Coverage Guidelines

Dynamic Stabilization Systems

Disclaimer:
Please note that Baptist Health Plan Coverage Guidelines may be updated throughout the year. A printed version may not be the most up to date version available. The health plan reserves the right to review and update this policy as needed. Refer to the website to ascertain that you are utilizing the most current available version. Clinical guideline policies are not intended to serve as treatment guidelines or treatment recommendation. Treating providers must use their own clinical judgment in rendering care to their patient population.

DEFINITION

Dynamic stabilization systems describe devices that provide immobilization and stabilization of the spine for the treatment of low back pain as a result of conditions secondary to spinal instability such as osteoarthritis, disc degeneration, or spondylolisthesis. The following list of dynamic stabilization devices include but are not limited to the following:

- **BAR Posterior Pedicle Screw System** describes a ball and socket system made up of pedicle screws, rods, and connectors manufactured from titanium, titanium alloy and cobalt chromium molybdenum alloy. BAR is used for single level fixation and employs a ball and socket approach that can be adjusted during implantation to optimize the distribution of stress of pain associated with instability across the vertebral body.

- **coflex Interlaminar Stabilization Device (Paradigm Spine LLC)** is an implantable titanium interspinous process device that reduces the amount of lumbar spinal extension possible while preserving range of motion in flexion, axial rotation, and lateral bending. The CREO® Stabilization System implants are spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5).

- **Dynesys® Dynamic Stabilization System** involves semi-rigid fixation that allows marginal lengthening and shortening between two screws as opposed to a rigid metal bar, allowing closer to normal motion patterns of the lumbar spine, which helps to protect the integrity of adjacent spinal segments.

- **Dynesys Top-Loading Spinal System** is a modification of the original that offers a top-loading, cannulated screw option, which allows for a less invasive paraspinal approach.

- **Isobar® Semi-Rigid Rod** provides stabilization and controlled motion of the spine by simultaneously sharing the load between the spine and interbody device.

- The NFix II dynamic stabilization system describes a posterior pedicle screw based approach that consists of polyaxial titanium alloy pedicle screws that are fixed to a semi-rigid polycarbonate urethane-sleeved rod. This system utilizes low-profile rods that can be used
in both single- or multi-level applications.\textsuperscript{11}

- REVERE\textsuperscript{®} Stabilization Systems describe a range of dynamic stabilization devices with different approaches and/or connectors. The REVERE Stabilization Systems are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.\textsuperscript{12}

- Zimmer\textsuperscript{®} DTO\textsuperscript{®} implant and OPTIMA\textsuperscript{™*} ZS Transition Screw involves the combination of a cord-rod construct, which offers the ability to transition from a rigid to dynamic stabilization system.\textsuperscript{13}

### COVERAGE CRITERIA

Dynamic stabilization systems are not currently considered medically necessary or are considered experimental / investigational.

### MEDICAL BACKGROUND

Low back pain is an important source of morbidity in the US, estimated to affect between 60% and 80% of American adults at some point their life. In most cases, low back pain can be managed through conservative, non-operative interventions including immobilization, non-narcotic pain relievers, muscle relaxants, and physical therapy or exercise programs. However, between 5% and 10% of patients suffering from low back pain will be characterized as chronic and debilitating. In these cases, surgical intervention is medically necessary following the failure of conservative management.\textsuperscript{14, 15}

Among the many surgical options for patients suffering from low back pain, the use of dynamic stabilization devices has been proposed. The purpose of this technology is to stabilize the spine using various methods of implanted spacers, rods and screws. Indications for dynamic stabilization devices may include spondylolisthesis, scoliosis, kyphosis, synovial facet joint cysts, autologous bone grafting, and degenerative disc disease as an alternative or as an adjunct to spinal fusion surgery.\textsuperscript{16, 17}

Despite the proposed clinical significance of this technology, dynamic stabilization devices remain unproven in terms of safety and efficacy. Medical technology reviews from Hayes, Inc. rated “investigational” exist for coflex Interlaminar Stabilization Device and Dynesys\textsuperscript{®} Dynamic Stabilization System.\textsuperscript{18, 19} A review of that literature indicates no evidence to suggest any clinical importance of this technology as published evidence is limited and of poor quality. For example, a 2008 study of 37 consecutive patients undergoing Dynesys for lumbar stenosis, degenerative disc disease, and segment instability demonstrated no advantage to alternative procedures and 19% of study participants required surgical revision at the one-year follow up.\textsuperscript{20} Another 2008 study of 19 patients with lumbar spinal stenosis and spondylolisthesis undergoing Dynesys showed that 47% of patients had recurring degenerative disease at the 4-year follow up period.\textsuperscript{21} A 2014 study of 26 patients undergoing dynamic stabilization using Isobar as adjunct to spinal fusion identified disc degeneration in adjacent levels at a two-year follow up period.\textsuperscript{22} Among complications reported in the literature include broken and misplaced screws, dislodged systems, and cerebrospinal fistula.\textsuperscript{23} Further, dynamic stabilization device implants under the product name CD HorizoN Agile Dynamic Spinal Stabilization were recalled by the
manufacturer Medtronic beginning in December, 2007 following reports of device failures following implantation.\textsuperscript{24} Despite this, a review of the FDA database found several dynamic stabilization devices being proposed for marketing the US.\textsuperscript{25} Marketing websites for Zimmer and Globus Medical, companies that manufacture dynamic stabilization devices outline the benefits of their products. However, marketing for these systems is limited given unproven efficacy and looming safety concerns. Isobar\textsuperscript{®} Semi-Rigid Rod was recalled from the market following device failures and is currently not available in the US.\textsuperscript{26,27}

**REGULATORY INFORMATION**

No legislative mandates were found for coverage of Dynamic Stabilization System devices in either Kentucky or Indiana.\textsuperscript{28}

Baptist Health Plan Coverage Guidelines are created to provide members and providers with peer-reviewed, current medical information.

State and federal laws/mandates and contract language have priority over Coverage Guidelines and must be taken into consideration before eligibility for coverage is determined.

Baptist Health Plan Coverage Guidelines may or may not mirror Centers for Medicare & Medicaid Services benefits or coverage offered by any other health insurance company.

For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern. In addition, coverage for Medicare Advantage members may differ. This is a result of applicable coverage statements by the Center for Medicare and Medicaid Services (CMS). The National Coverage Determinations, Local Coverage Determinations, and Local Medical Review Policies may be found at the CMS website, \url{http://www.cms.gov}. Please note that for all plans, the member’s health plan benefits that are in effect on the rendered date of service must be used in coverage determinations.

**COVERAGE DETAIL**

CODES INCLUDE BUT MAY NOT BE LIMITED TO THE FOLLOWING:

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<th>CPT\textsuperscript{©} Codes</th>
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<td>Unlisted procedure, spine</td>
<td>This code should be used to describe Dynamic Stabilization Systems</td>
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<tr>
<td>ICD.9® Procedure Codes</td>
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<td>Insertion of Infusion Device into Lumbosacral Joint</td>
<td>By approach</td>
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</tbody>
</table>

**REFERENCES**


19 Hayes, Inc. Hayes Medical Technology Directory. Dynesys® Dynamic Stabilization System


SEARCH TERMS

Back pain
BAR Posterior Pedicle Screw System
coflex Interlaminar Stabilization Device
Dynesys® Dynamic Stabilization System
Implantable
Implants
Isobar® Semi-Rigid Rod
NFix II Dynamic Stabilization System
OPTIMA™ ZS Transition Screw
Paraspinal
REVERE® Stabilization Systems
Spinal
Spine
Zimmer® DTO® implant