Cigna Medical Coverage Policy

Subject **Interspinous Process Spacer Devices**

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Table of Contents

Hyperlink to Related Coverage Policies

Lumbar Fusion for Spinal Instability and Degenerative Disc Conditions
Mechanical Devices for the Treatment of Back Pain
Minimally Invasive Treatment of Back and Neck Pain

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Coverage Policy

Cigna does not cover interspinous process spacer devices for any indication because they are considered experimental, investigational or unproven.

General Background

An interspinous process spacer device is an implant designed to preserve motion and provide symptomatic relief of pain associated with degenerative disc disease or spinal stenosis, with or without degenerative spondylolisthesis. Spinal stenosis is a narrowing of the vertebral canal that may lead to compression of the spinal nerves or nerve roots, especially in the lumbar vertebrae. Lumbar stenosis is commonly seen in an aging or degenerative spine. Bony overgrowth and ligament enlargement into the spinal canal, intervertebral disc herniation, or vertebral slippage (i.e., spondylolisthesis) may cause nerve compression resulting in low back pain, leg fatigue and pain, and reduced capacity for physical activity. Neurogenic claudication is a combination of low back and leg pain, with numbness and motor weakness when standing or walking that is relieved by sitting or lying. Treatment for back pain may include pharmacological therapy (e.g., non-steroidal anti-inflammatory drugs (NSAIDs), analgesics, muscle relaxants), exercise, spinal manipulation, acupuncture, cognitive-behavioral therapy, and physical therapy. Various interventional and surgical procedures may be considered if these measures are unsuccessful. Surgical options include decompressive procedures (e.g., laminectomy) alone, or decompression and fusion. Fusion is frequently performed with rigid implant fixation systems, including pedicle screws and interbody cages. The use of interspinous process spacer devices has been proposed as a less invasive dynamic stabilization alternative (Kim, 2007; Snyder, et al., 2004; Sengupta and Herkowitz, 2003).

U.S. Food and Drug Administration (FDA)
X-STOP® Interspinous Process Decompression (IPD) System (St. Francis Medical Technologies, Inc., Alameda, CA): The X-STOP system received FDA approval through the premarket approval (PMA) process on November 21, 2005. St. Francis Medical Technologies was subsequently acquired by Kyphon, Inc. (Sunnyvale, CA), and Kyphon was acquired by Medtronic, Inc., (Minneapolis, MN), in November, 2007.

The X-STOP System is a titanium implant with two components: a spacer assembly consisting of a tissue expander, an oval spacer and a fixed wing; and a wing assembly consisting of an adjustable wing and locking screw. The X-STOP procedure is performed under general or local anesthesia. A midline incision is made over the appropriate spinal level to display the spinous processes and their interspinous ligaments. The X-STOP device is positioned in the space between the flexed spinous processes to act as a physical block in order to prevent extension at the stenotic level and increase the dimensions of the spinal canal and intervertebral foramina. The procedure is designed to prevent extension when standing or walking, relieving pressure on the nerves.

According to the FDA approval order, the device is indicated for treatment of patients aged 50 or older with neurogenic intermittent claudication (NIC) secondary to a confirmed diagnosis of lumbar spinal stenosis, with x-ray, magnetic resonance imaging (MRI), and/or computed tomography (CT) evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal narrowing. It is indicated for patients with moderately impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, with or without back pain, and who have undergone at least six months of nonoperative treatment. The approval order states that the X-STOP may be implanted at one or two lumbar levels in patients for whom operative treatment is indicated at no more than two levels.

A modified version of the device, marketed as the X-STOP PEEK IPD System, received FDA approval though the PMA process on August 8, 2008.The body of the modified implant is composed of a polyetheretherketone (PEEK) outer ring; the remainder of the device is made of titanium alloy.

coflex® Interlaminar Technology (Paradigm Spine, LLC, New York, NY): The coflex Interlaminar Technology received FDA approval through the PMA process on October 17, 2012. According to the FDA Summary of Safety and Effectiveness, the coflex® Interlaminar Technology is an interlaminar stabilization device indicated for use in one or two 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).

