Name of Policy:
Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

Policy #: 282
Category: Surgery

Latest Review Date: April 2015
Policy Grade: B

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. 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.
**Description of Procedure or Service:**
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 two 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.

**Policy:**
**Interspinous distraction devices do not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered *investigational* as a treatment of neurogenic intermittent claudication.

Use of an **interlaminar stabilization device following decompressive surgery does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered *investigational*.

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

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**Proprietary Information of Blue Cross and Blue Shield of Alabama**
**Medical Policy #282**
**Key Points:**
This policy was originally created in 2006 and was updated regularly with searches of the MEDLINE database. The most recent literature search was performed through March 11, 2015. The literature on this technology is dominated by reports from non-U.S. centers on devices that have not received FDA approval, though a number of them are in trials at U.S. centers. As of April 2015, only the X-STOP and Coflex devices have FDA approval for use in the U.S., and the Superion is under FDA review. This policy focuses on devices that are approved for use in the U.S. Following is a summary of the key literature to date.

**Interspinous Distraction Devices**

*Systematic Reviews*

Two recent systematic reviews 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 two randomized controlled trials (RCTs) and three 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 two 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%).

*Randomized Controlled Trials*

**X-STOP versus Nonsurgical Therapy**

Multiple reports have been published from a single prospective randomized trial, conducted for FDA approval that compared the X-STOP device to medical therapy. This study randomized 191 patients from nine clinical centers in the U.S. to implantation of the X-stop device or medical therapy. Inclusion criteria were neurogenic intermittent claudication caused by lumbar spinal stenosis, 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 six weeks, six months, one year and two 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 two years compared with 7% improvement in the control group, which had medical (nonoperative) therapy including epidural...
injection. In a separate paper, Anderson and colleagues, reporting on a subset of 75 randomized patients who had spondylolisthesis (out of the total 191 patients with one- or two-level lumbar spinal stenosis), 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 (SF-36) from the same trial. The patients, who had to meet a number of inclusion/exclusion criteria, were assessed at baseline and at six weeks, six months, one year, and two 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 to 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 six-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 three years. By three years, the overall failure rate was 12.3% of X-STOP patients compared with 50% of patients with continued nonsurgical management.

X-STOP versus Decompression
Two randomized trials have compared implantation with X-STOP versus decompression. A randomized non-inferiority trial of the X-STOP compared to decompressive surgery was published by Stomqvist et al in 2013. One hundred patients with symptomatic one- or two-level lumbar spinal stenosis 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, visual analog score (VAS) for leg and back pain, or Short Form (SF)-36. Thirteen patients (26%) in the X-STOP group had additional surgery (typically decompression) compared to three patients (6%) in the decompression group, and there was one 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 (NCT00546949). Intention-to-treat analysis showed no significant differences between the groups in primary and secondary outcome measures at up to two-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, two patients had fracture of the spinous process and one 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 versus X-STOP
In 2015, results were published from an FDA-regulated, multicenter randomized, investigational
device exemption (IDE), and non-inferiority trial comparing the Superion interspinous spacer
with the X-STOP. A total of 391 patients with intermittent neurogenic claudication despite six
months of nonsurgical management were enrolled, randomized, and implanted with either
Superion or X-STOP spacers, and followed for two years. The primary end point was a
composite of clinically significant improvement in at least two of three 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
two-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 intent-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 two 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. Interpretation of this study is limited by the lack of a control group treated by
surgical decompression.

Wallis versus Decompression
In 2014, Marsh et al reported an RCT that compared decompression alone (n=30) versus
decompression with a Wallis implant (n=30). Follow-up at an average of 40 months showed no
significant differences between the groups in VAS for back or leg pain or in the ODI.
Improvement in back pain was 3.5 of 10 with the Wallis implant compared with 2.7 without
(p<0.192). Improvement in ODI was 19.3 with the Wallis implant compared with 10.6 without
(p=0.079). Additional study in a larger population is needed.

