



Kansas City

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Interspinous and Interlaminar Stabilization / Distraction Devices (Spacers)

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Origination: 2/2007

Last Review: 9/2014
Next Review: 9/2015

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for interspinous and interlaminar stabilization / distraction devices. This is considered investigational.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

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

Use of an interlaminar stabilization device following decompressive surgery is considered **investigational**.

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.

Background

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 posterior dynamic 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. Other interspinous spacers require removal of the interspinous ligament and are secured around the upper and lower spinous processes. Interlaminar implants are inserted between the adjacent lamina and spinous processes following decompressive surgery.

Regulatory Status

In November 2005, the X-STOP® Interspinous Process Decompression (IPD®) System (Kyphon-now part of Medtronic Spine LLC) was approved by the U.S. Food and Drug Administration (FDA) for “treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to

a confirmed diagnosis of lumbar spinal stenosis.” It is approved for patients with moderately impaired physical function who have had a regimen of at least 6 months of non-operative treatment and who have relief of their pain when in flexion. The device is approved for implantation at 1 or 2 lumbar levels in patients whose condition warrants surgery at no more than 2 levels. The X-STOP PEEK (polyetheretherketone) received approval in 2006 and is a modified version of the X-STOP that includes a PEEK spacer and additional 16-mm spacer size. The indications are the same as for the X-STOP titanium model.

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

- an allergy to titanium or titanium alloy;
- spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable *in situ*, such as:
 - significant instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1.0 (on a scale of 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 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 6 months of non-operative treatment. The coflex® is intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).

The FDA lists the following contraindications to use of the coflex®:

- Prior fusion or decompressive laminectomy at any index lumbar level.
- Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (e.g., compression fracture).
- Severe facet hypertrophy that requires extensive bone removal which would cause instability.
- Grade II or greater spondylolisthesis.
- Isthmic spondylolisthesis or spondylolysis (pars fracture).
- Degenerative lumbar scoliosis (Cobb angle of greater than 25 degrees).
- Osteoporosis.
- Back or leg pain of unknown etiology.
- Axial back pain only, with no leg, buttock, or groin pain.
- Morbid obesity defined as a body mass index >40.
- Active or chronic infection - systemic or local.
- Known allergy to titanium alloys or magnetic resonance imaging (MRI) contrast agents.
- Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction.

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

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

Data has demonstrated that spinous process fractures can occur with coflex® implantation. Potential predictors for spinous process fractures include:

- Over-decompression during surgery leading to instability in the spine,
- Resection of the spinous process to: 14 mm,
- Height of the spinous process 23 mm pre-operatively,
- Osteopenia or osteoporosis, and
- "Kissing" spinous processes.

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

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

The Wallis System (originally from Abbott Spine; currently from Zimmer Spine) was introduced in Europe in 1986. The first generation Wallis implant was a titanium block; the second generation device is composed of a plastic-like polymer that is inserted between adjacent processes and held in place with a flat cord that is wrapped around the upper and lower spinous processes. The Wallis System is currently being tested in an FDA-regulated clinical trial. Also in a FDA-regulated clinical trial is the DIAM Spinal Stabilization System (Medtronic Sofamor Danek), which is a soft interspinous spacer with a silicone core. The DIAM system requires removal of the interspinous ligament and is secured with laces around the upper and lower spinous processes. Other clinical trials underway at U.S. centers are studying the In-Space (Synthes), Superior® (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.

Rationale

This policy was originally created in 2006 and was updated regularly with searches of the MEDLINE database. The most recent literature review was performed through April 22, 2014. The literature on this technology is dominated by reports from non-U.S. centers on devices that have not received U.S. Food and Drug Administration (FDA) approval, though a number of them are in trials at U.S. centers. As of April 2014, only the X-STOP and Coflex devices have 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.

Interspinous Distraction Devices

Systematic Reviews

In 2009, Chou et al 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 next,(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 with standard decompressive surgery.

Kabir et al, in a 2010 systematic review, observed that apart from the randomized controlled trial (RCT) performed for 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 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 1 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 with 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 a single prospective randomized trial, conducted for FDA approval, which 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 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 et al, reporting on a subset of 75 randomized patients who had spondylolisthesis (of 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 with both baseline and control subjects. There was a large loss to follow-up (42%) in the medical-treatment group; 6% of the experimental and 26% of the control subjects underwent laminectomy.

A randomized noninferiority trial of the X-STOP compared with decompressive surgery was published by Stromqvist et al in 2013.(7) One hundred patients with symptomatic 1- or 2-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 SF-36. Thirteen patients (26%) in the X-STOP group had additional surgery (typically decompression) compared with 3 patients (6%) in the decompression group, and there was 1 spinous process fracture. The X-STOP patients who later underwent decompression were not considered to be treatment failures.

Preliminary results have been published from an FDA-regulated, multicenter randomized, investigational device exemption (IDE), noninferiority trial comparing the Superior interspinous spacer with the X-STOP.(8) Nonblinded results at 6-month follow-up showed similar efficacy for the 2 devices. Twenty percent of patients in the Superior group and 23% of patients in the X-STOP had complications. The FDA-mandated primary end point 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 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 (SD=16.0; range, 8-80) preoperatively, 22.7 (SD=15.6; range 0-85) at 6 weeks postoperatively, and 20.3 (SD=17.5; range 0-42) 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.

