Dynamic Stabilization of the Spine

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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.

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 the Centers of Medicare and Medicaid Services (CMS) policies, when available. 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 CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and 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.

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 it 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.
### Medical Policy Manual

*Medicare coverage guidance is not available for dynamic stabilization of the spine. Therefore, the health plan’s medical policy is applicable.*

### 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)*;
- **REVERSE™** Stabilization System *(Globus Medical)*;
- **TRANSITION®** Stabilization System *(Globus Medical)*;
- **Dynesys®** and DTO (Dynesys-to-Optima) *(Zimmer Spine, Inc)*;
- **Isobar®** *(Scientx)*;
- **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.)*.

*Medical devices that are not approved for marketing by the Food and Drug Administration (FDA) are considered investigational by Medicare and are not considered reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve functioning of a malformed body member. Program payment, therefore, may not be made for medical
procedures and services performed using devices that have not been approved for marketing by the FDA or for those not included in an FDA-approved investigational (IDE) trial.\[2\] 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 and New and Emerging Medical Technologies and Procedures*, 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
2. Noridian LCD for Non-Covered Services (L35008) (This LCD can be found on the Medicare Coverage Database website)

**CODING**

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*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.*