Subject: Facet Joint Allograft Implants for Facet Disease		Original Effective Date: 6/17/2020
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DISCLAIMER

This Molina clinical policy 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 document and provide the directive for all Medicare members.[1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [5-6 10-12]

The facet joint is a synovial joint between the superior articular process of one vertebra and the inferior articular process of the vertebra directly above it. There are two facet joints in each spinal motion segment. The biomechanical function of each pair of facet joints is to guide and limit movement of the spinal motion segment. In the lumbar spine, for example, the facet joints function to protect the motion segment from anterior shear forces, excessive rotation and flexion. These functions can be disrupted by degeneration, dislocation, fracture, injury, instability from trauma, osteoarthritis, and surgery. In the thoracic spine the facet joints function to restrain the amount of flexion and anterior translation of the corresponding vertebral segment and function to facilitate rotation.

Facet joint allografts use specially designed bone dowels made from allograft material (donated cortical bone) that are inserted into the facet joints that is designed to stop facet joints from moving and is intended to eliminate or reduce back pain caused by facet joint dysfunction. Inserting the facet joint allograft is a minimally invasive back procedure that is performed with or without bone grafting and/or the use of posterior intrafacet implants such as fixation systems, facet screw systems or anti-migration dowels. The facet joints are generally small as compared to the intervertebral space. Consequently, limited amounts of bone-growth promoting substances may be inserted into the joint. Some of the bone-growth promoting substances tend to disperse post-operatively resulting in a less robust fusion. Furthermore, the overlying fibrous tissue may further disperse the bone-growth promoting substances as a result of contact, friction, and/or the ingrowth of fibrous mass. These and other factors may result in pseudarthrosis or inadequate fusion.

FDA: These products are currently being marketed for facet joint allografts: BacFast, NuFix™ and TruFUSE®. Allograft devices are regulated by the FDA as human cells, tissue and cellular and tissue-based products, and they are generally processed by licensed tissue banks.

- BacFast (Biologix Technologies, Beirut Lebanon) is a allograft that is hyper-demineralized to expose the collagen surface of a bone allograft and is engineered with a focus on fusion as well as facet stabilization.

- TruFUSE® (minSURG Corp., Clearwater, Florida) is a cortical allograft posterior fusion option. The procedure can be performed open, minimally invasively through a cylindrical tissue retractor, or entirely percutaneously. TruFUSE uses specially shaped, small pieces of human bone, called allograft, to stabilize the spine. A compaction reamer is used to make a tunnel in the facet joint. The allograft is then inserted to secure the facet joints. By stopping the joint from moving, TruFUSE provides support that allows for fusion. According to the manufacturer it may be used for treatment of degenerative disc disease, degenerative joint disease, osteoarthritis and other indications for spinal fusion for any location from C1-C2 to L4-L5.
- NuFix™ (NuFix, Inc., Birmingham, Alabama) is another facet stabilization and fusion device constructed of allograft bone. It is placed in the facet joint after an appropriate drill hole has been made. This effectively "locks" the facet joint preventing flexion, extension and rotation. This procedure can be done both open and percutaneously with fluoroscopic assistance.

RECOMMENDATION CLINICAL CRITERIA

Surgically implanted allografts as a stand-alone procedure to treat facet joint pain are considered experimental, investigational and unproven due to insufficient published evidence to assess the safety and/or impact on health outcomes on facet joint pain.

SUMMARY OF MEDICAL EVIDENCE [2-6]

The current peer reviewed clinical evidence is limited to small, uncontrolled trials with lack of blinding or long-term follow-up. Randomized, controlled trials comparing these allograft materials to standard bone grafting and instrumentation techniques to achieve fusion of the facet joints are needed to determine long-term efficacy and impact on health outcomes. An outline of some of the published studies is below.