Uncontrolled Series
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.
Mean visual analog scale (VAS) score was reduced from 61.2 to 39 on a 100-point scale at six
weeks postoperatively and maintained to the two-year evaluation. Mean ODI scores were 32.6
(range 8-80, SD: 16.0) preoperatively, 22.7 (range 0-85, SD: 15.6) at six weeks postoperatively,
and 20.3 (range 0-42, SD: 17.5) at two years. No complications were associated with use of the
device. Eight patients required removal of the device and microsurgical decompression because
of unsatisfactory outcome.

Case series from other institutions have found good outcomes in only about a third of patients
-treated with the X-STOP. For example, one study found that by 12 months, clinically significant
improvement in symptoms and physical function was reported by 54% and 33% of the 24
patients, respectively, and 29% of patients required caudal epidural after 12 months for
recurrence of symptoms of neurogenic claudication. In another series with 46 patients the
overall clinical success rate, defined as an improvement of the ODI by at least 15 points or a satisfaction rating of “very satisfied”, was 36%. A third series of 65 patients found that a good outcome was achieved in 31% of patients.

In a 2010 paper, Rolfe and colleagues evaluated outcomes of a series of 179 patients with and without scoliosis in order to test a contraindication which limits X-STOP use to patients with a maximum scoliosis of 25 degrees. Patients, who received the device between January 2006 and May 2007, were divided into three groups: Group 1 without scoliosis (controls, n=116), Group 2 patients with low scoliosis (11-25 degrees, n=41), and Group 3 (high scoliosis, n=22). At one year, 56% of Group 1 and Group 2 patients, but only 18% of Group 3 patients, achieved improvement of 15 or more points on ODI. Satisfaction rates were 76% for Group 1, 78% for Group 2, and 59% for Group 3. On average, all three groups improved for each outcome: Group 1 (ODI: 17.3, VAS: 2.0, standing time 39 minutes, and walking time 43 minutes), Group 2 (ODI: 20.0, VAS: 1.9, standing time 65 minutes, and walking time 64 minutes), Group 3 (ODI: 7.2, VAS: 0.9, standing time 18 minutes, and walking time 16 minutes). The authors conclude that surgeons and patients must be aware that overall lumbar scoliosis greater than 25 degrees may portend less favorable outcomes.

**Adverse Events**

A number of papers focus on complications with the X-STOP device.

Barbagallo et al analyzed complications in a series of 69 patients and proposed an anatomic scoring system for patient selection. At a mean follow-up of 23 months, eight complications (11.5%) were recorded: four device dislocations and four spinous process fractures.

Bowers et al reviewed records of 13 patients implanted with the X-STOP device at one U.S. center. Nine patients had severe and four had moderate stenosis. Average follow-up was 42.9 months (range, 3-48 months). Initially, pain improved an average of 72%; however, preoperative pain returned in 77% of the patients. The overall complication rate was 38%, including three spinous process fractures and two instances of new onset radiculopathy. Eleven of the 13 patients required additional spinal surgery.

A prospective observational study found a high rate of spinous process fractures in 38 patients (50 implants, 97.4% follow-up) after implantation of the X-STOP titanium (n=34), X-STOP PEEK (n = 8), or Aspen (n=8) devices. Although no fracture was identifiable on plain radiographs, postoperative computed tomography (CT) identified nondisplaced spinous process fractures in 11 patients (28.9% of patients, 22% of levels). Direct interview of patients and review of medical records indicated that five fractures were associated with mild to moderate lumbar back pain, and six fractures were asymptomatic. Three of the 11 patients underwent device removal and laminectomy for persistent pain. Fractures in three other patients had healed by one year.

Verhoof et al reported that, in a cohort of 12 consecutive patients with symptomatic lumbar spinal stenosis caused by degenerative spondylolisthesis who were treated with X-STOP and followed up for a mean of 30.3 months, eight patients had complete relief of symptoms postoperatively while three had no relief. Recurrence of pain, neurogenic claudication, and
worsening of neurologic symptoms were observed in three patients within 24 months. Postoperative radiographs and magnetic resonance imaging (MRI) did not show changes in percentage of slip or spinal dimensions. Seven patients had posterior fusion within 24 months. The authors did not recommend the device for treatment of spinal stenosis complicating degenerative spondylolisthesis.

