

Molina Clinical Policy

Intervertebral Stabilization Devices for Spinal Fusion:

Policy No. 343

Last Approval: 10/12/2022

Next Review Due By: October 2023



DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

This policy addresses the use of flexible intervertebral stabilization devices as an adjunct to spinal fusion procedures to provide immobilization and stabilization of spinal segments.

Open decompression and/or spinal fusion methods, which aim to stabilize the spinal column, have been the standard surgical treatments for degenerative spinal disease. The standard spinal fusion procedure for rigid spinal fixation employs pedicle screws, rods, cages and plates. Technological advancements have led to the development of a new class of spinal device implants that are designed to maintain or restore intervertebral motion by restricting or dampening the motion of the spinal column without completely restricting motion, as would be the case in a conventional spinal fusion procedure.

Dynamic stabilization system, 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, also known as failed back surgery syndrome. Dynamic stabilization systems (such as the Dynesys[®] Spinal System) are designed to limit segmental motion and thus prevent further lumbar spine degeneration. Dynamic stabilization employs flexible materials rather than rigid devices to stabilize the affected spinal segment. These flexible materials can be attached to the vertebrae with synthetic cords or pedicle screws. These devices differ from conventional spinal fusion instruments, which is a rigid fixation, in that they are flexible and permit some movement of the spine segments.

Regulatory Status

Several intervertebral stabilization devices have received U.S. Food and Drug Administration (FDA) *510(k) clearance process as an adjunct to interbody fusion *include but are not limited to the following*:

- **Isobar™ Spinal System (K991326)**
The design of dynamic spinal stabilization devices may potentially be semi-rigid. These devices allegedly permit less spinal motion than non-rigid devices, but more than conventional spinal fusion instruments. The CD Horizon Agile Dynamic Spinal Stabilization Device and the Isobar Spinal System is an example of a semi-rigid device.
- **CD Horizon Agile™ Dynamic Stabilization device (K060615)**
- **Dynesys[®] System (K031511)**
The Dynesys Spinal System, was cleared by the FDA via a 510(k) pre-market notification in March 2004. According to the product labeling, it is indicated to provide stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence or neurological impairment, kyphosis; and failed previous fusion (pseudoarthrosis). In addition, the product labeling states that the Dynesys system is intended for use in persons who meet all of the following criteria:
 1. Patients who are receiving fusions with autologous graft only; and
 2. Patients who are having the device attached to the lumbar or sacral spine; and
 3. Patients who are having the device removed after the development of a solid fusion mass.

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- BioFlex® (K072321)
- DSS™ (Dynamic Soft Stabilization) Stabilization System (K090099)
- IO™ Expandable Lumbar Interbody Fusion System (K210800)
- aprevo™ Transforaminal IBF (K210542)

*The 510(k) review process does not involve or necessitate a thorough examination of clinical trial data demonstrating the safety and efficacy of the device under consideration. A manufacturer only needs to demonstrate that their device is functionally similar to a predicate device previously cleared or approved by the FDA to qualify for 510(k) clearance. As a result, many devices cleared through this process have yet to be proven safe and effective based on the merits of data collected prospectively from clinical trials of the devices in question.

RELATED POLICIES

Intervertebral Stabilization devices for spinal fusion addressed in this policy differ from interspinous process fixation devices and interspinous decompression devices. Please refer to the following MCPs concerning these devices:

- MCP-222: Interspinous Decompression Devices for Spinal Stenosis (X Stop, non-fusion Coflex)
- MCP-339: Interspinous Process Fixation Devices for Spinal Fusion

COVERAGE POLICY

Intervertebral Stabilization Devices as an adjunct to spinal fusion **are considered experimental, investigational and/or unproven** for any indication, due to insufficient clinical evidence of safety and efficacy in published peer-reviewed medical literature.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Overall, there is a paucity of evidence in the peer-reviewed published medical literature to support the long-term safety and effectiveness of intervertebral stabilization devices when used in combination with interbody fusion or as a stand-alone procedure. Due to the limited study size and short follow-up period of two years of the available studies, the long-term efficacy and safety of the procedure are not known. Large well-designed randomized controlled trials are needed to demonstrate the clinical utility of intervertebral stabilization devices compared with established standard surgical approaches involving pedicle screw-rod-cage-plate fixation with lumbar fusion procedures. The evidence is insufficient to conclusively demonstrate that spinal dynamic stabilization devices improve health outcomes for patients with any level of spine problems. Therefore, the use of these devices by any technique at any level of the spine is regarded as experimental.

