# Interspinous Process Decompression Spacers

INDEPENDENT CARE HEALTH PLAN

**Effective Date:** 10/08/2024
**Revision Date:** 10/08/2024
**Review Date:** 09/24/2024
**Policy Number:** WI.PA-1139
**Line of Business:** Medicare

## Medicare Advantage Medical Coverage Policy

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## Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

## Related CMS Documents

**Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA). Refer to CMS website for the most current applicable CMS Online Manual System (IOMs) and Transmittals.**

There are no NCDs/LCDs/LCAs for interspinous process decompression spacers.

## Description

Interspinous process decompression, also known as interspinous process distraction, is a minimally invasive surgical procedure that is proposed to relieve the symptoms of lumbar spinal stenosis in an individual who does not respond to conservative, nonsurgical treatment. The procedure involves implanting spacers between the spinous processes of the vertebrae which appear to be the source of the symptoms, purportedly creating more space for the spinal cord and nerves in the spinal canal. 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.

An example of a US Food & Drug Administration (FDA) approved interspinous process spacer includes, but may not be limited to, the **Superion Indirect Decompression System**. Use of the Superion device may also be referred to as the **Vertiflex procedure**.

## Coverage Determination

*iCare follows the Medicare requirements that only allow coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.*

## Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

*Services that are not medically reasonable and necessary may result in unnecessary exposure to potential complications. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.*

**Interspinous process decompression spacers** will **not** be considered medically reasonable and necessary.

A review of the current medical literature shows that the **evidence is insufficient** to determine that this service is standard medical treatment. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

## Summary of Evidence

***Interspinous process decompression spacers (Superion Indirect Decompression/Vertiflex procedure)***
An evidence-based clinical resource[12] noted that while radiologic improvement in spinal canal and neuroforaminal narrowing in patients with spinal stenosis can be measured after surgery, these changes are not correlated with clinical benefit and are not maintained over time in most patients. These procedures also appear to be associated with higher rates of subsequent surgery than for patients initially treated with laminectomy. The authors concluded that it is unclear how this newer procedure compares with the

standard surgical procedure, decompressive laminectomy, in terms of effectiveness, side effects, recovery time, and long-term outcomes.

Onggo, et al[10] reports that observational studies of different interspinous process devices show improvements in clinical outcomes and patient satisfaction at short-term follow-up, and when compared to other decompression procedures. The authors, however, also pointed out several limitations to the studies that were looked at, including mismatch of implant type and patient population, which has the potential to confound and dilute the real outcomes, as well as only looking at short- and medium-term outcomes. It was concluded that future studies should focus on the newer generation of devices, longer-term follow-up and improved patient selection to better characterize this procedure.

Welton, et al[13] provides a retrospective review of 189 individuals who received lumbar level Superion interspinous spacers (SISS) compared with 378 who underwent primary lumbar spine laminectomy or laminotomy. The authors conclude that rates of 30-day complications in the SISS group are not significantly different from patients undergoing laminectomy or laminotomy. However, rates of 2-year device-specific complications within Superion interspinous spacer and cumulative risk associated with these complications should be considered further as they likely represent need for additional procedures for an individual and substantial cost to the healthcare system.

## Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

| CPT® Code(s) | Description | Comments |
|---|---|---|
| 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) | |
| **CPT® Category III Code(s)** | **Description** | **Comments** |
| No code(s) identified | | |
| **HCPCS Code(s)** | **Description** | **Comments** |
| C1821 | Interspinous process distraction device (implantable) | |

## References

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2. ECRI Institute. Clinical Evidence Assessment. Superion Indirect Decompression System (Boston Scientific Corp.) for treating lumbar spinal stenosis. https://www.ecri.org. Published June 20, 2019. Updated August 19, 2022.

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4. Gala R, Russo G, Whang P. Interspinous implants to treat spinal stenosis. Curr Rev Musculoskelet Med. 2017;10:182-188.

5. Hayes, Inc. Evolving Evidence Review. Superion Interspinous Spacer System (Vertiflex) for treatment of neurogenic claudication caused by spinal stenosis. https://evidence.hayesinc.com. Published September 17, 2021. Updated April 21, 2023.

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7. North American Spine Society (NASS). Coverage Policy Recommendations. Interspinous devices without fusion. https://www.spine.org. Published May 2014.

8. North American Spine Society (NASS). Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care. Diagnosis and treatment of degenerative lumbar spinal stenosis. https://www.spine.org. Published 2007. Updated 2011.

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10. 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.

11. Tapp S, Brook M, Tostenson T, 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;18:584-592.

12. UpToDate, Inc. Lumbar spinal stenosis: treatment and prognosis. https://www.uptodate.com. Updated July 2024.

13. Welton L, Krieg B, Trivedi D, et al. Comparison of adverse outcomes following placement of Superion Interspinous Spacer device versus laminectomy and laminotomy. *Int J Spine Surg.* 2021;15(1):153-160.

## Change Summary

09/24/2024 Annual Review, No Coverage Change