Dynamic Stabilization Systems

Policy Number: 7.01.506
Origination: 5/2006
Last Review: 5/2014
Next Review: 5/2015

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for the Dynamic Stabilization Systems. This is considered investigational.

When Policy Topic is covered
Not Applicable

When Policy Topic is not covered
Dynamic stabilization systems for the treatment of disorders of the lumbar or sacral spine are considered investigational.

Description of Procedure or Service
Subacute and chronic low back pain is a significant health problem, affecting 60% to 80% of adults in the United States at some time in their lives. In most cases, low back pain is temporary and can be relieved through rest and conservative therapies such as nonsteroidal anti-inflammatory drugs, muscle relaxants, and an appropriate exercise program. However, for 5% to 10% of patients, low back pain becomes a chronic and disabling condition. In addition to being one of the leading reasons for visits to primary-care physicians, low back pain is one of the most common reasons for nonsurgical hospital admissions in adults aged < 65 years. Low back pain is also a common cause of work-related disability.

Instability in the spine due to osteoarthritis, disc degeneration, or abnormalities of spinal ligaments can lead to spondylolisthesis, a slippage or sliding of a vertebra relative to the adjacent vertebrae. In most cases, the affected vertebra slides forward; however, backward slippage can also occur. Surgical treatment for this disorder typically involves spinal decompression with or without spinal fusion.

Dynamic stabilization systems are used in spinal surgery, and some are intended to provide stabilizing support to the spinal column during bone fusion. Traditional spine stabilization systems use screws to provide support and anchor the spine to metallic rods in spinal surgery during bone fusion. In dynamic systems, the rigid bars are replaced with flexible polymer cords, moveable screw heads, and springs that allow patients to bend and rotate.

The following dynamic stabilization devices have received clearance from the FDA for use in spinal fusion of the thoracic, lumbar and/or sacral spine for degenerative spondylolisthesis with neurologic impairment, and for failed previous fusion (pseudoarthrosis):

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>AccuFlex™ System (K0520690)</td>
<td>Globus Medical</td>
</tr>
<tr>
<td>BioFlex System with Nitinol spring rod and memory loops (Bio-Spine) (K072321)</td>
<td>Bio-Spine</td>
</tr>
<tr>
<td>CD Horizon Agile™ Dynamic Stabilization device (K060615)</td>
<td>Medtronic Sofamor Danek, Inc</td>
</tr>
<tr>
<td>Cosmic ™™ Posterior Dynamic System</td>
<td>Ulrich GmbH &amp; Co.</td>
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Rationale

Evidence evaluated for this report was obtained primarily from a search of the peer-reviewed medical literature in the MEDLINE and EMBASE databases spanning the years 2002 to November 2007. Studies were selected for detailed review if they were published in the peer-reviewed literature in English-language journals and evaluated the Dynesys Dynamic Stabilization System for degenerative spondylolisthesis. The latter criterion led to exclusion of a randomized controlled study by Korovessis et al. (2004) since this study used the Twinflex® spinal stabilization device (Eurosurgical; France). This criterion also led to exclusion of studies by Grob et al. (2005), Putzier et al. (2005), and Beastall et al. (2007) since few or none of the patients enrolled in these studies had degenerative spondylolisthesis.

The literature search identified five uncontrolled studies that evaluated the Dynesys Dynamic Stabilization System for degenerative spondylolisthesis. However, only one of these studies evaluated the Dynesys System as an adjunct to spinal fusion, which is the sole FDA-approved use of this device, and in this study only 15% of patients underwent spinal fusion. Consequently, all of the reviewed studies evaluated the Dynesys System exclusively or primarily for an off-label use. Although the size of these studies varied (n=26 to 101), all of them involved assessments of disability and back and/or leg pain at least 2 years after device implantation.

- The largest available study is a multicenter, uncontrolled evaluation of the Dynesys System conducted by Welch et al. (2007) in conjunction with the device manufacturer. This study enrolled 101 patients who had lateral stenosis (n=63), central canal stenosis (n=58), Grade I degenerative spondylolisthesis (n=52), Grade I degenerative retrolisthesis (n=10), and/or other unidentified disorders (n=34). Degenerative spondylolisthesis was the primary indication for surgery in 20 (20%) patients. In addition to implantation of the Dynesys System, an unidentified number of patients underwent surgical decompression as needed. It appears that the majority of patients underwent this procedure since all enrolled patients met criteria that qualified them for decompressive surgery. Mean duration of surgery was 184 minutes (range 75 to 340), mean blood loss was 451 mL (range 75 to 1750), and mean hospital stay was 3.4 days (range 2 to 13). One year after Dynesys device implantation, mean back pain had improved from 80.3 to 25.5, mean leg pain improved from 54.0 to 29.4, mean Oswestry Disability Index (ODI) decreased from 55.6% to 26.3%, and mean General Health score increased from 41.6 to 49.4. These improvements were statistically significant (P<0.01); however, 20 (20%) patients had not completed 1 year of follow-up and outcomes were not reported separately for patients who had spondylolisthesis. Moreover, outcomes were not reported separately for patients who did and did not undergo surgical decompression. At 1 year of
follow-up, 11 (11%) patients had undergone reintervention due to radiculopathy, increased pain, or worsening of spinal instability and Dynesys implants were removed from 3 (3%) patients.

