INTERNATIONAL FIXATION (FUSION) DEVICES

MEDICARE ADVANTAGE POLICY CRITERIA

Important Notes Regarding this Policy:

This policy addresses only spinous process fixation orthoses, which are intended for fixation or fusion rather than as motion preserving devices. 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 to achieve supplemental fusion. One such device is the **Coflex-F fusion device** (see the device list below for additional examples).

This policy does **not** address interspinous process spacers or interlaminar stabilization devices, such as the **X-STOP** or the **non-fusion coflex® Interlaminar Stabilization Device**.

### POLICY GUIDELINES

**REGULATORY STATUS**

The following is a list of interspinous fixation devices which have received clearance to market by the U.S. Food and Drug Administration (FDA). This list may not be all-inclusive. Please note, these interspinous fixation devices are intended to be used as an adjunct to interbody fusion. Therefore, use of one of these devices for a stand-alone procedure would be considered an off-label use.

- Affix™ II and Affix II Mini Spinous Process Plate System (Nuvasive®)
- Aileron® Posterior Fusion System (Life Spine®)

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<table>
<thead>
<tr>
<th>CMS Coverage Manuals*</th>
<th>None</th>
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</thead>
<tbody>
<tr>
<td>National Coverage Determinations (NCDs)*</td>
<td>None</td>
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<tr>
<td>Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*</td>
<td>None</td>
</tr>
<tr>
<td>Medical Policy Manual</td>
<td>Medicare coverage guidance is not available for spinous process fixation orthoses. Therefore, the health plan’s medical policy is applicable.</td>
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**NOTE:** If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. ([Medicare IOM Pub. No. 100-04, Ch. 23, §30 A](https://www.cms.gov/files/document/medicare-iom-pub-no-100-04-ch-23-s30-a.pdf)). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an **objective, evidence-based process, based on authoritative evidence**. ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](https://www.cms.gov/files/document/medicare-iom-pub-no-100-16-ch-4-s90-5.pdf)). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan’s evidence-assessment process (see Cross References).
• Aspen® Spinous Process Fixation System (previously Lanx®, but now acquired by BioMet)
• Axle™ Interspinous Fusion System (X-Spine)
• BacFus® Spinous Process Fusion Plate (RTI Surgical™ [formerly Pioneer® Surgical])
• BridgePoint™ Spinous Process Fixation System (Alphatec Spine®)
• coflex-F® Implant Systems (Paradigm Spine)
• Inspan™ Spinous Process Plate System (SpineFrontier®)
• InterBRIDGE Interspinous Posterior Fixation System (LDR Spine)
• Minuteman® Interspinous Interlaminar Fusion Device (percutaneous spinal fusion) (Spinal Simplicity)
• Octave™ Posterior Fusion System (Life Spine®)
• PrimaLOK™ SP Interspinous Fusion System (OsteoMed Spine)
• SP-Fix™ Spinous Process Fixation System (Globus Medical)
• Spire™ Stabilization System (Medtronic Sofamor Danek)
• ZIP™ MIS Interspinous Fusion System (Aurora Spine)

Note, the fact a service, procedure, or device is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While FDA determinations regarding safety and effectiveness may be considered, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

Dynamic Stabilization of the Spine, Surgery, Policy No. M-143

Percutaneous Axial Anterior Lumbar Fusion, Surgery, Policy No. M-157

REFERENCES

1. CPT Assistant December 2013 Q&A regarding the non-fusion CoFlex® Interlaminar Stabilization Device

CODING
**NOTE:** If reporting for the *non-fusion coflex*® *Interlaminar Stabilization Device*, the code listed below is not appropriate coding. Based on its FDA data, the non-fusion coflex® Interlaminar Stabilization Device is not a rigid fixation device (such as pedicle screws or spinous process clamps), but rather, it is a device that still allows motion. Therefore, use of this medical policy and use of CPT code 22840 or 22899 would be incorrect.[1]

There are no specific codes for spinal instrumentation using the spinous process fixation orthoses. The appropriate code for reporting this procedure is 22899; it is inappropriate to use the posterior pedicle fixation CPT codes 22840-22844 or interspace instrumentation codes 22853, 22854, or 22859. It is also inappropriate to use the CPT codes for conventional spinal fusion 22610-22632 because the procedure for insertion of this device is significantly different than conventional fusion techniques (e.g., pedicle screw fixation).

<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
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<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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*IMPORTANT NOTE: Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan’s web control as these sites are not maintained by the health plan.*