FDA approval was based on the randomized multicenter Investigational Device Exemption Trial conducted by Davis, et al. (2013), discussed below. The manufacturer is required to conduct two post-approval studies to provide long term device performance and to evaluate device performance under actual conditions of use (U.S. FDA website).

Additional Devices: Several interspinous process spacer devices are currently under evaluation in clinical trials but have not received FDA approval, including the following:

- Wallis® Dynamic Posterior Stabilization System (Zimmer, Inc., Minneapolis, MN)
- Diam™ Spinal Stabilization System (Medtronic LLC, Minneapolis, MN)

Posterior non-pedicle supplemental fixation devices (e.g., Lanx Spinal Fixation System™ [Lanx, Inc., Broomfield CO], Aspen™ Spinous Process System [Lanx, Inc., Broomfield CO]) have been explored as a method of temporary spinal fixation while waiting for bony fusion to occur, as an alternative to pedicle screws. These devices differ from interspinous process spacer devices (e.g., X-STOP) in that they are used for fixation rather than for motion preservation. Although FDA approved, the safety and efficacy of these devices has not been established in the published medical literature. Refer to the Coverage Policy, Lumbar Fusion for Spinal Instability and Degenerative Disc Conditions for information on these devices.

Literature Review
X-STOP® Interspinous Process Decompression (IPD) System:

A prospective cohort study was conducted by Kim et al. (2012) to identify risk factors associated with early spinous process fracture after interspinous process surgery (IPS) for lumbar stenosis and neurogenic claudication (n=38 patients, 50 levels). Implants included 42 X-STOP devices (34 titanium 8 polyetheretherketone) and 8 Aspen devices. Degenerative spondylolisthesis appeared to be strongly associated with the occurrence of spinous process fracture after IPS surgery; eleven spinous process fractures were identified by CT in 11 patients (22.0%). The rate of spondylolisthesis seen on preoperative radiographs was 100% (`11 of 11) in patients with fractures compared to 33.3% of patients without fracture (p=.0001).

Tuschel et al. conducted a retrospective review to analyze implant survival and failure modes of the X-STOP device in 46 patients with neurogenic claudication. At a mean follow-up of 34 months (range 24-70 months) the revision rate was 30%, primarily due to lack of improvement, with most revisions occurring within 12 months. Kaplan-Meier Survivorship analysis predicted an implant survival probability of 0.68 at 48 months postoperatively. The authors stated that clinical outcome after X-STOP implantation might be considerably less favorable than previously published, and patient selection might be a reason for early revision surgery.

Kim et al. (2011) conducted a prospective observational study to provide a more accurate estimate of the rate of acute spinous process fractures associated with interspinous process spacer surgery. The authors noted that postoperative spinous process fractures have been reported in 1–5.8% of patients in previous series, based on routine biplanar radiographic evaluation. Most fractures, however, occur between the base and midportion of the spinous process in an area that is typically difficult to visualize on plain radiographs due to device design. A total of 38 patients (50 implants) completed follow-up and were included in the analysis. The devices included the Medtronic X-STOP (34), X-STOP PEEK (8), and Lanx Aspen (8). Postoperative computed tomography (CT) revealed 11 non-displaced spinous process fractures in 11 patients (28.9%). Five fractures were associated with mild to moderate back pain, while six were asymptomatic, and none were visible on plain radiographs. The device was removed and laminectomy performed in three patients. Although not statistically significant, a trend toward poorer outcomes was seen in patients with fractures, as measured by symptom severity, physical function, and satisfaction rates. A larger study is needed to establish this association. The authors concluded that interspinous process spacer surgery appears associated with a higher rate of early postoperative spinous process fracture than previously reported. Unrecognized fractures may be responsible for a significant number of patients with unsatisfactory outcomes, and CT imaging is required to identify the majority of such fractures.

A case series by Kuchta et al. (2008) evaluated two-year results of X-STOP implantation in 175 patients with neurogenic intermittent claudication due to lumbar spinal stenosis. Patients were evaluated using the VAS score and Oswestry disability index. The average preoperative VAS score was 61.1 (range, 20–100) and decreased to an average of 39.0 (range 0–100) at six weeks ($p < 0.005$). Mean VAS at 6, 12, and 24 months was 35.8 (range 0–100); 38.6 (range 0–100); and 39.0 (range 0–75), respectively. The average preoperative ODI score was 32.6 (range 8–80) and decreased to an average of 22.7 at six weeks (range 0–85). The average ODI score at 6, 12, and 24 months was 21.5 (range 0–66); 15.3 (range 0–44); and 20.3 (range 0–42), respectively. Removal of the device was required in 8 of 175 patients because of unsatisfactory effect, and a microsurgical decompression was performed.

