

## MEDICAL POLICY – 7.01.591

# Interspinous Fixation (Fusion) Devices

BCBSA Ref. Policy: 7.01.138

Effective Date: July 1, 2024

Last Revised: June 11, 2024

Replaces: N/A

RELATED MEDICAL POLICIES:

7.01.107 Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

7.01.542 Lumbar Spinal Fusion

Select a hyperlink below to be directed to that section.

[POLICY CRITERIA](#) | [CODING](#) | [RELATED INFORMATION](#)  
[EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)

 Clicking this icon returns you to the hyperlinks menu above.

## Introduction

Back pain is a common symptom and, for some, can lead to disability. Devices that keep specific areas of the spine rigid are known as interspinous fixation devices. Surgeons attach these devices to the bones of the spine (vertebrae) to prevent the joints from bending and twisting as they normally would. The intent of the devices is to decrease pain. These devices are typically used as part of fusion surgery. The device holds the spine in place while the implanted bone material eventually fuses the vertebrae together. Occasionally the device might be used without fusion surgery in order to relieve pressure on the spinal cord or nerve. Interspinous fixation devices are considered unproven. There is not enough evidence to show whether these devices are effective when used during a fusion surgery or on their own. The health plan considers these devices investigational.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

Devices	Investigational
<b>Interspinous fixation (fusion) devices</b>	<p><b>Interspinous fixation (fusion) devices are considered investigational for any indication, including but not limited to use:</b></p> <ul style="list-style-type: none"> <li>In combination with interbody fusion</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>Alone for decompression in individuals with spinal stenosis</li> </ul> <p>Examples of investigational devices include, but are not limited to, the following: (See <a href="#">Appendix</a> for examples of stand-alone devices)</p> <ul style="list-style-type: none"> <li>Aerial Interspinous Fixation (Globus)</li> <li>Affix (NuVasive)</li> <li>Aileron (Life Spine)</li> <li>Aspen (Lanx, acquired by BioMet)</li> <li>Axle (X-Spine)</li> <li>BacFuse (Pioneer Surgical)</li> <li>BridgePoint (Alphatec Spine)</li> <li>Coflex-IF (Paradigm Spine)</li> <li>Inspan (Spine Frontier)</li> <li>InterBRIDGE Interspinous Posterior Fixation System (LDR Spine)</li> <li>Minuteman (Spinal Simplicity)</li> <li>Octave (Life Spine)</li> <li>PrimaLOK (OsteoMed)</li> <li>SP-Fix (Globus)</li> <li>SP-Link System (Medical Designs LLC)</li> <li>Spire (Medtronic)</li> <li>ZIP MIS Interspinous Fusion System (Aurora Spine)</li> </ul>

## Coding

There are no specific CPT codes for insertion of these devices (see [Regulatory Status](#)). The following add on codes might be used, but should not be reported as stand-alone services:

Code	Description
CPT	



Code	Description
22840	Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)
22853	Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)
22854	Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
22859	Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

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

The name of the specific fixation device used for the procedure should be included in the clinical documentation.

## Related Information

N/A

## Evidence Review



## Description

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 individuals with spinal stenosis and/or spondylolisthesis.

## Background

Contemporary models of 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 to be 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 is proposed that IFDs are less invasive and present fewer risks than pedicle or facet screws. While biomechanical 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.<sup>1</sup> 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 [Related Policies](#)). 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 individuals with spinal stenosis. If IFDs are used alone as a spacer, there is a risk of spinous process fracture.

