02-20000-36

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Subject: Interspinous and Interlaminar Stabilization/Distraction (Spacers) and Fixation (Fusion) Devices

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Interspinous spacers are devices implanted between vertebral spinous processes. Interlaminar spacers are implanted between adjacent lamina and have 2 sets of wings that are placed around the inferior and superior spinous processes. These implants aim to restrict painful motion while otherwise enabling normal motion. The devices (spacers) distract the laminar space and/or spinous processes and restrict extension. This procedure theoretically enlarges the neural foramen and decompresses the cauda equina in patients with spinal stenosis and neurogenic claudication.

One type of interspinous implant is inserted between the spinous processes through a small (4–8 cm) incision and acts as a spacer between the spinous processes, maintaining the flexion of that spinal interspace. The supraspinous ligament is maintained and assists in holding the implant in place. The surgery does not include any laminotomy, laminectomy, or foraminotomy at the time of insertion, thus reducing the risk of epidural scarring and cerebrospinal fluid leakage. Other interspinous spacers require removal of the interspinous ligament and are secured around the upper and lower spinous processes. Interlaminar implants are inserted between the adjacent lamina and spinous processes.

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 to be 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 either 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. Interspinous fixation (fusion) devices contrast with interspinous distraction devices (spacers), which are used alone for decompression and are typically not fixed to the spinous process. For use in combination with fusion, it is proposed that fixation systems are less invasive and present fewer risks than pedicle or facet screws. However, while biomechanical studies indicate that fixation devices may be similar to pedicle screw-rod constructs in limiting the range of flexion-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 device. There is also a potential for spinous process fracture.

POSITION STATEMENT:

Interspinous and interlaminar distraction devices are considered **experimental or investigational** for all indications, including as treatment of spinal stenosis.

Interlaminar stabilization devices used alone, or following decompressive surgery is considered **experimental or investigational**.

Interspinous fixation (fusion) devices are considered **experimental or investigational** for any indication, including but not limited to use in combination with interbody fusion, or used alone for decompression to treat spinal stenosis.

There is insufficient clinical evidence in the peer reviewed literature demonstrating the safety and efficacy of these procedures, or demonstrating the effects of these procedures on long-term health outcomes.

BILLING/CODING INFORMATION:

The following codes may be used to describe distraction devices:

CPT Coding

22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level **(Investigational)**
22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure) **(Investigational)**
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level **(Investigational)**
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) **(Investigational)**

There are no specific CPT codes for insertion of interspinous fixation (fusion) devices.

HCPCS Coding

C1821	Interspinous process distraction device (implantable) **(Investigational)**

REIMBURSEMENT INFORMATION:

Refer to sections entitled **POSITION STATEMENT** and **PROGRAM EXCEPTIONS**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Interspinous Process Decompression (L34006) located at fcso.com.

DEFINITIONS:

Neural foramen: the passage formed by the inferior and superior notches on the pedicles of adjacent vertebrae; it transmits a spinal nerve and vessels.

Neurogenic claudication: a type of claudication that is accompanied by pain and paresthesias in the back, buttocks, and lower limbs and is relieved by stooping or sitting. The usual cause is a mechanical disturbance due to posture, and a rare cause is ischemia of the cauda equina.

Spinal stenosis: narrowing of the vertebral canal, nerve root canals, or intervertebral foramina of the lumbar spine caused by encroachment of bone upon the space; symptoms are caused by compression of the cauda equina and include pain, paresthesias, and neurogenic claudication. The condition may be either congenital or due to spinal degeneration.

RELATED GUIDELINES:

Total Facet Arthroplasty, 02-20000-37

OTHER:

Index terms:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

- Affix™ Next Gen Spinous Process Plate System
- Affix II and Affix II Mini Spinous Process Plating System
- Aileron™ Interspinous Fixation System
- Aperius® PercLID System
- Aspen™ MIS Fusion System
- Aspen Spinous Process Fixation System
- Aurora Spine ZIP™ MIS Interspinous Fusion System
- Axle™ Interspinous Fusion System

- BacFuse® Spinous Process Fusion Plate
- BioFlex intervertebral stabilization device
- BridgePoint™ Spinous Process Fixation System
- CD HORIZON SPIRE Z Spinal System or plate
- CD Horizon Agile Dynamic Stabilization Device
- coflex® Interlaminar Technology implant
- coflex-F® Implant System
- CoRoent Extensure
- DIAM™ Spinal Stabilization System
- DSS Dynamic Soft Stabilization System
- Dynabolt Dynamic Stabilization System
- Dynesys Spinal System
- ExtenSure
- Falena® Interspinous Decompression Device
- FLEXUS™
- Helifix Interspinous Spacer System
- In-Space
- Inspan™
- Interbridge Interspinous Posterior Fixation System
- Isobar Spinal System
- Minuteman™ Interspinous Interlaminar Fusion Device
- NFix®
- NL-Prow™ Interspinous Spacer
- PrimaLOK™ SP Interspinous Fusion System
- Octave™
- Satellite Spinal System
- Spire™ MIS Spinal Fixation System
- Stabilimax NZ Dynamic Spine Stabilization System
- Stabilink MIS Interspinous Fixation Device
- Stenofix
- Superion™ ISS Interspinous Spacer
- SP-Fix™ Spinous Process Fixation Plate
- VertiFlex® Spinous Process Fixation Plate
- X-STOP® Interspinous Process Decompression System (IPD®)
- X-STOP® PEEK Interspinous Process Decompression (IPD®)

- Wallis® System
- Zip Mis Interspinous Fusion System
- Zodiak DynaMo System

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 05/24/18.

GUIDELINE UPDATE INFORMATION:

07/15/08	New Medical Coverage Guideline.
04/15/09	HCPCS code C1821 deleted from policy.
06/15/09	Scheduled review; no change in position statement. Update references.
04/15/10	Annual review; added investigational statement for dynamic spinal stabilization to position statement; description of dynamic spinal stabilization devices added to description section; references updated; and guideline title revised.
12/15/11	Scheduled review; no change in position statement. Updated description section and references.
11/15/12	Scheduled review; position statement maintained. Revised description and Medicare Advantage program exception (added utilization guidelines). Updated references.
07/15/13	Revision; updated description section (coflex® Interlaminar Technology implant language). Revised Program Exceptions section and index terms. Updated references.
11/15/13	Scheduled review. Revised MCG title and description section. Maintained position statement. Revised index terms. Updated references.
01/01/15	Scheduled review. Position statement maintained. Revised description section and index terms. Updated references.
10/15/15	Scheduled review. Revised description section and index terms. Updated references.
01/01/17	Annual CPT/HCPCS update. Added 22867, 22868, 22869, 22870. Deleted 0171T, 0172T.
02/15/17	Scheduled review. Maintained Position Statement section. Updated references.
06/15/18	Unscheduled review. Maintained Position Statement section. Revised index terms. Updated references.
02/22/19	Revision: added code C1821.