Verhoof et al. (2007) reported outcomes of X-STOP implantation in 12 consecutive patients with symptomatic lumbar stenosis caused by degenerative spondylolisthesis. The authors noted that only one other study had investigated the clinical effects of the X-STOP in patients whose spinal stenosis was caused by spondylolisthesis. All patients had low back pain, neurogenic claudication and radiculopathy. The mean follow-up was 30.3 months. Complete relief of symptoms was observed in eight patients immediately following the procedure, and four patients experienced no improvement. At 12 weeks, two patients who initially had experienced symptom relief experienced a recurrence of pain, neurogenic claudication, and radiculopathy, and at 24 months, a third patient experienced a recurrence of symptoms. The implant was removed in the seven patients with persistent or recurrent symptoms, and decompression and posterolateral fusion with instrumentation was performed. The authors stated that, because of the high failure rate, they do not recommend the X-STOP for the treatment of spinal stenosis complicating degenerative spondylolisthesis, and that spondylolisthesis should be considered a contraindication for the X-STOP device.

Siddiqui et al. (2007) conducted a small retrospective study to evaluate the clinical outcome of patients with symptomatic lumbar spinal stenosis treated with X-STOP implantation, and to compare this data with previous studies. Forty consecutive patients were enrolled between January 2003 and December 2006. Two patients were excluded from the study because conversion to surgical decompression was required due to intraoperative

fracture of spinous processes during the X-STOP procedure. One patient was declared unfit for surgery due to medical comorbidities and was also excluded. Patients were evaluated preoperatively and at three months, six months and one year, using with the Zurich Claudication Questionnaire (ZCQ), ODI, and Standard Form (SF)-36. Only 24 of 37 patients completed the full set of questionnaires. At a mean follow-up of 12 months, mean ODI scores had improved from 48 to 37, mean ZCQ Symptom Severity scores improved from 3.4 to 2.8, and mean ZCQ Physical Function scores improved from 2.5 to 2.2. Improvements were observed in five of the ten SF-36 sub-scores. The published study does not state whether any of the improvements noted were statistically significant, however. The X-STOP was removed in two patients who were noted to have dorsally slipped implants at one year, with symptoms of neurogenic claudication. Both patients were treated with decompression and fusion.

Zucherman et al. (2005) conducted a randomized controlled multicenter trial to determine the safety and efficacy of the X-STOP in patients with NIC secondary to lumbar spinal stenosis. FDA approval was based primarily on the results of this trial. Patients with spondylolisthesis of greater than grade one on a one to four scale were excluded from participation. Patients were randomized to treatment with the X-STOP (n=100) or nonoperative therapies (n=91). Patients randomized to the control group received at least one epidural steroid injection following enrollment and were prescribed additional epidural steroid injections, nonsteroidal anti-inflammatory medications, analgesics and physical therapy as needed. The primary outcome measure was the Zurich Claudication Questionnaire (ZCQ), a patient-completed validated instrument to evaluate NIC. Assessments were made prior to treatment and at six weeks, six months, one year and two years, and were based on ZCQ symptom severity and physical function domains and the patient satisfaction domain. Seven patients in the X-STOP group and 10 patients in the control group were lost to follow-up. At each follow-up, patients in the X-STOP group had significantly better outcomes in each domain of the ZCQ. At two years, the X-STOP patients improved by 45.4% over the mean baseline symptom severity score, compared to 7.4% in the control group. The mean improvement in the physical function domain was 44.3% in the X-STOP group and -0.4% in the control group, and 73.1% of patients in the X-STOP group were satisfied with their treatment compared to 35.9% of the control group. The authors concluded that the X-STOP provides a conservative yet effective treatment for patients suffering from lumbar spinal stenosis. Although this study demonstrated positive results, it is difficult to generalize these findings, since the study included a highly selected patient population; those with spondylolisthesis higher than grade one on a scale of one to four were excluded from the study. In addition, the follow-up period was relatively short, and a significant number of patients were lost to follow-up and were not included in the analysis.

