MEDICAL POLICY

POLICY TITLE	INTERSPINOUS FIXATION (FUSION) DEVICES
POLICY NUMBER	MP-1.151

Original Issue Date (Created):	**6/1/2017**
Most Recent Review Date (Revised):	**3/31/2021**
Effective Date:	**8/1/2021**

I. POLICY

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

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

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure for these indications.

II. PRODUCT VARIATIONS TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO - Refer to FEP Medical Policy Manual MP-7.01.107 Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers). The FEP Medical Policy Manual can be found at: *https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies*.

III. DESCRIPTION/BACKGROUND TOP

Interspinous fixation (fusion) devices are being developed to aid in the stabilization of the spine. They are being 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.

Contemporary models of interspinous fixation devices (IFDs) have evolved from spinous process wiring with bone blocks and early device designs (e.g., 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. 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. 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.

REGULATORY STATUS

The following IFDs have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. This list may not be exhaustive.

Aerial™ Interspinous Fixation (Globus Medical Inc.)
Affix™ (NuVasive)
Aileron™ (Life Spine)
Aspen™ (Lanx, acquired by BioMet)
Axle™ (X-Spine)
BacFuse® (Pioneer Surgical)
BridgePoint™ (Alphatec Spine)
coflex-IF® (Paradigm Spine)
Inspan™ (Spine Frontier)
InterBRIDGE® Interspinous Posterior Fixation System (LDR Spine)
Minuteman™ (Spinal Simplicity)
PrimaLOK™ (OsteoMed Spine)
Octave™ (Life Spine)
Spire™ (Medtronic)
SP-Fix™ (Globus)

ZIP® MIS Interspinous Fusion System (Aurora Spine).

Food and Drug Administration product code: PEK.

IFDs are intended for use as an adjunct to interbody fusion. For example, the indication for the coflex-IF® implant is as:

> "a posterior, nonpedicle supplemental fixation device intended for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1-S1). It is intended for attachment to the spinous processes for the purpose of achieving stabilization to promote fusion in patients with degenerative disc disease – defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies – with up to Grade 1 spondylolisthesis."

A number of interspinous plate systems have also been cleared for marketing by the Food and Drug Administration.

Use of an IFD for a stand-alone procedure is considered off-label.

IV. RATIONALE

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SUMMARY OF EVIDENCE

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-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 when used alone for decompression. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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NA

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered:

CPT Codes®								
22899								

IX. REFERENCES

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2. Lopez AJ, Scheer JK, Dahdaleh NS, et al. Lumbar spinous process fixation and fusion: a systematic review and critical analysis of an emerging spinal technology. Clin Spine Surg. Nov 2017;30(9):E1279-E1288. PMID 27438402

3. Kim HJ, Bak KH, Chun HJ, et al. Posterior interspinous fusion device for one-level fusion in degenerative lumbar spine disease: comparison with pedicle screw fixation - preliminary report of at least one year follow up. J Korean Neurosurg Soc. Oct 2012;52(4):359-364. PMID 23133725

4. Vokshoor A, Khurana S, Wilson D, et al. Clinical and radiographic outcomes after spinous process fixation and posterior fusion in an elderly cohort. Surg Technol Int. Nov 2014;25:271-276. PMID 25433267

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 31, 2021.

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 31, 2021.

8. Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.138, Interspinous Fixation (Fusion) Devices May, 2020.

X. POLICY HISTORY

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MP 1.151	**CAC 1/31/17 New policy adopting BCBSA.** Investigational for all indications. Coding reviewed.
	Admin coding update 9/1/17: Removed codes 22853, 22854 and 22859 and replaced them with 22899.
	11/29/2017 Consensus review. No changes to the policy statements. Rationale and references updated.
	8/9/18 Consensus review. No change to policy statements. References reviewed. Rationale condensed. 4/2/2019 Coding review. No changes.
	5/21/19 Consensus review. No change to policy statements. References updated. Summary of evidence reviewed.
	4/15/2020: Consensus Review. No Change to policy statement. References reviewed and updated. Coding reviewed with no changes.
	3/31/2021 Consensus Review. No change to policy statement. Regulatory Status section updated. References reviewed and updated. Coding reviewed with no changes.

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