



# Louisiana

## **Interspinous Fixation (Fusion) Devices**

**Policy #** 00679

**Original Effective Date:** 10/01/2019

**Current Effective Date:** 09/26/2020

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Interspinous and Interlaminar Stabilization/Distracton Devices (Spacers) is addressed separately in medical policy 00221.*

## **Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers interspinous fixation (fusion) devices are considered to be **investigational\*** for any indication, including but not limited to use:

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

## **Policy Guidelines**

Clinical input has identified potential exceptions when the devices might be considered medically necessary, such as patients with small pedicles where pedicle screws could not be safely placed.

## **Background/Overview**

Contemporary models of interspinous fixation devices 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. Interspinous fixation devices are placed under direct visualization, while screw and rod systems may be placed under direct visualization or percutaneously. Use of an interspinous fixation device in combination with a unilateral pedicle screw system has also been proposed. Interspinous fixation devices are not intended for stand-alone use.

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Interspinous Fixation (Fusion) Devices

Policy # 00679

Original Effective Date: 10/01/2019

Current Effective Date: 09/26/2020

For use in combination with fusion, it has been proposed that interspinous fixation devices are less invasive and present fewer risks than pedicle or facet screws. While biomechanics studies have indicated that interspinous fixation devices 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 interspinous fixation device. There is also a potential for spinous process fracture.

Unlike interspinous fixation devices, interspinous distraction devices (spacers) are used alone for decompression and are typically not fixed to the spinous process (see medical policy 00221). In addition, interspinous distraction devices have been designed for dynamic stabilization, whereas interspinous fixation devices are rigid. However, interspinous fixation devices might also be used to distract the spinous processes and decrease lordosis. Thus, interspinous fixation devices could be used off-label without interbody fusion as decompression (distraction) devices in patients with spinal stenosis. If interspinous fixation devices are used alone as a spacer, there is a risk of spinous process fracture.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

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

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Interspinous Fixation (Fusion) Devices

Policy # 00679

Original Effective Date: 10/01/2019

Current Effective Date: 09/26/2020

- Octave<sup>TM†</sup> (Life Spine)
- Spire<sup>TM†</sup> (Medtronic)
- SP-Fix<sup>TM†</sup> (Globus)
- SP-Link<sup>TM†</sup> System (Medical Designs LLC)
- ZIP<sup>®†</sup> MIS Interspinous Fusion System (Aurora Spine)
- UniVise<sup>TM†</sup> Spinous Process Fixation Plate

### **Rationale/Source**

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 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 interspinous fixation devices with interbody fusion, the evidence includes a systematic review of nonrandomized comparative studies and case series and 2 small randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. The randomized trials found comparable benefits for interspinous fixation devices with interbody fusion for those undergoing spinal fusion compared with interbody fusion with pedicle screws, but the comparative safety was less clear. One risk is spinous process fracture, while a potential benefit is a reduction in adjacent segment degeneration. Additionally, the RCTs had important methodological and relevancy weaknesses that limited their interpretation. Randomized trials with longer follow-up are needed to evaluate the risks and benefits following use of interspinous fixation devices 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 interspinous fixation device 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 interspinous fixation devices as a stand-alone procedure. RCTs are needed that evaluate health outcomes following use of interspinous fixation devices as a stand-alone for decompression. The evidence is insufficient to determine the effects of the technology on health outcomes.

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Interspinous Fixation (Fusion) Devices

Policy # 00679

Original Effective Date: 10/01/2019

Current Effective Date: 09/26/2020

### **Supplemental Information**

#### **Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 3 physician specialty societies (2 reviewers) and 2 academic medical centers while this policy was under review in 2012. Input was mixed. Some indications where the devices might be medically necessary were noted, such as patients with small pedicles where pedicle screws could not be safely placed.

