



MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Medical Policy

Interspinous and Interlaminar Stabilization/Distraktion Devices (Spacers)

Table of Contents

- [Policy: Commercial](#)
- [Coding Information](#)
- [Information Pertaining to All Policies](#)
- [Policy: Medicare](#)
- [Description](#)
- [References](#)
- [Authorization Information](#)
- [Policy History](#)

Policy Number: 584

BCBSA Reference Number: 7.01.107

NCD/LCD: NA

Related Policies

- Facet Arthroplasty, #[174](#)
- Interspinous Fixation - Fusion Devices, #[436](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Interspinous or interlaminar distraction devices as a stand-alone procedure are considered [INVESTIGATIONAL](#) as a treatment of spinal stenosis.

Use of an interlaminar stabilization device following decompressive surgery is considered [INVESTIGATIONAL](#).

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is not a covered service.
Commercial PPO and Indemnity	This is not a covered service.
Medicare HMO Blue SM	This is not a covered service.
Medicare PPO Blue SM	This is not a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code 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 as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

CPT Codes

CPT codes:	Code Description
22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level
22870	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)

HCPCS Codes

HCPCS codes:	Code Description
C1821	Interspinous process distraction device (implantable)

Description

Spinal Stenosis

Lumbar spinal stenosis (LSS), which affects over 200,000 people in the United States, involves a narrowed central spinal canal, lateral spinal recesses, and/or neural foramina, resulting in pain as well as limitation of activities such as walking, traveling, and standing. In adults over 60 in the United States, spondylosis (degenerative arthritis affecting the spine) is the most common cause. The primary symptom of LSS is neurogenic claudication with back and leg pain, sensory loss, and weakness in the legs. Symptoms are typically exacerbated by standing or walking and relieved with sitting or flexion at the waist.

Some sources describe the course of LSS as “progressive” or “degenerative,” implying that neurologic decline is the usual course. Longer term data from the control groups of clinical trials as well as from observational studies suggest that, over time, most patients remain stable, some improve, and some deteriorate.^{1, 2}

The lack of a valid classification for LSS contributes to wide practice variation and uncertainty about who should be treated surgically and which surgical procedure is best for each patient.^{3, 4} This uncertainty also complicates research on spinal stenosis, particularly the selection of appropriate eligibility criteria and comparators.⁵

Treatment

Appropriate surgical treatments for patients with spinal stenosis not responding to conservative treatments include decompression with or without spinal fusion. There are many types of decompression surgery and types of fusion operations. In general, spinal fusion is associated with more complications

and a longer recovery period and, in the past, was generally reserved for patients with spinal deformity or moderate grade spondylolisthesis.

Conservative treatment for spinal stenosis may include physical therapy, pharmacotherapy, epidural steroid injections, and many other modalities.⁶ The terms “nonsurgical” and “nonoperative” have also been used to describe conservative treatment. Professional societies recommend that surgery for LSS should be considered only after a patient fails to respond to conservative treatment, but there is no agreement about what constitutes an adequate course or duration of treatment.

The term “conservative management” may refer to “usual care” or to specific programs of nonoperative treatment, which use defined protocols for the components and intensity of conservative treatments, often in the context of an organized program of coordinated, multidisciplinary care. The distinction is important in defining what constitutes a failure of conservative treatment and what comparators should be used in trials of surgical vs nonsurgical management. The rationale for surgical treatment of symptomatic spinal stenosis rests on the Spine Patient Outcomes Research Trial (SPORT), which found that patients who underwent surgery for spinal stenosis and spondylolisthesis had better outcomes than those treated nonoperatively. The SPORT investigators did not require a specified program of nonoperative care but rather let each site decide what to offer.⁸ These findings provide some support for the view that, in clinical trials, patients who did not have surgery may have had suboptimal treatment, which can lead to a larger difference favoring surgery. The SPORT investigators asserted that their nonoperative outcomes represented typical results at a multidisciplinary spine center at the time, but recommended that future studies compare the efficacy of specific nonoperative programs to surgery.

