02-20000-36

Original Effective Date: 07/15/08

Reviewed: 12/08/23

Revised: 03/15/24

Subject: Interspinous and Interlaminar Stabilization/Distraction (Spacers) and Fixation (Fusion) Devices

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Interspinous and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension to reduce pain in those 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 the adjacent lamina and spinous processes to provide dynamic stabilization either following decompression surgery or as an alternative to decompression surgery.

Interspinous fixation (fusion) devices are being developed to aid in the stabilization of the spine. They are evaluated as alternatives to pedicle screw and rod constructs in combination with interbody fusion. Interspinous fixation devices (IFDs) are also being evaluated for stand-alone use in individuals with spinal stenosis and/or spondylolisthesis.

POSITION STATEMENT:

Interspinous and interlaminar distraction devices are considered **experimental or investigational** for all indications, including as treatment of spinal stenosis.

Interlaminar stabilization devices used alone, or following decompressive surgery is considered **experimental or investigational**.

Interspinous fixation (fusion) devices are considered **experimental or investigational** for any indication, including but not limited to use in combination with interbody fusion, or used alone for decompression to treat spinal stenosis.

There is insufficient clinical evidence in the peer reviewed literature demonstrating the safety and efficacy of these procedures, or demonstrating the effects of these procedures on long-term health outcomes.

BILLING/CODING INFORMATION:

The following codes may be used to describe distraction devices:

CPT Coding

22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level **(Investigational)**
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) **(Investigational)**
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level **(Investigational)**
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) **(Investigational)**

HCPCS Coding

C1821	Interspinous process distraction device (implantable) **(Investigational)**

There are no specific CPT codes for insertion of interspinous fixation (fusion) devices.

REIMBURSEMENT INFORMATION:

Refer to sections entitled **POSITION STATEMENT** and **PROGRAM EXCEPTIONS**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

DEFINITIONS:

Neural foramen: the passage formed by the inferior and superior notches on the pedicles of adjacent vertebrae; it transmits a spinal nerve and vessels.

Neurogenic claudication: a type of claudication that is accompanied by pain and paresthesias in the back, buttocks, and lower limbs and is relieved by stooping or sitting. The usual cause is a mechanical disturbance due to posture, and a rare cause is ischemia of the cauda equina.

Spinal stenosis: narrowing of the vertebral canal, nerve root canals, or intervertebral foramina of the lumbar spine caused by encroachment of bone upon the space; symptoms are caused by compression of the cauda equina and include pain, paresthesias, and neurogenic claudication. The condition may be either congenital or due to spinal degeneration.

RELATED GUIDELINES:

Total Facet Arthroplasty, 02-20000-37

OTHER:

Index terms:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

- Affix™ Next Gen Spinous Process Plate System
- Affix II and Affix II Mini Spinous Process Plating System
- Aileron™ Interspinous Fixation System
- Aperius® PercLID System
- Aspen™ MIS Fusion System
- Aspen Spinous Process Fixation System
- Aurora Spine ZIP™ MIS Interspinous Fusion System
- Axle™ Interspinous Fusion System
- BacFuse® Spinous Process Fusion Plate
- BioFlex intervertebral stabilization device
- BridgePoint™ Spinous Process Fixation System
- CD HORIZON SPIRE Z Spinal System or plate
- CD Horizon Agile Dynamic Stabilization Device
- coflex® Interlaminar Technology implant
- coflex-F® Implant System
- CoRoent Extensure
- DIAM™ Spinal Stabilization System
- DSS Dynamic Soft Stabilization System
- Dynabolt Dynamic Stabilization System
- Dynesys Spinal System
- ExtenSure

- Falena® Interspinous Decompression Device
- FLEXUS™
- Helifix Interspinous Spacer System
- In-Space
- Inspan™
- Interbridge Interspinous Posterior Fixation System
- Isobar Spinal System
- Minuteman™ Interspinous Interlaminar Fusion Device
- NFix®
- NL-Prow™ Interspinous Spacer
- PrimaLOK™ SP Interspinous Fusion System
- Octave™
- Satellite Spinal System
- Spire™ MIS Spinal Fixation System
- Stabilimax NZ Dynamic Spine Stabilization System
- Stabilink MIS Interspinous Fixation Device
- Stenofix
- Superion™ ISS Interspinous Spacer
- SP-Fix™ Spinous Process Fixation Plate
- VertiFlex®
- X-STOP® Interspinous Process Decompression System (IPD®)
- X-STOP® PEEK Interspinous Process Decompression (IPD®)
- Wallis® System
- Zip Mis Interspinous Fusion System
- Zodiak DynaMo System

