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Medicare Advantage Policy Manual **Policy ID:** M-SUR172

Interspinous Fixation (Fusion) Devices

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual but they may also be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Spinous process fixation orthoses are used as a minimally invasive alternative to pedicle screw instrumentation with interbody fusion, as well as for stand-alone use in patients with spinal stenosis and/or spondylolisthesis. They are different from interspinous process spacers (e.g., X-STOP) and dynamic stabilization systems in that spinous process fixation orthoses are intended for fixation/fusion rather than as motion preserving devices. They may be referred to as an interspinous anchor, spinous fixation system, or spinal interlaminal fixation orthosis.

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***.

CMS Coverage Manuals

None

National Coverage Determinations (NCDs)

For Medicare Coverage Determinations and Articles, see the Medicare Coverage Database

None

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles

For Medicare Coverage Determinations and Articles, see the Medicare Coverage Database

None

Medical Policy Manual

Medicare coverage guidance is not available for spinous process fixation orthoses. Therefore, the health plan's medical policy is applicable.

Interspinous Fixation (Fusion) Devices, Surgery, Policy No. 172 *(For the **non-fusion coflex® Interlaminar Stabilization implant device**, do not use SUR172) (see "NOTE" below)*

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*). 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*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

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®)
- 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

1. Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149
2. Dynamic Stabilization of the Spine, Surgery, Policy No. M-143
3. 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).

Codes	Number	Description
CPT	22899	Unlisted procedure, spine
HCPCS	None	