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Medicare Advantage Policy Manual

Policy ID: M-SUR143

Dynamic Stabilization of the Spine

Published: 09/01/2023

Next Review: 05/2024

Last Review: 07/2023

Medicare Link(s) Revised: N/A

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

Dynamic stabilization, also known as soft stabilization or flexible stabilization, has been proposed as an adjunct or alternative to spinal fusion for the treatment of severe refractory pain due to degenerative spondylolisthesis, or continued severe refractory back pain following prior fusion (this may sometimes be referred to as failed back surgery syndrome). Dynamic stabilization uses flexible materials rather than rigid devices to stabilize the affected spinal segment(s). These flexible materials may be anchored to the vertebrae by synthetic cords or by pedicle screws, but dynamic stabilization differs from rigid spinal fusion because is intended to preserve the mobility of the spinal segment.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: This policy considers only dynamic stabilization devices across pedicle screws. See “Cross References” below for separate Medicare Advantage policies for other surgical spinal stabilization and fusion techniques.

CMS Coverage Manuals*	See “References” ^[1]
National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	None
Medical Policy Manual	<i>Medicare coverage guidance is not available for dynamic stabilization of the spine. Therefore, the health plan’s medical policy is applicable.</i>

Dynamic Stabilization of the Spine, Surgery, [Policy No. 143](#)
(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

Examples of the dynamic stabilization devices addressed by this policy include, **but are not limited to**, the following:

- AccuFlex™ System (*Globus Medical*);
- REVERE™ Stabilization System (*Globus Medical*);
- TRANSITION® Stabilization System (*Globus Medical*);
- Dynesys® and DTO (Dynesys-to-Optima) (*Zimmer Spine, Inc*);
- Isobar® (*Scient’x*);
- Dynabolt™ Dynamic Stabilization System (formerly Modified VertiFlex® Spinal Screw System) (*VertiFlex, Inc*)
- DSS (Dynamic Soft Stabilization) system (*Paradigm Spine*); and,

- NFix™ II Dynamic Stabilization System (*N Spine, Inc.*).

Note, the fact a 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. While the FDA determines safety and effectiveness of a device or drug, it does not establish medical necessity. Medicare may adopt FDA determinations regarding safety and effectiveness, but CMS or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

According to the Medicare Benefit Policy Manual, Chapter 14, while U.S. Food and Drug Administration (FDA) approval does not automatically guarantee coverage under Medicare, in order to even 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 not be considered medically reasonable or necessary.^[1] The following dynamic stabilization devices have not received FDA clearance, and therefore, would not be covered by Medicare Advantage:

- Bronsard's Ligament
- FASS (Fulcrum Assisted Soft Stabilization) (*AO International*)
- Graf ligament (*SEM Co*)
- Leeds-Keio Ligamentoplasty (*Neoligament LTD*)
- LemiFlex Spinal Stabilization System (*Simpirica Spine*)
- NFlex™ Controlled Motion System (indicated for non-fusion only) (*N Spine, Inc.*)
- Stabilimax NZ® Dynamic Spine Stabilization System (*Applied Spine Technologies Inc.*)

CROSS REFERENCES

[Investigational \(Experimental\) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services](#), Medicine, Policy No. M-149

[Interspinous Fixation \(Fusion\) Devices](#), Surgery, Policy No. M-172

REFERENCES

1. Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, [§10 – Coverage of Medical Devices](#)

CODING

Codes	Number	Description
CPT	22899	Unlisted procedure, spine
	64999	Unlisted procedure, nervous system
HCPCS	None	

***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.