Cohere Medicare Advantage Policy - Interspinous Process Devices with Open Decompression

Clinical Policy for Medical Necessity Review

Version: 3
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Policy Information:

Specialty Area: Musculoskeletal Care
Policy Name: Interspinous Process Devices with Open Decompression
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Interspinous Process Devices with Open 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 with open decompression.

Description

The North American Spine Society (NASS) defines an interspinous process device with decompression as the insertion of a device intended to flexibly stabilize the spinous processes following neural decompression.[3] For interspinous process devices with decompression, their coverage recommendations apply to all interspinous process devices intended to be inserted during the same operative session as the direct decompression procedures.[4]

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]

Medical Necessity Criteria

Indications

Interspinous process devices are considered appropriate if **ALL** of the following are **TRUE**[4,5,7]:

- Degenerative lumbar stenosis in a patient over 50 years old[4]; **AND**
- The patient is suffering from pain, numbness, or cramping in the legs[7]; **AND**
- Diagnosis of mild to moderate degenerative lumbar spinal stenosis,[7] with no more than a Grade I degenerative spondylolisthesis[4]; **AND**
- Degenerative lumbar stenosis associated with neurogenic claudication that is relieved by lumbar flexion[4]; **AND**
- Neurogenic claudication that has been differentiated from other claudication sources[7]; **AND**
- Degenerative lumbar stenosis with no more than 25° of degenerative scoliosis[4]; **AND**
- Degenerative lumbar stenosis and failure of nonoperative treatment (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids)[4,7]; **AND**
- The patient can sit for at least 50 minutes without pain[5]; **AND**
- The patient can walk at least 50 feet[5]; **AND**
- Advanced imaging (MRI or CT) demonstrating **ALL** of the following[5]:
  - Evidence of mild to moderate (50% or less) central canal stenosis; **AND**
  - The stenosis is confined to one or two lumbar levels.

Non-Indications

Interspinous process devices are not considered appropriate if **ANY** of the following are **TRUE**[4,8,9]:

- Back or leg pain of unclear etiology[8]; **OR**
- Advanced stenosis that is defined by **ANY** of the following[5,8]:
  - Greater than 2 levels of moderate lumbar stenosis[8]; **OR**
  - One level of severe stenosis[8]; **OR**
  - L5-S1 intervertebral space[5]; **OR**
- Previous decompression at the planned level for surgery[8]; **OR**
- An allergy to titanium or titanium alloy[5,8]; **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[5]:

- Instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade II or higher[4,8]; **OR**
- An ankylosed segment at the affected level(s)[5]; **OR**
- Fracture of the spinous process, pars interarticularis, or laminae (unilateral or bilateral)[8]; **OR**
- Degenerative scoliosis greater than 25 degrees[4,8]; **OR**

- Cauda equina syndrome, defined as neural compression causing neurogenic bladder or bowel dysfunction[4,8]; **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 standard deviations (SD) below the mean of adult normals[4,5,8]; **OR**
- Active systemic infection or infection localized to the site of implantation[5,8]; **OR**
- Prior fusion or decompression procedure at the index level[5,8]; **OR**
- Morbid obesity, defined as a body mass index (BMI) greater than 40 kilograms per square meter[5,8]; **OR**
- Symptoms are not relieved by flexion[4]; **OR**
- The patient has primarily axial back pain that is unrelated to activity.[4]
- 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
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).
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 with open 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.[5]
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments. Tapp et al. reported that, when used appropriately, minimally invasive procedures, such as interspinous spacer devices, can be cost-effective and improve patient outcomes.[6]

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to interspinous process device procedures for patients who have been 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 the importance of minimally invasive treatments for lumbar spinal stenosis in achieving favorable outcomes[7]
- 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.[1,4]
- Reduction in complications and adverse effects: Proper use of the interspinous process device criteria helps to 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.[8]
- Enhanced overall patient satisfaction and healthcare experience. 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.[7]

Medical Evidence

The United States Food and Drug Administration (FDA) approved the VertiFlex Superion interspinous spacer in 2015. The device is 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.[9]

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.[7]

In their 2014 coverage policy, NASS conditionally recommended that interspinous distraction devices without direct decompression or fusion would be appropriate in a select group of patients. They discuss the benefits of operative versus nonoperative treatment, and that surgical intervention has been proven superior in a number of studies.[1] NASS updated the coverage recommendations (2025) for any device that includes fixation to the spinous processes for stabilizing the motion segment after decompression (discectomy, laminectomy, laminotomy) without the intent of creating a fusion (absence of bone graft placement).[4]

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.[8]

References

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7. 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
8. 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
9. US Food & Drug Administration (FDA). Premarket approval (PMA). Superion Interspinous Spacer. Published June 18, 2015.

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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). No changes to procedure codes. 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).