MEDICAL POLICY – 7.01.138

Interspinous Fixation (Fusion) Devices

BCBSA Ref. Policy: 7.01.138

Effective Date: July 1, 2018

Last Revised: June 22, 2018

Replaces: N/A

RELATED MEDICAL POLICIES:
7.01.107 Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)
7.01.130 Axial Lumbosacral Interbody Fusion
7.01.542 Lumbar Spinal Fusion

Select a hyperlink below to be directed to that section.

<table>
<thead>
<tr>
<th>POLICY CRITERIA</th>
<th>CODING</th>
<th>RELATED INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVIDENCE REVIEW</td>
<td>REFERENCES</td>
<td>HISTORY</td>
</tr>
</tbody>
</table>

∞ 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
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

**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:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>22840</td>
<td>Posterior non-segmental instrumentation (eg, 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)</td>
</tr>
<tr>
<td>22853</td>
<td>Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>22854</td>
<td>Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, 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)</td>
</tr>
<tr>
<td>22859</td>
<td>Insertion of intervertebral biomechanical device(s) (eg, 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)</td>
</tr>
</tbody>
</table>

**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 patients 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 patients with spinal stenosis and/or spondylolisthesis.

Background

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 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 indicate 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 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 patients 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 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 and rod fixation). The evidence is insufficient to determine the effects of the technology on health outcomes.

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. Randomized controlled trials that evaluate health outcomes following use of IFDs when used alone for decompression are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

**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

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01455805</td>
<td>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</td>
<td>50</td>
<td>Dec 2020</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01560273</td>
<td>A Multi-Center Prospective Study Evaluation Aspen Spinous Process Fixation System for Use in Posterolateral Fusion (PLF) in Patients With Spondylolisthesis</td>
<td>25</td>
<td>Sep 2015 (terminated)</td>
</tr>
<tr>
<td>NCT01016314</td>
<td>A Multi-Center Prospective Randomized Study to Evaluate the Efficacy of the Aspen Spinous Process System for Use in Anterior Lumbar Interbody Fusion (ALIF)</td>
<td>39</td>
<td>Jan 2016 (completed)</td>
</tr>
<tr>
<td>NCT01549366</td>
<td>A Multi-Center Prospective Randomized Study Comparing Supplemental Posterior Instrumentation, Aspen™ Spinous Process System Versus Pedicle Screw Fixation, in Lateral Lumbar Interbody Fusion (LLIF) or Anterior Lumbar Interbody Fusion (ALIF)</td>
<td>64</td>
<td>Jan 2016 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

Denotes industry-sponsored or cosponsored trial

Clinical Input Received 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. The 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

The North American Spine Society issued a coverage position in 2004 on the use of interspinous devices with lumbar fusion. The Society recommended that interspinous fixation with fusion for stabilization was currently not indicated as an alternative to pedicle screw fixation with lumbar fusion procedures.

Medicare National Coverage

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

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.

- 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)
• ZIP® MIS Interspinous Fusion System (Aurora Spine)

Food and Drug Administration 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 Food and Drug Administration.

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

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/13/12</td>
<td>New policy. Policy created with literature search through July 2012; considered investigational.</td>
</tr>
<tr>
<td>01/29/13</td>
<td>Update Related Policies, add 7.01.130.</td>
</tr>
<tr>
<td>12/04/13</td>
<td>Replace policy. Policy updated with literature review through July 30, 2013; policy statement unchanged.</td>
</tr>
<tr>
<td>04/20/15</td>
<td>Update Related Policies. Edit title to 7.01.542.</td>
</tr>
<tr>
<td>11/10/15</td>
<td>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.</td>
</tr>
<tr>
<td>08/01/16</td>
<td>Annual review approved July 12, 2016. Policy statement unchanged. No references added.</td>
</tr>
<tr>
<td>10/11/16</td>
<td>Policy moved into new format; no change to policy statements.</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Coding update, added new CPT codes 22853, 22854, and 22859 with effective date of 01/01/17.</td>
</tr>
<tr>
<td>01/13/17</td>
<td>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.</td>
</tr>
<tr>
<td>01/01/18</td>
<td>Coding update, removed CPT code 22851 as it was terminated 1/1/17.</td>
</tr>
<tr>
<td>07/01/18</td>
<td>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.</td>
</tr>
</tbody>
</table>
Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

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.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
• Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  • Qualified sign language interpreters
  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
  • Qualified interpreters
  • Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Amharic):
لا يوجد هذا الإشعار معلومات هامة. قد يحتوي هذا الإشعار معلومات مهمة بخصوص طبلك أو الطبلك المتعلقة التي تزيد من خلافات على ما ينتمي تأهيل الصحة والسلامة في هذا الإشعار. يجب أن يكون الإجراءات التي ترد في هذه المعلومات معرفة بتفويضاتbrane Blue Cross. يندرج ضمن هذه المعلومات ما يخصك دينه أو لكنه يخصك. يرجى إبلاغنا في كل حال بالفقرات على هذه المعلومات والعلامات بالإضافة إلى كلالة. أصل
800-722-1471 (TTY: 800-842-5357) 55603

中文 (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請按電話 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):

Français (French):

Kreyól ayisyen (Creole):

Deutsche (German):

Hmoob (Hmong):

Iloko (Ilocano):
Daytoy a Pakdaak ket Naglaon ini Napateg nga Impormasn. Daytoy a pakdaak mabalin nga adda ket naglaon ini napateg nga impormasn maipanggep iti aksiparowyen yowo coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a pesa iti daytoy a pakdaak. Mabalin nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a neluding nga adda alaw tapo mapatgalaiddyo ti coverage ti salun-ayyo yowo tulong kadagit gastos. Adda karbenganyo a mangala iti daytoy nga impormasn ken tulong ti bukodyo a pagasasao nga awan ti bayadayo. Tumawag ti numero nga yooj 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas claras en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).