A recent trial by Delitto et al (2015) compared surgical decompression with a specific therapy program emphasizing physical therapy and exercise.⁹ Patients with lumbar spinal stenosis and from 0 to 5 mm of slippage (spondylolisthesis) who were willing to be randomized to decompression surgery vs an intensive, organized program of nonsurgical therapy were eligible. Oswestry Disability Index scores were comparable to those in the SPORT trial. A high proportion of patients assigned to nonsurgical care (57%) crossed over to surgery (in SPORT the proportion was 43%), but crossover from surgery to nonsurgical care was minimal. When analyzed by treatment assignment, Oswestry Disability Index scores were similar in the surgical and nonsurgical groups after 2 years of follow-up. The main implication is that about one-third of patients who were deemed candidates for decompression surgery but instead entered an intensive program of conservative care achieved outcomes similar to those of a successful decompression.¹⁰

Diagnostic criteria for fusion surgery are challenging because patients without spondylolisthesis and those with grade 1 spondylolisthesis are equally likely to have predominant back pain or predominant leg pain.¹¹ The SPORT trial did not provide guidance on which surgery is appropriate for patients who do not have spondylolisthesis, because nearly all patients with spondylolisthesis underwent fusion whereas nearly all those who did not have spondylolisthesis underwent decompression alone. In general, patients with predominant back pain have more severe symptoms, worse function, and less improvement with surgery (with or without fusion). Moreover, because back pain improved to the same degree for the fused spondylolisthesis patients as for the unfused spinal stenosis patients at 2 years, the SPORT investigators concluded that it was unlikely that fusion led to the better surgical outcomes in patients with spondylolisthesis than those with no spondylolisthesis.^{12, 13}

Throughout the 2000s, decompression plus fusion became more widely used until, in 2011, it surpassed decompression alone as a surgical treatment for spinal stenosis.^{14, 15, 16} However, in 2016, findings from two randomized trials of decompression alone vs decompression plus fusion were published. The Swedish Spinal Stenosis Study (SSSS) found no benefit of fusion plus decompression compared with decompression alone in patients who had spinal stenosis with or without degenerative spondylolisthesis.¹⁷ The Spinal Laminectomy versus Instrumented Pedicle Screw (SLIP) trial found a small but clinically meaningful improvement in the Physical Component Summary score of the 36-Item Short-Form Health Survey but no change in Oswestry Disability Index scores at 2, 3, and 4 years in patients who had spinal stenosis with grade 1 spondylolisthesis (3-14 mm).¹⁸ The patients in SLIP who had laminectomy alone had higher reoperation rates than those in SSSS, and the patients who

underwent fusion had better outcomes in SLIP than in SSSS. While some interpret the studies to reflect differences in patient factors—in particular, SSSS but not SLIP included patients with no spondylolisthesis, the discrepancy may also be influenced by factors such as time of follow-up or national practice patterns.^{19, 20, 21, 22, 23, 24} As Pearson (2016) noted, it might have been helpful to have patient-reported outcome data on the patients before and after reoperation, to see whether the threshold for reoperation differed in the 2 settings.²⁵ A small trial conducted in Japan, Inose et al (2018) found no difference in patient-reported outcomes between laminectomy alone and laminectomy plus posterolateral fusion in patients with 1-level spinal stenosis and grade 1 spondylolisthesis; about 40% of the patients also had dynamic instability.²⁶ Certainty in the findings of this trial is limited because of its size and methodologic flaws.

Spacer Devices

Investigators have sought less invasive ways to stabilize the spine and reduce the pressure on affected nerve roots, including interspinous and interlaminar implants (spacers). These devices stabilize or distract the adjacent lamina and/or spinous processes and restrict extension in patients with lumbar spinal stenosis and neurogenic claudication.

Other types of dynamic posterior stabilization devices are pedicle screw/rod-based devices and total facet replacement systems; they are not discussed in this evidence review.

Interspinous Implants

Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract the neural foramina and decompress the nerves. One type of interspinous implant is inserted between the spinous processes through a small (4-8 cm) incision and acts as a spacer between the spinous processes, maintaining 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 Spacers

Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization either following decompression surgery or as an alternative to decompression surgery. Interlaminar spacers have 2 sets of wings placed around the inferior and superior spinous processes. They may also be referred to as interspinous U. These implants aim to restrict painful motion while enabling normal motion. The devices (spacers) distract the lamina space and/or spinous processes and restrict extension. This procedure theoretically enlarges the neural foramen and decompresses the cauda equina in patients with spinal stenosis and neurogenic claudication.

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. 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 either following decompression surgery or as an alternative to decompression surgery.

The following conclusions are based on a review of the evidence, including, but not limited to, published evidence and clinical expert opinion, via BCBSA's Clinical Input Process.

