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

Last Approval: 10/14/2026
Next Review Due By: October 2027

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. 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 (Hayes 2025).

Regulatory Status

Several intervertebral stabilization devices have received U.S. Food and Drug Administration (FDA) 510(k) clearance under the product codes NQP, KWP, MNI and MNH. 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 (FDA 2024).

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 unproven** for any indication, due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

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SUMMARY OF MEDICAL EVIDENCE

Randomized Controlled Trials

Nasser at al. (2024) conducted a randomized controlled Investigational Device Exemption trial evaluating the safety and efficacy of lumbar facet arthroplasty using the TOPS System (Total Posterior Spine System) compared to instrumented lumbar fusion in patients with lumbar spinal stenosis and Grade 1 degenerative spondylolisthesis. The TOPS system is a dynamic intervertebral stabilization device designed to preserve motion at the treated spinal segment while providing posterior stabilization. A total of 321 adult patients were randomized in a 2:1 ratio, with 219 assigned to the facet arthroplasty group and 102 to the fusion group. The primary endpoint Composite Clinical Success (CCS) at 24 months, was evaluated in 160 patients who either completed the full follow up period or were classified as early clinical failures (113 in the arthroscopically group and 47 in the fusion group). CCS was achieved in 73.5% of patients in the Arthroscopy group compared to 25.5% in fusion group representing a statistically significant between-group difference ($p < 0.001$). Patients treated with facet arthroplasty demonstrated superior outcomes across multiple validated patient-reported measures, including the Oswestry Disability Index (ODI), Visual Analog Scale (VAS) for back pain, and all components of the Zurich Claudication Questionnaire (ZCQ). While overall complication rates were comparable between the groups, the fusion cohort experienced a higher incidence of symptomatic adjacent segment degeneration. The arthroplasty device also preserved segmental motion, which may reduce biomechanical stress on adjacent levels and contribute to improved functional outcomes. Despite these encouraging short-term results, the study had several limitations. The follow-up duration was limited to 24 months, restricting assessment of long-term durability, radiographic stability, and sustained clinical benefit. The study was industry- funded, and blinding of patients, surgeons, and radiologists was not feasible, introducing potential detection bias. Additionally, strict inclusion exclusion criteria may limit generalizability, and the primary outcome analysis included only approximately half of the randomized cohort well this was consistent with the trials pre-specified statistical plan. Further long-term studies are necessary to validate its safety, durability, and comparative effectiveness.

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.

Systematic Reviews and Meta-Analyses

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

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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 adjacent segment degeneration (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.

