



MASSACHUSETTS

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Medical Policy

Allograft Injection for Degenerative Disc Disease

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Policy Number: 838

BCBSA Reference Number: 7.01.166 (For Plan internal use only)

NCD/LCD: N/A

Related Policies

Artificial Intervertebral Disc: Lumbar Spine #[592](#)

Orthopedic Applications of Stem Cell Therapy (Including Allografts and Bone Substitutes Used with Autologous Bone Marrow) #[254](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Injection of allograft into the intervertebral disc for the treatment of degenerative disc disease is considered [INVESTIGATIONAL](#).

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is not a covered service.
Commercial PPO and Indemnity	This is not a covered service.
Medicare HMO Blue SM	This is not a covered service.
Medicare PPO Blue SM	This is not a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
0627T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level
0628T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; each additional level (List separately in addition to code for primary procedure)
0629T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; each additional level (List separately in addition to code for primary procedure)
0630T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; each additional level (List separately in addition to code for primary procedure)

Description

Degenerative Disc Disease

Back pain is a common condition in adults. Most episodes of back pain are self-limited and will resolve within 1 month, but a small percentage will persist and become chronic. Chronic back pain can arise from a variety of etiologies including musculoskeletal pain, vertebral compression fractures, spinal stenosis, disc herniation, or other degenerative changes to the disc that compress the nerve roots and lead to radiculopathy. Age-related degeneration of the intervertebral discs is common and includes numerous biochemical and morphologic changes; the most common of which is loss of glycosaminoglycan and associated loss in water content. Pro-inflammatory molecules increase, while endplate calcification impairs nutrient flow. Together, these lead to an increase in cell death in the nucleus pulposus. Although degenerative changes to the disc are frequently observed on imaging, their contribution to back pain in the absence of radiculopathy is uncertain. Spine imaging, such as magnetic resonance imaging, computed tomography, or plain radiography, shows that lumbar disc degeneration is widespread, but for most people does not cause symptoms. Because many degenerative changes of the disc that are seen on imaging are asymptomatic, identifying the source of the back pain is challenging.

Treatment

Conservative management of back pain is the first-line treatment for most patients. Nonsteroidal anti-inflammatory drugs or other analgesics are used for symptom relief. Duloxetine or tramadol are recommended second-line pharmacologic therapies by the American College of Physicians.¹ Additionally, modification of activity in conjunction with some form of exercise therapy is frequently prescribed early in the course of symptoms. For patients with persistent nonradicular back pain, guidelines recommend interdisciplinary rehabilitation, which is defined as an integrated approach using physical rehabilitation in conjunction with a psychological or psychosocial intervention.¹ Opioids may also be prescribed. Although spinal fusion surgery is frequently performed for non-specific back pain with degenerative changes to the disc, surgery has not been shown to be more effective than comprehensive conservative treatment. Cell therapy is being explored as a method to regenerate the intervertebral disc by rehydration, height restoration, and repopulating native cells.

Summary

Degeneration of the intervertebral discs is commonly observed in imaging and has been proposed to be a source of back pain. In order to treat the observed changes in the discs, cellular therapies such as mesenchymal stem cells are being studied. One of these cellular therapies involves the intradiscal injection of a mixture of nucleus pulposus allograft and viable cells into the degenerated disc.

For individuals with degenerative disc disease who receive a viable allograft injection, the evidence includes 12-month results from an RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Results from the first 12 months of the planned 36 months of follow-up did not find statistically significant differences between the active allograft, placebo allograft, and conservative management groups on the co-primary pain and disability endpoints. However, the proportion of treatment responders was significantly greater in the active allograft group on some, but not all pain and disability response outcomes. Given the various important comparator and outcome relevance, data completeness, and power limitations, evidence from well-conducted trials demonstrating consistent improvements in health outcomes is still needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
6/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2021	New medical policy describing investigational indications. Effective 10/1/2021.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

References

1. Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. *Ann Intern Med.* Apr 04 2017; 166(7): 514-530. PMID 28192789
2. U.S. Food and Drug Administration. Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use Guidance for Industry and Food and Drug Administration Staff. 2017
<https://www.regulations.gov/document?D=FDA-2017-D-6146-0003> Accessed April 8, 2022.
3. Mesoblast. Chronic Low Back Pain Due to Disc Degeneration. 2022.
<https://www.mesoblast.com/product-candidates/spine-orthopedic-disorders/chronic-discogenic-low-back-pain> Accessed April 8, 2022.
4. Amirdelfan K, Bae H, McJunkin T, et al. Allogeneic mesenchymal precursor cells treatment for chronic low back pain associated with degenerative disc disease: a prospective randomized, placebo-controlled 36-month study of safety and efficacy. *Spine J.* Feb 2021; 21(2): 212-230. PMID 33045417
5. Mesoblast. Single Dose of Mesoblast's Allogeneic Cell Therapy Provides Durable Pain Reduction for At Least Three Years in Patients with Degenerative Disc Disease: Global Newswire. January 11, 2022. <https://www.globenewswire.com/news-release/2022/01/12/2365313/0/en/Single-Dose-of-Mesoblast-s-Allogeneic-Cell-Therapy-Provides-Durable-Pain-Reduction-for-at-Least-Three-Years-in-Patients-With-Degenerative-Disc-Disease.html> Accessed April 9, 2022.
6. Katz NP, Paillard FC, Ekman E. Determining the clinical importance of treatment benefits for interventions for painful orthopedic conditions. *J Orthop Surg Res.* Feb 03 2015; 10: 24. PMID 25645576
7. Parker SL, Mendenhall SK, Shau DN, et al. Minimum clinically important difference in pain, disability, and quality of life after neural decompression and fusion for same-level recurrent lumbar stenosis:

understanding clinical versus statistical significance. *J Neurosurg Spine*. May 2012; 16(5): 471-8. PMID 22324801

8. Beall DP, Wilson GL, Bishop R, et al. VAST Clinical Trial: Safely Supplementing Tissue Lost to Degenerative Disc Disease. *Int J Spine Surg*. Apr 2020; 14(2): 239-253. PMID 32355632
9. Beall DP, Davis T, DePalma MJ, et al. Viable Disc Tissue Allograft Supplementation; One- and Two-level Treatment of Degenerated Intervertebral Discs in Patients with Chronic Discogenic Low Back Pain: One Year Results of the VAST Randomized Controlled Trial. *Pain Physician*. Sep 2021; 24(6): 465-477. PMID 34554689
10. North American Spine Society. Evidence-based clinical guidelines for multidisciplinary spine care: Diagnosis and treatment of low back pain. 2020. <https://www.spine.org/Portals/0/assets/downloads/ResearchClinicalCare/Guidelines/LowBackPain.pdf> . Accessed April 8, 2022.