For individuals who have spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis who receive an interspinous or interlaminar spacer as a stand-alone procedure, the evidence includes 2 randomized controlled trials of 2 spacers (Superior Interspinous Spacer, coflex interlaminar implant). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Overall, the use of interspinous or interlaminar distraction devices (spacers) as an alternative to spinal

decompression has shown a high failure and complication rates. A pivotal trial compared the Superior Interspinous Spacer with the X-STOP (which is no longer marketed), without conservative care or standard surgery comparators. The trial reported significantly better outcomes with the Superior Interspinous Spacer on some measures. For example, the trial reported more than 80% of patients experienced improvements in certain quality of life outcome domains. Interpretation of this trial is limited by questions about the number of patients used to calculate success rates, the lack of efficacy of the comparator, and the lack of an appropriate control group treated by surgical decompression. The coflex interlaminar implant (formerly called the interspinous U) was compared with decompression in the multicenter, double-blind Foraminal Enlargement Lumbar Interspinous distraX ion trial. Functional outcomes and pain levels were similar in the 2 groups at 1-year follow-up, but reoperation rates due to the absence of recovery were substantially higher with the coflex implant (29%) than with bony decompression (8%). For patients with 2-level surgery, the reoperation rate was 38% for coflex and 6% for bony decompression. At 2 years, reoperations due to the absence of recovery had been performed in 33% of the coflex group and 8% of the bony decompression group. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis who receive an interlaminar spacer with spinal decompression surgery, the evidence includes randomized controlled trials and nonrandomized comparative studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Use of the coflex interlaminar implant as a stabilizer after surgical decompression has been studied in 2 situations as an adjunct to decompression compared with decompression alone (superiority) and as an alternative to spinal fusion after decompression (noninferiority). In a randomized controlled trial conducted in a patient population with moderate-to-severe lumbar spinal stenosis with significant back pain and up to grade 1 spondylolisthesis, there was no difference in the primary outcome measure, the Oswestry Disability Index (ODI), between the patients treated with coflex plus decompression vs. decompression alone. "Composite clinical success" (CCS), defined as a minimum 15-point improvement in ODI score, no reoperations, no device-related complications, no epidural steroid injections in the lumbar spine, and no persistent new or worsening sensory or motor deficit, was used to assess superiority. A greater proportion of patients who received coflex plus decompression instead of decompression alone achieved the composite endpoint. However, the superiority of coflex plus decompression is uncertain because the difference in the CCS was primarily driven by a greater proportion of patients in the control arm who received a secondary rescue epidural steroid injection. Because the trial was open-label, surgeons' decision to use epidural steroid injection could have been affected by their knowledge of the patient's treatment. Consequently, including this component in the composite clinical success measure might have overestimated the potential benefit of treatment. This bias could have been mitigated using protocol-mandated standard objective clinical criteria to guide decisions about secondary interventions and subsequent adjudication of these events by an independent blinded committee. Greater certainty about the net health outcome of adding coflex to decompression surgery might be demonstrated when the 5-year follow-up results of these trials and an ongoing trial (NCT02555280) on decompression with and without the coflex implant in the United States are published. To be useful for clinical decision-making, this study should report the patient-reported effectiveness measures for both back pain (ODI and/or back visual analog scale) and the claudication (Zurich Claudication Questionnaire and/or leg visual analog scale) in all patients at 5 years.

For decompression with coflex vs decompression with spinal fusion, the pivotal randomized controlled trial, conducted in a patient population with spondylolisthesis no greater than grade 1 and significant back pain, showed that stabilization of decompression with the coflex implant was noninferior to decompression with spinal fusion for the composite clinical success measure. However, there is uncertainty about the net benefit of routinely adding spinal fusion to decompression in patients with no or low-grade spondylolisthesis. Therefore, demonstrating the noninferiority of coflex plus spinal decompression vs spinal decompression plus fusion, a comparator whose benefit on health outcomes is uncertain, makes it difficult to apply the results of the study.