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 range of motion (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 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.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Liu et al. (2026) conducted a retrospective review of subjects who underwent dynamic stabilization using the Dynesys system or transforaminal lumbar interbody fusion (TLIF) for single segment degenerative spondylolisthesis and spinal stenosis. A total of 75 subjects were enrolled with 35 undergoing dynamic stabilization with the Dynesys system and 40 undergoing TLIF. Mean follow-up was 80.5 months (range 61.3-119.3 months) and all included subjects received follow-up for a minimum of 5 years. Similar rates of neurogenic claudication and radicular pain were noted between groups. The preoperative Pfirrmann grade was significantly lower in the Dynesys group compared to the TLIF group (3.11 ± 0.58 vs. 3.88 ± 0.72, $p < 0.001$). The Dynesys group experienced a lower disc degeneration rate than the TLIF group (17.14% vs. 42.5%, $p = 0.018$). Six patients in the Dynesys group experienced one-grade progression while 14 patients in the TLIF group experienced one-grade progression and 3 patients experienced two-grade progression. Two patients in the Dynesys group experienced one-grade progression in endplate degeneration while four patients in the TLIF group experienced one-grade progression, though the difference was not statistically significant. Radiological ASD occurred in 15 (42.85%) patients in the Dynesys group compared to 28 (70%) patients in the TLIF group with the difference being significant ($p = 0.017$). Preoperative ROM was significantly higher in the Dynesys group compared to the TLIF group (8.3 ± 3.7° vs. 6.3±2.9°, $p = 0.009$). The ROM at final follow-up improved in the Dynesys group (9.5±4.3°) while the TLIF group showed less improvement (7.1±4.8°). The differences between groups at final follow-up was statistically significant, but the change in ROM within groups (preoperative vs. final follow-up) was not statistically significant. Mean VAS scores for back pain in the Dynesys group decreased from 6.9±1.9 to 0.8±1.2 ($p < 0.05$) with similar improvements noted in the TLIF group (7.2±1.7 vs. 0.3±0.8, $p < 0.05$). Similar improvements were noted in VAS scores for leg pain (Dynesys = 6.7±1.6 vs. 0.2±0.7, $p < 0.05$; TLIF = 6.9±1.3 vs. 0.6±0.7, $p < 0.05$). ODI scores also significantly improved in both groups Dynesys = 45.2±9.3 vs. 4.7±8.4, $p < 0.05$; TLIF = 44.9±11.4 vs. 3.4±3.8, $p < 0.05$). Japanese Orthopedic Association scores also significantly improved in both groups (Dynesys = 7.3±1.5 vs. 27.2±3.5, $p < 0.05$; TLIF = 7.1±1.9 vs. 26.8±4.8, $p < 0.05$). One patient in the TLIF group experienced clinical ASD. Nine patients (Dynesys = 4, TLIF = 5) experienced screw loosening, though none required revision. Researchers noted that this study shows that dynamic stabilization systems appear to decrease disc degeneration and the incidence of radiological ASD. However, researchers noted that the study was limited to a single-center and the sample size was small. Further studies with larger sample sizes from multiple centers are needed to determine the effectiveness of dynamic stabilization systems in preventing clinical ASD.

Orunoglu et al. (2025) completed a cross-sectional study to compare “the structural, functional, and neuromuscular outcomes of dynamic versus rigid lumbar fixation.” A total of 75 participants were included across three groups: dynamic rod, rigid rod, and healthy control. Participants were recruited based on retrospective review and surgical participants were excluded “if they had a) undergone stabilization without screws or had a history of revision surgery, b) a systemic inflammatory disease, c) a history of psychiatric illness or cognitive limitations preventing cooperations, d) undergone surgery due to infection, tumor, or trauma, or e) were pregnant at the time of the study. All surgical procedures were conducted by the same surgeon. Age and height were similar across all groups, while weight and BMI were slightly higher in the rigid rod group, although there was no statistically significant difference. Time since surgery and surgical levels were similar across both surgical groups. Mean multifidus muscle volume was significantly higher in the dynamic rod group compared to the rigid rod group (27.37±2.46cm vs. 24.73±2.83cm, $p < 0.001$). Mean erector spinae muscle volume was significantly higher in the dynamic rod group compared to the rigid rod group

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(81.21±4.56cm vs. 76.34±4.43cm, p < 0.001). Mean intervertebral disc degeneration scores using the Pfirrmann scale were significantly higher in the dynamic rod group compared to the rigid rod group (2 [range 1-3] vs. 0 [range 0-2], p = 0.018). No statistically significant differences were noted in disc height loss or facet joint degeneration scores. Mean ODI scores were significantly lower in the healthy control group (4.44±2.82) compared to the surgical groups, while the scores in the dynamic rod group (10.08±5.47) were lower than the rigid rod group (13.84±6.16). Similar outcomes were observed for the Nottingham Health Profile scores with the only statistically significant measures being pain, emotional reactions, and physical activity. The healthy control group outcomes for the McGill Torso Endurance tests were significantly higher than both surgical groups while the dynamic rod group outperformed the rigid rod group when comparing surgical groups. Similar statistically significant outcomes were observed in the lumbar deep muscle activation measurements. Researchers noted that the time since surgery correlated with progressive degeneration and muscle atrophy with this effect being more pronounced in the rigid rod group. Additionally, "negative correlations were observed between time since surgery and both multifidus muscle volume and erector spinae volume, reflecting a consistent decline in paraspinal muscle mass in both fixation modalities."

