

Interspinous Decompression and Interlaminar Stabilization Devices (Spacers)

Date of Origin: 09/2008

Last Review Date: 04/22/2021

Effective Date: 05/01/2021

Dates Reviewed: 07/2010, 07/2011, 06/2012, 04/2013, 04/2014, 04/2015, 07/2016, 06/2017, 04/2019, 04/2020, 04/2021

Developed By: Medical Necessity Criteria Committee

I. Description

Lumbar spinal stenosis (LSS) results in narrowing of the spinal canal, which may lead to compression of the thecal sac and neural elements. The LSS is the most common cause of lumbar neurogenic claudication, a syndrome that may be characterized by radiating pain down one or both legs during ambulation. Investigators have sought less invasive ways to stabilize the spine and reduce the pressure on affected nerve roots, including interspinous and interlaminar implants (spacers). Lumbar interspinous process decompression (IPD), also known as interspinous distraction or posterior spinal distraction, and interlaminar stabilization have been proposed as minimally invasive alternatives to laminectomy and fusion.

The Interspinous process decompression is a minimally invasive surgical procedure designed to alleviate painful symptoms of lumbar spinal stenosis in those patients who do not respond to conservative, nonsurgical treatment. The procedure involves placing interspinous process decompression spacers between the spinous processes of the symptomatic lumbar disc levels. The spacers can be implanted at one or two lumbar levels and are designed to remain in place without being permanently affixed to the bone or ligamentous structures of the spine. Numerous interspinous devices have been marketed but most are not FDA approved and considered investigational.

Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization following decompressive surgery or as an alternative to decompression surgery. The spacers have two sets of wings that are placed around the inferior and superior spinous processes (they may also be referred to as interlaminar implants). They aim to restrict painful motion while otherwise enabling normal motion.

Overall, the spacer devices stabilize or distract the adjacent lamina and/or spinous processes and restrict extension in patients with lumbar spinal stenosis and neurogenic claudication.

II. Criteria: CWQI HCS-0041A

- A. Moda Health considers interspinous distraction devices and interlaminar stabilization devices investigational. Evidence based literature has not demonstrated that interspinous decompression devices or interlaminar stabilization systems provide significant advantage over surgical decompression and/or fusion.
- B. Interspinous decompression devices and interlaminar stabilization devices include but are not limited to the following:
 - a. Aperius™ - PercLID™ System
 - b. Coflex® Interlaminar Stabilization Device
 - c. DIAM™ Spine Stabilization System
 - d. Falena® Interspinous Decompression Device
 - e. FLEXUS™
 - f. Helifix® Interspinous Spacer System
 - g. In-Space
 - h. NL-Prow™ Interspinous Spacer System
 - i. Stenofix
 - j. Superior® Interspinous Spacer System
 - k. Wallis® System
 - l. X-STOP® Interspinous Process Decompression (IPD®) System (discontinued in 2015)
 - m. X-STOP® PEEK (Polyetheretherketone) (withdrawn from market)

III. Information Submitted with the Prior Authorization Request:

1. Chart notes for spine procedure requests should include any devices to be used

IV. CPT or HCPC codes NOT covered:

Codes	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)
C1821	Interspinous process distraction device (implantable)
22899	Unlisted procedure, spine

V. Annual Review History

Review Date	Revisions	Effective Date
04/2013	Annual Review: Added table with review date, revisions, and effective date.	04/24/2013
04/2014	Annual Review: No changes	04/30/2014
04/2015	Annual Review: Added Section II regarding Coflex considered E/I	04/25/2015
07/2016	Annual Review: X-STOP changed to investigational – combined interspinous distraction devices and interlaminar stabilization devices into one criteria. Added brand names of different devices.	10/1/2016
07/2017	Annual Review: Updated the codes, updated to new template	07/26/2017
04/2019	Annual Review: Updated the title, background information	05/01/2019
04/2020	Annual Review: No changes	05/01/2020
04/2021	Annual Review: No changes	05/01/2021

