MASSACHUSETTS

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Medical Policy

Interspinous Fixation - Fusion Devices

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Policy Number: 436

BCBSA Reference Number: 7.01.138
NCD/LCD: NA

Related Policies

- Interspinous Distraction Devices (Spacers), #584

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPo Blue℠ Members

Interspinous fixation (fusion) devices are **INVESTIGATIONAL** for any indication, including but not limited to use:

- In combination with interbody fusion, or
- Alone for decompression in patients with spinal stenosis.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is **not** a covered service.
Commercial PPO and Indemnity	This is **not** a covered service.
Medicare HMO Blue℠	This is **not** a covered service.
Medicare PPO Blue℠	This is **not** a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There is no specific CPT code for this service.

Description

Contemporary models of interspinous fixation devices (IFDs) have evolved from spinous process wiring with bone blocks and early device designs (eg, Wilson plate, Meurig-Williams system, Daab plate). The newer devices range from paired plates with teeth to U-shaped devices with wings that are attached to the spinous process. They are intended as an alternative to pedicle screw and rod constructs to aid in the stabilization of the spine with interbody fusion. IFDs are placed under direct visualization, while screw and rod systems may be placed under direct visualization or percutaneously. Use of an IFD in combination with a unilateral pedicle screw system has also been proposed. IFDs are not intended for stand-alone use.

For use in combination with fusion, it has been proposed that IFDs are less invasive and present fewer risks than pedicle or facet screws. While biomechanics studies have indicated that IFDs may be similar to pedicle screw-rod constructs in limiting the range of flexion and extension, they may be less effective than bilateral pedicle screw-rod fixation for limiting axial rotation and lateral bending.[1,] There is a potential for a negative impact on the interbody cage and bone graft due to focal kyphosis resulting from the IFD. There is also a potential for spinous process fracture.

Unlike IFDs, interspinous distraction devices (spacers) are used alone for decompression and are typically not fixed to the spinous process (see medical policy #584). In addition, interspinous distraction devices have been designed for dynamic stabilization, whereas IFDs are rigid. However, IFDs might also be used to distract the spinous processes and decrease lordosis. Thus, IFDs could be used off-label without interbody fusion as decompression (distraction) devices in patients with spinal stenosis. If IFDs are used alone as a spacer, there is a risk of spinous process fracture.

Summary

Interspinous fixation (fusion) devices are being developed to aid in the stabilization of the spine. They are evaluated as alternatives to pedicle screw and rod constructs in combination with interbody fusion. Interspinous fixation devices (IFDs) are also being evaluated for stand-alone use in patients with spinal stenosis and/or spondylolisthesis.

For individuals who are undergoing spinal fusion who receive an IFD with interbody fusion, the evidence includes a systematic review of nonrandomized comparative studies and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. There is a lack of evidence on the efficacy of IFDs in combination with interbody fusion. One risk is spinous process fracture, while a potential benefit is a reduction in adjacent segment degeneration. Randomized trials with longer follow-up are needed to evaluate the risks and benefits following use of IFDs compared with the established standard (pedicle screw with rod fixation). The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have spinal stenosis and/or spondylolisthesis who receive an IFD alone, the evidence includes a retrospective series. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. There is a lack of evidence on the efficacy of IFDs as a stand-alone procedure. Randomized controlled trials are needed that evaluate health outcomes following use of IFDs as a stand-alone for decompression. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
5/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
5/2018	New references added from BCBSA National medical policy. Background and summary clarified.
5/2017	New references added from BCBSA National medical policy.
11/2015	New references added from BCBSA National medical policy.
4/2013	BCBSA National medical policy review. New policy describing non-coverage. Effective 4/1/2013.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

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5. Sclafani JA, Liang K, Ohnmeiss DD, et al. Clinical outcomes of a polyaxial interspinous fusion system. Int J Spine Surg. Feb 2014;8. PMID 25694912
6. North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion. 2004; https://www.spine.org/PolicyPractice/CoverageRecommendations/AboutCoverageRecommendations.aspx. Accessed March 6, 2017.
7. North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion. 2014; https://www.spine.org/ProductDetails?productid={7D67EEB8-4CC7-E411-9CA5-005056AF031E}. Accessed March 15, 2019.
8. North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion (Draft for comment only). 2019; https://www.spine.org/Portals/0/Documents/PolicyPractice/CoverageRecommendations/InterspinousFixationFusionDRAFT.pdf. Accessed March 15, 2019.