Medicare Medical Policy

Interspinous Fixation Devices

MEDICARE MEDICAL POLICY NUMBER: 460

Effective Date: 9/1/2026

Last Review Date: 6/2026

Next Annual Review: 6/2027

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Notes: This policy does **not** apply to the following spinal surgical procedures or devices:

- Conventional spinal fusion
- Dynamic stabilization devices
- Interspinous spacers

Interspinous process spacers and dynamic stabilization systems are motion preserving devices, while interspinous fixation devices (IFDs) provide *rigid* spinal fixation. The former are addressed in a separate Medicare medical policy (see Cross References below, or review the health plan's comprehensive list of medical policies to find the applicable spinal service policy).

Service	Medicare Guidelines
Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below*)	
• **Medicare Coverage Manuals:** Medicare does not have criteria for interspinous process fixation (fusion) devices in a coverage manual.	
• **National Coverage Determination (NCD):** Medicare does not have an NCD for interspinous process fixation (fusion) devices.	
• **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review, no Medicare Administrative Contractors (MACs) have LCDs for interspinous process fixation (fusion) devices.	
• Therefore, in the absence of **fully established** Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(6)(i)(C) as there are no Medicare coverage criteria available. All surgical procedures carry a certain level of risk of complications or adverse outcomes, such as post-operative surgical site infection, blood clots, etc. However, spinal surgeries present unique complication risks, such as neurological deficits and adjacent-segment disease. Spine surgery complications can have significant impact for an individual, including poor surgical outcomes, which can lead to poor health-related quality of	

life, as well as negative financial impact for additional or repeat procedures. Medically unnecessary procedures can result in unnecessary exposure to such complications. Therefore, the use of Company criteria is intended to avoid medically unnecessary services that carry high risks of adverse outcomes and which may interfere with the pursuit of other treatments with established clinical efficacy. • ***NOTE:*** *The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*	
Interspinous Fixation (or Fusion) Devices (IFDs) *Criteria apply for IFD either:* • *In combination with interbody fusion,* ***or*** • *As a stand-alone procedure for decompression in patients with spinal stenosis.*	Company medical policy for Interspinous Fixation Devices I. This service is considered **not medically necessary** for Medicare based on the Company medical policy. *See Policy Guidelines below.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

- Artificial Intervertebral Discs, MP263
- Spinal Fusion and Decompression Procedures, MP358
- Spinal Stabilization Devices and Interspinous Spacers, MP392

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

General

Back pain can be caused by many conditions, including but not limited to, degenerative disc disease (DDD), scoliosis or kyphosis (abnormal spinal curvatures), spondylolisthesis, trauma resulting in spinal nerve compression or vertebral instability caused by infections or tumors. Spinal fusion (or spinal arthrodesis) is a surgical treatment for spinal pain that fuses two or more vertebral bodies in the spinal

column. The most common goal of spinal fusion surgery is to **restrict** spinal motion in order to relieve pain symptoms.

Spinal fusion may be performed using a minimally invasive or open approach, and may also be performed in conjunction with a laminectomy, laminotomy, foraminectomy, foraminotomy, laminoplasty, corpectomy or facetectomy procedure.

In addition to open or minimally invasive technique, the spine may also be approached with the graft placed, from various angles, such as an anterior (front of the body) approach, posterior (back of the body) approach, lateral (from the side) approach or by a combination anterior/posterior approach. A fusion can be performed with or without the use of supplemental hardware such as plates, screws or cages that serve as an internal splint while the bone graft heals, but current practice generally does include the use of hardware in addition to the grafts. Traditional hardware used in spinal fusion procedures include plates, screws and/or cages.

Interspinous Process Fixation Devices

Interlaminar lumbar instrumented fusion or ILIF using an interspinous process fusion device has been proposed as an alternative to traditional fusion procedures.

Devices used for ILIF are interlaminar or interspinous fixation devices, rather than traditional hardware. ILIF devices are described as non-pedicle supplemental fixation systems and are attached to the spinous processes of adjoining vertebrae.

Examples of these devices include, but may not be limited to, the Aurora Zip MIS Interspinous Fusion System, coflex-F, PrimaLOK SP, and the StabiLink MIS Spinal Fixation System. Spinous process fixation devices are marketed as a minimally invasive alternative to pedicle screw instrumentation in spinal interbody fusion. They may also be referred to as an interspinous anchor, spinous fixation system, or spinal interlaminal fixation orthosis.

Interspinous fixation devices are not intended for stand-alone use, while interspinous distraction devices (spacers; e.g., X-STOP) are used alone for decompression and are typically not fixed to the spinous process. In addition, interspinous distraction devices have been designed for dynamic stabilization, whereas interspinous fixation devices are rigid. However, interspinous fixation devices might also be used to distract the spinous processes and decrease lordosis. Because IFDs are not intended for stand-alone use, use of these items as a stand-alone procedure ***without*** interbody fusion as decompression (distraction) devices in patients with spinal stenosis is considered **off-label** use. If interspinous fixation devices are used alone as a spacer, there is a risk of spinous process fracture. In addition to being considered a minimally invasive alternative to standard spinal fusion procedures, these devices also **differ** from interspinous process spacers (e.g., X-STOP) and dynamic stabilization systems in that they are intended for fixation/fusion rather than as motion preserving devices.

MEDICARE AND MEDICAL NECESSITY

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current

standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

In addition:

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

The Plan's Medicare policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

Since there are not fully established coverage criteria for interspinous fixation devices (IFDs) available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied. See the Medicare Coverage Criteria table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

Examples of related devices include, but may not be limited to, the following:

- Aerial Interspinous Fixation (Globus)
- Affix (NuVasive)
- Aileron (Life Spine)
- Aspen (Lanx, acquired by BioMet)
- Axle (X-Spine)
- BacFuse (Pioneer Surgical)
- BridgePoint (Alphatec Spine)
- Coflex-F (Paradigm Spine)*****
- Inspan (Spine Frontier)

- InterBRIDGE Interspinous Posterior Fixation System (LDR Spine)
- Minuteman (Spinal Simplicity)
- Octave (Life Spine)
- PrimaLOK (OsteoMed)
- SP-Fix (Globus)
- SP-Link System (Medical Designs LLC)
- Spire (Medtronic)
- StabiLink® MIS Interspinous Fixation System
- ZIP MIS Interspinous Fusion System (Aurora Spine)

***NOTE:** The Coflex-F device listed above is different from the non-fusion coflex® Interlaminar Implant, which is addressed in the separate Medicare medical policy for Spinal Stabilization Devices and Interspinous Spacers (see Cross References above).*

FDA product code: PEK.

BILLING GUIDELINES AND CODING

GENERAL

There are **no** specific codes for spinal instrumentation using the spinous process fixation orthoses. Therefore, this service should be billed with unlisted code 22899. Codes for posterior pedicle fixation (22840-22844) or codes for interspace instrumentation (22853, 22854, or 22859) are inappropriate for these devices. In addition, while this procedure is typically performed in conjunction with a spinal fusion procedure, the use of codes for conventional spinal fusion (22610-22632) would not be accurate because insertion techniques of this device is significantly different than conventional fusion techniques (e.g., pedicle screw fixation).

Finally, HCPCS code C1821 is not applicable to these devices. Code C1821 is specific to "interspinous process distraction deices," which are different from interspinous fixation deices addressed by this medical policy.

CODES*		
CPT	22899	Unlisted procedure, spine
HCPCS	None	

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.

- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
9/2026	New Medicare Advantage medical policy