Kondrashov et al. (2006) conducted a small case series to evaluate the X-STOP in 18 patients. Inclusion criteria were based on the FDA PMA approval criteria. Twelve patients had the X-STOP implanted at either L3–4 or L4–5 levels, and six patients had the device implanted at both L3–4 and L4–5 levels. The mean preoperative Oswestry Disability Index (ODI) score was 45 (range 20–80). At an average follow-up of 51 months (range 45–61months), the mean ODI score was 15 (range 0–36). Using a 15-point improvement from baseline as the criterion for success, the authors reported that 14 of 18 patients had a successful outcome. It is difficult to draw conclusions from this study because of the small number of patients studied, limited follow-up, and the lack of a control group treated with nonsurgical or traditional surgical approaches.

In a review of dynamic interspinous process technology, Christie et al. (2005) discuss several available spinal implants, including the X-STOP, Wallis and Diam devices. The authors state that, although outcomes of patients treated with the X-STOP have been reported as comparable to outcomes of patients treated with laminectomy, a direct comparison between these two methods in a controlled clinical trial has yet to be reported. The concept of dynamic stabilization is an attractive alternative to fusion, especially in younger patients who would bear a greater burden on adjacent segments during their prolonged follow-up. In addition, the procedure does not limit potential therapeutic options. The authors stated that, although early results of experimental use of interspinous implants are promising, no meaningful comparison can be made between any of these implants at this time, nor can a comparison be made between implants and traditional surgical approaches such as laminectomy and/or fusion.

Kim and Albert discuss concerns and controversy regarding this technology in a review of interspinous process spacers, including the X-STOP, Wallis, and Diam devices. The authors state that interspinous spacer implants are designed to produce increased segmental kyphosis (spinal process flexion) at the treated level, and concern has been raised about the potentially harmful effect of local kyphosis on adjacent segments. There are no long-clinical data regarding the effects of increased kyphosis resulting from placement of interspinous process

spacers. The authors also state that, because the spinous process normally serves as an origin and insertion site for muscles and ligaments, and does not normally act as a compressive load bearing structure, it is possible that compression loading of the spinous processes and cyclic device motion may lead to local tissue changes and pain generation. Another concern raised by the authors is the lack of evidence of the impact of interspinous implants on the intricate system of reflex arcs that have been hypothesized to be responsible for maintaining segmental stability during motion and positioning of the spine. In addition, the lumbar functional spinal unit demonstrates viscoelasticity under conditions of constant compression and tension, yet this phenomenon is not accounted for in current device insertion techniques. The X-STOP device involves fairly rapid sizing of the interspinous space with a dilator to select the appropriately sized implant. Progressive subsidence over time was also mentioned as a concern.

coflex® Interlaminar Technology: FDA approval of the coflex® Interlaminar Technology was based on an Investigational Device Exemption (IDE) randomized, multicenter trial conducted by Davis et al. (2013a) to evaluate the safety and efficacy of Coflex interlaminar stabilization compared with posterior spinal fusion for the treatment of one-and two-level spinal stenosis and degenerative spondylolisthesis (n=322). Patients were randomized to receive laminectomy and coflex interlaminar stabilization or laminectomy (n=215), or spinal fusion with spinal instrumentation (n=107). Patients were required to meet strict inclusion and exclusion criteria. The primary outcome measure was overall success, defined as a 15-point reduction in Oswestry Disability Index (ODI), no reoperations, no major device-related complications, and no postoperative epidural injections. Outcomes were also assessed based on ODI score, Short-Form 12 (SF-12), visual analogue scale (VAS), Zurich claudication questionnaire (ZCQ), and radiographic outcomes. Two year results were available in 95.3% of the coflex group and 97.2% in the fusion (control) group. At 24 months, 135 of 204 Coflex patients (66.2%) and 60 of 104 (57.7%) of the fusion patients met the criteria for overall success (p=0.999). At 24 months, the difference between groups in ODI scores, SF-12 mental health outcomes scores, or VAS scores was not statistically significant. Improvement in SF-12 physical component scores was higher in the coflex group compared to fusion controls (p=0.050). There was also significant improvement in each of the ZCQ domains at 24 months. Increased angulation was seen in the fusion group compared to the coflex group (p=0.002). The overall adverse event rate was similar between groups, but coflex had a higher reoperation rate (10.7% vs. 7.5%, p=0.426).

