important reminder

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

description

The spinous process fixation orthosis is marketed as a minimally invasive alternative to pedicle screw instrumentation in spinal interbody fusion. The device is inserted through a small incision over the spinal level being fused. It includes an enclosure in which bone graft material is placed.

medical policy criteria

Implantation of spinous process fixation orthoses is considered investigational for all indications.

note: A summary of the supporting rationale for the policy criteria is at the end of the policy.

cross references

1. Dynamic Stabilization of the Spine, Surgery, Policy No. 143
2. Interspinous and Interlaminar Stabilization and Distraction Devices (Spacers), Surgery, Policy No. 155
3. Percutaneous Axial Anterior Lumbar Fusion, Surgery, Policy No. 157
4. Total Facet Arthroplasty, Surgery, Policy No. 171
5. Image-Guided Minimally Invasive Spinal Decompression (IG-MSD) for Spinal Stenosis, Surgery, Policy No. 176

**BACKGROUND**

This device may also be referred to as an interspinous anchor, spinous fixation system, or spinal interlaminar fixation orthosis. It differs from interspinous process spacers (e.g., X-STOP) and dynamic stabilization systems in that it is intended for fixation/fusion rather than as motion preserving devices.

**REGULATORY STATUS**

There are a number of spinous process fixation orthoses under investigation, some of which have received approval for marketing from the U.S. Food and Drug Administration (FDA) for single-level fixation with bone graft material for achieving supplemental fusion. **These devices are not approved for stand-alone use, and the list may not be exhaustive:**

<table>
<thead>
<tr>
<th>Device name</th>
<th>Manufacturer</th>
<th>FDA Approved?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affix™ Spinous Process Plate Systems</td>
<td>NuVasive®</td>
<td>Yes</td>
</tr>
<tr>
<td>Aileron® Posterior Fusion System and Interspinous</td>
<td>Life Spine®</td>
<td>Yes</td>
</tr>
<tr>
<td>Fixation System</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspen® Spinous Process Fixation System</td>
<td>Lanx® (acquired by BioMet)</td>
<td>Yes</td>
</tr>
<tr>
<td>Axle™ Interspinous Fusion System</td>
<td>X-Spine</td>
<td>Yes</td>
</tr>
<tr>
<td>BacFus® Spinous Process Fusion Plate</td>
<td>RTI Surgical™ (formerly</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Pioneer® Surgical)</td>
<td></td>
</tr>
<tr>
<td>BridgePoint™ Spinous Process Fixation System</td>
<td>Alphatec Spine®</td>
<td>Yes</td>
</tr>
<tr>
<td>coflex-F® Implant Systems*</td>
<td>Paradigm Spine</td>
<td>Yes</td>
</tr>
<tr>
<td>Inspan™ Spinous Process Plate System</td>
<td>SpineFrontier®</td>
<td>Yes</td>
</tr>
<tr>
<td>InterBRIDGE Interspinous Posterior Fixation System</td>
<td>LDR Spine</td>
<td>Yes</td>
</tr>
<tr>
<td>Minuteman® Interspinous Interlaminar Fusion Device</td>
<td>Spinal Simplicity</td>
<td>Yes</td>
</tr>
<tr>
<td>(percutaneous spinal fusion)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Octave™ Posterior Fusion System</td>
<td>Life Spine®</td>
<td>Yes</td>
</tr>
<tr>
<td>PrimaLOK™ SP Interspinous Fusion System</td>
<td>OsteoMed Spine</td>
<td>Yes</td>
</tr>
<tr>
<td>SP-Fix™ Spinous Process Fixation System</td>
<td>Globus Medical</td>
<td>Yes</td>
</tr>
<tr>
<td>Spire™ Stabilization System</td>
<td>Medtronic Sofamor Danek</td>
<td>Yes</td>
</tr>
<tr>
<td>ZIP™ MIS Interspinous Fusion System</td>
<td>Aurora Spine</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*The non-fusion coflex® Interlaminar Implant is addressed separately in the medical policy for Interspinous and Interlaminar Stabilization/Distraction Devices, see Cross References.*
EVIDENCE SUMMARY

Evaluating the safety and effectiveness of spinous process fixation orthoses requires randomized comparisons with spinal fusion using conventional devices (e.g., pedicle screws). These comparisons are necessary to determine whether the benefits of spinous process fixation orthoses outweigh any risks and whether they offer advantages over conventional devices (e.g., pedicle screws, rods, cages) with respect to the following:

- Pain and functioning
- Durability of treatment effects (the benefits of spinal surgery are known to diminish over time; therefore, it cannot be assumed that any early benefits will remain stable in the long term)
- Adverse events (e.g., vertebral fracture)
- Device failure/replacement
- Impact on future surgical options in the same or adjacent spinal levels.