Gavaskar et al., (2010) conducted a prospective, non-randomized study of 30 patients with low-grade spondylolisthesis of lumbar and lumbosacral spine who underwent facet fusion using two cortical screws and bone grafts. Visual analogue scale and Oswestry disability assessment were used to measure outcomes which revealed twenty-nine of the thirty patients with significant improvement at one-year follow-up. The study is limited to short-term follow-up, subjective outcomes and lack of comparison to other treatment modalities. [4]

Cook et al., (2015) evaluated the mechanical stability of 2 lumbar facet fixation technologies before and after repeated cyclic loading. Six human lumbar specimens were implanted with both types of allograft, one at L2-3 and the other at L4-5, on a randomized basis. All specimens were subjected to pure-moment flexibility testing before and after implantation and after 2500 and 5000 cycles of flexion-extension bending. Each specimen was scanned with computed tomography before and after cyclic loading to measure device migration. Only dowel 1 resulted in a statistically significant reduction in flexion-extension range of motion at the treatment level. This reduction was significant at baseline testing ($P = .03$) and after 2500 cycles of flexion-extension loading ($P = .048$) but was not significant after 5000 cycles of loading. One of the bone dowels extruded posteriorly out of the joint space during baseline axial torsion flexibility testing, which was before any cyclic loading. The authors concluded that the data obtained in this study do not indicate efficacy of fixation for cylindrical bone dowels in the lumbar facet joint. Significant fixation was detected only for one of the devices and was no longer present after a relatively short duration of repeated loading. Furthermore, considerable magnitudes of device migration were detected. [2]

Dusad et al., (2018) evaluated the clinico-radiological efficacy of stand-alone minimally invasive transarticular screw (MIS-TAS) fixation without supplemental Gallie fixation in the management of mobile C1-C2 instability. Patients with mobile atlantoaxial instability and & 2 years follow-up were included and managed by stand-alone TAS fixation using the Magerl technique and morselized allograft without additional fixation. Patient demographics and intra-operative parameters were noted. Clinical parameters (Visual Analog Scale [VAS] and Oswestry Disability Index [ODI]),

neurology (modified Japanese Orthopaedic Association [mJOA]), and radiological factors (anterior atlanto-dens interval and space available for cord) were evaluated pre and postoperatively. Computed tomography (CT) was performed in patients who did not show interspinous fusion on X-ray at 1 year, to verify intra-articular fusion. A total of 82 consecutive cases were evaluated. Significant improvement was noticed in clinical (mean preoperative VAS=7.2±2.19, postoperative VAS=3.3±1.12; mean preoperative ODI=78.3±4.83, postoperative ODI=34.05±3.26) and neurological features. Radiological evidence of fusion was noted in 97.5% cases at final follow-up. Seventeen patients were found to have no interspinous fusions upon X-rays, but CT revealed facet fusion in all patients except in two. Inadvertent vertebral artery injury was noted in three cases. The authors concluded that stand-alone TAS fixation with morselized allograft provides excellent radiological and clinical outcomes. The addition of a supplementary tension band and structural graft are not essential. This provides the opportunity to avoid the complications associated with graft harvesting and wiring. The study lacked a control group for comparison using a more standard arthrodesis technique. [3]

Professional Society Guidelines and Opinions [7-9]

The American Association of Neurological Surgeons published a technical assessment of TruFuse in 2009. They concluded that there is insufficient information to evaluate the safety and utility of this device or make recommendations regarding clinical usage. [7]