REFERENCES:

1. AHRQ National Guideline Clearinghouse. Guideline Summary 10647: Low back pain medical treatment guidelines. Colorado Division of Workers' Compensation. Denver (CO): Colorado Division of Workers' Compensation; 2014 Feb 3.
2. American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) Joint Section on the Disorders of the Spine and Peripheral Nerves (DSPS): Comments on NASS Coverage Policy Recommendations on Lumbar Interspinous Device without Fusion and Decompression.
3. American Society of Pain and Neuroscience (ASPN). ASPN Position Statement: Appropriate Performance of Minimally Invasive Surgical Procedures 10/21). Accessed at https://aspnpain.com/aspn-position-statement-appropriate-performance-of-minimally-invasive-surgical-procedures/.

4. Antony A, Stevenson J, Trimble T, Block J. Perspective: A Proposed Diagnostic and Treatment Algorithm for Management of Lumbar Spinal Stenosis: An Integrated Team Approach. Pain Physician. 2022 Dec;25(9):E1467-E1474.

5. Badve SA, Kurra S, Geisler FH, Metkar U, Tallarico R, Lavelle W. Nerve Root Sedimentation Sign: Can It Predict the Success for Surgical Intervention in Patients With Symptomatic Lumbar Spinal Stenosis? Cureus. 2020 Aug 17;12(8):e9803. doi: 10.7759/cureus.9803.

6. Bae HW, Lauryssen 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. Int J Spine Surg. 2015 May 11;9:15.

7. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.107 -- Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers), 05/23.

8. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.138 -- Interspinous Fixation (Fusion) Devices, 05/21.

9. Boston Scientific Corporation. Vertiflex™Procedure: Superion™ Indirect Decompression System. Value Dossier For The Implantation Of An InterSpinous Spacer (ISS) (October 27, 2021).

10. Brussee P, Hauth J, Donk RD, et al. Self-rated evaluation of outcome of the implantation of interspinous process distraction (X-Stop) for neurogenic claudication. Eur Spine J 2007 Oct 31.

11. Byun DH, et al. Finite element analysis of the biomechanical effect of coflex™ on the lumbar spine. Korean J Spine. 2012 Sep;9(3):131-6.

12. Cairns K, Deer T, Sayed D, van Noort K, Liang K. Cost-effectiveness and Safety of Interspinous Process Decompression (Superion). Pain Med. 2019 Dec 1;20(Suppl 2):S2-S8. doi: 10.1093/pm/pnz245.

13. California Technology Assessment Forum (CTAF). An Interspinous Distractor (X STOP) For The Treatment of Spinal Stenosis of The Lumbar Spine. (06/21/06).

14. Celik H, Derincek A, Kosal I. Surgical Treatment of the Spinal Stenosis with an Interspinous Distraction Device: Do We Really Restore the Foraminal Height? Turkish Neurosurgery 2012, Vol: 22, No: 1, 50-54.

15. Centers for Medicare & Medicaid (CMS). Local Coverage Determination (LCD) for Interspinous Process Decompression (L34006) (10/01/15) (Retired 04/01/20).

16. Che W, et al. Single-Level Rigid Fixation Combined with Coflex: A Biomechanical Study. Med Sci Monit. 2016 Mar 29;22:1022-7.

17. Chen M, Tang H, Shan J, Chen H, Jia P, Bao L, Feng F, Shi G, Wang R. A new interspinous process distraction device BacFuse in the treatment of lumbar spinal stenosis with 5 years follow-up study. Medicine (Baltimore). 2020 Jun 26;99(26):e20925. doi: 10.1097/MD.0000000000020925.

18. Chin KR, Pencle FJR, Benny A, Seale JA. Greater than 5-year follow-up of outpatient L4-L5 lumbar interspinous fixation for degenerative spinal stenosis using the INSPAN device. J Spine Surg. 2020 Sep;6(3):549-554. doi: 10.21037/jss-20-547.

