Spinal Allogeneic Tissue-Based Injections

Clinical Guidelines for Medical Necessity Review

Version: 1.0
Effective Date: August 28, 2023

Important Notices

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Guideline Information:

Specialty Area: Diseases & Disorders of the Musculoskeletal System (M00-M99)
Guideline Name: Spinal Tissue-Based Injections (Single Service)

Literature review current through: August 23, 2023
Document last updated: August 23, 2023
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Spinal Allogeneic Tissue-Based Injections

General Guidelines

- **Units, Frequency, & Duration:** This service is experimental/investigational.
- **Criteria for Subsequent Requests:** This service is experimental/investigational.
- **Recommended Clinical Approach:** Allogeneic tissue products are often used when conservative treatments have failed (e.g., activity modification, progressive relaxation, spinal manipulation, physical therapy, physiotherapy, pharmacological treatment). Products are injected into discs of the lumbar spine to regenerate tissue.[1]
- **Exclusions:** This policy addresses tissue-based injections for spine indications only; however, there may be indications in other specialties where this treatment is considered medically necessary and supported by the medical literature.

Medical Necessity Criteria

Indications

➔ **Spinal Allogeneic Tissue-Based Injections** is considered appropriate if **ALL** of the following are **TRUE**:

- ◆ Currently, there are no evidence-based indications for this service in the peer-reviewed, published literature.

Non-Indications

➔ **Spinal Allogeneic Tissue-Based Injections** are not considered appropriate if **ALL** of the following are **TRUE**:

- ◆ These injections are considered experimental/ investigational for treating musculoskeletal conditions. These include but are not limited to **ANY** of the following[1-2]:
  - Chronic back pain; **OR**
  - Herniated disc; **OR**
  - Sciatica; **OR**
  - Degenerative disc disease; **OR**
  - Intervertebral disc degeneration; **OR**

- Discogenic back pain; **OR**
- Radicular pain

Site of Service Criteria

Outpatient

Procedure Codes (HCPCS/CPT)

HCPCS/CPT Code	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 CT guidance, lumbar; first level
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)

Medical Evidence

Studies on the level of efficacy of allogenic tissue injections are below.

- Sanapati et al. (2018) performed a meta-analysis on the efficacy of mesenchymal stem cells (MSCs) and platelet-rich plasma (PRP) for the treatment of low back pain. Management of discogenic low back pain, radicular pain, facet joint pain, and sacroiliac joint pain improved. Future high-quality RCTs are needed.[2]

- Barakat et al. (2019) found that cell therapy for discogenic back pain shows benefits in existing studies, but further research is required.[3]

- Three studies evaluated cell therapy for degenerative disc disease:
    - Soufi et al. (2023) performed a systematic review of 11 clinical studies, including one randomized control trial (RCT). The role of cell therapy shows potential benefits for pain; there is no consensus in existing clinical trials.[4]
    - Matta et al. (2020) note the potential of cell therapy for pain improvement. Future research is required, ideally extensive, well-controlled studies, including those addressing disability. Biological factors that may reduce efficacy also warrant investigation (e.g., reduced pH, avascular status, long-term inflammation, progressive cell death).[5]
    - Amirdelfan et al. (2021) performed a multicenter RCT at 13 clinical locations (12 in the United States, 1 in Australia). The studies include 100 patients with a modified Pfirrmann score ranging from 3-6. Evaluation occurred at 1, 3, 6, 12, 24, and 36 months following single injections of STRO-3+ adult allogeneic mesenchymal precursor cells (MPCs) combined with hyaluronic acid. Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) also improved. Adverse effects were low.[6]

- Kaye et al. (2022) note that nonsteroid anti-inflammatory drugs are the first line of treatment when non-pharmacological therapy is unsuccessful. Tramadol or duloxetine is a second line of treatment. Opioids are for patients who do not respond to other treatments; patients are to receive education on the risks and benefits.[7]

Lewandrowski et al. (2023) performed a small retrospective study to evaluate the safety and efficacy of allogeneic MSC injections in the lumbar intervertebral discs. Initial findings show improved pain scores and clinical functioning. Using Pfirrmann grading, MRI scans at follow-up show improvement after two years. Future research can strengthen the evidence of healing and reversal of degenerative changes in current studies.[8]

National and Professional Organizations

The **American Society of Interventional Pain Physicians (ASIPP)** published a guideline on interventional techniques for chronic spinal pain. The ASIPP does not address cell therapy.[9]

The **North American Spine Society (NASS)** guideline does not address recommendations on allograft injections for low back pain.[10]

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. 2017 Apr 4;166(7):514-530. doi: 10.7326/M16-2367. PMID: 28192789.
2. Sanapati J, Manchikanti L, Atluri S, et al. Do regenerative medicine therapies provide long-term relief in chronic low back pain: A systematic review and meta analysis. Pain Physician. 2018 Nov;21(6):515-540. PMID: 30508983.
3. Barakat AH, Elwell VA, Lam KS. Stem cell therapy in discogenic back pain. J Spine Surg. 2019 Dec;5(4):561-583. doi: 10.21037/jss.2019.09.22. PMID: 32043007; PMCID: PMC6989932.
4. Soufi KH, Castillo JA, Rogdriguez FY, et al. Potential role for stem cell regenerative therapy as a treatment for degenerative disc disease and low back pain: A systematic review. Int J Mol Sci. 2023 May 17;24(10):8893. doi: 10.3390/ijms24108893. PMID: 37240236; PMCID: PMC10219191.
5. Matta A, Erwin WM. Injectable biologics for the treatment of degenerative disc disease. Curr Rev Musculoskelet Med. 2020 Dec;13(6):680-687. doi: 10.1007/s12178-020-09668-2. PMID: 32705541; PMCID: PMC7661671.
6. 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. 2021 Feb;21(2):212-230. doi: 10.1016/j.spinee.2020.10.004. PMID: 33045417.
7. Kaye AD, Edinoff AN, Rosen YE, et al. Regenerative medicine: Pharmacological considerations and clinical role in pain management. Curr Pain Headache Rep. 2022 Oct;26(10):751-765. doi: 10.1007/s11916-022-01078-y. PMID: 36074255; PMCID: PMC9453705.
8. Lewandrowski KU, Dowling A, Carlos J, et al. Pain relief after allogenic stem cell disc therapy. Pain Physician. 2023 Mar;26(2):197-206. PMID: 36988365.
9. Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: Guidance and recommendations. Pain Physician. 2013 Apr;16(2 Suppl):S49-283. PMID: 23615883.
10. Kreiner DS, Matz P, Bono CM, et al. Guideline summary review: An evidence-based clinical guideline for the diagnosis and treatment of low back pain. Spine J. 2020 Jul;20(7):998-1024. doi: 10.1016/j.spinee.2020.04.006. PMID: 32333996.

Clinical Guideline Revision History/Information

Original Date: August 28, 2023	
Review History	