Coverage policy

Select Health of South Carolina considers the use of the Coflex® interlaminar stabilization device (Paradigm Spine LLC, New York, NY) to be clinically proven and, therefore, medically necessary when the following criteria are met (Guyer, 2016; Li, 2017; Musacchio, 2016; Schmidt, 2018; Schmier, 2014):

- Diagnosis of at least moderate lumbar spinal stenosis between L1 and L5 of one or two contiguous vertebrae, confirmed by radiography, with or without spondylolisthesis, which requires surgical decompression.
- Confirmation by radiographic study of the absence of gross angular or transitory instability of the spine at index or adjacent levels.
- Member must experience relief in flexion from their symptoms of leg, buttock, or groin pain, with or without back pain, and have undergone a regimen of at least six months of unsuccessful...
non-operative treatment consisting of non-steroidal anti-inflammatory drugs and at least one of the following: rest, restriction of activities of daily living, physical therapy, or steroid injections.
- Member is skeletally mature.

Limitations:

Stabilization with the coflex device is not appropriate for members with the following conditions (Donnally, 2018; Guyer, 2016; Jackson, 2016):

- More than two vertebral levels requiring surgical decompression.
- Conditions resulting in gross instability of the lumbar spine, including:
  - Prior surgical procedure that resulted in gross translatory instability of the lumbar spine.
  - Prior fusion, implantation of a total disc replacement, or complete laminectomy at index level.
  - Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma, tumor, or infection.
  - Severe facet hypertrophy requiring extensive bone removal that would cause gross instability.
  - Radiographic confirmation of gross angular or translatory instability of the spine at index or adjacent levels with sagittal plane translation > 4.0 mm as spondylolisthesis or retrolithesis
  - Osteopenia and osteoporosis.
  - Degenerative lumbar scoliosis (Cobb angle > 25° lumbar segmental).
- Isthmic spondylolisthesis or spondylolysis (pars fracture).
- Back or leg pain of unknown etiology.
- Axial back pain only, with no leg, buttock, or groin pain.
- Obesity defined as a body mass index ≥ 35.
- Active or chronic infection at a systemic or localized level, including infection with human immunodeficiency virus. Clinicians should exercise caution in referring patients who are prone to infection for elective spinal stabilization surgery.
- History of Paget disease, osteomalacia, or any other metabolic bone disease (excluding osteopenia, which is addressed above).
- Rheumatoid arthritis or other autoimmune disease requiring chronic steroid use.
- Active malignancy: a member with a history of any invasive malignancy (except nonmelanoma skin cancer), unless they have been treated with curative intent and there has been no clinical signs or symptoms of the malignancy for at least five years. Patients with a primary bony tumor are excluded as well.
- Known allergy to titanium alloys or magnetic resonance contrast agents.
- Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction.
- Active tobacco use. Members who use tobacco should cease tobacco use for at least four weeks before surgery and at least six months after surgery.
• Uncertain commitment to rehabilitation. Members must express commitment to adhere to recommendations for post-surgery limitations, activity, and exercise.

Alternative covered services:

• Conservative nonsurgical treatments for lumbar spinal stenosis, including nonsteroidal anti-inflammatory drugs, analgesics, muscle relaxants, epidural steroids, physical therapy, and bracing.
• Alternative surgical options including decompressive procedures such as laminotomy, hemilaminotomy, laminectomy, hemilaminectomy, laminoplasty, foraminotomy, and facetectomy. Patients may undergo surgical spinal fusion.

Background

Spinal stenosis is a narrowing of the spinal canal resulting in pressure on the spinal cord and/or nerve roots. The narrowing may involve a small or large area of the spine. Causes can be inherited or acquired and most often result from a gradual, degenerative aging process. The cervical and lumbar spinal regions are generally affected (National Institute of Arthritis and Musculoskeletal and Skin Diseases, 2016). Neurogenic intermittent claudication is a common symptom of lumbar spinal stenosis. It includes weakness, cramping, pain or numbness in the legs, and, in more severe cases, bowel and bladder dysfunction and foot disorders. Lumbar spinal stenosis is a leading preoperative diagnosis in Americans, particularly those who are age 60 or older.