The American Academy of Pain Medicine (AAPM) at their 2011 annual meeting, presented a retrospective case series on minimally invasive facet fusion procedures, such as the Trufuse, for the treatment of facet mediated low back pain and instability due to Grade 1 spondylolisthesis. In this procedure, a cannula is used to guide a drill into lumbar facet joint. A tapered allograft of cortical bone is inserted and tamped to secure press fit with the allograft dowel using real time fluoroscopy to ensure successful placement. This mitigates the risk of foraminal trespass and dowel back out. The AAPM stated that literature about the Trufuse is sparse, however. A retrospective chart review was conducted. Eight adult patients underwent Trufuse. Post-op care included wearing of a lumbosacral orthosis for 3 months. The primary clinical outcome measures were the Oswestry Disability Index (ODI). A telephone interview was performed at 2 years follow-up, by an independent operator. ODI improved from 73% to 13% in 3 out of 8 patients who subsequently stopped their pain medications and were discharged. They were also compliant in wearing their brace. Five patients had no improvement in ODI and continued to require analgesics. These 5 patients were not compliant with use of the lumbar brace. No patient demonstrated deterioration in the ODI. Dowel dislodgement was identified on CT scanning, in those who failed treatment. The AAPM conclude that Trufuse is one of the minimally invasive techniques in spine surgery that may benefit a subset of patients with lumbar facet mediated pain; treatment failure may be due to dowel dislodgement and lack of compliance with brace utilization. [8]

The International Society for Advancement of Spine Surgery (ISASS) Policy Statement from 2011 states that for "lumbar fusion surgery for facet syndrome is no longer commonly supported and should only be performed in the context of a prospective clinical research study." [9]

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
0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical
0220T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic

0221T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar
0222T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; each additional vertebral segment

HCPCS	Description
	N/A

ICD-10	Description: [For dates of service on or after 10/01/2015]
	Any/All

REFERENCES

Government Agency

1. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National coverage determination (NCD) Search. Accessed at: http://www.cms.gov/medicare-coverage-database/

Peer Reviewed Publications

2. Cook DJ, Yeager MS et al. Lumbar intrafacet bone dowel fixation. Neurosurgery. 2015 Apr;76(4):470-8; discussion 478. doi: 10.1227/NEU.0000000000000652. Accessed at: https://www.ncbi.nlm.nih.gov/pubmed/25621985
3. Dusad T, Kundnani V et al. Minimally Invasive Microscope-Assisted Stand-Alone Transarticular Screw Fixation without Gallie Supplementation in the Management of Mobile Atlantoaxial Instability. Asian Spine J. 2018 Aug; 12(4): 710–719. Accessed at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6068403/
4. Gavaskar, A., Achimuthu, R. Transfacetal fusion for low-grade degenerative spondylolisthesis of the lumbar spine: results of a prospective single center study. J Spinal Disord Tech. 2010 May; 23(3):162-5. PMID 20072033.
5. Park, Y., Kim, J., et al. Facet fusion in the lumbosacral spine: A 2-year follow-up study. Neurosurgery (2002) 51: 88-96 PMID 12182439.
6. Pirris, S. M., Nottmeier, E.W. et al. Radiographic fusion rate after implantation of facet bone dowels. Spine J. 2014 Sep 1; 14(9):2102-11. PMID24448193.

Professional Society Guidelines & Statements

7. American Association of Neurologic Surgeons. Technical Assessment of TruFuse. (2009 – December). Available at: http://www.aans.org
8. Trangco-Evans, RA., Bejjani, FJ., et al. TruFuse Facet Fusion Outcome: A Retrospective Case Series. American Academy of Pain Medicine (AAPM), Presented at the 2011 AAPM Annual Meeting. Available at: www.painmed.org
9. International Society for Advancement of Spine Surgery (ISASS). [website]: https://www.isass.org/
    - Coverage Criteria for Decompression with Interlaminar Stabilization. December, 2016.
    - Policy Statement on Lumbar Spinal Fusion Surgery. July 15, 2011.

Other Resources

10. BacFast (Biologix Technologies. [website]: http://biologixtechnologies.com/products.html
11. TruFuse Facet Fusion. ©miniSURG™ Corp. Clearwater, Florida: TruFUSE® Procedure. Available at http://www.minisurg.com.
12. NuFix Precision Machined Allograft Antimigration Dowel. Birmingham, Alabama. Available at http://www.NuFix.org.
13. AMR Peer Review Network: Policy reviewed by practicing MD board certified in Orthopaedic Surgery. May 21, 2020.

Revision/Review History:

2020: New Policy