Cohere Medicare Advantage Policy - Interspinous Process Devices without Decompression

Clinical Policy for Medical Necessity Review

Version: 3
Revision Date: June 26, 2025

Important Notices

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Other Notices:

Policy Information:

Specialty Area: Musculoskeletal Care
Policy Name: Interspinous Process Devices without Decompression
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Interspinous Process Devices without Decompression

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.

- There are no applicable NCDs and/or LCDs for Interspinous Process Devices without Decompression.

Description

NASS defines an interspinous process device without decompression as the insertion of a device intended to distract the spinous processes to affect neural decompression indirectly.[10]

Designed as an alternative to lumbar fusion or decompression, interspinous spacers were developed to provide a less invasive surgical treatment for LSS with intermittent neurogenic claudication (NC).[1] These devices do not alter the bony anatomy of the spinal column; yet, via indirect methods, they can stabilize and decompress the local anatomy and offer treatment for lumbar stenosis. As the name suggests, interspinous spacers are positioned between the spinous processes. This reduces lumbar extension at the treated levels but allows preserved lateral and rotational movement. By fixing the stenotic segment in a slightly flexed position, the interspinous spacer decreases the symptoms of NC.[2] The first of these devices was given US Food and Drug Administration (FDA) approval in 2005.[3]

The North American Spine Society (NASS) recently published new coverage recommendations (2025) for interspinous devices without fusion and without decompression, conclude that the present data support interspinous devices only when open surgery (e.g., laminectomy) on a patient with degenerative lumbar spinal stenosis is not a medically safe treatment option because of comorbidities, as determined by a spine surgeon.[9]

Medical Necessity Criteria

Indications

Interspinous process devices without decompression are considered appropriate if **ALL** of the following are **TRUE**[4,5,7-9]:

- The patient is skeletally mature[5]; **AND**
- Suffering from pain, numbness, or cramping in the legs[5]; **AND**
- Diagnosis of mild to moderate degenerative lumbar spinal stenosis, with or without grade 1 spondylolisthesis, with the presence of neurogenic claudication symptoms (Grade B, Level I)[5]; **AND**
- Neurogenic claudication is relieved by lumbar flexion[9]; **AND**
- Neurogenic claudication has been differentiated from other claudication sources[5]; **AND**
- The patient can sit for at least 50 minutes without pain[9]; **AND**
- The patient can walk at least 50 feet[9]; **AND**
- Failure of conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of at least 6 months[5,9]; **AND**
- Mild to moderate stenosis as assessed on advanced imaging (CT or MRI), defined as a 25-50% reduction in lateral/central foraminal diameter compared to adjacent levels[9]; **AND**
- No more than 25° of degenerative scoliosis[9]; **AND**
- No more than a Grade I degenerative spondylolisthesis[9]; **AND**
- Open surgery (e.g., laminectomy) is not a medically safe treatment option because of comorbidities, as determined by a spine surgeon.[9]

Non-Indications

Interspinous process devices are not considered appropriate if **ANY** of the following is **TRUE**[4, 6-9]:

- Back or leg pain of unclear etiology[6]; **OR**
- Advanced stenosis that is defined by **ANY** of the following[4,6]:
  - Greater than 2 levels of moderate lumbar stenosis[6]; **OR**
  - One level of severe stenosis[6]; **OR**
  - L5-S1 intervertebral space[4]; **OR**
- Previous decompression at the planned level for surgery[6]; **OR**
- An allergy to titanium or specific metal alloys[4,6]; **OR**

- Spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in situ, such as **ANY** of the following[4]:
  - Instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1 (on a scale of 1 to 4)[6,9]; **OR**
  - An ankylosed segment at the affected level(s)[4]; **OR**
  - Fracture of the spinous process, pars interarticularis, or laminae (unilateral or bilateral)[6]; **OR**
  - Degenerative scoliosis greater than 25 degrees[6,9]; **OR**
  - Prior decompression with removal of spinous proces**s; OR**
- Cauda equina syndrome, defined as neural compression causing neurogenic bladder or bowel dysfunction[4,6]; **OR**
- Diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA scan or equivalent method) in the spine or hip that is more than 2.5 SD below the mean of adult normal values[4,6]; **OR**
- Active systemic infection or infection localized to the site of implantation[4,6]; **OR**
- Prior fusion or decompression procedure at the index level[4,6]; **OR**
- Morbid obesity, defined as a body mass index (BMI) greater than 40 kilograms per square meter[4,6,9]; **OR**
- Pregnancy[6]; **OR**
- Advanced deformity at the proposed level of implantation[6]; **OR**
- Symptoms are not relieved by flexion[9]; **OR**
- The patient is medically suitable for a direct decompressive procedure (e.g., laminectomy)[9]; **OR**
- Fixed motor deficit.[9]**, OR**
- Congenital spinal stenosis, **OR**
- Spondylolysis **OR**
- Spina Bifida occulta at the planned level.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
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).