First-line treatments for symptomatic lumbar spinal stenosis include rest, nonsteroidal anti-inflammatory drugs, muscle relaxants, corset use, physical therapy, and lumbar epidural steroid injections. For persons with moderate-to-severe symptoms, surgical decompression, with or without spinal fusion and discectomy, may be indicated. However, they are associated with serious complications and high operative risk, particularly for elderly patients. The effectiveness of nonsurgical treatments, the extent of pain and patient preferences may all factor into the decision to have surgery (National Institute of Arthritis and Musculoskeletal and Skin Diseases, 2016).

Interspinous dynamic stabilization is a minimally invasive technique that implants a titanium spacer or plate between the spinous processes or attaches to the spinous processes affected by stenosis (North American Spine Society, 2011). Interspinous dynamic stabilization achieves sagittal balance and segment stability by widening the spinal canal and decompressing the nerve, thereby reducing pain. Its theoretical advantages are using minimally invasive surgical techniques rather than direct decompression (e.g., laminotomy, laminectomy, or foraminotomy) at the time of insertion, reducing the risk of epidural scarring and cerebrospinal fluid leakage. Unlike conventional fusion that prevents spinal segment movement, interspinous dynamic stabilization restricts spinal movement in the direction that causes pain, while permitting mobility in the other directions, and may be performed alone or with surgical decompression.
Coflex Interlaminar Technology is an interspinous spacer or plate device approved by the U.S. Food and Drug Administration for treating neurogenic intermittent claudication caused by lumbar spinal stenosis between L1 and L5 (Food and Drug Administration, 2017). It is intended for patients with at least moderately impaired physical function who experience relief in flexion from their symptoms of leg, buttock, or groin pain, with or without back pain, and have undergone a regimen of at least six months of unsuccessful nonoperative treatment. Coflex is designed to be implanted midline, between adjacent lamina of one or two contiguous lumbar motion segments after surgical decompression of stenosis at the affected levels, to provide stabilization while preserving normal segmental motion at the treated level. Continued approval of this class III device is contingent upon the submission of periodic reports and the results of post-market studies assessing long-term safety and effectiveness.

**Searches**

Select Health of South Carolina searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on March 16, 2018. Search terms were: “back” (MeSH), “back pain” (MeSH), and “prostheses and implants” (MeSH), along with free text terms “coflex,” “interlaminar stabilization,” and “smoking.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Early studies of the coflex interlaminar stabilization device were based on small samples with relatively short follow-up periods, limiting the ability to derive conclusions regarding the device’s benefits. We examined recent publications for results with a likelihood of greater validity. We have identified two systematic reviews that include an analysis of the coflex device. A systematic review and meta-analysis comparing decompression with either fusion or coflex for lumbar spinal stenosis (Li, 2017) included eight studies in a qualitative synthesis and eight in a meta-analysis. Two of these, the only randomized controlled trials, are based on work with the same cohort. Therefore, seven samples in all were
included. Final follow-up ranged between one and five years after baseline measures. The results showed that combined decompression and coflex was more effective than decompression with fusion in terms of the Oswestry Disability Index; however, heterogeneity resulted in low-quality evidence for seven of the included studies. The improvement was discernible at 6, 12, and 24 months, but there was no perceived difference at 60 months. Five studies reported length of hospital stay and six reported blood loss. Both of those analyses resulted in greater benefit seen with coflex, both at a statistically significant difference. No significant difference was found in scores on the visual analogue scale for back pain or in major device-related complications. Coflex was not inferior in terms of functional clinical outcomes, including Oswestry Disability Index and visual analogue scale pain score. Therefore, the authors found the coflex interlaminar stabilization device to be safe and effective compared with decompression plus fusion for the treatment of lumbar spinal stenosis.