Case series from other institutions have found good outcomes in only about a third of patients treated with the X-STOP.(10-13) For example, 1 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.(11) 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%.(12) A third series of 65 patients found that a good outcome was achieved in 31% of patients.(10)

In a 2010 paper, Rolfe et al evaluated outcomes of a series of 179 patients with and without scoliosis to test a contraindication which limits X-STOP use to patients with a maximum scoliosis of 25°.(14) 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°, 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; walking time 43 minutes), group 2 (ODI, 20.0; VAS, 1.9; standing time 65 minutes; walking time 64 minutes), group 3 (ODI, 7.2; VAS, 0.9; standing time 18 minutes; walking time 16 minutes). The authors conclude that surgeons and patients must be aware that overall lumbar scoliosis greater than 25° 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.(15) 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 1 U.S. center.(16) 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.(17) Although no fracture was identifiable on plain radiographs, postoperative computed tomography 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 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.(18) 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.

Interlaminar Stabilization Devices

Randomized Controlled Trials

The pivotal IDE trial for coflex® Interlaminar Technology was a nonblinded randomized multicenter noninferiority trial of decompression plus coflex® compared with decompression plus posterolateral fusion and pedicle screw fixation.(19,20) A total of 344 patients were randomized in a 2:1 ratio (215 coflex®, 107 fusion controls, with 22 protocol violators). This study was conducted in a restricted population with numerous exclusion criteria. Compared with 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 mL) and a shorter hospital stay (1.9 vs 3.2 days). Composite clinical success (a combination of a minimum 15-point improvement in ODI, no reoperations, no device-related complications, and no epidural steroid injections in the lumbar spine) at 24 months achieved noninferiority compared with posterolateral fusion (66.2% coflex®, 57.7% fusion). Secondary effectiveness criteria, which included the ZCQ, VAS for leg and back pain, SF-12, time to recovery, patient satisfaction, and several radiographic end points, tended to favor the coflex® group by Bayesian analysis. (In this analysis, nonoverlapping confidence intervals imply statistically reliable group differences.) For example, ZCQ composite success was achieved in 78.3% of coflex® patients (95% confidence interval [CI], 71.9% to 84.7%) compared with 67.4% of controls (95% CI, 57.5% to 77.3%). The percentage of device-related adverse events was the same for the 2 groups (5.6% coflex®, 5.6% control), and 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).(21) FDA considered the data in this nonblinded 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®).

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.(22) 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 2 groups at 1-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).

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.(23) Two-year follow-up from this study was published in 2012-2013.(24) 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 (1 or 2 levels). The indications for the 2 groups were identical, and use of the device was considered incidental to the surgery. No significant differences were observed between the groups on the ODI, RMDS, VAS for pain, and pain-free walking distance. At 2-year follow-up, there were no significant differences between the 2 groups for any of the outcome measures in this nonrandomized controlled cohort study, suggesting that additional placement of the coflex® device does not improve the clinical outcome of decompressive surgery. RCTs are needed to determine the efficacy of the coflex® interlaminar implant with greater certainty.

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 and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension to reduce pain in patients with lumbar spinal stenosis and neurogenic claudication. Although the randomized device trials report short-term improvements in symptoms and functional status when compared with nonoperative therapy, a number of questions remain. Overall, high-quality comparative data are limited. There is a need for longer-term (>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 selection criteria; for instance, whether patients with any degree of spondylolisthesis should be excluded from this treatment. In addition, recent case series indicate that outcomes may be less favorable than those reported in the multicenter 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 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.(25)

The 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).(1,26) The net benefit was considered moderate through 2 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.(27) 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.(28) 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 (eg, 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.

Medicare National Coverage

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

The Centers for Medicare and Medicaid Services approved a special add-on payment for hospitals that offer surgery using the patented X STOP® Interspinous Process Decompression (IPD(R)) System ("X STOP") in 2007.(29)

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Billing Coding/Physician Documentation Information

| | |
|--------------|---|
| 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) |
| 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) |
| 22101 | Partial excision of posterior vertebral component (eg, spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; thoracic |
| 22899 | Unlisted procedure, spine |
| C1821 | Interspinous process distraction device (implantable) |

At this time, there is no specific CPT code for this procedure. The category III codes should be used. The CPT codes listed above may be used incorrectly.

Additional Policy Key Words

X-Stop

Policy Implementation/Update Information

| | |
|--------|--|
| 2/1/07 | New policy; considered investigational. |
| 2/1/08 | No policy statement changes. |
| 2/1/09 | No policy statement changes. |
| 2/1/10 | No policy statement changes. |
| 2/1/11 | No policy statement changes. |
| 2/1/12 | No policy statement changes. |
| 5/1/12 | No policy statement changes. |
| 5/1/13 | No policy statement changes. |
| 5/1/14 | Investigational policy statement added on interlaminar stabilization devices; interlaminar stabilization added to title. |
| 9/1/14 | Updated code definitions. No policy statement changes. |

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