and 48 for surgical decompression patients. The study was terminated after planned mid-term analysis because of the higher reoperation rate (33%) with X-STOP.

Superion ISS Device vs X-STOP Device

In 2015, 2- and 3-year results were published from an FDA-regulated, industry-sponsored, multicenter randomized, investigational device exemption (IDE), noninferiority trial comparing the Superion 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 the Superion ISS 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 (28%) patients (54 Superion ISS, 57 X-STOP) 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; on 100-point scale) 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 by 63% of Superion ISS patients and by 67% of X-STOP patients (p=0.061). Rates of complications and reoperations (44 [23.2%] Superion, 38 [18.9%] X-STOP) were similar between groups. Spinous process fractures, reportedly asymptomatic, occurred in 16.4% of Superion ISS patients and 8.5% of X-STOP 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.

coflex Device
An industry-sponsored, European, multicenter, randomized, double-blind trial (Foraminal Enlargement Lumbar Interspinous distraXion: 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.

**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.\textsuperscript{24,25} Four-year follow-up was reported in 2015 and 5 year follow-up in 2016.\textsuperscript{26,27} 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 confidence intervals imply statistically reliable group differences.) For example, ZCQ composite success was achieved in 78.3% of coflex patients (95% confidence interval [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.\(^{27}\) 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.\(^{29}\) 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.\(^{30}\) Two-year follow-up was published in 2014.\(^{31}\) 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...
Table 1. Summary of Key Active Trials

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<td>NCT02457468</td>
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<td>Mar 2016</td>
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NCT: national clinical trial
* Denotes industry-sponsored or cosponsored trial.

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 review are listed in Table 1.
**Policy Title** | **Interspinous Distraction Devices and Interlaminar Stabilization/Distraction Devices (Spacers), and Dynamic Stabilization Devices**
---|---
**Policy Number** | MP-1.111

### Summary of Evidence

The evidence for an interspinous or interlaminar spacer as a stand-alone procedure in individuals who have spinal stenosis includes randomized controlled trials (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 Interspinous Spacer (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. Food and Drug Administration 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.

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 with and without the coflex implant is published. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical Input Received From 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.

Practice Guidelines and Position Statements

North American Spine Society
In 2014, the North American Spine Society (NASS) published specific coverage policy recommendations on lumbar interspinous device without fusion. NASS recommended that interspinous distraction devices may be indicated for degenerative lumbar stenosis with the following criteria: (a) associated with neurogenic claudication that is relieved by lumbar flexion, (b) patients older than 50 years old, (c) failure of nonoperative treatment, (d) no more than 25° of degenerative scoliosis, (e) no more than a grade I degenerative spondylolisthesis, and (f) open surgery (e.g., laminectomy) is not a medically safe treatment option because of comorbidities. NASS stated that interspinous distraction devices are not indicated in cases that do not fall within these parameters.
American Pain Society
The 2009 guidelines from the American Pain Society indicated that interspinous spacer devices, based on fair evidence, have a B recommendation (panel recommends that clinicians consider offering the intervention).\textsuperscript{33,34} The net benefit was considered moderate through 2 years, with insufficient evidence to estimate the net benefit for long-term outcomes.

National Institute for Health and Care Excellence
The U.K.’s National Institute for Health and Care Excellence published guidance in November 2010 stating that “Current evidence on interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication 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 evidence reviewed consisted mainly of reports on X-STOP.\textsuperscript{35}

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination (NCD)

Dynamic Stabilization Devices
The Dynesys Spinal System (Centerpulse Spine-Tech, Inc., Minneapolis, MN) was cleared by the FDA via a 510(k) pre-market notification in March 2004. According to the product labeling, it is indicated to provide stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence or neurological impairment, kyphosis; and failed previous fusion (pseudoarthrosis). In addition, the product labeling states that the Dynesys system is intended for use in persons who meet all of the following criteria:

- Patients who are receiving fusions with autologous graft only; and
- Patients who are having the device attached to the lumbar or sacral spine; and
- Patients who are having the device removed after the development of a solid fusion mass.

Although the Dynesys has been in clinical use for several years, there is insufficient evidence demonstrating that implantation of this device results in improved health outcomes compared to standard treatments.
MEDICAL POLICY

<table>
<thead>
<tr>
<th>POLICY TITLE</th>
<th>INTERSPINOUS DISTRACTION DEVICES AND INTERLAMINAR STABILIZATION/DISTRACTION DEVICES (SPACERS), AND DYNAMIC STABILIZATION DEVICES</th>
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V. DEFINITIONS

FORAMEN is a passage or opening; an orifice, a communication between two cavities of an organ, or a hole in a bone for passage of vessels or nerves.

FORAMINOTOMY is surgical enlargement of the intervertebral foramen.

LAMINA is a thin flat layer or membrane or the flattened part of either side of the arch of the vertebra.

LAMINECTOMY is the excision of a vertebral posterior arch, usually to remove a lesion or herniated disk.

LAMINOTOMY is a division of one of the vertebral laminae.

NEUROGENIC CLAUDICATION is leg pain or numbness that occurs with standing or walking and is relieved by sitting or resting with the spine flexed. It is typically caused by lumbar disk disease.

SPINOUS PROCESS is the prominence at the posterior part of each vertebra.

STENOSIS is the constriction or narrowing of a passage or orifice.

VERTEBRAE are any of the thirty-three (33) bony segments of the spinal column.

VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.
VII. DISCLAIMER

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

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<tr>
<th>CPT Codes®</th>
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<tr>
<td>22867</td>
<td>Interspinous process distraction device (implantable)</td>
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IX. REFERENCES

Dynamic Stabilization Devices


**MEDICAL POLICY**

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Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)


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prospective case control study of 60 patients. Eur Spine J. Feb 2010;19(2):283-289. PMID 19967546


X. POLICY HISTORY

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<tr>
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<td>CAC 1/26/10 Consensus</td>
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<td>CAC 4/26/11 Consensus</td>
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<td>CAC 6/26/12 Consensus review; no changes, references updated.</td>
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<td>7/18/13 Admin code review complete.</td>
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<td>CAC 11/26/13 Minor revision. Added an additional investigational statement that use of an interlaminar stabilization device following decompressive surgery is considered investigational. Policy title revised to Interspinous Distraction Devices and Interlaminar Stabilization/Distraction Devices (Spacers), and Dynamic Stabilization Devices. References updated. Background updated. FEP variation revised to refer to the FEP manual. Medicare variation removed. Policy coded.</td>
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<th>References updated. Rationale added. Consensus Coding - 11/14/2014 CLBJ</th>
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<td><strong>CAC 11/24/15</strong> Consensus review. No changes to the policy statements. In the contraindications for X-STOP in the regulatory status section, the 4th and 5th bullets were combined, and in the contraindications for coflex in the same section the Cobb angle in the 6th bullet was corrected to &gt;25 degrees. Background, reference and rationale update. LCD number changed from L31686 to L35094 due to Novitas update to ICD 10. Coding updated.</td>
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<th><strong>CAC 9/27/16</strong> Consensus review. No change to the policy statements. References, and rationale updated. Variations reformatted. Coding reviewed.</th>
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<tr>
<th><strong>Administrative Updated 1/1/17:</strong> Removed NOC code (22899) and deleted codes (0171T-0172T); added new codes (22867-22870) effective 1/1/17.</th>
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