An updated Hayes review (2017) found that coflex may result in similar improvements in pain, disability, function, and quality of life compared with decompression surgery alone or decompression with fusion, and concluded that further research was necessary to identify long-term outcomes and necessity for reoperation rates, biomechanical spinal effects, and optimal patient selection criteria.

The randomized controlled trial with the largest sample and longest follow-up period of which we are aware was included in the Li (2017) and Hayes (2017) analyses. Musacchio (2016) published a report of the five-year outcomes of a 21-site prospective randomized controlled trial which randomized participants with moderate to severe lumbar stenosis at one or two contiguous levels and up to Grade I spondylolisthesis at a 2:1 ratio to either decompression and interlaminar stabilization (n = 215) using the coflex device or decompression combined with fusion (n = 107). Measures were taken at baseline and at six weeks and three, six, 12, 18, 24, 36, 48, and 60 months after surgery. The examined outcomes were chosen according to the Food and Drug Administration four-point success criteria (> 15-point improvement in the Oswestry Disability Index score; absence of reoperation, revision, removal, or supplemental fixation; absence of major device-related complication; and absence of epidural steroid injection after surgery). At five years, the two arms had roughly equivalent findings on the four-point success criteria and on rates of reoperation and revision with no statistically significant difference between the groups (16.3 percent in the decompression with interlaminar stabilization group compared with 17.8 percent in the decompression with fusion group, \( P = .09 \)). However, in a sub-analysis within the two-level cohort at month 60, a higher proportion of the coflex arm achieved success compared with the fusion arm (55.1 percent versus 35.3 percent; borderline statistical significance at \( .05 < P < .065 \)). Both groups had statistically significant improvement through 60 months (> 15 points) in the Oswestry Disability Index score, with the difference between the groups not statistically significant. The visual analog scale, Short Form-12 and Zürich Claudication Questionnaire scores followed a similar pattern of maintained significant improvement throughout follow-up. However, the Short Form-12 and Zürich Claudication Questionnaire scores were higher for the coflex group during early follow up compared with the fusion group, with the difference being statistically significant. Additionally, foraminal height, disc space height, and range of motion at the index level were maintained through five years in the coflex group. The authors concluded that statistically significant improvements on multiple outcome assessments were achieved in both groups and were maintained at the five-year final
measurement. While there were statistically significant differences during early follow-up on some clinical measures favoring the coflex arm, there were no significant differences favoring the fusion arm at any point.

More recently, a German multicenter randomized controlled trial not included in the Li (2017) or the Hayes (2017) review enrolled 115 in a decompression-plus coflex arm and 110 in decompression alone (Schmidt, 2018). At two years, a composite analysis of four items (survivorship, Oswestry Disability Index scores, and absence of neurological deterioration or device- or procedure-related severe adverse events) was statistically superior for the compression plus coflex arm \( (P = .017) \). Additionally, in the coflex arm, there was increased walking distance, decreased compensatory pain management, and maintenance of radiographic foraminal height as compared with the decompression-alone arm. There were no statistically significant differences in one- or two-year survival rates without secondary surgical intervention \( (P = .72) \). Those in the decompression alone group were 228.0 percent more likely to have lumbar injections \( (4.5 \text{ percent for the coflex arm versus 14.8 percent for decompression alone}; P = .0065) \); and more likely to have narcotic use at every follow-up point \( \text{at final 24-month follow-up, narcotic use was 16.7 percent for coflex versus 23 percent for decompression alone; difference not statistically significant} \). At 24 months, the compensatory effect of the narcotics was analyzed through examining leg pain. Narcotic use was associated with no statistically significant difference in leg pain in the coflex arm between participants taking narcotics and those not taking narcotics, while there was a statistically significant difference in leg pain in the decompression-alone group between participants taking narcotics compared with those not taking narcotics. The authors state that this study is the first level one study comparing outcomes between adding an interlaminar stabilization device after decompression surgery and decompression alone. They conclude that decompression combined with the interlaminar stabilization device results in a statistically significant improvement on the four-point validated composite score, increases walking tolerance, decreases compensatory pain management, and maintains foraminal height, thereby extending the durability and sustainability of decompression.