Erdogan et al. (2025) conducted a retrospective, two-center analysis of "113 patients who underwent unilateral posterior spinal stabilization between 2019 and 2023." Patients were included in the analysis if they had completed two years of clinical and radiological follow-up. Patients were divided into two groups: unilateral rigid stabilization (n = 41) and unilateral dynamic stabilization (n = 72). The mean age across all 113 patients was 59.65±11.84 years. Gender composition was 54 female (47.79%) and 59 male (52.21%). Two-level stabilization was performed in 61 patients (53.98%), three-level stabilization was performed in 33 patients (29.20%), and four-level stabilization was performed in 19 patients (16.81%). Primary pathology consisted of disc herniation (n = 44), foraminal stenosis (n = 17), spinal stenosis (n = 23), tumoral lesion (n = 15), and spondylolisthesis (n = 14). The region of operation consisted of cervical (n = 5), thoracal (n = 8), thoracolumbar (n = 8), lumbar (n = 74), and lumbosacral (n = 18). VAS scores improved significantly across both cohorts (mean preoperative = 8.33±1.46 vs. 24-month follow-up = 2.76±1.81, p < 0.001) with no significant difference noted between cohorts (p = 0.59). No significant difference was noted between the number of levels of stabilization or type of stabilization between baseline and all follow-up periods. For radiological outcomes based on type of stabilization, no significant difference was noted between preoperative and all follow-up periods. Those undergoing unilateral dynamic stabilization experienced a significant increase in superior adjacent disc height at early preoperative imaging (p = 0.03). Those undergoing unilateral rigid stabilization experienced a significant decrease in superior adjacent disc height at the 24-month follow-up (p = 0.01). No significant differences were noted in superior adjacent disc height when stratified by level of stabilization or when level of stabilization was stratified by follow-up. There were no significant differences in foraminal height index based on stabilization type (p = 0.98) or number of stabilization levels (p = 0.49). Pseudoarthrosis was more common in the unilateral rigid stabilization group (39.02% vs. 16.67%, p < 0.01) while fusion rates were significantly higher in the unilateral rigid stabilization group (85.37% vs. 27.78%, p < 0.001). A total of 17 patients developed adjacent segment disease during the follow-up period with those undergoing three or four levels of stabilization experiencing a higher incidence of adjacent segment disease. No postoperative infections, revisions (wound or surgical), or rod fractures occurred. Researchers noted that "lack of significant differences in VAS reduction between…groups underscores the comparable efficacy of both modalities." However, they also note that a limitation of the study was a lack of longer-term outcomes to assess late-onset adjacent segment disease or delayed hardware failure. Additionally, the study was retrospective in nature and the decision on type of stabilization (rigid or dynamic) was based on surgeon preference rather than randomization.

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 VAS scores for back and leg pain, and ODI 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 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 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

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years after the operation, while retaining partial range of motion of the surgical segment. The authors conclude that 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.

National and Specialty Organizations

The **North American Spine Society (NASS)** *Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain* (2020) 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	Description
22899	Unlisted procedure, spine [when specified as insertion of a dynamic intervertebral pedicle-based stabilization device]

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APPROVAL HISTORY

10/14/2026	Policy reviewed. No changes to coverage criteria.
10/08/2025	Policy reviewed. No changes to coverage criteria.
10/09/2024	Policy reviewed. No changes to coverage criteria.
10/12/2023	Policy reviewed. No changes to coverage criteria. IRO Peer Review on September 6, 2023, by a physician board-certified in Orthopedic Surgery.
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 coverage criteria.
09/16/2020	Policy reviewed. No changes to coverage criteria.
09/18/2019	New policy. IRO Peer Review July 18, 2019, by a practicing board-certified in Orthopedic Surgery physician.

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