Clinical input supplements and informs the interpretation of the published evidence. Clinical input respondents were mixed in the level of support of this indication. While some of the expert opinion supported a potential benefit in carefully selected individuals, other experts were not confident of a clinically meaningful benefit or use in generally accepted medical practice, citing long-term complications

leading to removal of the device. Some clinical input suggested that spacers may have utility in patients who are high risk for general anesthesia. Consideration of existing studies as indirect evidence regarding the outcomes of using spacers in this subgroup is limited by substantial uncertainty regarding the balance of potential benefits and harms. The main source of uncertainty about the benefits versus risks of using coflex plus laminectomy in patients who are not able to have general anesthesia is whether revisions, removals, and other secondary surgical procedures can be conducted safely if they are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
2/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
7/2018	New references added from BCBSA National medical policy. Summary clarified.
6/1/2017	BCBSA National medical policy review. Policy statements edited for clarity. The intent of the policy is unchanged.
1/2017	Clarified coding information for the 2017 code changes.
5/2016	New references added from BCBSA National medical policy.
6/2015	New references added from BCBSA National medical policy.
9/2014	New references added from BCBSA National medical policy.
11/2013	BCBSA National medical policy review. New investigational indications described; interlaminar stabilization added to title. Effective 11/1/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
1/2012	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
12/14/2011	New policy describing non-covered indications. Effective 12/14/2011.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

References

1. Lurie J, Tomkins-Lane C. Management of lumbar spinal stenosis. *BMJ*. 2016;352:h6234.
2. Lurie JD, Tosteson TD, Tosteson A, et al. Long-term outcomes of lumbar spinal stenosis: eight-year results of the Spine Patient Outcomes Research Trial (SPORT). *Spine (Phila Pa 1976)*. 2015;40(2):63-76.
3. Schroeder GD, Kurd MF, Vaccaro AR. Lumbar spinal stenosis: How is it classified? *The Journal of the American Academy of Orthopaedic Surgeons*. 2016;24(12):843-852.
4. Haig AJ, Tomkins CC. Diagnosis and management of lumbar spinal stenosis. *Jama*. 2010;303(1):71-72.
5. Genevay S, Atlas SJ, Katz JN. Variation in eligibility criteria from studies of radiculopathy due to a herniated disc and of neurogenic claudication due to lumbar spinal stenosis: a structured literature review. *Spine (Phila Pa 1976)*. 2010;35(7):803-811.
6. Chou R, Deyo R, Friedly J, et al. Nonpharmacologic therapies for low back pain: a systematic review for an American College of Physicians Clinical Practice Guideline. *Ann Intern Med*. 2017;166(7):493-505.
7. Birkmeyer NJ, Weinstein JN, Tosteson AN, et al. Design of the Spine Patient Outcomes Research Trial (SPORT). *Spine (Phila Pa 1976)*. 2002;27(12):1361-1372.