We identified one cost effectiveness study that estimated costs over five years comparing coflex to fusion (Schmier, 2014). Over five years, costs were lower for care for those implanted with coflex compared with those undergoing the fusion procedure. Average Medicare payments were estimated at \$15,182 for coflex compared with \$26,863 for the fusion procedure, a difference of \$11,681 over five years. The mean quality-adjusted life years were higher for patients implanted with coflex compared with controls \( (3.02 \text{ versus 2.97}) \). These results suggest that the coflex device results in more benefit at lower costs than fusion. The cost advantage was greater in an evaluation of commercial insurance payments. Additionally, subgroup analyses showed that the cost advantage for coflex was greater for two-level procedures compared to one-level procedures.

A recommendation from the International Society for the Advancement of Spinal Surgery, specific to coflex, reviews the evidence and finds that in patients with stenosis where a direct surgical decompression has been deemed medically necessary and there is no gross instability \( \text{greater than grade 1} \), non-fusion interlaminar stabilization can provide controlled reliable motion (Guyer, 2016). The International Society for the Advancement of Spine Surgery argues for insurance coverage and provides
suggestions for coverage indications and limitations. These suggested coverage indications and limitations, along with other reviewed literature, provide the basis for this policy.

Comorbidities and risk factors for poor surgical outcomes:

Several patient-level factors, some of them not modifiable, have been associated with spinal surgery outcomes. Diabetes mellitus has been associated with higher postsurgical infection rates (Meng, 2015; Pull ter Gunne, 2012). Well-controlled infection with human immunodeficiency virus, despite a lack of progression to acquired immune deficiency syndrome, is associated with higher rates of adverse events, wound complications, neurologic and respiratory complications, and in-hospital mortality, leading the authors to suggest that providers carefully consider alternatives for this population (Donnally, 2018).

Numerous studies have found obesity to be associated with poor outcomes from spinal surgery, including major medical complications, blood loss, nerve injury, surgical site infection, venous thromboembolism, extended length of surgery, and revision rate (Cao, 2016; Castle-Kirsbaum, 2017; Epstein, 2016; Jiang, 2014; Meng, 2015; Pull ter Gunne, 2012). Morbid obesity, defined as a body mass index equal to or greater than 35 kg/m$^2$ plus two major comorbid factors (e.g., hypertension, diabetes, etc.) or a level of morbidly obese III ($\geq$40 kg/m$^2$), is associated with major perioperative complications and postsurgical wound complications (Epstein, 2017).

Many publications have identified smoking as a risk factor for adverse outcomes of spinal surgery. A dose-related association has been identified between tobacco smoking and surgically treated lumbar spinal stenosis, with poorer rates of union post-fusion surgery. Heavier smokers and those with two levels of fusion experience higher rates of non-union than non- or lighter smokers and those having one level of fusion (Jackson, 2016). Current smoking of those undergoing spinal surgery has been associated with postsurgical cellulitis and deep vein thrombosis, and with poor surgical outcomes, including a higher rate of surgical site infections, post-surgical wound complications, and with a lack of reduction in pain after spinal surgery (Behrend, 2017; Bydon, 2015; Chieng, 2015; Choma, 2011; Elsamadicy, 2017; Kong, 2017; Meng, 2015; Saeedinia, 2015; Xing, 2015). Other researchers have not found smoking to be associated with adverse outcomes of spinal surgery (Bono, 2017; Seo, 2017). Addressing pre-surgical patient smoking may reduce surgical site infections (Blood, 2017). Jackson’s (2016) review of the literature on smoking cessation and spinal surgery concluded that ceasing smoking at least four weeks before elective spinal surgery and refraining from smoking for at least six months after surgery are both associated with numerous benefits, including reduced pain, improved fusion, higher postoperative patient satisfaction, and higher rates of returning to work.

Policy updates:

None.