19. Chou R, Loeser JB et al. Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain: An Evidence-Based Clinical Practice Guideline from the American Pain Society. SPINE Volume 34, Number 10, pp 1066–1077 ©2009.

20. Chou R, Huffman LH. Guideline for the Evaluation and Management of Low Back Pain: Evidence Review. American Pain Society, Publisher, Glenview, IL. © American Pain Society, 2009.

21. ClinicalTrials.gov. A 5-year Superion™ IDS Clinical Outcomes Post-Approval Evaluation (SCOPE). Identifier: NCT04192591. Verified by Boston Scientific Corporation, February 2024.

22. Clinical Trials.gov. Effects of XSTOP® Versus Laminectomy Study (EXELS). Identifier: NCT00558129 Verified by Kyphon, November 2007.

23. Clinical Trials.gov. Long-Term Outcomes for Lumbar Spinal Stenosis Patients Treated with X STOP®. Identifier: NCT00534092. Verified by Kyphon, July 2011. Last updated 02/16/12 with study results.

24. Clinical Trials.gov. Treatment of Lumbar Spinal Stenosis; Comparison of Two Different Surgical Methods; X-Stop (LSSS). Identifier: NCT00546949. Verified by Norwegian University of Science and Technology, October 2007.

25. Clinical Trials.gov. Post-Approval Clinical Trial Comparing the Long Term Safety and Effectiveness Coflex vs. Fusion to Treat Lumbar Spinal Stenosis. Identifier: NCT00534235. Verified by Paradigm Spine, November 2012.

26. Clinical Trials.gov. A Randomized Controlled Trial Comparing Surgical Decompression With an Interlaminar Implant in Patients With Intermittent Neurogenic Claudication Caused by Lumbar Stenosis (FELIX). Identifier: NCT01727752. Verified by Paradigm Spine, November 2012.

27. ClinicalTrials.gov. Efficacy of the Aspen Spinous Process System in Anterior Lumbar Interbody Fusion (ALIF). Identifier: NCT01016314. Verified by Biomet, Inc.: December 2013.

28. ClinicalTrials.gov. An Evaluation of Interlaminar Lumbar Instrumented (ILIF™). Identifier: NCT01019057. Verified by NuVasive: July 2014.

29. ClinicalTrials.gov. Clinical Trial Comparing Decompression With and Without Coflex™ Interlaminar Technology Treating Lumbar Spinal Stenosis. Identifier: NCT01316211. Verified by Paradigm Spine (October 2016).

30. ClinicalTrials.gov. The Coflex®COMMUNITY Study: An Observational Study of Coflex® Interlaminar Technology. Identifier: NCT02457468. Verified by Predicted, Reported and Observed Outcomes Foundation (December 2016),

31. ClinicalTrials.gov. Post-Approval 'Real Conditions of Use' Study (PAS003). Identifier: NCT02555280. Verified by Paradigm Spine (October 2016).

32. ClincalTrials.gov. A 5-year Superion™ IDS Clinical Outcomes Post-Approval Evaluation (SCOPE). Identifier: NCT04192591. Sponsor: Boston Scientific Corporation (May 2023).

33. Coe JD et al. NFlex Dynamic Stabilization System: Two-Year Clinical Outcomes of Multi-Center Study. J Korean Neurosurg Soc 51 : 343-349, 2012.

34. Davis R, Auerbach JD, Bae H, Errico TJ. Can low-grade spondylolisthesis be effectively treated by either coflex intermalimar stabilization or laminectomy and posterior spinal fusion? Two-year clinical and radiographic results from the randomized, prospective, multicenter US investigational device exemption trial. J Neurosurg: Spine | May 31, 2013.

35. 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). Aug 15 2013;38(18):1529-1539.

36. Deer TR, Grider JS, Pope JE, et al. The MIST Guidelines: The Lumbar Spinal Stenosis Consensus Group Guidelines for Minimally Invasive Spine Treatment. Pain Pract. 2019;19(3):250–274. doi:10.1111/papr.12744. PMID: 30369003.

37. Deer T, Sayed D, Michels J, Josephson Y, Li S, Calodney AK. A Review of Lumbar Spinal Stenosis with Intermittent Neurogenic Claudication: Disease and Diagnosis. Pain Med. 2019;20(Suppl 2):S32-S44. doi:10.1093/pm/pnz161.