## 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



and two 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 IFDs 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 IFDs compared with the established standard (pedicle screw with rod fixation). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with 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. RCTs are needed that evaluate health outcomes following use of IFDs as a stand-alone for decompression. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## Ongoing and Unpublished Clinical Trials

Some currently ongoing and 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
<b>Ongoing</b>			
<a href="#">NCT01455805<sup>a</sup></a>	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	Mar 2024
<b>Unpublished</b>			
<a href="#">NCT01560273<sup>a</sup></a>	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)



NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01549366 <sup>a</sup>	System Versus Pedicle Screw Fixation, in Lateral Lumbar Interbody Fusion (LLIF) or Anterior Lumbar Interbody Fusion (ALIF)	64	Jan 2016 (completed)

NCT: national clinical trial

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

## 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 three physician specialty societies (two reviewers) and two academic medical centers while this policy was under review in 2012. The input was mixed. Some indications where the devices might be medically necessary were noted, such as individuals with small pedicles where pedicle screws could not be safely placed.

## Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

## North American Spine Society

In 2019, the North American Spine Society issued a coverage position on the use of interspinous devices with lumbar fusion.<sup>6</sup> 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 individuals 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.”

## Medicare National Coverage

There is no national coverage determination.

## Regulatory Status

The following IFDs have been cleared for marketing by the US Food and Drug Administration (FDA) 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)
- Octave (Life Spine)
- Spire (Medtronic)
- SP-Fix (Globus)
- SP-Link System (Medical Designs LLC)
- ZIP MIS Interspinous Fusion System (Aurora Spine)

FDA product code: PEK.

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

A posterior, non-pedicle 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 FDA.

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

## References

1. Wu JC, Mummaneni PV. Using lumbar interspinous anchor with transforaminal lumbar interbody fixation. *World Neurosurg.* May 2010; 73(5): 471-2. PMID 20920928
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. 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.* May 2017; 9(2): 198-205. PMID 28544495
4. 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.* Apr 2018; 12(2): 172-184. PMID 30276077
5. Sclafani JA, Liang K, Ohnmeiss DD, et al. Clinical outcomes of a polyaxial interspinous fusion system. *Int J Spine Surg.* 2014; 8. PMID 25694912



6. North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion. Revised December 2019. <https://www.spine.org/Product-Details?productid=%7B7D67EEB8-4CC7-E411-9CA5-005056AF031E%7D>. Accessed May 14, 2024.

## Appendix

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**Note: This policy does not apply to stand-alone spine cages. These examples are provided for informational purposes only. This list may not be all inclusive.**

- A-CIFT SoloFuse (SpineFrontier)
- ACIS cage (Synthes)
- Acromed Lumbar I/F Cage (Depuy)
- Aero AL (Stryker)
- Aero C (Stryker)
- Aesculap PEEK
- Alamo Spine Cage (Alliance Spine)
- Aleutian Spacer System (K2M)
- ALIF Spine Truss System (4web)
- Alphatec Novel TL Spacer System
- Anatomic PEEK PTC cervical fusion system (Medtronic)
- Ancora spacer (Zimmer)
- AnyPlus PEEK TLIF (GS Medical)
- Apache spacer (Genesys)
- Arch ODL spacer (Synthes)
- Arena-C (SpineFrontier)
- Ascential (Stryker)
- Athlet (Signus)



- Avenue-L (Zimmer Biomet)
- AVS Anchor-L Lumbar Cage System (Stryker)
- AVS AS PEEK (Stryker)
- AVS Navigator (Stryker)
- AVS PL PEEK (Stryker)
- BAK Interbody Fusion System (Zimmer)
- Bengal Corpectomy Cage (Depuy)
- BoneBac Interbody System (Thompson MIS)
- Brantigan (DePuy)
- Brigade (Nuvasive)
- Bullet-Tip PEEK VBR/IBF (RTI Surgical)
- CALIX cage (X-Spine)
- Cambria anterior cervical interbody system (Integra\Theken Spine)
- Capstone PEEK Cage (Medtronic)
- Cascadia TL implant system (K2M)
- Cavetto cage (Neurostructures)
- Cezanne II (Accel Spine)
- Chesapeake Spinal System (K2M)
- Cimplicity (SpineSmith)
- Clariance TLIF cage
- Clydesdale (Medtronic)
- Co Roent XL (Nuvasive)
- Coalition Spacer (Globus)
- Concorde Bullet Spine System (DePuy Synthes)