Summary of clinical evidence:
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schmidt (2018)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td></td>
<td>• In this seven-site German randomized controlled trial, 110 participants received decompression alone, and 115 received decompression along with the coflex device. Participants had diagnoses of moderate-to-severe lumbar spinal stenosis at one or two adjacent segments in sites from L-3 to L-5. Overall, there was 91 percent retention at 24 months of follow-up.</td>
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<td></td>
<td>• The composite score of four items (survivorship, Oswestry Disability Index scores, and absence of neurological deterioration or device- or procedure-related severe adverse events) was statistically superior for the compression-plus coflex arm ((p = 0.017)). Additionally, there was increased walking distance, decreased compensatory pain management, and maintenance of radiographic foraminal height in the coflex arm compared with the decompression-only arm, extending the durability and sustainability of a decompression procedure. Those in the decompression-alone arm were more likely to have a secondary procedure (borderline statistically significant at (p = 0.055)); 228 percent more likely to have lumbar injections (4.5 percent for the coflex arm versus 14.8 percent for decompression alone; (p = 0.0065)); and more likely to have narcotic use at every follow-up point (16.7 percent for coflex versus 23 percent for decompression alone at 24 months). In the coflex arm, foraminal height and disc height were mainly maintained, whereas in the decompression-alone arm, there was a significant decrease at 24 months postoperatively ((p &lt; 0.001)). There was no difference between groups in individual patient-reported outcomes on the Oswestry Disability Index, the visual analog scale, or the Zürich Claudication Questionnaire when they were analyzed individually.</td>
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<tr>
<td>Hayes (2017)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td></td>
<td>• This systematic review of one randomized controlled trial and two prospective cohort studies (46 to 322 total patients per study) is an update of a previous (2016) review.</td>
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<td></td>
<td>• Overall quality: low due to inadequate follow-up time, small sample size; retrospective design; lack of a control group; and heterogeneous patient populations, study designs, treatment protocols, and comparators.</td>
</tr>
<tr>
<td></td>
<td>• Results suggest the coflex device with decompression surgery (laminectomy or laminotomy) may result in similar improvements in pain, disability, function, and quality of life compared with decompression surgery alone or decompression with fusion.</td>
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<tr>
<td></td>
<td>• Adverse events between groups were similar.</td>
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<tr>
<td></td>
<td>• More comparative data are needed to identify long-term reoperation rates, biomechanical effects on the spine, and optimal patient selection criteria.</td>
</tr>
<tr>
<td>Li (2017)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td></td>
<td>• This meta-analysis aimed to investigate whether combining decompression and coflex results in better performance for patients with lumbar spinal stenosis compared with decompression and fusion surgery. Ten studies that compared coflex with fusion surgery were included.</td>
</tr>
<tr>
<td></td>
<td>• The results showed that combined decompression and coflex was more effective than the control procedure in terms of the Oswestry Disability Index, length of hospital stay and blood loss. No significant difference was found in visual analogue scale and major device-related complications.</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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<td><strong>Bae (2016)</strong>&lt;br&gt;Three-year follow-up of the prospective, randomized, controlled trial of coflex interlaminar stabilization vs instrumented fusion in patients with lumbar stenosis.</td>
<td>• Compared with conventional decompression plus fusion surgery, coflex was not inferior in terms of functional clinical outcomes, including Oswestry Disability Index and visual analogue scale pain score. Moreover, coflex showed less blood loss, shorter length of stay, and similar device-related complications compared with decompression plus fusion surgery. Therefore, the coflex interlaminar stabilization device was found to be safe and effective compared with decompression plus fusion for the treatment of lumbar spinal stenosis.</td>
</tr>
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</table>