**Interlaminar Stabilization Devices**

**Randomized Controlled Trials**

The pivotal investigational device exemption (IDE) trial for Coflex® Interlaminar Technology was a non-blinded randomized multi-center non-inferiority trial of decompression plus Coflex compared to decompression plus posterolateral fusion with pedicle screw fixation. A total of 344 patients were randomized in a 2:1 ratio (215 CoFlex and 107 fusion controls, with 22 protocol violators). This study was conducted in a restricted population with numerous exclusion criteria. Compared to fusion, implantation of the Coflex device required less operative time (98.0 vs. 153.2 minutes) and resulted in less blood loss (109.7 vs. 348.6 cc) and a shorter hospital stay (1.9 vs. 3.2 days). Composite clinical success (a combination of a minimum 15-point improvement in Oswestry Disability Index (ODI), no reoperations, no device-related complications, and no epidural steroid injections in the lumbar spine) at 24 months achieved non-inferiority compared to posterolateral fusion (66.2% Coflex and 57.7% fusion). Secondary effectiveness criteria, which included the ZCQ, visual analog score (VAS) for leg and back pain, Short Form-12 (SF-12), time to recovery, patient satisfaction, and several radiographic endpoints, tended to favor the Coflex group by Bayesian analysis. (In this analysis, non-overlapping 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%, 84.7%) compared to 67.4% of controls (95% CI: 57.5%, 77.3%). The percentage of device-related adverse events was the same for the two groups (5.6% Coflex and 5.6% control), and a similar percentage 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, but the reoperation rate trended higher in the CoFlex® cohort (14.1% vs 5.9%, p=0.18. The FDA considered the data in this non-blinded study to support reasonable assurance of safety and effectiveness for device approval, but approval is conditional on two 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).

A European multicenter, randomized, double-blind trial (FELIX) compared implantation of CoFlex® (without bony decompression) versus bony decompression in 159 patients with intermittent neurogenic claudication due to lumbar spinal stenosis. Functional outcomes measured by the ZCQ and Modified Roland-Morris Disability Questionnaire (RMDS), and pain measured with VAS and the McGill Pain Questionnaire, were similar in the two groups at one-year follow-up. Surgery time was shorter, but reoperation rates due to absence of recovery were higher in the CoFlex® group compared with the bony decompression group (29% vs 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 two years, reoperations due to absence of recovery had been performed in 33% of the CoFlex® group compared with 8% of the bony decompression.
group, VAS back pain at final follow-up was also higher in the CoFlex® group (36 mm vs 28 mm/100).

**Controlled Cohort Studies**

In 2010, Richter et al reported a prospective case control study of the CoFlex® device in 60 patients who underwent decompressive surgery. Two-year follow-up from this study was published in 2014. Decompression involved a partial laminotomy, removal of ligamentum flavum, and undercutting facetectomy. The surgeon determined whether the midline structures were preserved or resected and whether the CoFlex® device was implanted (one or two levels). The indications for the two groups were identical, and use of the device was considered incidental to the surgery. No significant differences were observed between the groups on the Oswestry disability index (ODI), the Roland-Morris disability questionnaire (RMS), VAS for pain, and pain-free walking distance. At two-year follow-up, there were no significant differences between the two groups for any of the outcome measures in this non-randomized controlled cohort study, suggesting that additional placement of the CoFlex® device does not improve the clinical outcome of decompressive surgery. Randomized controlled trials are needed to determine the efficacy of the Coflex interlaminar implant with greater certainty.

**Summary**

Interspinous and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension in order to reduce pain in patients with lumbar spinal stenosis and neurogenic claudication. The randomized trials that compare the devices with nonoperative therapy report greater short-term improvements in symptoms and functional status for the device groups. While this establishes that the use of interspinous spacers can lead to better short-term symptom relief than continued conservative therapy, there is a need for longer term (more than two years) outcome data on the durability of symptom relief, the need for repeat procedures, and implant survival. Trials comparing these devices with standard decompressive surgery report that symptomatic outcomes are similar, but there is a higher reoperation rate for the devices compared with standard decompressive surgery. Longer term studies are in progress as part of the postapproval requirements of the U.S. Food and Drug Administration.

**Practice Guidelines and Position Statements**

The United Kingdom’s National Institute for Health and Clinical Excellence (NICE) 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.

2009 guidelines from the American Pain Society indicate that interspinous spacer devices, based on fair evidence, have a B recommendation (panel recommends that clinicians consider offering the intervention). The net benefit was considered moderate through two years, with insufficient evidence to estimate the net benefit for long-term outcomes.

In 2011, the North American Spine Society (NASS) updated their guidelines on the diagnosis and treatment of degenerative lumbar spinal stenosis. They concluded there is insufficient
evidence at this time to make a recommendation for or against the placement of an interspinous process spacing device in patients with lumbar spinal stenosis. These guidelines remain posted on the NASS website as of March 2014. In 2014, 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 spondylolistheses, and (f) open surgery (e.g., laminectomy) is not a medically safe treatment option because of comorbidities. NASS states that interspinous distraction devices are not indicated in cases that do not fall within these parameters.

U.S. Preventive Services Task Force Recommendations
Not Applicable

Key Words:

Approved by Governing Bodies:
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 six months of non-operative treatment and who have relief of their pain when in flexion. The device is approved for implantation at one or two lumbar levels in patients whose condition warrants surgery at no more than two 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 to 4);
  - an ankylosed segment at the affected level(s);
  - acute fracture of the spinous process or pars interarticularis;
  - significant scoliosis (Cobb angle greater than 25 degrees);
• cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction;
• diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA scan [dual energy x-ray absorptiometry] or some comparable study) in the spine or hip that is more than 2.5 [standard deviations] SD below the mean of adult normals in the presence of one 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 six months of non-operative treatment. The CoFlex® is intended to be implanted midline between adjacent lamina of one or two contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).

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.
• 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 two post-approval studies to provide longer-term device performance and device performance under general conditions of use. One study will provide five-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 five 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 for 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.

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.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

**Coding:**

**CPT Codes:**

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<td>Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level (List separately in addition to code for primary procedure)</td>
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**HCPCS Codes:**

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<td>C1821</td>
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**References:**


**Policy History:**

Medical Policy Group, June 2006 (1)
Medical Policy Administration Committee, June 2006
Available for comment July 5-August 18, 2006
Medical Policy Group, June 2008 (1)
Medical Policy Panel May 2009
Medical Policy Group, June 2009 (2)
Medical Policy Administration Committee, July 2009
Medical Policy Group, August 2011
Medical Policy Group (2): 2012 Updates—Description, Key Points, Key Words, Approved by Governing Bodies, References
Medical Policy Panel, December 2012
Medical Policy Group, March 20013 (2): Policy updated with literature review through September 2012; policy statement unchanged, FDA approval information added on Corflex® Interlaminar Technology implant, Key Words, Key Points and References updated.
Medical Policy Panel, May 2013
Medical Policy Group, August 2013 (2): Policy updated with literature review through April 2013. Investigational policy statement added on interlaminar stabilization devices; interlaminar stabilization added to title. Policy statement added that interlaminar stabilization device following decompressive surgery is investigational. Description, Key Points, and References updated to reflect changes.

Available for comment August 22 through October 5, 2013

Medical Policy Panel, May 2014

Medical Policy Group, May 2014 (4): Updated Key Points and References, No changes in policy statement at this time.

Medical Policy Panel, April 2015

Medical Policy Group, April 2015 (2): Updated Key Points, Approved by Governing Bodies, and References; no change to policy statement.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.