8. Fritz JM, Lurie JD, Zhao W, et al. Associations between physical therapy and long-term outcomes for individuals with lumbar spinal stenosis in the SPORT study. *The spine journal : official journal of the North American Spine Society*. 2014;14(8):1611-1621.
9. Delitto A, Piva SR, Moore CG, et al. Surgery versus nonsurgical treatment of lumbar spinal stenosis: a randomized trial. *Ann Intern Med*. 2015;162(7):465-473.
10. Katz JN. Surgery for lumbar spinal stenosis: informed patient preferences should weigh heavily. *Ann Intern Med*. 2015;162(7):518-519.
11. Pearson A, Blood E, Lurie J, et al. Predominant leg pain is associated with better surgical outcomes in degenerative spondylolisthesis and spinal stenosis: results from the Spine Patient Outcomes Research Trial (SPORT). *Spine (Phila Pa 1976)*. 2011;36(3):219-229.
12. Pearson A, Blood E, Lurie J, et al. Degenerative spondylolisthesis versus spinal stenosis: does a slip matter? Comparison of baseline characteristics and outcomes (SPORT). *Spine (Phila Pa 1976)*. 2010;35(3):298-305.
13. Abdu WA, Lurie JD, Spratt KF, et al. Degenerative spondylolisthesis: does fusion method influence outcome? Four-year results of the spine patient outcomes research trial. *Spine (Phila Pa 1976)*. 2009;34(21):2351-2360.
14. Deyo RA, Mirza SK, Martin BI, Kreuter W, Goodman DC, Jarvik JG. Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. *Jama*. 2010;303(13):1259-1265.
15. Dartmouth Institute. Variation in the care of surgical conditions: spinal stenosis. 2014.
16. Yoshihara H, Yoneoka D. National trends in the surgical treatment for lumbar degenerative disc disease: United States, 2000 to 2009. *The spine journal : official journal of the North American Spine Society*. 2015;15(2):265-271.
17. Forsth P, Olafsson G, Carlsson T, et al. A randomized, controlled trial of fusion surgery for lumbar spinal stenosis. *The New England journal of medicine*. 2016;374(15):1413-1423.
18. Ghogawala Z, Dziura J, Butler WE, et al. Laminectomy plus fusion versus laminectomy alone for lumbar spondylolisthesis. *The New England journal of medicine*. 2016;374(15):1424-1434.
19. Peul WC, Moojen WA. Fusion surgery for lumbar spinal stenosis letter.. *The New England journal of medicine*. 2016;375(6):601.
20. El Tecle NE, Dahdaleh NS. Fusion surgery for lumbar spinal stenosis letter.. *The New England journal of medicine*. 2016;375(6):597.
21. Forsth P, Michaelsson K, Sanden B. Fusion surgery for lumbar spinal stenosis letter.. *The New England journal of medicine*. 2016;375(6):599-600.
22. Su BW, Vaccaro AR. Fusion surgery for lumbar spinal stenosis letter.. *The New England journal of medicine*. 2016;375(6):597-598.
23. Vasudeva VS, Chi JH. Fusion surgery for lumbar spinal stenosis letter.. *The New England journal of medicine*. 2016;375(6):598.
24. Dijkerman ML, Overvest GM, Moojen WA, Vleggeert-Lankamp CLA. Decompression with or without concomitant fusion in lumbar stenosis due to degenerative spondylolisthesis: a systematic review. *Eur Spine J*. 2018;27(7):1629-1643.
25. Pearson AM. Fusion in degenerative spondylolisthesis: how to reconcile conflicting evidence. *J Spine Surg*. 2016;2(2):143-145.
26. Inose H, Kato T, Yuasa M, et al. Comparison of decompression, decompression plus fusion, and decompression plus stabilization for degenerative spondylolisthesis: a prospective, randomized study. *Clin Spine Surg*. 2018;31(7):E347-E352.
27. Food and Drug Administration. Premarket Approval Application: coflex® Interlaminar Technology (P110008). 2012; https://www.accessdata.fda.gov/cdrh_docs/pdf11/P110008a.pdf. Accessed May 18, 2018.
28. Patel VV, Whang PG, Haley TR, et al. Superior Interspinous Process Spacer for intermittent neurogenic claudication secondary to moderate lumbar spinal stenosis: two-year results from a randomized controlled FDA-IDE pivotal trial. *Spine (Phila Pa 1976)*. 2015;40(5):275-282.
29. Patel VV, Nunley PD, Whang PG, et al. Superior((R)) InterSpinous Spacer for treatment of moderate degenerative lumbar spinal stenosis: durable three-year results of a randomized controlled trial. *Journal of pain research*. 2015;8:657-662.
30. Nunley PD, Patel VV, Orndorff DG, Lavelle WF, Block JE, Geisler FH. Superior interspinous spacer treatment of moderate spinal stenosis: 4-year results. *World neurosurgery*. 2017;104:279-283.

