Subject: Intervertebral Stabilization Devices for Spinal Fusion		Original Effective Date: 9/18/19
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.[1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [2] 18-20

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.

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).

Note: Intervertebral Stabilization devices for spinal fusion in this MCP differ from Interspinous process fixation devices and Interspinous Decompression devices. Please see the following related MCP's 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.

RECOMMENDATION

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.

SUMMARY OF MEDICAL EVIDENCE [3-17]

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. A summary of the relevant studies are outlined below.

Bieri et al, (2018) 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). The authors indicated that there are no published prospective comparative studies evaluating the DSS stabilization system. [3]

Lee et al, (2016) 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. [8]

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 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. [6]

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

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

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Government Agency

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Review/Revision History:

9/2019: New Policy