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS' required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for Interspinous Process Devices without Decompression may include:

- Adverse effects from delayed or denied treatment: Delays or denials in interspinous process device procedures can lead to increased symptoms and complications, particularly in patients with lumbar spinal stenosis. According to Deyo et al., interspinous spacers provide a less invasive alternative to decompression or fusion, with lower rates of complications and repeat operations in the Medicare population.[2]
- Risks with inappropriate surgical procedures: These include infection, bleeding requiring a transfusion, injury to neurovascular structures, anesthetic risk, and the need for repeat or additional procedures due to implant failure or complications. The FDA's Summary of Safety & Effectiveness Data (SSED) for the Superion® InterSpinous Spacer highlights the importance of proper patient selection and procedural technique to minimize these risks.[4]
- Increased healthcare costs and complications include inappropriate use of emergency services and additional treatments. When used appropriately, Tapp et al. reported that minimally invasive procedures, such as interspinous spacer devices, can be cost-effective and improve patient outcomes.[3]

The clinical benefits of using these criteria for Interspinous Process Devices without Decompression may include:

- Improved patient outcomes by ensuring timely and appropriate access to interspinous process device procedures for patients selected for the best outcomes. The goal is to provide accurate diagnostics and effective treatment planning, reducing the risk of complications and improving overall patient health. The MIST guidelines emphasize, in one of the consensus points, the importance of minimally invasive treatments for the management of lumbar spinal stenosis.[5]
- Enhanced diagnostic accuracy is crucial for complex conditions such as lumbar spinal stenosis. NASS provides coverage recommendations that support the use of interspinous devices in appropriate clinical scenarios, ensuring that patient selection is evidence-based.[1]
- Reduction in complications and adverse effects: Proper use of the interspinous process device criteria helps avoid unnecessary interventions and their associated risks, thus safeguarding patient health. Onggo et al. noted that minimally invasive interspinous process devices are associated with lower complication rates than traditional surgical methods.[6]
- Enhanced overall patient satisfaction: Ensuring that interspinous process devices are used appropriately leads to better patient outcomes and higher satisfaction rates due to effective treatment and reduced complications. Deer et al. emphasized that up-to-date guides utilizing minimally invasive techniques can standardize procedures and improve outcomes.[5]

Medical Evidence

The United States Food and Drug Administration (FDA) approved the VertiFlex Superion interspinous spacer in 2015, intended to treat skeletally mature patients suffering from neurogenic intermittent claudication secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, and confirmed by X-ray, MRI and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing.[4]

Deer et al. (2018) formulated several recommendations for minimally invasive spine treatment for lumbar spinal stenosis. Their systematic review concluded that such treatments must be used judiciously and algorithmically. There were 11 consensus recommendations made throughout the document, including obtaining radiographic evidence, differentiating between neurogenic claudication and other claudication sources, and following anticoagulation recommendations.[5]

In its 2014 coverage policy, NASS conditionally recommended that interspinous distraction devices without direct decompression or fusion would be appropriate in a select group of patients. The society discusses the benefits of operative versus nonoperative treatment and the superiority of surgical intervention in several studies.[1] NASS recently published new coverage recommendations (2025) for interspinous devices without fusion and without decompression, reviewing literature and data available as of May 2023.[9] They conclude that the present data support interspinous devices only when open surgery (e.g., laminectomy) on a patient with degenerative lumbar spinal stenosis is not a medically safe treatment option because of comorbidities, as determined by a spine surgeon.

Onggo et al. (2021) concluded in a systematic review that interspinous spacers, compared to open decompression with interbody fusion, had similar outcomes with reduced operative time, length of stay, blood loss, and improved segment mobility. Future directions include the implantation of interspinous spacers with open decompression as an alternative to

decompression and interbody fusion for stable grade 1 spondylolisthesis and central stenosis. The group recommends future studies.[6]

References

1. North American Spine Society (NASS). Coverage policy recommendations. Interspinous devices without fusion. Published May 2014. https://www.spine.org/

2. Deyo RA, Martin BI, Ching A, et al. Interspinous spacers compared with decompression or fusion for lumbar stenosis: Complications and repeat operations in the Medicare population. *Spine*. 2013;38(10):865–872. doi: 10.1097/BRS.0b013e31828631b8

3. Tapp SJ, Martin BI, Tosteson TD, et al. Understanding the value of minimally invasive procedures for the treatment of lumbar spinal stenosis: The case of interspinous spacer devices. *Spine J.* 2018;18(4):584–592. doi: 10.1016/j.spinee.2017.08.246

4. US Food & Drug Administration (FDA). Summary of safety & effectiveness data (SSED). Superion® InterSpinous Spacer (ISS). Published May 15, 2015. https://www.accessdata.fda.gov/cdrh_docs/pdf14/p140004b.pdf

5. Deer T, Grider J, Pope J, et al. The MIST guidelines: The Lumbar Spinal Stenosis Consensus Group guidelines for minimally invasive spine treatment. *Pain Pract.* 2019;19(3):250-274

6. Onggo J, Nambiar M, Maingard J, et al. The use of minimally invasive interspinous process devices for the treatment of lumbar canal stenosis: a narrative literature review. *J Spine Surg.* 2021;7(3):394-412

7. US Food & Drug Administration (FDA). Premarket approval (PMA). Superion interspinous spacer. Published June 18, 2015. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p140004

8. 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

9. North American Spine Society (NASS) coverage recommendations. Interspinous devices without fusion & without decompression. Revised March 2025. https://www.spine.org/

10. North American Spine Society (NASS). Appropriate use criteria for degenerative lumbar spondylolisthesis. Published 2020. https://www.spine.org/

Clinical Guideline Revision History/Information

Original Date: May 31, 2024		
Review History		
Version 2	06/10/2024	422.101 Disclaimer added
Version 3	06/26/2025	Annual review. Added updated coverage recommendations (2025) from the North American Spine Society (NASS). Medical necessity criteria were revised, updated, and expanded: Added several indications and non-indications .from North American Spine Society (NASS) coverage recommendations, Interspinous device with decompression, revised March 2025, and from the MIST guidelines: The Lumbar Spinal Stenosis Consensus Group guidelines for minimally invasive spine treatment, and referenced the source for every indication and non-indication. Literature review - The Medical Evidence section was updated (including references). No changes to procedure codes.