

Interspinous Decompression and Interlaminar Stabilization Devices (Spacers)

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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. 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 claudification.

II. Criteria: CWQI HCS-0041A

- A. Moda Health considers interspinous distraction devices and interlaminar stabilization devices and dynamic 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)
- C. Use of any spinal dynamic stabilization device is considered Investigational for the treatment of disorders of the spine at any level. The listed devices are considered Investigational but not limited to all the following;
 - a. Aspen Spinous Fixation System
 - b. BioFlex System
 - c. DSS Dynamic Soft Stabilization System
 - d. Dynabolt Dynamic Stabilization System
 - e. Dynamic Stabilization
 - f. Dynesys Spinal System
 - g. Isobar Spinal System
 - h. Spondylolisthesis
 - i. Stabilimax NZ Dynamic Spine Stabilization System
 - j. TOPS system

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
03/2022	Annual Review: No changes	04/01/2022
04/2023	Annual Review: No changes	05/01/2023
04/2024	Annual Review: No changes	05/01/2024
06/2024	Update: Added list of dynamic stabilization devices considered investigational	

VI. References

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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