Medical Policy

BlueCross BlueShield of Kansas
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Title: Interspinous Distraction Devices (Spacers)

Professional
Original Effective Date: October 18, 2004
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DESCRIPTION

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.

Interspinous spacers are devices implanted between vertebral spinous processes. These interspinous implants aim to restrict painful motion while otherwise enabling normal

motion. The devices (spacers) distract the 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.

The 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.

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 I 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. 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 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 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 a 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.

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.

POLICY

Interspinous distraction devices are considered **experimental / investigational** as a treatment of neurogenic intermittent claudication.

RATIONALE

This policy was updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period of October 2011 through September 2012.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 September 2011, only the X-STOP device has FDA approval for use in the U.S., and this policy does not address other devices. Following is a summary of the key literature to date.

Systematic Reviews

In 2009, Chou and colleagues presented a review of evidence related to surgical treatments for low back pain for the American Pain Society. (1) They concluded, on the basis of the randomized trial data described below, (2) that the evidence was fair quality and that an interspinous spacer

device is superior to nonsurgical therapy for 1- or 2-level spinal stenosis with symptoms relieved with forward flexion but that insufficient evidence exists to judge long-term benefits or harms. Of note, the reviewers considered the Zucherman et al. (2) and Anderson et al. (3) reports as 2 separate studies, while this analysis considers the Anderson et al. to be a subset of the Zucherman et al. study. No trial had compared an interspinous spacer device to standard decompressive surgery.

Kabir et al., in a 2010 systematic review, observed that apart from the randomized controlled trial (RCT) performed for U.S. Food and Drug Administration (FDA) approval, other studies with X-STOP were not of high methodologic quality. (4) The authors observed that results at 2 years were analyzed using only the Zurich Claudication Questionnaire (ZCQ), while analysis of 1-year results also included the Short-Form 36 (SF-36). They also noted concerns about the trial raised by the FDA: First, the block randomization employed could potentially be used to select patients more likely to respond to the intervention. Second, outcomes in both groups were worse than expected, suggesting that power calculations were invalid. Third, results from one center were clearly superior to those of other centers. Four-year follow-up included only 18 of the original 100 patients, and Oswestry Disability Index (ODI) scores were reported instead of ZCQ scores. Studies of the other devices (DIAM, Coflex, Wallis, DIAM) included in the review showed satisfactory outcomes to varying degrees; however, it was stated that “due to small numbers and poor design of studies, it is difficult to clearly define indications for their use in lumbar degenerative disease”. The authors concluded that X-STOP may improve outcomes compared to nonoperative treatment in a select group of patients 50 years of age or older with radiologically confirmed lumbar canal stenosis and neurogenic claudication who have improvement of symptoms on flexion; however, they suggest that further good quality trials are required to clearly identify indications for the use of the devices.

Randomized Controlled Trials

Multiple reports have been published from the single prospective randomized trial, conducted for FDA approval, that compared the X-STOP device to medical therapy.

This study randomized 191 patients from 9 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 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. (2) 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 1- or 2-level lumbar spinal stenosis), found a success rate of 63% in treated patients compared with 13% in controls. (3) Four-year follow-up was reported for 18 of the treated patients in the study. (5) Hsu et al. reported quality-of-life data (SF-36) from the same trial. (6) 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 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.

The pivotal investigational device exemption (IDE) trial for coflex® Interlaminar Technology was a non-blinded randomized multi-center non-inferiority trial of coflex® compared to posterolateral fusion with pedicle screw fixation. (7) 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 2 groups (5.6% coflex® and 5.6% control), and a similar percentage of asymptomatic spinous process fractures were observed. 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 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®).

Preliminary results have been published from a U.S. Food and Drug Administration (FDA)-regulated multicenter randomized IDE non-inferiority trial comparing the Superion interspinous spacer to the X-STOP. (8) Non-blinded results at 6-month follow-up showed similar efficacy for the 2 devices. Twenty percent of patients in the Superion group and 23% of patients in the X-STOP had complications. The FDA-mandated primary endpoint of this trial is noninferiority to X-STOP at 2 years, with additional postmarketing surveillance for 10 years. Over 300 patients are expected to be enrolled. Interpretation of this study is limited by the lack of blinding and lack of control groups treated by surgical decompression or medical management.

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. (9) Mean visual analog scale (VAS) score was reduced from 61.2 to 39 on a 100-point scale at 6 weeks postoperatively and maintained to the 2-year evaluation. Mean ODI scores were 32.6 (range 8-80, SD: 16.0) preoperatively, 22.7 (range 0-85, SD: 15.6) at 6 weeks postoperatively, and 20.3 (range 0-42, SD: 17.5) at 2 years. No complications were associated with use of the device. Eight patients required removal of the device and microsurgical decompression because of unsatisfactory outcome.

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. (10) Patients, who received the device between January 2006 and May 2007, were divided into 3 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 1 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 3 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

Brussee et al. reviewed pre- and postoperative ZCQ and Short Form-36 (SF-36) questionnaires completed by 65 patients who received the X-STOP device between 2003 and 2006. (11) A good outcome was achieved by 31% of patients. Good outcome was not related to body-mass index (BMI) or number of implanted devices but was related to the absence of orthopedic co-morbidity or male gender. The authors concluded that X-STOP does improve the clinical situation; however, a good outcome is achieved less often than previously reported.

Siddiqui and colleagues conducted a prospective observational study of 40 of 45 consecutive patients implanted with the X-STOP device. (12) Patients were evaluated at 3, 6, and 12 months using the ZCQ, ODI, and SF-36. Only 24 patients (60%) completed all questionnaires and were analyzed. By 12 months, clinically significant improvement in symptoms and physical function was noted by 54% and 33% of the 24 patients, respectively. Postoperatively, 29% of patients required caudal epidural after 12 months for recurrence of symptoms of neurogenic claudication. The authors concluded that while the device offers significant short-term improvement over a 1-year period, results are less favorable than those reported in the multicenter randomized trial.

A 2011 study assessed implant survival in a retrospective analysis of 46 consecutive patients (61 devices) with a minimum follow-up of 24 months. (13) Inclusion criteria were the same as in the pivotal randomized trial by Zucherman et al. (2) At a mean follow-up of 34 months (range, 24-70 months), 14 patients (30.4%) had undergone revision surgery to remove the implant. Most revisions occurred within the first 12 months. Revisions were due to lack of improvement (n=6), worsening of low back pain (n=1), recurrence of symptoms after initial good outcome (n=4), implant dislocation (n=2), and fracture of a spinous process (n=1). Two additional patients were lost to follow-up, and one patient was unhappy with the result and did not complete the questionnaires. Kaplan-Meier analysis predicted an implant survival of 34% at 53 months. The mean time until implant removal was 15.4 months. In the remaining 29 patients who did not undergo revision surgery, clinical outcomes improved significantly. VAS for lumbar pain decreased from 4.8 to 3.2 and VAS for leg pain decreased from 5.4 to 2.0. The ODI improved from 39.9 to 24.7 and the SF-36 physical component score improved from 30.2 to 38.4. The overall clinical success rate was 36%, defined as an improvement of the ODI by at least 15 points or a patient's satisfaction rating of "very satisfied". The authors concluded that clinical outcomes after X-STOP implantation might be considerably less favorable than what has been previously published and that further research is needed to improve patient selection.

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. (14) At a mean follow-up of 23 months, 8 complications (11.5%) were recorded: 4 device dislocations and 4 spinous process fractures.

Bowers et al. reviewed records of 13 patients implanted with the X-STOP device at one U.S. center. (15) Nine patients had severe and 4 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 3 spinous process fractures and 2 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. (16) Although no fracture was identifiable on plain radiographs, postoperative computed tomography (CT) identified nondisplaced spinous process factures in 11 patients (28.9% of patients, 22% of levels). Direct interview of patients and review of medical records indicated that 5 fractures were associated with mild to moderate lumbar back pain, and 6 fractures were asymptomatic. Three of the 11 patients underwent device removal and laminectomy for persistent pain. Fractures in 3 other patients had healed by 1 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, 8 patients had complete relief of symptoms postoperatively while 4 had no relief. (17) Recurrence of pain, neurogenic claudication, and worsening of neurologic symptoms were observed in 3 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.

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.

2009

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 felt data were sufficient to demonstrate improved outcomes.

2011

In response to requests, input was received from 2 physician specialty societies and 2 academic medical centers while this policy was under review in March 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 but felt the technology had a role in the treatment of selected patients with neurogenic intermittent claudication.

Summary

Interspinous implants (spacers) distract the spinous processes and restrict extension in order to reduce pain in patients with lumbar spinal stenosis and neurogenic claudication. Although the randomized device trials report short-term improvements in symptoms and functional status when compared to non-operative therapy, a number of questions remain. Overall, high-quality comparative data are limited. There is a need for longer-term (more than 2 years) outcome data on symptom relief, the need for repeat procedures, and implant survival. Future studies need to better control for potential biases and avoid other methodologic issues, including follow-up of patients in the control group and consistent use of outcome measurements. There are also questions about patient section criteria; for instance, whether patients with any degree of spondylolisthesis should be excluded from this treatment. In addition, comparisons with decompressive surgery are lacking, and recent case series indicate that outcomes may be less favorable than those reported in the multi-center randomized trial. Because the impact of this technology on net health outcome is not known, these devices are considered investigational.

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. (18)

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). (1, 19) The net benefit was considered moderate through 2 years, with insufficient evidence to estimate the net benefit for long-term outcomes.

In 2007, the North American Spine Society published new guidelines on the diagnosis and treatment of degenerative lumbar spinal stenosis. (20) They concluded that with a single Level 1 study on the X-STOP, "there remains insufficient evidence to make a recommendation." These guidelines remain current in October 2012.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

0171T Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion, and imaging guidance), lumbar; single level

0172T 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)

C1821 Interspinous process distraction device (implantable)

- Effective January 1, 2007, there are specific CPT category III codes for this procedure: 0171T, 0172T.
- Effective January 1, 2007, there is also a HCPCS "C" Medicare pass-through code for the device: C1821
- Prior to 2007, the procedure should have been coded using CPT code 22899 (unlisted procedure, spine).

DIAGNOSES

Experimental / Investigational for all diagnoses related to this medical policy.

REVISIONS

02-08-2010	The Interspinous Distraction Devices (Spacers) medical policy is a new freestanding policy developed from the Minimally Invasive Procedures for Spine Pain medical policy which was effective October 18, 2004. The Minimally Invasive Procedures for Spine Pain is no longer an active medical policy.
06-27-2011	Description updated.
	Rationale updated.
	In Coding section: • Removed CPT code 22899 as there are specific codes for this service.
	References updated.
02-24-2012	Description updated.
	Rationale updated.
	References updated.
03-19-2013	Description updated.
	Rationale updated.
	References updated.

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