38. Deyo RA, et al. Interspinous spacers compared with decompression or fusion for lumbar stenosis: complications and repeat operations in the Medicare population. Spine (Phila Pa 1976). 2013 May 1;38(10):865-72.

39. ECRI. Target Database Report. Interspinous process decompression to treat spinal stenosis. Plymouth Meeting, PA: ECRI. 09/07.

40. ECRI Institute Product Brief. Coflex and Coflex-F Implants (Paradigm Spine, LLC) for Lumbar Spinal Disorders. October 2013.

41. Epstein NE. A review of interspinous fusion devices: High complication, reoperation rates, and costs with poor outcomes. Surg Neurol Int 2012, 3:7.

42. Fabrizi AP, Maina R, Schiabello L. Interspinous spacers in the treatment of degenerative lumbar spinal disease: our experience with DIAM and Aperius devices. Eur Spine J. 2011 May;20 Suppl 1:S20-6.

43. Falowski SM, Sayed D, Deer TR, Brescacin D, Liang K. Biomechanics and Mechanism of Action of Indirect Lumbar Decompression and the Evolution of a Stand-alone Spinous Process Spacer. Pain Med. 2019 Dec 1;20(Suppl 2):S14-S22. doi: 10.1093/pm/pnz129.

44. Florida Society of Interventional Pain Physicians. Position Statement: Interspinous Indirect Decompression Systems Without Fusion (December 2021).

45. Gala RJ, et al. Interspinous implants to treat spinal stenosis. Curr Rev Musculoskelet Med. 2017 Jun;10(2):182-188.

46. Gaxxeri R, et al. Controversies about interspinous process devices in the treatment of degenerative lumbar spine diseases: past, present, and future. Biomed Res Int. 2014;2014:975052.

47. Grob D, Benini A, Junge A, Mannion AF. Clinical Experience With the Dynesys Semirigid Fixation System for the Lumbar Spine: Surgical and Patient-Oriented Outcome in 50 Cases After an Average of 2 Years. SPINE Volume 30, Number 3, pp 324–331 ©2005.

48. Hagedorn JM, Yadav A, D'Souza RS, et al. The incidence of lumbar spine surgery following Minimally Invasive Lumbar Decompression and Superion Indirect Decompression System for treatment of lumbar spinal stenosis: a retrospective review. Pain Pract. 2022 Jun;22(5):516-521. doi: 10.1111/papr.13111. Epub 2022 Apr 12.

49. Hartman J, Granville M, Jacobson RE. The Use of Vertiflex® Interspinous Spacer Device in Patients With Lumbar Spinal Stenosis and Concurrent Medical Comorbidities. Cureus. 2019;11(8):e5374. Published 2019 Aug 12. doi:10.7759/cureus.5374.

50. Hayes, Inc. Health Technology Brief. X Stop® Interspinous Process Decompression System (Kyphon Inc.) for Lumbar Spinal Stenosis. Lansdale, PA: Hayes, Inc.; 11/13/07.

51. Hayes, Inc. Hayes alert. FDA Clears New Implant to Treat Lumbar Stenosis. Lansdale, PA: Hayes, Inc.; 01/17/06.

52. Heyrani N, Picinic Norheim E, Elaine Ku Y, Nick Shamie A. Interspinous process implantation for the treatment of neurogenic intermittent claudication. Anesth Pain Med. 2012 Summer;2(1):36-41.

53. Hobart J, Gilkes C, Adams W, Germon T. Interspinous spacers for lumbar foraminal stenosis: formal trials are justified. Eur Spine J. 2013 Mar;22 Suppl 1:S47-53.

54. Holinka J, Krepler P, Matzner M, Grohs JG. Stabilising effect of dynamic interspinous spacers in degenerative low-grade lumbar instability. International Orthopaedics (SICOT) (2011) 35:395–400.

55. International Society for the Advancement of Spine Surgery. Policy Statement: Decompression with Interlaminar Stabilization (November 2016). Accessed at https://www.isass.org/public-policy/isass-policy-statement-decompression-with-interlaminar-stabilization/.

56. Kim HJ, Bak KH, Chun HJ, Oh SJ, Kang TH, Yang MS. Posterior Interspinous Fusion Device for One-Level Fusion in Degenerative Lumbar Spine Disease: Comparison with Pedicle Screw Fixation - Preliminary Report of at Least One Year Follow Up. J Korean Neurosurg Soc 52: 359-364, 2012.

57. Kondrashov DG, Hannibal M, Hsu KY et al. Interspinous process decompression with the X-STOP device for lumbar spinal stenosis: a 4-year follow-up study. J Spinal Disord Tech 2006; 19(5): 323-7.

58. Kumar N, Shah SM, Ng YH, Pannierselvam VK, Dasde S, Shen L. Role of coflex as an adjunct to decompression for symptomatic lumbar spinal stenosis. Asian Spine J. 2014 Apr;8(2):161-9.

59. Landi A. Elastic resistance of the spine: Why does motion preservation surgery almost fail? World J Clin Cases. 2013 Jul 16;1(4):134-9.

60. Landi A. Interspinous posterior devices: What is the real surgical indication? World J Clin Cases. 2014 Sep 16;2(9):402-8.

61. Lee SH, et al. A Systematic Review of Interspinous Dynamic Stabilization. Clin Orthop Surg. 2015 Sep;7(3):323-9.

62. Liu X, et al. Magnetic resonance imaging on disc degeneration changes after implantation of an interspinous spacer and fusion of the adjacent segment. Int J Clin Exp Med. 2015 Apr 15;8(4):6097-102.

63. Machado GC, Ferreira PH, Harris IA, Pinheiro MB, Koes BW, van Tulder M, Rzewuska M, Maher CG, Ferreira ML. Effectiveness of surgery for lumbar spinal stenosis: a systematic review and meta-analysis. PLoS One. 2015 Mar 30;10(3):e0122800.

64. Maida G, Marcati E, Sarubbo S. Heterotopic Ossification in Vertebral Interlaminar/Interspinous Instrumentation: Report of a Case. Case Reports in Surgery Volume 2012, Article ID 970642.

65. Manufacturer Instructions for Use: coflex® Interlaminar Technology, 2012. (Paradigm Spine; New York, NY)

66. Miller LE, Block JE. Interspinous Spacer Implant in Patients with Lumbar Spinal Stenosis: Preliminary Results of a Multicenter, Randomized, Controlled Trial. Pain Research and Treatment Volume 2012, Article ID 823509.

67. Modhia U, et al. Readmission rates after decompression surgery in patients with lumbar spinal stenosis among Medicare beneficiaries. Spine (Phila Pa 1976). 2013 Apr 1;38(7):591-6.

68. Moojen WA et al. Effectiveness of interspinous implant surgery in patients with intermittent neurogenic claudication: a systematic review and meta-analysis. Eur Spine J (2011) 20:1596–1606.

69. Moojen WA, et al. Interspinous process device versus standard conventional surgical decompression for lumbar spinal stenosis: randomized controlled trial. BMJ. 2013 Nov 14;347:f6415.

70. Musacchio MJ, 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. Int J Spine Surg. 2016; 10: 6.

71. National Institute for Clinical Excellence (NICE): Non-rigid stabilisation procedures for the treatment of low back pain. Issue date: June 2006.

72. National Institute for Clinical Excellence (NICE). Interventional procedure guidance 365: Interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication. Issue Date: November 2010.

73. National Institute for Clinical Excellence (NICE). Interventional procedure guidance 366: Non-rigid stabilisation techniques for the treatment of low back pain. Issue date: November 2010.

74. National Institute for Clinical Excellence (NICE): Treating neurogenic claudication caused by lumbar spinal stenosis using a spacer device between the vertebrae (patient guide). November 2010.

75. North American Spine Society. Evidence-based clinical guidelines for multidisciplinary spine care: Diagnosis and Treatment of Degenerative Lumbar Spondylolisthesis (2008).

76. North American Spine Society. Coverage Policy Recommendation: Lumbar Interspinous Device without Fusion and with Decompression (May 2018).

77. North American Spine Society. Evidence-based clinical guidelines for multidisciplinary spine care: Diagnosis and Treatment of Degenerative Lumbar Spondylolisthesis, 2nd Edition (2014).

78. North American Spine Society. Evidence-based clinical guidelines for multidisciplinary spine care: Diagnosis and treatment of degenerative lumbar spinal stenosis. January 2007; Revised 2011.

79. North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion. Accessed at https://www.spine.org.

80. North American Spine Society. NASS coverage policy recommendations: Interspinous device without fusion. 2014. Accessed at https://www.spine.org.

81. North American Spine Society (NASS). NASS and MPW Advocate for Medicare Advantage Coverage of Interspinous Spacer Devices. NASS Insider. April 19, 2022.

82. Nunley PD, Deer TR, Benyamin RM, Staats PS, Block JE. Interspinous process decompression is associated with a reduction in opioid analgesia in patients with lumbar spinal stenosis. J Pain Res. 2018 Nov 20;11:2943-2948. doi: 10.2147/JPR.S182322.

83. 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. Clin Interv Aging. 2017 Sep 6;12:1409-1417. doi: 10.2147/CIA.S143503.

84. Nunley PD, Patel VV, Orndorff DG, Lavelle WF, Block JE, Geisler FH. Interspinous Process Decompression Improves Quality of Life in Patients with Lumbar Spinal Stenosis. Minim Invasive Surg. 2018 Jul 2;2018:1035954. doi: 10.1155/2018/1035954.

85. Onggo JR, Nambiar M, Maingard JT, Phan K, Marcia S, Manfrè L, Hirsch JA, Chandra RV, Buckland AJ. The use of minimally invasive interspinous process devices for the treatment of lumbar canal stenosis: a narrative literature review. J Spine Surg. 2021 Sep;7(3):394-412. doi: 10.21037/jss-21-57.

86. Oster BA, Kikanloo SR, Levine NL, Lian J, Cho W. Systematic Review of Outcomes Following 10-Year Mark of Spine Patient Outcomes Research Trial (SPORT) for Degenerative Spondylolisthesis. Spine (Phila Pa 1976). 2020 Jun 15;45(12):820-824. doi: 10.1097/BRS.0000000000003485.

87. Paradigm Spine Press Release: U.S. FDA PMA Approval Of Its Landmark Coflex® Interlaminar Technology: The 1st Comparative Effectiveness Study For the Treatment Of Spinal Stenosis. October 17, 2012; New York, NY.

88. Parker SL, Anderson LH, Nelson T, Patel VV. Cost-effectiveness of three treatment strategies for lumbar spinal stenosis: Conservative care, laminectomy, and the Superion interspinous spacer. Int J Spine Surg. 2015 Jul 9;9:28.

89. Patel VV, Whang PG, Haley TR, Bradley WD, Nunley PD, Miller LE, Block JE, Geisler FH. Two-year clinical outcomes of a multicenter randomized controlled trial comparing two interspinous spacers for treatment of moderate lumbar spinal stenosis. BMC Musculoskelet Disord. 2014 Jul 5;15:221.

90. Pintauro M, et al. Interspinous implants: are the new implants better than the last generation? A review. Curr Rev Musculoskelet Med. 2017 Jun;10(2):189-198.

91. Ploumis A, et al. Surgical treatment of lumbar spinal stenosis with microdecompression and interspinous distraction device insertion. A case series. J Orthop Surg Res. 2012 Oct 29;7:35.

92. Putzier M. The surgical treatment of the lumbar disc prolapse: nucleotomy with additional transpedicular dynamic stabilization versus nucleotomy alone. Spine (Phila Pa 1976). 2005 Mar 1;30 (5): E109-14.

93. Putzier M et al. Dynamic stabilization adjacent to single-level fusion: Part II. No clinical benefit for asymptomatic, initially degenerated adjacent segments after 6 years follow-up. Eur Spine J (2010) 19:2181–2189.

94. Richter A, Schutz C, Hauck M, Halm H. Does an interspinous device (CoflexTM) 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) 19:283–289.

95. Rosner HL, Tran O, Vajdi T, Vijjeswarapu MA. Comparison analysis of safety outcomes and the rate of subsequent spinal procedures between interspinous spacer without decompression versus minimally invasive lumbar decompression. Reg Anesth Pain Med. 2024 Jan 11;49(1):30-35. doi: 10.1136/rapm-2022-104236.

