Interspinous Fixation Devices

MEDICAL POLICY NUMBER: 459

Effective Date: 9/1/2026

Last Review Date: 6/2026

Next Annual Review: 6/2027

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. 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.

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

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Note: This policy does not address other spinal stabilization devices or interspinous spacers. See the policy, Spinal Stabilization Devices and Interspinous Spacers (Company), for all other devices.

I. Interspinous fixation devices (see Policy Guidelines for examples) are considered **not medically necessary** for all indications.

Link to Evidence Summary

POLICY CROSS REFERENCES

- **Spinal Stabilization Devices and Interspinous Spacers (Company)**

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

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to determine the medical necessity of the request, the following documentation must be provided at the time of the request. Medical records to include documentation of all of the following:

- All medical records and chart notes pertinent to the request. This includes:
    - History
    - Physical examination
    - Treatment plan

BACKGROUND

General

Spinal fusion is a surgical procedure designed to permanently join (fuse) two or more adjacent vertebrae, thereby eliminating motion at the affected spinal segment. This is typically accomplished using bone graft material, often in conjunction with instrumentation such as rods, screws, or cages, to stabilize the spine while the fusion matures. The primary goal of spinal fusion is to reduce pain and neurologic symptoms by stabilizing a diseased or unstable spinal segment, correcting deformity, or preventing abnormal motion that contributes to nerve compression. Common indications for spinal fusion include degenerative disc disease, spondylolisthesis, spinal stenosis with instability, deformity (e.g., scoliosis), trauma, infection, and certain neoplastic conditions.

Interspinous Fixation Devices

Interspinous fixation devices (IFDs) are implantable spinal implants designed to stabilize adjacent vertebrae by securing to the spinous processes—the bony projections at the back of the spine. These devices are placed in the interspinous space to restrict motion at a specific spinal level, helping maintain alignment and provide mechanical support, most often as part of a spinal fusion procedure. Interspinous fixation devices are intended to promote stability and facilitate fusion by limiting flexion, extension, and translation of the affected segment, typically through a posterior and less invasive surgical approach than traditional pedicle screw systems.

Interspinous fixation devices differ from traditional spinal fusion instrumentation primarily in their method of stabilization, invasiveness, and biomechanical support. Traditional fusion typically uses pedicle screws and rods anchored into the vertebral bodies to provide rigid, multi-planar stabilization across the spinal segment, making it suitable for a wide range of conditions, including significant instability or deformity. In contrast, interspinous fixation devices are placed between the spinous processes through a less invasive posterior approach and provide more limited stabilization, primarily restricting extension and posterior column motion.

IFDs are distinct from interspinous process “distraction” devices (IPDs) used primarily for decompression in lumbar spinal stenosis. While IPDs are designed to maintain increased interspinous spacing and indirectly decompress neural elements, IFDs are intended to provide rigid or semi-rigid fixation to promote stabilization and facilitate fusion.

Examples of interspinous fixation devices (not an exhaustive list):

- Aileron Interspinous Fixation System
- Aurora Spine ZIP MIS Interspinous Fusion System
- Axle Interspinous Fusion System
- BridgePoint Spinous Process Fixation System
- Minuteman G3 Interspinous Interlaminar Fusion Device
- PrimaLOK SP Interspinous Fusion System
- SP-Fix Spinous Process Fixation Plate
- StabiLink MIS Interspinous Fixation System

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of interspinous fixation devices. Below is a summary of the available evidence identified through May 2026.

In 2025, Hayes published an evolving evidence review of interspinous nonpedicle fixation devices for lumbar spinal fusion.[1] The review included 2 fair-quality and 2 very-poor quality studies suggesting that interspinous process fixation devices (IPFDs) offer similar fusion rates, pain reduction, and functional improvement compared to conventional instruments for lumber spinal fusion. Hayes concluded that there is currently minimal support for the devices over standard care. The report also identified a systematic review of IFPDs that found an unclear benefit of the devices.

In 2023, ECRI published an evidence analysis of Minuteman Fixation Devices (Spinal Simplicity) for spinal fusion procedures. The authors identified two case series that were at high risk of bias.[2] They concluded that there were too few data on outcomes of interest to assess the efficacy and safety of the device.

In 2024, Baranidharan and colleagues reported two-year results from a multicenter randomized controlled trial comparing the Minuteman interspinous fixation device with open surgical decompression for lumbar spinal stenosis.[3] Forty-three participants were randomized (20 to fixation, 23 to decompression), with 75% and 83% available for follow-up at 24 months, respectively. Clinical success was defined by ≥30% improvement in pain and disability measures and improvement in ZCQ function. At 24 months, leg pain success was similar between groups (72% fixation vs. 76% decompression), while back pain, ODI disability, and ZCQ success rates were lower in the fixation group. Improvements in walking distance were greater with fixation, while sit-to-stand gains were not significantly different.

Deviations from randomization reduced the fixation sample size, and noninferiority of interspinous fixation compared with decompression was not established.

CLINICAL PRACTICE GUIDELINES

In 2025, North American Spine Society (NASS) published recommendations on Interspinous Devices for Fusion. They offer specific criteria with the following rationale:

"There has been an increasing body of published literature on outcomes related to interspinous devices which affix to the spinous processes for the purposes of augmenting fusion. There is still limited evidence published about outcomes of such devices that are used for stabilization of a motion segment, but the evidence has improved with regards to the quality of studies that support this technique. There are published prospective studies that support the use of this technology for stabilization of single-level degenerative spondylolisthesis when combined with a direct decompression and fusion. Trials comparing interspinous fixation (ISF) to PS are limited due to small sample size and methodological uncertainties but suggest similar clinical outcomes when either is performed as a supplement to interbody fusion. However, there is some evidence that interspinous devices which affix to spinous processes may be less mechanically stabilizing than PS constructs. **Overall, there are insufficient prospective randomized trials with sufficient follow-up to determine the relative effectiveness and safety of this class of devices in comparison to PS fixation**."[4]

EVIDENCE SUMMARY

There is currently not enough evidence to support the use of interspinous fixation devices for any indication. The available studies are at a high risk of bias, and higher quality, long term randomized studies are needed to show benefit over standard treatment. Furthermore, no clinical guidelines offer strong support for interspinous devices, referring to the lack of well-designed and executed studies supporting their efficacy and safety. Therefore, interspinous fixation devices are considered not medically necessary for any indication.

HEALTH EQUITY CONSIDERATIONS

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.

The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly

reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online here.

BILLING GUIDELINES AND CODING

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 above code list 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.
- 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

1. Hayes. Interspinous Nonpedicle Fixation Devices for Lumbar Spinal Fusion. April 9, 2025. https://evidence.hayesinc.com/report/eer.interspinous5212. Accessed 5/6/2026.
2. ECRI. Minuteman Fixation Devices (Spinal Simplicity) for Spinal Fusion Procedures. November 29, 2023. . https://members.ecri.org/evidenceanalysis/minuteman-fixation-devices-spinal-simplicity-for-spinal-fusion-procedures. Accessed 5/6/2026.

3. Baranidharan G, Bretherton B, Feltbower RG, et al. 24-Month Outcomes of Indirect Decompression Using a Minimally Invasive Interspinous Fixation Device versus Standard Open Direct Decompression for Lumbar Spinal Stenosis: A Prospective Comparison. *J Pain Res.* 2024;17:2079-2097.
4. NASS. Interspinous Devices for Fusion. Revised March 2025. file:///F:/My%20Documents/Downloads/CoverageRecommendations_InterspinousDevicesFusion%20(3).pdf. Accessed 5/6/2026.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
9/2026	New policy.