BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.166 Allograft Injection for Degenerative Disc Disease

Effective Policy Date: October 1, 2023

Original Policy Date: October 2021

Related Policies:

7.01.87 - Artificial Intervertebral Disc: Lumbar Spine
8.01.52 - Orthopedic Applications of Stem Cell Therapy (Including Allografts and Bone Substitutes Used With Autologous Bone Marrow)

Allograft Injection for Degenerative Disc Disease

Description

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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.

OBJECTIVE

The objective of this evidence review is to determine whether intradiscal viable allograft injection improves the net health outcome in individuals with degenerative disc disease.

POLICY STATEMENT

Injection of allograft into the intervertebral disc for the treatment of degenerative disc disease is considered **investigational**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

VIA Disc Matrix (Vivex Biomedical) is composed of human disc tissue donated from cadavers with viable cells. It consists of a nucleus pulposus allograft suspension that is mixed with a minimum of 6 x 10^6 cryopreserved cells. The cell source and method of processing has not been disclosed, and it is not clear if VIA Disc Matrix meets the U.S. Food and Drug Administration (FDA) criteria for what is considered minimal manipulation and homologous use for human cells, tissues, and cellular and tissue-based products (HCT/Ps).

The FDA regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation, Title 21, parts 1270 and 1271. In 2017, the FDA published clarification of HCT/Ps.[2,]

HCT/Ps are defined as human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. If an HCT/P does not meet the criteria below and does not qualify for any of the stated exceptions, the HCT/P will be regulated as a drug, device, and/or biological product and applicable regulations and premarket review will be required.

An HCT/P is regulated solely under section 361 of the Public Health Service (PHS) Act and Title 21 Code of Federal Regulations (CFR) Part 1271 if it meets all of the following criteria:

1. "The HCT/P is minimally manipulated;
2. The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;
3. The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and
4. Either:
    1. The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
    2. The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
        1. Is for autologous user
        2. Is for allogeneic use in a first-degree or second-degree blood relative; or
        3. Is for reproductive use"

An investigational device trial of Rexlemestrocel-L (MPC-06-ID, Mesoblast) has been completed and is currently under FDA review.

RATIONALE

Summary of Evidence

For individuals with degenerative disc disease who receive a viable allograft injection, the evidence includes 12-month results from an randomized controlled trial (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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or the National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Physicians

In 2017, the American College of Physicians recommended that "For patients with chronic low back pain, clinicians and patients should initially select nonpharmacologic treatment with exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction (moderate-quality evidence), tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, low-level laser therapy, operant therapy, cognitive behavioral therapy, or spinal manipulation. (Grade: strong recommendation, low-quality evidence).

In patients with chronic low back pain who have had an inadequate response to nonpharmacologic therapy, clinicians and patients should consider pharmacologic treatment with nonsteroidal anti-inflammatory drugs as first-line therapy, or tramadol or duloxetine as second-line therapy. Clinicians should only consider opioids as an option in patients who have failed the aforementioned treatments and only if the potential benefits outweigh the risks for individual patients and after a discussion of known risks and realistic benefits with patients. (Grade: weak recommendation, moderate-quality evidence)."[1,]

North American Spine Society et al

In 2020, the North American Spine Society, along with 9 other societies, published multidisciplinary evidence-based guidelines on the diagnosis and treatment of low back pain.[10,] There were 82 clinical questions that were addressed in the comprehensive evidence review. Regarding degenerative disc disease, the guideline gave a grade A recommendation that provocative discography without manometric measurements correlates with both pain reproduction in the presence of moderate to severe disc degeneration on MRI/CT [magnetic resonance imaging/computed tomography] discography and with the presence of endplate abnormalities on MRI imaging. There was insufficient evidence to make a recommendation for or against the use of intradiscal bone marrow concentrate in patients with discogenic low back pain, and no review of intradiscal allograft injection.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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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 March 14, 2023.
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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 March 13, 2023.
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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 March 13, 2023.

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2021	New policy	Policy created with literature review through April 14, 2021. Considered investigational.
June 2022	Replace Policy	Policy updated with literature review through February 14, 2022; reference added. Policy statement unchanged.
September 2023	Replace policy	Policy updated with literature review through February 13, 2023; no references added. Policy statement unchanged.