31. Nunley PD, Patel VV, Orndorff DG, Lavelle WF, Block JE, Geisler FH. Five-year durability of stand-alone interspinous process decompression for lumbar spinal stenosis. *Clinical interventions in aging*. 2017;12:1409-1417.
32. Moojen WA, Arts MP, Jacobs WC, et al. Interspinous process device versus standard conventional surgical decompression for lumbar spinal stenosis: randomized controlled trial. *BMJ*. 2013;347:f6415.
33. Moojen W, Arts M, Jacobs W, et al. The Felix Trial: clinical results after one year and subgroup analysis: Introducing new implants and imaging techniques for lumbar spinal stenosis doctoral dissertation., Universiteit Leiden; 2014;69-90.
34. Moojen WA, Arts MP, Jacobs WC, et al. IPD without bony decompression versus conventional surgical decompression for lumbar spinal stenosis: 2-year results of a double-blind randomized controlled trial. *Eur Spine J*. 2015;24(10):2295-2305.
35. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): coflex Interlaminar Technology. 2012; https://www.accessdata.fda.gov/cdrh_docs/pdf11/P110008b.pdf. Accessed May 18, 2018.
36. Davis RJ, Errico TJ, Bae H, Auerbach JD. Decompression and Coflex interlaminar stabilization compared with decompression and instrumented spinal fusion for spinal stenosis and low-grade degenerative spondylolisthesis: two-year results from the prospective, randomized, multicenter, Food and Drug Administration Investigational Device Exemption trial. *Spine (Phila Pa 1976)*. 2013;38(18):1529-1539.
37. Davis R, Auerbach JD, Bae H, Errico TJ. Can low-grade spondylolisthesis be effectively treated by either coflex interlaminar stabilization or laminectomy and posterior spinal fusion? Two-year clinical and radiographic results from the randomized, prospective, multicenter US investigational device exemption trial: clinical article. *Journal of neurosurgery Spine*. 2013;19(2):174-184.
38. Bae HW, Laurysen C, Maislin G, Leary S, Musacchio MJ, Jr. Therapeutic sustainability and durability of coflex interlaminar stabilization after decompression for lumbar spinal stenosis: a four year assessment. *International journal of spine surgery*. 2015;9:15.
39. Musacchio MJ, Laurysen C, Davis RJ, et al. 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. *International journal of spine surgery*. 2016;10:6.
40. Bae HW, Davis RJ, Laurysen C, Leary S, Maislin G, Musacchio MJ, Jr. Three-year follow-up of the prospective, randomized, controlled trial of coflex interlaminar stabilization vs instrumented fusion in patients with lumbar stenosis. *Neurosurgery*. 2016;79(2):169-181.
41. Simon RB, Dowe C, Grinberg S, Cammisa FP, Abjornson C. The 2-Level Experience of Interlaminar Stabilization: 5-Year Follow-Up of a Prospective, Randomized Clinical Experience Compared to Fusion for the Sustainable Management of Spinal Stenosis. *International journal of spine surgery*. 2018;12(4):419.
42. Abjornson C, Yoon B-JV, Callanan T, Shein D, Grinberg S, Cammisa FP. Spinal stenosis in the absence of spondylolisthesis: can interlaminar stabilization at single and multi-levels provide sustainable relief? *International journal of spine surgery*. 2018;12(1):64-69.
43. Schmidt S, Franke J, Rauschmann M, Adelt D, Bonsanto MM, Sola S. Prospective, randomized, multicenter study with 2-year follow-up to compare the performance of decompression with and without interlaminar stabilization. *Journal of neurosurgery Spine*. 2018:1-10.
44. Lachin JM. Fallacies of last observation carried forward analyses. *Clinical trials*. 2016;13(2):161-168.
45. Röder C, Baumgartner B, Berlemann U, Aghayev E. Superior outcomes of decompression with an interlaminar dynamic device versus decompression alone in patients with lumbar spinal stenosis and back pain: a cross registry study. *Eur Spine J*. 2015;24(10):2228-2235.
46. Crawford CH, 3rd, Glassman SD, Mummaneni PV, Knightly JJ, Asher AL. Back pain improvement after decompression without fusion or stabilization in patients with lumbar spinal stenosis and clinically significant preoperative back pain. *Journal of neurosurgery Spine*. 2016;25(5):596-601.
47. Richter A, Schutz C, Hauck M, Halm H. Does an interspinous device (Coflex) improve the outcome of decompressive surgery in lumbar spinal stenosis? One-year follow up of a prospective case control study of 60 patients. *Eur Spine J*. 2010;19(2):283-289.
48. Richter A, Halm HF, Hauck M, Quante M. Two-year follow-up after decompressive surgery with and without implantation of an interspinous device for lumbar spinal stenosis: a prospective controlled study. *Journal of spinal disorders & techniques*. 2014;27(6):336-341.

49. Tian NF, Wu AM, Wu LJ, et al. Incidence of heterotopic ossification after implantation of interspinous process devices. *Neurosurgical focus*. 2013;35(2):E3.
50. Lee N, Shin DA, Kim KN, et al. Paradoxical radiographic changes of Coflex Interspinous device with minimum 2-year follow-up in lumbar spinal stenosis. *World neurosurgery*. 2016;85:177-184.
51. Guyer RD, Musacchio MJ, Cammisa FP, Lorio MP. ISASS recommendations/coverage criteria for decompression with interlaminar stabilization - coverage indications, limitations, and/or medical necessity. *International journal of spine surgery*. 2016;10:Article 41.
52. North American Spine Society. NASS Coverage Policy Recommendations: Lumbar interspinous device without fusion & with decompression. Burr Ridge, IL: NASS; 2018.
53. Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine (Phila Pa 1976)*. 2009;34(10):1066-1077.
54. Chou R, Baisden J, Carragee EJ, Resnick DK, Shaffer WO, Loeser JD. Surgery for low back pain: a review of the evidence for an American Pain Society Clinical Practice Guideline. *Spine (Phila Pa 1976)*. 2009;34(10):1094-1109.
55. National Institute for Health and Care Excellence. Interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication IPG365.. 2010; <https://www.nice.org.uk/guidance/IPG365>. Accessed May 18, 2018.