#### **Practice Guidelines and Position Statements**

##### **North American Spine Society**

In 2019, the North American Spine Society issued a coverage position on the use of interspinous devices with lumbar fusion. The North American Spine Society noted that although there is still limited evidence, interspinous fixation with fusion for stabilization may be considered when utilized in the context of lumbar fusion procedures for patients with diagnoses including stenosis, disc herniations, or synovial facet cysts in the lumbar spine, as an adjunct to cyst excision which involves removal of greater than 50 percent of the facet joint and when utilized in conjunction with a robust open laminar and/or facet decortication and fusion, and/or a robust autograft inter- and extra-spinous process decortication and fusion, and/or an interbody fusion of the same motion segment. The North American Spine Society also noted that "No literature supports the use of interspinous fixation without performing an open decortication and fusion of the posterior bony elements or interbody fusion."

##### **U.S. Preventive Services Task Force Recommendations**

Not applicable.

##### **Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Interspinous Fixation (Fusion) Devices

Policy # 00679

Original Effective Date: 10/01/2019

Current Effective Date: 09/26/2020

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this evidence review are listed in Table 1.

**Table 1. Summary of Key Trials**

| NCT No.                  | Trial Name   | Planned Enrollment | Completion Date       |
|--------------------------|--|--------------------|-----------------------|
| <i>Ongoing</i>           |  |                    |                       |
| NCT01455805 <sup>a</sup> | Efficacy and Quality of Life Following Treatment of Lumbar Spinal Stenosis, Spondylolisthesis or Degenerative Disc Disease With the Minuteman Interspinous Interlaminar Fusion Implant Versus Surgical Decompression | 50                 | March 2024            |
| <i>Unpublished</i>       |  |                    |                       |
| NCT01560273 <sup>a</sup> | A Multi-Center Prospective Study Evaluation Aspen Spinous Process Fixation System for Use in Posterolateral Fusion (PLF) in Patients With Spondylolisthesis  | 25                 | Sep 2015 (terminated) |
| 01549366 <sup>a</sup>    | System Versus Pedicle Screw Fixation, in Lateral Lumbar Interbody Fusion (LLIF) or Anterior Lumbar Interbody Fusion (ALIF)   |                    |                       |

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

## References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Interspinous Fixation (Fusion) Devices”, 7.01.138, May 2020.
2. Food and Drug Administration. UniVise Spinous Process Fixation Plate. FDA Center for Drug and Evaluation Research. 2013; [https://www.accessdata.fda.gov/cdrh\\_docs/pdf13/K132968.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf13/K132968.pdf)
3. Wu JC, Mummaneni PV. Using lumbar interspinous anchor with transforaminal lumbar interbody fixation. *World Neurosurg*. May 2010;73(5):471-472. PMID 20920928

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Interspinous Fixation (Fusion) Devices

Policy # 00679

Original Effective Date: 10/01/2019

Current Effective Date: 09/26/2020

4. 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
5. Huang WM, Yu XM, Xu XD, et al. Posterior Lumbar Interbody Fusion with Interspinous Fastener Provides Comparable Clinical Outcome and Fusion Rate to Pedicle Screws. Orthop Surg. 2017 May;9(2). PMID 28544495
6. Panchal R, Denhaese R, Hill C, et al. Anterior and Lateral Lumbar Interbody Fusion With Supplemental Interspinous Process Fixation: Outcomes from a Multicenter, Prospective, Randomized, Controlled Study. Int J Spine Surg. 2018 Apr;12(2). PMID 30276077
7. 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
8. North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion. Revised December 2019. <https://www.spine.org/coverage>.

### **Policy History**

Original Effective Date: 10/01/2019

Current Effective Date: 09/26/2020

07/03/2019 Medical Policy Committee review

07/18/2019 Medical Policy Implementation Committee approval. New policy.

07/02/2020 Medical Policy Committee review

07/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 07/2021

### **Coding**

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

*The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is*

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Interspinous Fixation (Fusion) Devices

Policy # 00679

Original Effective Date: 10/01/2019

Current Effective Date: 09/26/2020

*intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.*

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

| Code Type        | Code                  |
|------------------|-----------------------|
| CPT              | 22840                 |
| HCPCS            | No codes              |
| ICD-10 Diagnosis | All related diagnoses |

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Interspinous Fixation (Fusion) Devices

Policy # 00679

Original Effective Date: 10/01/2019

Current Effective Date: 09/26/2020

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.