Interspinous and Interlaminar Stabilization and Distraction Devices (Spacers)

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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 may 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

Spinal stenosis is a common cause of back pain and disability, particularly as individuals age. It can result from a number of pathologic processes, but for individuals over 60 years of age, spondylosis is the most common cause. The primary symptom of lumbar spinal stenosis is neurogenic claudication with back and leg pain, sensory loss, and weakness in the legs, and symptoms can be made worse by standing or walking and relieved with sitting or bending at the waist. Conservative treatments for spinal stenosis include physical therapy, pharmacotherapy, and epidural steroid injections. However, if conservative treatments fail, surgical approaches for spinal stenosis may be used. The standard surgical treatment for patients with moderate to severe spinal stenosis is decompression surgery with or without spinal fusion; however, less invasive methods to stabilize the spine and reduce the pressure

on affected nerve roots, including interspinous and interlaminar implants (spacers), are being investigated. Lumbar interspinous process decompression (IPD), also known as interspinous distraction or posterior spinal distraction, and interlaminar stabilization have been proposed as minimally invasive alternatives to laminectomy and fusion.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: This policy only addresses IPD devices. Dynamic stabilization devices across pedicle screws and the Coflex-F device are considered in separate medical policies (see Cross References below).

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	None
Medical Policy Manual	*Medicare coverage guidance is not available for interspinous process decompression (IPD), interspinous distraction or posterior spinal distraction. Therefore, the health plan's medical policy is applicable.* Interspinous and Interlaminar Stabilization and Distraction Devices (Spacers), Surgery, Policy No. 155 *(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

There are several interspinous implants and interlaminar spacers that have premarket approval (PMA) status by the U.S. Food and Drug Administration (FDA) and other interspinous implants and interlaminar spacers that are under investigation. The table below lists examples of devices with PMA approval.

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or 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 Medicare may adopt FDA determinations regarding safety and effectiveness, 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).

In addition, while an investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data, none of the IDE-approved devices in the table below are found on the Medicare Approved IDE Studies web page.[1]

DEVICE	MANUFACTURER	FDA APPROVED?
Aperius ™-PercLID ™ System	Medtronic	No
Coflex® Interlaminar Stabilization Device (formerly Interspinous U)	Paradigm Spine	Yes
DIAM™ Spinal Stabilization System	Medtronic Sofamor Danek	No IDE only
Falena ® Interspinous Decompression Device	Mikai Spine	No
FLEXUS ™	Globus Medical	No IDE only
Helifix® Interspinous Spacer System	Alphatec Spine®	No
In-Space	Synthes®	No IDE only
NL-Prow ™ Interspinous Spacer	Non-Linear Technologies	No
Stenofix	Synthes®	No
Superion® Indirect Decompression System	VertiFlex, Inc.	Yes
Wallis® System	Zimmer Spine (formerly Abbott Spine)	No IDE only
X-STOP® Interspinous Process Decompression (IPD®) System	Kyphon/Medtronic Spine	Withdrawn
X-STOP® PEEK (polyetheretherketone)	Medtronic	Withdrawn

These devices each have specific indications for which they are intended to be used, as well as contraindications that would prohibit use. Contraindications include, but may not be limited to, allergies to the substances that make up the device, spinal anatomy or disease that would prevent implantation or cause the device to be unstable, severe osteoporosis, infection,

compromised lumbar vertebral bodies caused by trauma or tumor, or morbid obesity, to name a few.

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

Total Facet Arthroplasty, Surgery, Policy No. M-171

Interspinous Fixation (Fusion) Devices, Surgery, Policy No. M-172

Image-Guided Minimally Invasive Spinal Decompression (IG-MSD) for Spinal Stenosis, Surgery, Policy No. M-176

REFERENCES

1. Medicare Approved IDE Studies; Available at: https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies

CODING

Codes	Number	Description
CPT	22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
	22868	; 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	; second level (List separately in addition to code for primary procedure)
	22899	Unlisted procedure, spine
HCPCS	C1821	Interspinous process distraction device (implantable)

***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.*