96. Sayed D, Grider J, Strand N, Hagedorn JM, Falowski S, Lam CM, Tieppo Francio V, Beall DP, Tomycz ND, Davanzo JR, Aiyer R, Lee DW, Kalia H, Sheen S, Malinowski MN, Verdolin M, Vodapally S, Carayannopoulos A, Jain S, Azeem N, Tolba R, Chang Chien GC, Ghosh P, Mazzola AJ, Amirdelfan K, Chakravarthy K, Petersen E, Schatman ME, Deer T. The American Society of Pain and Neuroscience (ASPN) Evidence-Based Clinical Guideline of Interventional Treatments for Low Back Pain. J Pain Res. 2022 Dec 6;15:3729-3832. doi: 10.2147/JPR.S386879. Erratum in: J Pain Res. 2022 Dec 24;15:4075-4076.

97. Schnake KJ. Dynamic Stabilization in Addition to Decompression for Lumbar Spinal Stenosis with Degenerative Spondylolisthesis. Spine (Phila Pa 1976). 2006 Feb 15;31(4): 442-9.

98. Sclafani JA, Liang K, Ohnmeiss DD, Gordon C. Clinical outcomes of a polyaxial interspinous fusion system. Int J Spine Surg. 2014 Dec 1;8.

99. Sears WR, et al. Incidence and prevalence of surgery at segments adjacent to a previous posterior lumbar arthrodesis. Spine J. 2011 Jan;11(1):11-20.

100. Shabat S, Miller LE, Block JE, Gepstein R. Minimally invasive treatment of lumbar spinal stenosis with a novel interspinous spacer. Clinical Interventions in Aging 2011:6 227–233.

101. Strube P et al. Dynamic stabilization adjacent to single-level fusion: Part I. Biomechanical effects on lumbar spinal motion. Eur Spine J (2010) 19:2171–2180.

102. Stoll TM. The dynamic neutralization system for the spine: a multi-center study of a novel non-fusion system. Eur Spine J. 2002 Oct;11 Suppl 2: S170-8. Epub 2002 Sep 10.

103. Superion™ Indirect Decompression System. Instructions For Use. Boston Scientific. Accessed at https://www.bostonscientific.com/content/dam/elabeling/nm/92479815-02_Rev_A_Indirect_Decompression_System_s.pdf.

104. The International Society for the Advancement of Spine Surgery (ISASS). Recommendations/Coverage Criteria for Decompression with Interlaminar Stabilization – Coverage Indications, Limitations, and/or Medical Necessity. Volume 10, Article 41. November 2016.

105. U.S. Department of Health and Human Services (2019, May). Pain Management B Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, Recommendations. Retrieved from U. S. Department of Health and Human Services website: https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html.

106. U.S. Food and Drug Administration (FDA), Rockville (MD): U.S. Department of Health and Human Services. Available from: http://www.fda.gov.

107. U.S. Food and Drug Administration (FDA). Approval Order P110008: coflex Interlaminar Technology (October 17, 2012). Accessed at http://www.fda.gov.

108. U.S. Food and Drug Administration (FDA), Approval Order P140004: Superion® InterSpinous Spacer (ISS). June 3, 2015. Accessed at https://fda.report/PMA/P140004/14/P140004A.pdf.

109. U.S. Food and Drug Administration (FDA. Summary of safety and effectiveness data: coflex Interlaminar Technology. 2012. Accessed at: http://www.accessdata.fda.gov/cdrh_docs/pdf11/P110008b.pdf.

110. U.S. Food and Drug Administration (FDA). Summary of safety and effectiveness data: Superion® InterSpinous Spacer (ISS). 2015. Accessed at https://fda.report/PMA/P140004/14/P140004B.pdf.

111. Verhoof OJ, Bron JL, Wapstra FH et al. High failure rate of the interspinous distraction device (X-Stop) for the treatment lumbar spinal stenosis caused by degenerative spondylolisthesis. Eur Spine J 2008; 17(2): 188-92.

112. Welch WC. Clinical outcomes of the Dynesys dynamic neutralization system: 1-year preliminary results. Neurosurg Focus. 2007 Dec 15;22 (1): E8.

