Molina Clinical Policy
Intervertebral Stabilization Devices for Spinal Fusion: Policy No. 343

Last Approval: 10/13/2021
Next Review Due By: October 2022

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.[1] References included were accurate at the time of policy approval and publication.

OVERVIEW

This MCP addresses the use of flexible intervertebral stabilization devices as an adjunct to spinal fusion procedures to provide immobilization and stabilization of spinal segments. These devices are designed to allow some degree of spinal flexibility following spinal fusion surgery. The most common surgery for chronic nonspecific low back pain with lumbar disc degenerative changes is spinal fusion, a procedure that fuses two or more vertebral bodies together. The goal is to restrict spinal motion and remove the degenerated disc (the presumed cause of pain) in order to relieve symptoms. A variety of fusion techniques are used. All involve the placement of a bone graft between the vertebrae. Fusion can be performed with or without supplemental hardware (instrumentation), such as pedicle rods, plates, screws, or cages that function as an internal splint while the bone graft heals. Fusion alters the normal mechanics of the spine and is associated with an increase in long-term degenerative changes in adjacent spine segments. The standard spinal fusion procedure for rigid spinal fixation involves the use of pedicle screws, rods, cages and plates.[2-4]

Intervertebral stabilization devices have been proposed as an alternative to the use of standard rigid frames to try to improve the disadvantages of rigid instrumentation and increase the outcome of spinal fusion surgery. These devices are fixed in place using pedicle screws which are attached to the vertebral bodies adjacent to the intervertebral space being fused but are designed using flexible materials which suggest stabilizing the joint while still providing some flexibility. Examples of intervertebral stabilization devices that have currently been approved by the 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 (Alphatec Spine, Inc. Carlsbad, CA), Dynesys® System (Zimmer Inc., Minneapolis MN), BioFlex® (BioSpine Co., Ltd, Sungdong-gu, Seoul Korea) and the DSSTM Stabilization System (Paradigm Spine, LLC, New York, NY).[2]

NOTE: Intervertebral Stabilization devices for spinal fusion in this MCP differ from interspinous process fixation devices and interspinous decompression devices. Please see the following MCPs for additional information concerning these devices: *Interspinous Decompression Devices for Spinal Stenosis (X Stop, non-fusion Coflex) MCP-222* and *Interspinous Process Fixation Devices for Spinal Fusion MCP-339.*

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 [5-10]

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. The available studies are small, with short follow-up of two years so 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.

Bieri, et al. published an analysis of data from the International Spine Tango Registry on 202 individuals who used the DSS stabilization system and 269 individuals who underwent PLIF. At a mean follow-up of 3 years, there was not a statistically significant difference in the mean Core Outcomes Measure Index (COMI) score improvement (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, there were significantly fewer repeat surgeries after DSS (0.8 per 100 observed person-years) than with PLIF (2.9 per 100 observed person-years). It was indicated that there are no published prospective comparative studies evaluating the DSS stabilization system.[5]

Lee, et al. conducted a meta-analysis of the literature on the efficacy of the Dynesys system to compare clinical and radiological outcomes between individuals who underwent surgery with Dynesys versus posterior lumbar interbody fusion (PLIF) for degenerative spinal disease. A total of 7 studies with 506 participants met the eligibility criteria. Only one was a randomized controlled trial (RCT), two were prospective cohort studies and four were retrospective cohort studies. Clinical and radiological outcomes, including the Owestry Disability Index (ODI) and pain measured by a visual analogue scale (VAS), were assessed at baseline and again at two years. Pooled analyses did not find significant differences between the two surgical methods in change in the ODI or in back or leg pain VAS scores. Rates of complications and length of hospital stay were similar in the two groups.[6]

Fu, et al. evaluated the functional and radiological outcomes of dynamic stabilization in conjunction with spinal fusion in a prospective study of 36 participants with follow-up for 24 months who underwent posterior Isobar dynamic stabilization for single-level degenerative lumbar disc disease with instability (DLDI) and mild adjacent level degeneration. Outcomes were assessed using functional [visual analog scale (VAS) and Oswestry Disability Index (ODI)] and radiological data (resting, functional X-rays and MRI). At 24 months, functional outcomes demonstrated significant improvement in mean VAS score by 38.9 points ($p<0.01$) and ODI by 22.4 points ($p<0.01$). Results indicated that individuals with single-level DLDI and mild adjacent level degeneration treated with Isobar semi-rigid stabilization demonstrated improvement in functional scores 2 years postoperatively. However, disc degeneration at the adjacent and index levels appears to continue despite using semi-rigid dynamic stabilization. The authors stated that additional long-term follow-up is ongoing to provide more extensive information.[7]

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 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

10/13/2021	Policy reviewed, no changes to criteria, updated references.
9/16/2020	Policy reviewed, no changes.
9/18/2019	New policy.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. http://www.cms.gov/mcd/search.asp. Accessed August 15, 2021.
2. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). Premarket approval (PMA) database. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. Accessed August 15, 2021.

National and Specialty Organizations

3. North American Spine Society (NASS). NASS coverage policy recommendations: Interspinous fixation with fusion. https://www.spine.org/coverage. Published May 2014. Accessed August 15, 2021.
4. Eck JC, Sharan A, Ghogawala Z, Resnick DK, Watters WC, Mummaneni PV, 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.

Peer Reviewed Publications

5. 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. Accessed August 15, 2021.
6. 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. Accessed August 15, 2021.
7. 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. Accessed August 15, 2021.

Other Peer Reviewed Publications

8. Chou R. Subacute and chronic low back pain: Surgical treatment. http://www.uptodate.com. Updated June 11, 2021. Accessed August 15, 2021. Registration and login required.
9. Levin K. Lumbar spinal stenosis: Treatment and prognosis. http://www.uptodate.com. Updated February 1, 2021. Accessed August 15, 2021. Registration and login required.
10. AMR Peer Review. Policy reviewed July 18, 2019 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the area of Orthopedic Surgery.

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

11. 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.
12. 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 Jan;40(1):E2. doi: 10.3171/2015.10.FOCUS15432. Accessed August 15, 2021.
13. 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. Accessed August 15, 2021.
14. Yang Y, Hong Y, et al. Comparison of clinical and radiographic results between isobar posterior dynamic stabilization and posterior lumbar inter-body fusion for lumbar degenerative disease: A four-year retrospective study. Clin Neurol Neurosurg. 2015 Sep;136:100-6. doi: 10.1016/j.clineuro.2015.06.003. Accessed August 15, 2021.
15. 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. Accessed August 15, 2021.

APPENDIX

Reserved for State specific information *(to be provided by the individual States, not Corporate). Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*