**Key points:**  
• These data are from the 36-month follow-up point of a prospective, randomized investigational device exemption study conducted at 21 clinical sites in the United States, comparing the coflex device after decompression to fusion after decompression.  
• In the coflex arm (n = 196), 62.2 percent achieved composite clinical success compared with 48.9 percent in the fusion arm (n = 94) (difference = 13.3 percent, 95% confidence interval 1.1 – 25.5, p = 0.03). The Bayesian posterior probabilities for noninferiority (margin = -10 percent) and superiority of coflex versus fusion were > 0.999 and 0.984, respectively.  
• Substantial improvements were observed in both groups for patient-reported outcomes, although the percentage with a clinically significant improvement (≥ 15) in the Oswestry Disability Index appeared larger for the coflex arm (p = 0.008). Radiographic measurements maintained index level and adjacent level range of motion in patients with coflex interlaminar stabilization. However, the range of motion at the level superior to fusion was increased (p = 0.005).  
• Coflex is proven to be effective and durable at improving overall composite clinical success without altering normal spinal kinematic motion at the index level of decompression or adjacent levels for lumbar spinal stenosis, while decompression alone and decompression combined with fusion have potential limitations. |
| **Musacchio (2016)**<br>Evaluation of decompression and Interlaminar Stabilization compared with decompression and fusion for the treatment of lumbar spinal stenosis: 5-year follow-up of a prospective, randomized, controlled trial. | **Key points:**  
• This study compared decompression with either coflex (n = 215) or fusion (n = 107). Five-year follow-up had 91 percent retention.  
• At five years, the two arms were roughly equivalent on the four-point success criteria (50.3 percent of the coflex arm and 44 percent of the fusion arm, no statistically significant difference). Rates of reoperation and revision rates were similar in the two groups (16.3 percent versus 17.8 percent; p > 0.90). Both groups had statistically significant improvement through 60 months in disability scores with 80.6 percent of the coflex arm and 73.2 percent of the fusion arm showing > 15-point improvement (p > 0.30). Visual analog, Short Form-12, and Zurich Caudification Questionnaire scores maintained significant improvement throughout follow-up, while the coflex arm showed superiority on the Short Form-12 and Zurich Caudification Questionnaire during early follow-up compared with fusion. In the coflex group, foraminal height, disc space height, and range of motion at the index level were sustained to five years.  
• There was no significant difference in narcotic use at month 60. |
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Schmier (2014)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td></td>
<td>• Model estimated costs over five years comparing coflex to fusion (control/standard treatment).</td>
</tr>
<tr>
<td></td>
<td>• Over five years, costs were lower for care for those implanted with coflex compared with those undergoing fusion procedure. Average Medicare payments were estimated at $15,182 for coflex compared with $26,863 for the fusion control, a difference of $11,681 over five years. The mean quality-adjusted life years were higher for patients implanted with coflex compared with controls (3.02 versus 2.97).</td>
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<tr>
<td></td>
<td>• Results suggest that coflex device results in more benefit at lower costs than fusion. The cost advantage was greater in evaluation of commercial insurance payments.</td>
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<tr>
<td></td>
<td>• Additionally, subgroup analyses showed that the cost advantage for coflex was greater for two-level procedures compared with one-level procedures.</td>
</tr>
</tbody>
</table>

**References**

**Professional society guidelines/other:**


Peer-reviewed references:


Elsamadicy AA, Adogwa O, Sergesketter A, et al. Reduced impact of smoking status on 30-day complication and readmission rates after elective spinal fusion (>/>=3 Levels) for adult spine deformity: a


National Coverage Determinations:

NCD 150.13. Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis.

Local Coverage Determinations:

L34006 Interspinous Process Decompression. CMS website.

L35094. Services that are not reasonable and necessary.

InterQual

InterQual Clinical Evidence Summary: Lumbar spinal stenosis. 2013.

InterQual Clinical Evidence Summary: Failed back surgery syndrome. 2013.

InterQual 2017 LOC: Outpatient REhabilitatation & chiropractic. Spinal disorders, lumbar: Chiropractic (adult)
**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<td>22867</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level</td>
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<td>22868</td>
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<td>M48.062</td>
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<td>M43.16</td>
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<tr>
<td>C1821</td>
<td>Interspinous process distraction device (implantable)</td>
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