Spinous process fixation devices are not approved by the U.S. Food and Drug Administration (FDA) for stand-alone use; therefore, this indication is considered off-label.

**Systematic Reviews**

Lopez (2017) published a systematic review (SR) evaluating the literature on lumbar spinous process fixation and fusion devices.[1] They included both interspinous plates and fixation devices, and excluded dynamic devices such as the X-Stop. A total of 15 articles met the inclusion and exclusion criteria, including four comparative studies (level III evidence), two case series (level IV evidence), and nine in vitro biomechanics studies (level V evidence). Two of the nonrandomized studies compared interspinous fixation devices (IFDs) to pedicle screws in patients undergoing interbody fusion and two included IFD alone or pedicle screws plus an IFD in patients undergoing interbody fusion. Use of an IFD decreased surgical time and blood loss compared to pedicle screws. No study showed that IFDs reduced the length of stay compared to pedicle screw implantation. The authors stated no class I or II evidence was available, the studies had methodological limitations, and data was inadequate to determine safety and efficacy. Randomized clinical trials (RCTs) are needed to examine the impact of IFDs on health outcomes.

**Randomized Clinical Trials**

No RCTs were identified.

**Nonrandomized Studies**

Included in the systematic review from Lopez (2017) above was a nonrandomized retrospective study by Kim (2012) that compared the SPIRE® IFD to pedicle screw implantation in patients who underwent posterior lumbar interbody fusion (PLIF).[2] Forty patients underwent IFD with PLIF and 36 underwent pedicle screw fixation with PLIF during the same time period. The two groups were comparable at baseline, but the treatment selection criteria were not described. At a minimum one-year follow-up, scores on the visual analog scale (VAS) for pain and on the Korean version of the Oswestry Disability Index improved to a similar extent in the two groups. For example, VAS scores in the IFD group improved from 7.16 to 1.3 while VAS scores in the pedicle screw group improved from 8.03 to 1.2. Range of motion at the adjacent segment was increased in the pedicle screw group but
not in the IFD group, and adjacent segment degeneration was more prevalent in the pedicle screw group (36.1%) than in the IFD group (12.5%, p=0.029). Other adverse events, such as deep infection and cerebrospinal fluid leakage, were higher in the pedicle screw group. The authors concluded a RCT with long-term follow-up is needed to confirm how the SPIRE® IFD impacts health outcomes.

Other clinical trial evidence for stand-alone procedures is limited to two retrospective chart reviews [3,4] (n=34 and n=86), nonrandomized case series [5-7], and ex vivo biomechanical studies on cadaver spines. Conclusions from cadaver studies cannot be used to determine the outcomes of device implantation in living human subjects.

**Summary**

Current studies are insufficient to reach conclusions about the safety and effectiveness of these devices due to significant methodological limitations such as small sample size, lack of a control group, short-term follow-up periods, and lack of randomized treatment allocation.

**PRACTICE GUIDELINE SUMMARY**

**NORTH AMERICAN SPINE SOCIETY (NASS)**


The NASS published a coverage position statement stating that the use of interspinous fixation with fusion is currently not indicated as an alternative to pedicle screw fixation with lumbar fusion procedures.[10] This recommendation is based on a determination that the current evidence “is limited, low-level evidence” and a lack of prospective, randomized, controlled trials with sufficient follow-up comparing the efficacy and safety of these devices with pedicle screws, the current gold standard for spinal fusion.

**SUMMARY**

There is not enough research to show that interspinous process fixation devices used alone or in combination with conventional spinal fusion devices improve health outcomes for any indication. No clinical guidelines based on research recommend interspinous process fixation devices. Therefore, interspinous process fixation devices used alone or in combination with conventional spinal fusion devices are considered investigational for all indications.

**REFERENCES**

2. Kim, HJ, Bak, KH, Chun, HJ, Oh, SJ, Kang, TH, Yang, MS. Posterior interspinous fusion device for one-level fusion in degenerative lumbar spine disease : comparison with


**CODES**

**NOTE:** There are no specific codes for spinal instrumentation using the spinous process fixation orthoses. The appropriate code for reporting this procedure is 22899.

<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>22899</td>
<td>Unlisted procedure, spine</td>
</tr>
<tr>
<td>HCPCS</td>
<td>None</td>
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</table>

**Date of Origin:** May 2010