VI. References

1. Asgarzadie F, Khoo LT. Minimally invasive operative management for lumbar spinal stenosis: overview of early and long-term outcomes. *Orthop Clin North Am.* 2007 Jul;38(3):387-99; abstract vi-vii.
2. Bono CM, Vaccaro AR. Interspinous process devices in the lumbar spine. *J Spinal Disord Tech.* 2007;20(3):255-261.
3. Chou R, Baisden J, Carragee EJ, et al. 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.
4. ECRI Institute. Interspinous process decompression to treat spinal stenosis. [Emerging Technology evidence report]. Plymouth Meeting (PA): ECRI Institute; 2009 Mar 9.
5. Gala, R. J., Russo, G. S. and Whang, P. G. (2017). Interspinous implants to treat spinal stenosis. *Current reviews in Musculoskeletal Medicine,* 10, 182-188.
6. Hayes alert. Winifred S. Hayes, Inc. 2006. FDA clears new implant to treat lumbar spinal stenosis. January 17, 2006.
7. Kabir SMR, Gupta SR, Casey ATH. Lumbar interspinous spacers: a systematic review of clinical and biomechanical evidence. *Spine (Phila Pa 1976).* 2010 Dec 1;35(25):E1499-506.
8. Kim DH, Albert TJ. Interspinous process spacers. *J Am Acad Orthop Surg.* 2007 Apr;15(4):200-7.
9. Kong DS, Kim ES, Eoh W. One-year outcome evaluation after interspinous implantation for degenerative spinal stenosis with segmental instability. *J Korean Med Sci.* 2007;22(2):330-335.
10. Kuchta J, Sobottke R, Eysel P, Simons P. Two-year results of interspinous spacer (X-Stop) implantation in 175 patients with neurologic intermittent claudication due to lumbar spinal stenosis. *Eur Spine J.* 2009 Jun;18(6):823-9. Epub 2009 Apr 22.
11. National Institute for Health and Clinical Excellence (NICE). Interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication. *Interventional Procedure Guidance 165.* London, UK: NICE; 2006.
12. National Institute for Health and Clinical Excellence (NICE). *Interventional procedure guidance 165. Interspinous distraction procedures for lumbar spinal stenosis.* London, UK: NICE; 2010 Nov. Accessed June 25, 2012. Available at URL address: <http://guidance.nice.org.uk/IPG365>
13. North American Spine Society (NASS). *Diagnosis and treatment of degenerative lumbar spinal stenosis.* Burr Ridge, IL: North American Spine Society (NASS); 2007.

14. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). Orthopaedic and Rehabilitation Devices Panel Meeting Brief Summary for August 31, 2004. Rockville, MD: FDA; updated September 3, 2004. Available at: <http://www.fda.gov/cdrh/panel/summary/ortho-083104.html>. Accessed January 9, 2006.
15. Watters WC 3rd, Bono CM, Gilbert TJ, Kreiner DS, Mazanec DJ, Shaffer WO, Baisden J et al. North American Spine Society. An evidence-based clinical guideline for the diagnosis and treatment of degenerative lumbar spondylolisthesis. Spine J. 2009 Jul;9(7):609-14. Epub 2009 May 17. Accessed Mar 13, 2011. Available at URL address: http://www.spine.org/Documents/Spondylolisthesis_Clinical_Guideline.pdf
16. Watters WC, Baisden J, Gilbert T, Kreiner DS, Resnick D, Bono C, et al. Degenerative lumbar spinal stenosis: an evidence-based clinical guideline for the diagnosis and treatment of degenerative lumbar spinal stenosis. Spine J. 2008 Mar-Apr;8(2):305-10. Epub 2007 Dec 21. Accessed Mar 13, 2011.
17. Physician Advisors
18. FDA U.S. Food and Drug Administration, coflex Interlaminar Technology – P110008, Summary of Safety and Effectiveness Data; Issued October 17,2012; Updated November 8, 2012
19. Coflex Interlaminar Stabilization, Your Back and Leg Pain, Paradigm Spine LLC
20. Stephen H. Hochschuler, M.D., Spine-health, Interspinous Process Spacers; Published 03/26/2007
21. Moojen, W. A et al (2013). Interspinous process device versus standard conventional surgical decompression for lumbar spinal stenosis: randomized control trial. BMJ 2013; 347 doi: <http://dx.doi.org/10.1136/bmj.f6415>, (Published 14 November 2013)
22. BioMed Research International, Controversies about Interspinous Process Devices in the Treatment of Degenerative Lumbar Spine Diseases: Past, Present, and Future; Volume 2014 (2014), Article ID 975052, 15 pages; <http://dx.doi.org/10.1155/2014/975052>

Appendix 1 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):
NA	

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC