Cohere Medicare Advantage Policy - Interspinous Process Devices without Decompression

Clinical Guidelines for Medical Necessity Review

Version: 2
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Important Notices

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Other Notices:

Guideline Information:

Specialty Area: Disorders of the Musculoskeletal System
Guideline Name: Cohere Medicare Advantage Policy - Interspinous Process Devices without Decompression

Date of last literature review: 6/10/2024
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Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Interspinous Process Devices without Decompression

Benefit Category

Not applicable.

Recommended Clinical Approach

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 both 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]

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of interspinous process devices without open decompression. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, adverse reactions, and infection.

The potential clinical harms of using these criteria 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: This includes inappropriate use of emergency services and additional treatments. Tapp et al. reported that minimally invasive procedures, such as the use of interspinous spacer devices, can be cost-effective and improve patient outcomes when used appropriately.[3]

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to interspinous process device procedures for the patients selected for 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.[4]
- Enhanced diagnostic accuracy: This is crucial for complex conditions such as lumbar spinal stenosis. The North American Spine Society (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 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 compared to traditional surgical methods.[8]
- 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.[4]

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

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

- ◆ Skeletally mature patients suffering from pain, numbness, or cramping in the legs (intermittent neurogenic claudication) secondary to a diagnosis of mild to moderate degenerative lumbar spinal stenosis, with or without grade 1 spondylolisthesis; **AND**
- ◆ Failure of conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 3 months. Documentation should include detailed evidence of the measures taken, rather than solely a physician's statement; **AND**

    - Advanced imaging (MRI or CT) demonstrating **ALL** of the following:
        - 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 is **TRUE**[5-8]:

- ◆ Advanced stenosis that is defined by **ANY** of the following:
  - Greater than 2 levels of moderate lumbar stenosis; **OR**
  - One level of severe stenosis; **OR**
  - L5-S1 intervertebral space; **OR**
- ◆ Previous decompression at the planned level for surgery; **OR**
- ◆ An allergy to titanium or titanium alloy; **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:
  - Instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1 (on a scale of 1 to 4); **OR**
  - An ankylosed segment at the affected level(s); **OR**
  - Fracture of the spinous process, pars interarticularis, or laminae (unilateral or bilateral); **OR**
  - Scoliosis (Cobb angle greater than 10 degrees); **OR**
- ◆ Cauda equina syndrome, defined as neural compression causing neurogenic bladder or bowel dysfunction; **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 normals; **OR**
- ◆ Active systemic infection or infection localized to the site of implantation; **OR**
- ◆ Prior fusion or decompression procedure at the index level; **OR**
- ◆ Morbid obesity, defined as a body mass index (BMI) greater than 40.

Site of Service Criteria

None.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
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)

Medical Evidence

The United States Food and Drug Administration (FDA) approved the VertiFlex Superion interspinous spacer in 2015, intended for moderate degenerative lumbar spinal stenosis.[5]

Deer et al. (2018) formulated several recommendations for minimally invasive spine treatment related to lumbar spinal stenosis. Their systematic review concluded that such treatments must be used in a judicious and algorithmic fashion. There were 11 consensus recommendations made throughout the document including obtaining radiographic evidence, differentiating between neurogenic claudication and other claudication sources as well as following anticoagulation recommendations.[4]

The North American Spine Society (NASS) conditionally recommended in their 2014 coverage policy that in a select group of patients, interspinous distraction devices without direct decompression or fusion would be appropriate. They discuss the benefits of operative versus nonoperative treatment, that surgical intervention has been proven superior in a number of studies.[1]

Onggo et al. (2021) concluded in a systematic review that interspinous spacers, compared to open decompression with interbody fusion, similar outcomes were achieved with reduced operative time, length of stay, blood loss and improved segment mobility. Future directions may include implantation of interspinous spacers with open decompression as an alternative to decompression and interbody fusion for stable grade 1 spondylolisthesis and central stenosis. Future studies are recommended by the group.[7]

References

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Clinical Guideline Revision History/Information

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