A substudy of this trial evaluated coflex interlaminar stabilization with laminectomy (n=99) compared to laminectomy with posterolateral spinal fusion (PSF) with instrumentation (n=51) in a subset of patients with low grade (grade 1) degenerative spondylolisthesis with spinal stenosis (Davis et al., 2013b). Overall success (as described above) was similar in both groups; 59 (62.8%) in the coflex group and 30 (62.5%) in the fusion group (p=1.000). Improvement from baseline in ODI, SF-12, VAS back and leg scores, and ZCQ scores was similar in both groups, with the exception of greater ZCQ satisfaction with coflex. The overall reoperation rate was 14.1% (14 of 99) in the coflex group and 5.9% (3 of 51) in the fusion group (p=0.18).

A randomized controlled double-blind trial was conducted at five neurosurgical centers in the Netherlands to assess whether interspinous process device implantation is more effective in the short term than conventional surgical decompression for patients with intermittent neurogenic claudication due to lumbar spinal stenosis. Patients with lumbar spinal stenosis at one or two levels with an indication for surgery were randomized to treatment with an interspinous process device (coflex device) (n=80) or surgical decompression (n=79).The difference in the primary outcome measure was the Zurich Claudication Questionnaire score (ZCS). The difference in ZCQ scores was not statistically significant between the interspinous process group and the standard decompression group at eight weeks (63% vs. 72%, p=0.44) or one year (66% vs. 69%, p=0.77). The repeat surgery rate in the interspinous group was significantly higher than in the standard decompression group, at 29% vs. 8% (p<0.001).(Moojen et al, for the Leiden-The Hague Spine Intervention Prognostic Study Group {SIPS}, 2013).

Professional Societies/Organizations
The North American Spine Society (NASS) evidence-based clinical guideline on the diagnosis and treatment of degenerative lumbar spondylolisthesis (Watters et al., 2009) includes an evaluation of interventional and surgical treatments, including interspinous spacers. The guideline states that there is insufficient evidence to recommend indirect surgical decompression for treatment of patients with symptomatic spinal stenosis associated with low grade degenerative lumbar spondylolisthesis whose symptoms have been recalcitrant to a trial of medical/interventional treatment.

NASS Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care, Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis (2011) state that there is insufficient evidence to make a recommendation for or against the placement of an interspinous process spacing device in patients with lumbar spinal stenosis. This recommendation was unchanged in a 2013 revision of the guideline.

Use Outside the U.S.
National Institute for Health and Clinical Excellence (NICE) (United Kingdom)
Interventional Procedures Guidance for interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication was originally issued by NICE in 2006, and updated on November, 2010. The revised guidance states that current evidence 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 guidance states that here are no major safety concerns, and that these procedures may be used provided that normal arrangements are in place for clinical governance, consent and audit. The guidance also states that patient selection should be carried out by specialist spinal surgeons who are able to offer patients a range of surgical treatment options.

Summary
The use of various interspinous process spacer devices have been proposed for the treatment of lumbar stenosis. The X-STOP® Interspinous Process Decompression (IPD) System is placed in the space between the flexed spinous processes to act as a physical block in order to prevent extension when standing or walking, relieving pressure on the nerves. The coflex® Interlaminar Technology is an interlaminar stabilization device implanted between adjacent spinal processes. It is designed to maintain a fixed distance between the spinous processes following surgical decompression. There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, durability, and long-term outcome of interspinous process spacer devices, or to determine how the use of these devices compares to alternative medical, interventional, or surgical treatment.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Experimental/Investigational/Unproven/Not Covered:

CPT®* Codes	**Description**
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)

HCPCS Codes	**Description**
C1821	Interspinous process distraction device (implantable)

Experimental/Investigational/Unproven/ not covered when used to report insertion of an interspinous process spacer device (e.g., coflex®, X-STOP®):

CPT®* Codes	Description
22840	Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)

22899	Unlisted procedure, spine

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