- Stoll et al. (2002) conducted another relatively large study of the Dynesys System. Although these investigators enrolled 83 patients, only 39 (47%) of these patients had a diagnosis of degenerative spondylolisthesis, which was secondary. Primary indications for Dynesys device implantation were: spinal stenosis (60%), degenerative discopathy (24%), disc herniation (8%), revision surgery (6%), or not reported (1%). In addition to implantation of 1 or more Dynesys devices, 56 (75%) patients underwent direct decompression, 3 (4%) underwent nucleotomy, and 8 (10%) underwent other procedures that were not described. At a mean of 38 months after implantation, 8 (10%) patients had undergone implant removal, in some cases due to persistent pain. In the 73 patients who were available for follow-up, low back pain on a 1 to 10 scale improved from 7.4 ± 2.6 at baseline to 3.1 ± 2.3 at final report. Likewise, ODI scores improved from 55% ± 20% to 23% ± 19%. However, results were not reported separately for patients who had degenerative spondylolisthesis and 5 (6%) patients underwent additional procedures after Dynesys implantation including extension of implantation to an adjacent spinal level, decompression of an adjacent segment, spinal fusion, or laminectomy of the index segment.

- The only available study in which all patients had degenerative spondylolisthesis was conducted by Schnake et al. (2006). These investigators enrolled 26 patients who had spinal stenosis that was treated with interlaminar decompression combined with implantation of a single Dynesys device. Outcomes were not reported for 1 (4%) patient who died of unrelated causes and 1 (4%) patient who fell and had a traumatic vertebral fracture. In the other 24 patients, pain on a 100-point scale improved from a mean score of 80 at baseline to a score of 23 at a mean of 26 months, a statistically significant difference (P<0.00001). Statistically significant improvements relative to baseline were also observed in mean walking distance, which improved from 250 meters to > 1000 meters (P<0.00001) and in number of patients using analgesics, which decreased from 19 to 6 (P<0.02). Of the 24 patients whose surgery outcomes were reported, 21 (88%) stated that they would undergo the operative procedure again. In spite of these improvements, the implant showed signs of failure in 4 (17%) patients, 5 (21%) patients still had claudication, 7 (29%) patients had degeneration of adjacent spinal segments, and mean overall spondylolisthesis increased by 2% (range 0% to 12%). Although this change in spondylolisthesis was not statistically significant, it did show a strong trend toward significance (P=0.056).

- Bothmann et al. (2007) performed a study that evaluated the Dynesys device for lumbar spinal degeneration. Although this study enrolled 54 patients, only 14 (26%) had degenerative spondylolisthesis. The other patients underwent surgery for spinal canal stenosis (41%), lumbar disc degeneration (17%), recurrent lumbar disc herniation (11%), or segmental instability (6%). All patients underwent Dynesys System implantation; however, 44 (81%) patients also underwent nerve root decompression with (n=8) or without (n=36) spinal fusion. A total of 40 (74%) patients completed 12 months of follow-up and they had the following improvements: mean back pain decreased from 8.3 ± 1.0 to 4.9 ± 2.8, mean leg pain decreased from 7.2 ± 1.8 to 2.9 ± 3.0, and mean Hannover Activities of Daily Living score increased from 34 ± 16 to 58 ± 31. These improvements were statistically significant (P<0.05). Although Bothmann et al. found that patients who underwent Dynesys implantation combined with decompression had better outcomes than patients who underwent Dynesys implantation alone (P=0.04), this result supports use of decompression and does not indicate whether use of the Dynesys device improved patient outcomes. A total of 12 (22%) patients required reoperation for complications and 5 of these reoperations included explantation of the Dynesys System.

- Scarfò and Muzii (2003) conducted a small, uncontrolled study of Dynesys device implantation for lumbar vertebral instability. These investigators enrolled 26 patients but 13 (50%) of these patients also underwent microsurgical decompression and only 14 (54%) of these patients had spondylolisthesis or pseudospondylolisthesis. Outcomes reported at an average of 24 months after surgery indicated that back pain ceased in 20 (77%) patients and decreased in the other 6 (23%)
patients. Neurological symptoms decreased and nerve root pain disappeared; however, these improvements were not reported quantitatively. Moreover, pain and neurological outcomes do not seem to have been reported separately for patients with spondylolisthesis. Although standard radiographs indicated that spondylolisthesis disappeared in 9 (64%) patients and improved in the other 5 (36%), the extent of spondylolisthesis at baseline was not reported and it was not reported whether the overall improvement was statistically significant compared with baseline.