DSS™ Stabilization System

Bieri et al. (2018) published the results of an analysis of data from the International Spine Tango Registry on 202 individuals who used the DSS stabilization system and 269 individuals who underwent (posterior lumbar interbody fusion) PLIF. There was not a statistically significant difference in the mean Core Outcomes Measure Index (COMI) score improvement after a follow-up of 3 years (3.4 points in the DSS group and 3.2 points in the PLIF group; $p=0.69$). Matched pairs were also similar in terms of back and leg pain relief, blood loss during surgery and complication rates. However, DSS resulted in significantly fewer repeat surgeries (0.8 per 100 observed person-years) than with PLIF (2.9 per 100 observed person-years). There have been no published prospective comparative studies evaluating the DSS stabilization system, according to the authors.

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Dynesys® Spinal System

The current evidence is insufficient to draw conclusions about whether any beneficial effect from dynamic stabilization provides a significant advantage over conventional fusion techniques due to a lack of data from well-designed, long-term RCTs. Although the Dynesys system has been in clinical use for several years, only one randomized controlled trial (RCT) and a few prospective comparative studies have been published which found that Dynesys did not improve pain and function significantly more than PLIF. A meta-analysis of 7 comparative studies also found no significant difference in length of hospital stay or complication rate between groups (Lee et al. 2016). The available data lacks strength, and the research consists of retrospective or prospective case series without controls. Furthermore, the complication and reoperation rates for dynamic stabilization are unknown in comparison to conventional fusion.

There have been published several retrospective comparative observational studies. Wu et al. (2017) reported the outcomes of Dynesys stabilization (n=26) and PLIF (n=31) in patients with lumbar degenerative degeneration. There were no statistically significant variations in ODI or VAS scores between groups after a mean follow-up of 50 months (range: 46 to 65 months). Hu et al. (2019) presented a retrospective analysis on patients with multisegment lumbar spinal stenosis, 22 of whom were treated with Dynesys stabilization and 44 of whom had PLIF. There were no statistically significant differences in clinical outcomes (pain and function) between the two groups after a minimum of 5 years of follow-up.

Several case series have been published in addition to controlled studies (Grob, 2005; Putzier, 2005; Schaeren, 2008; Schnake, 2006; Würzler-Hauri, 2008; Zhang, 2018). Welch et al. (2007) conducted a multicenter prospective FDA investigational device exemption (IDE) clinical trial in the United States. The trial included 101 participants from 6 IDE sites who were treated with the Dynesys device for dynamic stabilization. Participants were required to have degenerative spondylolisthesis or retrolisthesis (Grade I), central or lateral spinal stenosis, and their physician's determination that the participant required decompression and instrumented fusion for one or two contiguous spinal levels between L-1 and S-1 in order to be eligible. The authors reported a significant improvement in the mean pain and function scores between the baseline and 12-month follow-up assessments. It should be noted that this study lacked a control group and had only a 12-month follow-up, which is insufficient to determine the safety and durability of the Dynesys system.

Pham et al. (2016) conducted a systematic review of the literature on Dynesys stabilization system complications. The researchers reviewed 21 studies that included 1166 subjects with an average age of 55.5 years and a mean follow-up period of 33.7 months. The data showed a 4.3% rate of surgical-site infection, an 11.7% rate of pedicle screw loosening, a 1.6% rate of pedicle screw fracture, and a 7.0% rate of adjacent-segment disease (ASD). In the studies that reported surgical revision rates, 11.3% of patients required additional surgery. Reoperation was required for 40.6% of subjects who developed ASD. The authors concluded that the Dynesys stabilization system has a similar complication rate to lumbar fusion studies and a slightly lower incidence of ASD.

Lee et al. (2016) conducted a meta-analysis comparing the efficacy of the Dynesys pedicle-based dynamic stabilization system versus posterior lumbar interbody fusion (PLIF) in patients with degenerative lumbar spinal disease. Seven studies with a total of 506 participants met the eligibility criteria. Three was only one RCT, two prospective cohort studies and four were retrospective cohort studies. Clinical and radiological outcomes, including the Oswestry Disability Index (ODI) and pain measured on a visual analogue scale (VAS), were assessed at baseline and again at two years. Pooled analyses found no significant differences between in the ODI change or in back or leg pain VAS scores between the two surgical methods. The two groups had comparable rates of complications and length of hospital stay.

