Medicare Medical Policy

Back: Stabilization Devices and Interspinous Spacers

MEDICARE MEDICAL POLICY NUMBER: 392

Effective Date: 7/1/2023

Last Review Date: 5/2023

Next Annual Review: 5/2024

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, Providence Plan Partners, and Ayin Health Solutions 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.

Note: The plan has many policies regarding surgical procedures and devices used for spinal care. For example, the iFuse Implant System™ for sacroiliac joint fusion is addressed in the separate Medicare medical policy, *Back: Sacroiliac Joint Fusion or Stabilization*. Please see the health plan's list of medical policies to find the applicable spinal procedure policy.

Service	Medicare Guidelines
Back Stabilization Devices and Interspinous Spacers	Company medical policy for Back: Stabilization Devices and Interspinous Spacers I. These services are considered **not medically necessary** for Medicare plan members 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

- Back: Sacroiliac Joint Fusion or Stabilization, MP379

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

POLICY GUIDELINES

BACKGROUND

Dynamic Stabilization Devices

Dynamic stabilization devices provide an adjunct or alternative to spinal fusion for the treatment of chronic instabilities or deformities of the thoracic, lumbar, and sacral spine, including, but not limited to, degenerative spondylolisthesis or previous failed spinal fusion. In contrast to rigid devices that fully stabilize affected spinal segments, dynamic stabilization devices use flexible materials – anchored to the vertebrae by either synthetic cords or pedicle screws – which purport to preserve some measure of mobility of the spinal segment while also stabilizing the joint. Examples of dynamic stabilization devices include, but may not be limited to, the following:

- Aspen Spinous Fixation System
- AccuFlex™ System
- BioFlex System
- Bronsard's Ligament
- CD Horizon Agile™ Dynamic Stabilization Devices
- CD Horizon Spire Fixation System
- Cosmic™ Posterior Dynamic System
- DSS Stabilization
- DSS (Dynamic Soft Stabilization) System
- DTO (Dynesys-to-Optima)
- Dynabolt™ Dynamic Stabilization System
- Dynesys®
- Expedium™
- FASS (Fulcrum Assisted Soft Stabilization)
- Graf Ligament
- IsoBar® Spinal System
- Leeds-Keio Ligamentoplasty
- LemiFlex Spinal Stabilization
- NFix™ II Dynamic Stabilization
- NFLex™ Controlled Motion System
- REVERE Stabilization System
- Satellite™ Spinal System
- Stabilimax NZ Dynamic Spine Stabilization System
- TRANSITION® Stabilization System
- Viper™
- Zodiak DynaMo System

Interspinous Spacers

Interspinous spacers are small devices, implanted between vertebral spinous processes at one or two vertebral levels, that stabilize or distract adjacent lamina and/or spinous processes. The spacers are thought to alleviate pain in patients with spinal stenosis and neurogenic claudication by expanding the neural foramen, decompressing the nerves and limiting painful lumbar extension, while maintaining the

flexion of the spinal interspace. Examples of interspinous spacers include, but may not be limited to, the following:

- Aperius™ - PercLID™ System
- Coflex® Interlaminar Stabilization Device
- DIAM™ Spinal Stabilization System
- Falena® Interspinous Decompression Device
- FLEXUS™
- Helifix® Interspinous Spacer System
- In-Space
- NL-Prow™ Interspinous Spacer
- Stenofix
- Superion® Interspinous Spacer System
- Wallis System®

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)*.

The Company 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. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.) which addresses the medical necessity of a given medical service, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

Following an evidence review, it is concluded that the evidence does not support the safety and efficacy of dynamic stabilization devices and interspinous spacers. All systematic reviews to date note a paucity of long-term evidence from high-quality trials. The literature largely comprises small, uncontrolled studies with short-term follow-up. Moreover, no evidence-based clinical practice guidelines recommend dynamic stabilization devices or interspinous spacers in lieu of, or in addition to, interbody fusion and/or decompression fusion for the treatment of lumbar spinal stenosis.

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.

The following dynamic stabilization devices and interspinous spacers have received FDA clearance:

- Aspen Spinous Fixation System
- DSS Stabilization System[3]
- Dynesys®[4]
- Isobar Spinal System[5]
- Coflex® Interlaminar Stabilization Device[6]
- Superion Interspinous Spacer System[7]

Note: The Vertiflex™ Superion is one of only two interspinous spacer or spinous process plates with full FDA-approval. Following worldwide recalls, the formerly approved X-STOP devices had FDA-approval formally withdrawn in 2015.[8]

In order to be considered for coverage under Medicare, devices must be either FDA- or Institutional Review Board (IRB)-approved. Therefore, any device that has **not** received FDA-approval would be considered not medically necessary.[9]

BILLING GUIDELINES AND CODING

GENERAL

The following codes do not apply to minimally invasive dynamic stabilization procedures of the spine and should not be used to bill for these services: 22533, 22534, 22558, 22585, 22586, 22612, 22614, 22630, 22632, 22633, 22634, 22800, 22802, 22804, 22808, 22810, 22812, 22840, 22841, 22842, 22843, 22844, 22845, 22846, 22847, 22853, 22854, 22859.

CODES*		
CPT	22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
	22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)
	22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level
	22870	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)
	22899	Unlisted procedure, spine
	64999	Unlisted procedure, nervous system
HCPCS	C1821	Interspinous process distraction device (implantable)
	L8699	Prosthetic implant, not otherwise specified

***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

1. CMS Approved IDE Studies; Last Modified: 12/1/2021; Available at: https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies
2. Food and Drug Administration. Biomet Fusion System. Decision Date 2/28/3017. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K163543. Accessed 3/30/2023.
3. Food and Drug Administration. DSS Stabilization System. Decision Date 7/2/2010. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K101083. Accessed 3/30/2023.
4. Food and Drug Administration. Dynesys Spinal System. Decision Date, 3/5/2004. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K031511. Accessed 3/30/2023.
5. Food and Drug Administration. Isobar Spinal System. Decision Date, 1/15/2002. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K013447. Accessed 3/30/2023.
6. Food and Drug Administration. Coflex-F Implant System. Decision Date, 2/13/2012. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K112595. Accessed 3/30/2023.
7. Food and Drug Administration. Superion Interspinous Spacer. Decision Date, 5/20/2015. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140004. Accessed 3/30/2023.
8. Dou Q. Premarket Approval (PMA). Device: X Stop Interspinous Process Decompression System Withdrawl date: 04/30/2015. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P040001. Accessed 3/30/2023.
9. Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, §10 – Coverage of Medical Devices; Last updated: 11/6/2014; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c14.pdf; Accessed 3/30/2023

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
7/2023	New Medicare Advantage medical policy