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

Last Approval: 10/12/2023
Next Review Due By: October 2024

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

Degenerative spinal changes and/ or spinal stenosis requiring surgery, which aims to stabilize spinal column to reduce pain and restore quality of life, is most often treated with standard spinal fusion. Spinal fusion surgery 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. 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 under the product codes NQP and MAX. The devices, such as the Dynesys® System (K031511) and Isobar™ Spinal System (K991326), are approved as an adjunct to interbody fusion as Class II devices under the classifications of pedicle screw spinal systems, spinal interlaminar fixation orthosis, and intervertebral body fusion devices.

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

Guan et al. (2023) conducted a small retrospective comparison study to investigate the feasibility of the Isobar TTL and posterolateral fusion in a two-segment hybrid fixation approach combined with spinal decompression, for treating mild and moderate lumbar degenerative disease compared to posterolateral fusion alone. The authors sought to evaluate the effectiveness of this and determine whether it could provide a safe and reliable alternative to traditional surgical methods. Forty-five consecutive patients with two-level lumbar disc herniation or spinal stenosis were analyzed, 24 of whom underwent the TTL system and posterolateral fusion combined (TTL group), and 21 of whom underwent posterolateral fusion alone (Rigid group), all surgeries were successful with lower operation time and intraoperative bleeding rates in the TTL group. Upon a mean follow up of 56.09 months, all patients showed significant improvements in clinical outcomes, including visual analogue scale for back and leg pain, and Oswestry Disability Scores ($p < 0.05$); though the TTL group reported better than the Rigid group at 1 year after surgery and at the final follow-up ($p < 0.05$). Postoperative surgical segment range of motion (ROM) decreased in both groups ($p < 0.05$). The modified Pfirrmann classification of the superior adjacent segment was significantly increased in both groups at the last follow-up ($p < 0.05$). According to the UCLA classification, the incidence of adjacent segment degeneration (ASD) was 4.2% in the TTL group and 23.8% in the Rigid group. The Isobar TTL System utilized resulted in no evident indications of lumbar instability being detected on X-rays captured at a minimum of 4 years after the operation, while retaining partial range of motion of the surgical segment. The authors conclude the Isobar TTL system's clinical efficiency is equivalent or better than titanium rod fusion surgery, presenting an alternative treatment for individuals with mild and moderate lumbar degenerative disease.

Zhou et al. (2023) conducted a meta-analysis to compare the radiographic and clinical outcomes between Dynesys stabilization and instrumented fusion in the treatment of degenerative lumbar spine disease with or without grade I spondylolisthesis with a minimum follow-up period of 2 years. Seventeen studies, for a total of 1296 patients, met inclusion criteria. The results showed the Dynesys stabilization was associated with significantly lower postoperative visual analogue scale scores for low-back and leg pain, and lower rate of surgical revision than the fusion group. The Dynesys group also resulted in less ASD and increased range of motion compared to the fusion patients, leading to the conclusion that the Dynesys system showed comparable clinical outcomes and provided benefits in preserving the motion at the stabilized segments.

Meyer et al. (2022) conducted a multi-center double-blind prospective randomized controlled study comparing dynamic pedicle-based stabilization versus fusion in spinal degenerative disease. Two hundred and ninety-three patients with symptomatic mono- or bisegmental lumbar degenerative disease with or without stenosis and instability were enrolled and randomized 1:1 to undergo instrumented fusion or pedicle-based dynamic stabilization surgery. The primary endpoint was the Oswestry Disability Index (ODI) score, and secondary endpoints were pain, health-related quality of life, and patient satisfaction at 24 months. Two hundred and sixty-nine participants (137 in fusion group vs 132 in dynamic stabilization group) were analyzed to reveal that while inpatient stays did not differ between groups, the dynamic stabilization group had shorter duration of surgery with significantly less blood loss which resulted in lower inpatient hospital cost. Apart from those differences assessment of the primary and secondary data revealed no significant differences between the two groups, nor differences in adverse events reported (27 in the fusion group vs 26 in the dynamic stabilization group). The mean ODI scores for the fusion and dynamic stabilization groups were 45 ± 18 and 43 ± 17 at baseline, 30 ± 21 and 27 ± 20 at 3 months, 28 ± 22 and 28 ± 22 at 12 months, and 29 ± 22 and 30 ± 21 at 24 months, respectively. In conclusion, further observation is needed to assess screw loosening issues, slow fusion, and adjacent-segment degeneration in the present series of patients, further long-term observation, and a thorough analysis of further follow-up imaging by CT is necessary. A benefit of the less-invasive dynamic technique was proven in terms of reduced operating room time and intraoperative blood loss, with no functional outcome differences in comparison with fusion.

Wang et al. (2020) conducted a meta-analysis comparing the Dynesys system vs posterior decompression and fusion for the treatment of lumbar degenerative diseases. Seventeen studies were analyzed to reveal no significant differences in ODI and visual analogue score for leg pain, visual analogue score for back pain, L2-S1 ROM between

Dynesys and fusion group. Operation time, blood loss, length of stay and complications in the Dynesys group were significantly less than that in the fusion group. Adjacent-segment degeneration in the fusion group was significantly higher than that in the Dynesys group. Postoperative operated segment range of motion (ROM) was significantly less in the fusion group as compared to the Dynesys group. In conclusion, the data suggests the Dynesys system attains comparable clinical outcomes to spinal fusion with shorter surgery duration, increased ROM, and lower adjacent - segment degeneration rates. Further large randomized controlled trials with longer follow ups are needed to aid in establishing the clinical place of dynamic stabilization systems.

Hu et al. (2019) conducted a retrospective analysis of 22 patients treated with the Dynesys system versus 44 patients treated with lumbar fusion and rigid fixation in response to multi-segmental lumbar spinal stenosis in elderly patients. The mean follow-up time of the Dynesys group and fusion group was 68.50 ± 6.40 and 70.14 ± 7.26 months, respectively. Baseline data were similar between the two groups. There were no significant differences between the two groups in terms of improvement of clinical outcomes assessed via visual analogue scale and ODI scores. DS preserved a certain degree of ROM (3.74 ± 2.00) of surgical segments. The two groups provided similar outcomes in an increased ROM of proximal adjacent segment, the significantly lower disc height of the surgical segments and proximal adjacent segment, the improved lumbar lordosis angle, and the increased modified Pfirrmann score of the proximal adjacent segment at the final follow-up. The consistent clinical outcomes across both groups led the authors to conclude the Dynesys system is a safe and effective surgical treatment of multi-segmental lumbar spinal stenosis in the elderly population and preserves a certain degree of mobility of surgical segments.

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), as well as shorter surgery times. There have been no published prospective comparative studies evaluating the DSS stabilization system, according to the authors.

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.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Code

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

APPROVAL HISTORY

10/12/2023	Policy reviewed, no changes to criteria, updated references.
10/12/2022	Policy reviewed, no changes to criteria, updated references. 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.
09/16/2020	Policy reviewed, no changes to criteria, updated references.
09/18/2019	New policy. IRO Peer Review July 18, 2019 by a practicing board-certified in Orthopedic Surgery physician.

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