113. Welton L, Krieg B, Trivedi D, Netsanet R, Wessell N, Noshchenko A, Patel V. Comparison of Adverse Outcomes Following Placement of Superion Interspinous Spacer Device Versus Laminectomy and Laminotomy. Int J Spine Surg. 2021 Feb;15(1):153-160. doi: 10.14444/8020. Epub 2021 Feb 12.

114. Whang PG, Tran O, Rosner HL. Longitudinal Comparative Analysis of Complications and Subsequent Interventions Following Stand-Alone Interspinous Spacers, Open Decompression, or Fusion for Lumbar Stenosis. Adv Ther. 2023 Aug;40(8):3512-3524. doi: 10.1007/s12325-023-02562-6. Epub 2023 Jun 8.

115. Wu AM, Zhou Y, Li QL, Wu XL, Jin YL, Luo P, Chi YL, Wang XY. Interspinous spacer versus traditional decompressive surgery for lumbar spinal stenosis: a systematic review and meta-analysis. PLoS One. 2014 May 8;9(5):e97142.

116. Xin JH, Che JJ, Wang Z, Chen YM, Leng B, Wang DL. Effectiveness and safety of interspinous spacer versus decompressive surgery for lumbar spinal stenosis: A meta-analysis of randomized controlled trials. Medicine (Baltimore). 2023 Nov 17;102(46):e36048. doi: 10.1097/MD.0000000000036048.

117. Xu C, et al. Complications in degenerative lumbar disease treated with a dynamic interspinous spacer (Coflex). Int Orthop. 2013 Nov;37(11):2199-204.

118. Zang L, DU P, Hai Y, Su QJ, Lu SB, Liu T. Device related complications of the Coflex interspinous process implant for the lumbar spine. Chin Med J (Engl). 2013 Jul;126(13):2517-22.

119. Zhang JX, et al. Effectiveness of dynamic fixation Coflex treatment for degenerative lumbar spinal stenosis. Exp Ther Med. 2018 Jan;15(1):667-672.

120. Zhou D, Nong LM, DU R, Gao GM, Jiang YQ, Xu NW. Effects of interspinous spacers on lumbar degenerative disease. Exp Ther Med. 2013 Mar;5(3):952-956.

121. Zini C, Bellini M, Masala S, Marcia S. Percutaneous Interspinous Spacer in Spinal-Canal-Stenosis Treatment: Pros and Cons. Medicina (Kaunas). 2019;55(7):381. Published 2019 Jul 16. doi:10.3390/medicina55070381.

122. Zucherman JF, Hsu KY, Hartjen CA et al. A multicenter, prospective randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results. Spine 2005;0(12): 1351-8.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 12/08/23.

GUIDELINE UPDATE INFORMATION:

07/15/08	New Medical Coverage Guideline.
04/15/09	HCPCS code C1821 deleted from policy.
06/15/09	Scheduled review; no change in position statement. Update references.
04/15/10	Annual review; added investigational statement for dynamic spinal stabilization to position statement; description of dynamic spinal stabilization devices added to description section; references updated; and guideline title revised.
12/15/11	Scheduled review; no change in position statement. Updated description section and references.

11/15/12	Scheduled review; position statement maintained. Revised description and Medicare Advantage program exception (added utilization guidelines). Updated references.
07/15/13	Revision; updated description section (coflex® Interlaminar Technology implant language). Revised Program Exceptions section and index terms. Updated references.
11/15/13	Scheduled review. Revised MCG title and description section. Maintained position statement. Revised index terms. Updated references.
01/01/15	Scheduled review. Position statement maintained. Revised description section and index terms. Updated references.
10/15/15	Scheduled review. Revised description section and index terms. Updated references.
01/01/17	Annual CPT/HCPCS update. Added 22867, 22868, 22869, 22870. Deleted 0171T, 0172T.
02/15/17	Scheduled review. Maintained Position Statement section. Updated references.
06/15/18	Unscheduled review. Maintained Position Statement section. Revised index terms. Updated references.
06/15/20	Scheduled review. Revised description. Maintained position statement and updated references.
07/01/20	Added code C1821.
03/15/22	Scheduled review. Maintained position statement and updated references.
08/15/22	Unscheduled review. Updated references and maintained position statement.
06/15/23	Unscheduled review. Updated references and maintained position statement.
01/01/24	Position statements maintained.
03/15/24	Revision. Updated references and maintained position statement.