Results of these studies provide little evidence concerning the efficacy of the Dynesys Dynamic Stabilization System for degenerative spondylolisthesis. In all or all but one of the available studies, 50% to 100% of patients underwent surgical procedures other than Dynesys device implantation so it is not possible to determine which treatment effects could be attributed to the Dynesys device. Furthermore, in four of the reviewed studies, only 37% to 54% of the patients had spondylolisthesis and most or all of the outcomes were not reported separately for patients with and without spondylolisthesis. One of the five reviewed studies enrolled patients only if they had degenerative spondylolisthesis and this study found that overall, mean spondylolisthesis worsened by 2%. Although this change was not statistically significant, it did show a strong trend toward significance. In contrast, an uncontrolled trial with a small number of patients who had spondylolisthesis and who underwent Dynesys device implantation reported that spondylolisthesis improved or disappeared in all patients; however, this study did not report the extent of spondylolisthesis at baseline, nor did it report whether improvements in spondylolisthesis were statistically significant. Controlled studies with adequate follow-up and thorough assessment of outcomes are needed to determine whether the Dynesys Dynamic Stabilization System provides clinically significant benefits for patients who have degenerative spondylolisthesis.

Safety
According to the device manufacturer, the safety and effectiveness of the Dynesys System has not been established for indications other than the FDA-approved indications listed above. These indications do not include the off-label use of this device in the absence of spinal fusion; however, all of the available studies of this device evaluated it for off-label use without spinal fusion. The device manufacturer has also warned that implantation of the Dynesys System is a technically demanding procedure that involves risk of serious injury to the patient; therefore, this device should only be implanted by experienced spinal surgeons who have received specific training in the use of the Dynesys System.

Complications related to the Dynesys Dynamic Stabilization System include the following: screw loosening and breakage, screw malplacement, and intraoperative pedicle fracture. Some of the complications were severe enough that revision surgery was required. In a study that did not meet the criteria for review, Hopf et al. (2004) warned that that the Dynesys System reduces spinal mobility, has a relatively frequent incidence of revision surgery, and poses an inherent danger of segmental kyphotization. Other complications that occurred during implantation seemed attributable to surgical manipulations rather than device implantation. These complications were: infection, seroma, dural lesion, paresis, hypesthesia, scar neuroma, and cardiovascular and thromboembolic complications.

The FDA is requiring postmarket studies to address these potential risks for systems already on the market. In addition, the agency is requesting manufacturers with new dynamic stabilization systems or components to submit clinical information for regulatory review prior to marketing.

The postmarket surveillance studies must address the following:
- Fusion rate for dynamic stabilization systems compared with traditional stabilization systems.
- Incidence rate, severity, and time course of adverse events for dynamic stabilization systems compared with traditional stabilization systems.
- Type, incidence rate, and time course of subsequent surgical procedures for dynamic stabilization systems compared with traditional stabilization systems.
- Cause of failure for dynamic stabilization systems based on analysis of all reasonable available systems that have been removed from patients, along with any association between the patient’s demographic and clinical data and the device failure.
In reviewing the clinical data gathered from the postmarket surveillance studies, the FDA will consider whether labeling changes or additional preclinical and clinical testing requirements are necessary for these devices.

References


Billing Coding/Physician Documentation Information

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>22630</td>
<td>Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar</td>
</tr>
<tr>
<td>22632</td>
<td>Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (List separately in addition to code for primary procedure)</td>
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</table>
22851 Application of intervertebral biomechanical device(s) (eg, synthetic cage(s), threaded bone dowel(s), methylmethacrylate) to vertebral defect or interspace
22899 Unlisted procedure, spine
64999 Unlisted procedure, nervous system

**Additional Policy Key Words**
Dynesys Spinal System
Graf ligamentoplasty / Graf artificial ligament
Stabilimax NZ Dynamic Spine Stabilization System

**Policy Implementation/Update Information**
5/1/06 New policy.
5/1/07 No policy statement changes. Policy title changed from Lumbar Dynamic Stabilization to Dynesys® Dynamic Stabilization System.
5/1/08 No policy statement changes.
5/1/09 No policy statement changes.
5/1/10 No policy statement changes.
5/1/11 No policy statement changes.
5/1/12 No policy statement changes. Policy title changed from Dynesys® Dynamic Stabilization System to Dynamic Stabilization Systems.
5/1/13 No policy statement changes.
5/1/14 No policy statement changes.

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