- Construx Mini PTC Spacer System (Orthofix)
- Continental (Globus)
- Corelink Anterior Cervical Interbody Cage System (Foundation)
- Cornerstone PSR Spinal System (Medtronic)
- CoRoent Interbody Cage (Nuvasive)
- Cougar Cage System (Depuy)
- Coveris (Camber)
- C-Plus IBF (Pioneer Surgical\RTI Surgical)
- Crescent cage (Medtronic)
- Devex TLIF Cage (DePuy)
- Dorado (Spine Frontier)
- Ebi PEEK optima spacer (Biomet)
- Emerald cervical PEEK system (Glaser)
- Eminent Sidewinder DLIF PEEK Cage
- Endoskeleton TCS (Titan Spine)
- Express IBFD (Advanced Vertebral Solutions)
- Foundation Cervical Interbody Device (CoreLink)
- Fuse (Medtronic)
- FuseLox Lumbar Cage (Captiva Spine)
- Harpoon, Hawkeye, Hornet, Shark (ChoiceSpine)
- Honour cage (Nexxt Spine)
- Honour Orb (Nexxt Spine)
- IN:C2 spacer (SpineSmith)
- InFill Lateral Interbody Device (Pinnacle Spine)



- Innovasis Box PEEK IBF System
- Innovasis C-Box PEEK cage
- Interfuse - T (Vertebral Technologies)
- Irix-C (X Spine)
- Juliet TL Lumbar Interbody Fusion Device (Spineart)
- LANX Lateral Cage
- LDR ROI-A Implant System
- Leopard (DuPuy)
- Levo fixed cage (non-expandable) (Alphatec Spine)
- LLC Reveal VBR System (Theken)
- Lucent Magnum (Spinal Elements)
- Lucent TiBond Interbody System (Spinal Elements)
- Luna Interbody Fusion System (Benvenue)
- Magnum + Stand-alone Lumbar Interbody Fusion system (Spinal Elements)
- Maxim Surgical X-Treme interbody fusion system
- MectaLIF transforaminal lumbar interbody fusion device (Genesys)
- Medyssey BN
- NanoLOC (Titan)
- Nanovis cage
- Novel Spinal System (Alphatec Spine)
- OLIF PEEK (Medtronic)
- OLIF 51 (Medtronic)
- Orio-AL, Orio-C, Orio-PL, Orio-TL (SpineCraft)
- Osteofix Pillar (AL, SA, PL, TL)



- OsteoStim (Biomet)
- Pathway AVID (Custom Spine)
- Pillar SA PEEK Spacer (Orthofix)
- Pioneer Interbody Fusion (IBF)/Vertebral Body Replacement System (C-Plus)
- Precision Vault ALIF System (Precision Spine)
- Prevail Interbody Device (Medtronic)
- PRO-LINK Stand-Alone Cervical Spacer System (Life Spine)
- Pulse cervical cage system (DePuy)
- Ravine (K2M)
- Ray Threaded Fusion Cage (Synthes)
- Renovis PEEK ALIF Cage
- ROI-C (LDR)
- Scarlet AC-T Secured Anterior Cervical Cage (SpineArt)
- Silverstone IBF System (Altus Spine)
- Solitaire C Cervical Spacer System (Biomet)
- Spine 360 plate & cage for cervical fusion
- Spine 360 Cervical Interbody Fusion System
- Spine Vu c-POD Intervertebral Body Fusion Device (Integra\Theken)
- Stalif-C (Cervical Cage) (Centinel Spine)
- Stalif Midline and Stalif Midline ABO Screws (Centinel Spine)
- Stingray (Spine 360)
- Surgical Titanium Mesh (Depuy)
- Sustain-O (Globus)
- Syncage (Synthes)