Isobar™ Spinal System

Fu et al. (2014) evaluated the functional and radiological outcomes of dynamic stabilization in conjunction with spinal fusion in a prospective study of 36 participants who underwent posterior Isobar dynamic stabilization for single-level degenerative lumbar disc disease with instability (DLDI) and mild adjacent level degeneration and were followed for 24 months. Functional (VAS and ODI) and radiological data (resting, functional X-rays and MRI) were used to evaluate outcomes. At 24 months, the mean VAS score had increased by 38.9 points ($p<0.01$) and ODI had increased by 22.4 points ($p<0.01$). Individuals with single-level DLDI and mild adjacent level degeneration who were treated with Isobar semi-rigid stabilization showed improvement in functional scores 2 years postoperatively. Despite the use of semi-rigid dynamic stabilization, disc degeneration appears to continue at the adjacent and index levels. According to the authors, additional long-term follow-up is being conducted ongoing to offer additional detailed data. There has been no long-term follow-up identified to date.

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National and Specialty Organizations

The **North American Spine Society (NASS)** (2020) *Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain* address "motion preserving systems" treatment, which includes disc prosthesis and dynamic stabilization systems. According to the Guideline, a systematic review of the literature found no studies that adequately addressed whether, in patients undergoing surgery for low back pain, motion preserving systems:

- Decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate compared to fusion surgery, or
- Result in lower incidence of symptomatic adjacent segment disease.

The NASS Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Degenerative Lumbar Spondylolisthesis (2014) address "flexible fusion," which is defined as dynamic stabilization without arthrodesis, as a treatment for degenerative lumbar spondylolisthesis. The workgroup was unable to make a recommendation due to the paucity of literature concerning the outcomes of these procedures. The workgroup recommended the development of a large multicenter registry database and prospective studies with long-term follow-up comparing flexible fusion to medical or interventional treatment for this condition.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Code

CPT	Description
22899	Unlisted procedure, spine (when specified as insertion of a non-pedicle interspinous process fixation device)

HCPCS Codes – N/A

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/12/2022	Policy reviewed. Updated with current relevant studies and added guidelines. No change to coverage position. Added 'Related Policies' section and two additional intervertebral body fusion devices that received FDA 510(k) clearance in 2021 (the IO™ Expandable Lumbar Interbody Fusion System and the aprevo™ Transforaminal IBF). Updated references.
10/13/2021	Policy reviewed, no changes to criteria, updated references.
9/16/2020	Policy reviewed, no changes.
9/18/2019	New policy. IRO Peer Review. July 18, 2019 by an Practicing, board-certified physician in the area of Orthopedic Surgery.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Available from [CMS](#).
2. United States Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). Premarket approval (PMA) database. Available from [FDA](#). Accessed August 15, 2021.
3. United States Food and Drug Administration 510(k) Premarket Notification Database.
 - BioFlex System (2008). Available from [FDA](#).

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- DSS Stabilization System (2009). Available from [FDA](#).
- Dynesys Spinal System (2004). Available from [FDA](#).
- Isobar Spinal System (2008). Available from [FDA](#).
- aprevo™ Transforaminal IBF (2021). Available from [FDA](#).
- IO™ Expandable Lumbar Interbody Fusion System (2021). Available from [FDA](#).