- SYNFIX LR system (Synthes)
- T-Pal (Synthes)
- Timberline Cage (Lanx)
- TiNano (Aurora Spine)
- TiLink-T (Acuity Surgical)
- Titanium PL cage (Stryker)
- Tomcat (Choice Spine)
- Transcontinental (Globus)
- Tryptik CA (Spineart)
- Valeo C (Amedica)
- Valeo II LL (Amedica)
- Vault ALIF system (Precision Spine)
- Velofix (U & I Corporation)
- Vertigraft (Lifenet)
- Vertu TiBond PEEK cage
- Vu POD (Integra\Theken)
- XP L Spinal System (Arcadius)
- Zavation PEEK cage
- Zero-P Zero-Profile Anterior Cervical Interbody Fusion Device (Synthes)
- Zeus A (Amendia)
- Zeus C cervical spacer (Amendia)
- Zeus L (Amendia)
- Zeus T (Amendia)
- Zimmer TM-S cervical fusion device



- Zyston Curved Spacer System (Biomet)
- Zyston Straight Spacer System (Biomet)

## History

Date	Comments
11/13/12	New policy. Policy created with literature search through July 2012; considered investigational.
01/29/13	Update Related Policies, add 7.01.130.
12/04/13	Replace policy. Policy updated with literature review through July 30, 2013; policy statement unchanged.
11/20/14	Annual Review. Policy updated with literature review through July 28, 2014. References 3-4 added; others renumbered/removed. Policy statement unchanged.
04/20/15	Update Related Policies. Edit title to 7.01.542.
11/10/15	Annual Review. Added clarification to the Policy Guidelines that the codes in this policy describe additional intra-service work associated with the primary procedure and would not be reported as stand-alone services. Added a note to state the name of the device used in the procedure should be included in the clinical documentation. Policy updated with literature review through August 12, 2015; references 4-5 added. Policy statement unchanged.
08/01/16	Annual review approved July 12, 2016. Policy statement unchanged. No references added.
10/11/16	Policy moved into new format; no change to policy statements.
01/01/17	Coding update, added new CPT codes 22853, 22854, and 22859 with effective date of 01/01/17.
01/13/17	Clarified and corrected coding update. Note was added that CPT code 22851 was deleted as of 01/01/17 and replaced with three new CPT codes (22853, 22854, and 22859) effective 01/01/17.
07/01/17	Annual Review, approved June 6, 2017. Policy updated with literature review through February 23, 2017; references 2-3 added; one reference removed. Policy statement unchanged.
01/01/18	Coding update, removed CPT code 22851 as it was terminated 1/1/17.
07/01/18	Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; reference 6 updated. Policy statement unchanged. Removed CPT code 22851 as it was deleted and replaced with 3 other codes on 1/1/17.



Date	Comments
07/01/19	Annual Review, approved June 20, 2019. Policy updated with literature review through February 2019; references 7 and 8 added. Policy statement unchanged.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
06/10/20	Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.
08/01/20	Annual Review, approved July 23, 2020. Policy updated with literature review through February, 2020; references added. Policy statement unchanged.
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through January 11, 2021; no references added. Policy statement unchanged.
10/01/21	Coding update, Added HCPCS code C1831.
12/01/21	Coding update, Removed HCPCS code C1831.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through January 17, 2022; no references added. Policy statement unchanged.
10/01/22	Interim Review, approved September 26, 2022. Policy examples of investigational devices expanded and enlarged for viewing ease. Appendix added of examples of stand-alone spine cages for informational purposes only. Changed the wording from "patient" to "individual" throughout the policy for standardization.
07/01/23	Annual Review, approved June 12, 2023. Policy updated with literature review through January 16, 2023; no references added. Minor editorial refinement to policy statement; intent unchanged.
07/01/24	Policy renumbered from 7.01.138 to 7.01.591 Interspinous Fixation (Fusion) Devices, approved June 11, 2024. Policy updated with literature review through March 2, 2024; no references added. Policy statement unchanged.

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**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