Peer Reviewed Publications

1. Bieri KS, Goodwin K, Aghayev E, et al. Dynamic posterior stabilization versus posterior lumbar intervertebral fusion: A matched cohort study based on the Spine Tango Registry. *J Neurol Surg A Cent Eur Neurosurg* 2018; 79(03): 224-230. doi: 10.1055/s-0037-1615264.
2. Fu L, France A, Xie Y, et al. Functional and radiological outcomes of semi-rigid dynamic lumbar stabilization adjacent to single-level fusion after 2 years. *Arch Orthop Trauma Surg*. 2014 May;134(5):605-10. doi: 10.1007/s00402-014-1961-4.
3. Hu A, Sun C, Liang Y et al. Multi-segmental lumbar spinal stenosis treated with Dynesys stabilization versus lumbar fusion in elderly patients: a retrospective study with a minimum of 5 years' follow-up. *Arch Orthop Trauma Surg*. 2019; 139(10):1361-1368.
4. Lee CH, Jahng TA, Hyan SJ, et al. Dynamic stabilization using the Dynesys system versus posterior lumbar interbody fusion for the treatment of degenerative lumbar spinal disease: A clinical and radiological outcomes-based meta-analysis. *Neurosurg Focus*. 2016 Jan;40(1):E7. doi: 10.3171/2015.10.FOCUS15426.
5. Pham M, Mehta V, Patel N, et.al. Complications associated with the Dynesys dynamic stabilization system: A comprehensive review of the literature. *Neurosurg Focus*. 2016; 40(1):E2. doi: 10.3171/2015.10.FOCUS15432. PMID: 26721576.
6. Wu H, Pang Q, Jiang G. Medium-term effects of Dynesys dynamic stabilization versus posterior lumbar interbody fusion for treatment of multisegmental lumbar degenerative disease. *J Int Med Res* 2017; 45: 1562-1573. doi: 10.1177/0300060517708104

National and Specialty Society

1. North American Spine Society (NASS).
 - NASS coverage policy recommendations: Interspinous fixation with fusion. Available from [NASS](#). Published May 2014.
 - Evidence-based clinical guidelines for multidisciplinary spine care: Diagnosis and treatment of low back pain. Published 2020. Available from [NASS](#).

Other Peer Reviewed Publications (used in the development of this policy)

1. Bredin S, Demay O, et al. Posterolateral fusion versus Dynesys dynamic stabilization: Retrospective study at a minimum 5.5 years' follow-up. *Orthop Traumatol Surg Res*. 2017 Dec;103(8):1241-1244. doi: 10.1016/j.otsr.2017.07.020. Accessed August 15, 2021.
2. Chou R. Subacute and chronic low back pain: Surgical treatment. Available from [UpToDate](#). Updated June 11, 2021. Accessed September 2022. Registration and login required.
3. Eck JC, Sharan A, Ghogawala Z, et al. American Association of Neurological Surgeons (AANS) guideline update for the performance of fusion procedure for degenerative disease of the lumbar spine. Part 7: Lumbar fusion for intractable low-back pain without stenosis or spondylolisthesis. *J Neurosurg Spine*. 2014 Jul;21(1):42-7. doi: 10.3171/2014.4.SPINE14270. Accessed August 15, 2021.
4. Grob D, Benini A, Junge A, Mannion AF. Clinical experience with the Dynesys semirigid fixation system for the lumbar spine: Surgical and patient-oriented outcome in 50 cases after an average of 2 years. *Spine*. 2005; 30(3):324-331.
5. Levin K. Lumbar spinal stenosis: Treatment and prognosis. Available from [UpToDate](#). Updated February 1, 2021. Accessed September 2022. Registration and login required.
6. Putzier M, Schneider SV, Funk JF, et al. The surgical treatment of the lumbar disc prolapse: Nucleotomy with additional transpedicular dynamic stabilization versus nucleotomy alone. *Spine*. 2005; 30(5):E109-114.
2. Schaeren S, Broger I, Jeanneret B. Minimum four-year follow-up of spinal stenosis with degenerative spondylolisthesis treated with decompression and dynamic stabilization. *Spine*. 2008; 33(18):E636-642.
3. Schnake KJ, Schaeren S, Jeanneret B. Dynamic stabilization in addition to decompression for lumbar spinal stenosis with degenerative spondylolisthesis. *Spine*. 2006; 31(4):442-449.
4. Welch WC, Cheng BC, Awad TE, et al. Clinical outcomes of the Dynesys dynamic neutralization system: 1-year preliminary results. *Neurosurg Focus*. 2007 15; 22(1):E8.
5. Würzler-Hauri CC, Kalbarczyk A, Wiesli M, et al. Dynamic neutralization of the lumbar spine after microsurgical decompression in acquired lumbar spinal stenosis and segmental instability. *Spine*. 2008; 33(3):E66-72.
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7. Zhang Y, Zhang ZC, et al. Long-term outcome of Dynesys dynamic stabilization for lumbar spinal stenosis. *Chinese Medical Journal*. November 2018. 131(21):2537. doi:10.4103/0366-6999.244107.

APPENDIX

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.