Anthem

Medical Policy

Subject: Facet Joint Allograft Implants for Facet Disease
Document #: SURG.00114
Status: Reviewed

Publish Date: 09/27/2023
Last Review Date: 08/10/2023

Description/Scope

This document addresses surgically implanted allografts as a stand-alone procedure to treat facet joint pain. Facet joint pain can be caused by trauma or degenerative changes resulting in structural misalignment and instability of the vertebral column.

Note: Please see the following related document for additional information:

- SURG.00092 Implanted Devices for Spinal Stenosis

Position Statement

Investigational and Not Medically Necessary:

Allograft facet implants are considered **investigational and not medically necessary** for all indications.

Rationale

Facet joint pain is treated initially with conservative measures such as medication, immobilization of the affected spinal area and physical therapy. When conservative therapy fails, intermittent anesthetic injections or neurolytic techniques can be used to alleviate pain. Surgical fusion is reserved for those individuals for whom less invasive treatments have failed.

Use of facet allografts as a stand-alone procedure for facet pain has been proposed for symptomatic pain relief and possibly long-term fusion. This technique involves a minimally invasive procedure with fluoroscopic guidance. The affected facet surfaces are prepped for placement of an allograft dowel with instrumentation for expansion and stabilization of the facet joint space.

The allograft is made from bone obtained from both the femur and tibia. The allograft is processed by licensed tissue banks which are required to be fully compliant with all U.S. Food and Drug Administration (FDA) requirements for tissue processing in the United States. Therefore, the allografts are not subject to FDA 510k clearance and can be marketed.

There are no clinical trials that address the clinical efficacy and/or safety of these implants.

At this time, no major authoritative body has published a document supporting the use of facet allografting.

Background/Overview

Spinal fusion remains the gold standard for treatment of refractory back pain. However, this procedure is difficult and requires extended recovery time. Newer minimally invasive techniques are being developed using surgical approaches and instrumentation that will result in pain relief and less recovery time. Areas of concern are instrumentation, implant performance and possible migration.

Definitions

510k Clearance: The purpose of a 510(k) submission is to demonstrate that a device is “substantially equivalent” to a predicate device (one that has been cleared by the FDA or marketed before 1976). The 510(k) submitter compares and contrasts the subject and predicate devices, explaining why any differences between them should be acceptable. Human data are usually not required for a 510(k) submission; this decision is made at the discretion of the FDA. The FDA does not “approve” 510(k) submissions. It “clears” them.

Allograft: A graft of tissue obtained from a donor of the same species as, but with a different genetic make-up from, the recipient, as a tissue transplant between two humans.

Facet joints: Joints of the spine that connect the vertebrae and allow coordinated movement of the vertebral column.

Fluoroscopic guidance: Use of radiologic imaging to assist in the placement of instrumentation for invasive diagnostic and surgical procedures.

Neurolytic: Substance or procedure that destroys nerves.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

CPT	
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

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

1. Chou R, Baisden J, Carragee EJ, et al. Surgery for low back pain: a review of the evidence for an American Pain Society Clinical Practice Guideline. Spine (Phila Pa 1976). 2009; 34(10):1094-1109.
2. Harris EB, Massey P, Lawrence J, et al. Percutaneous techniques for minimally invasive posterior lumbar fusion. Neurosurg Focus. 2008; 25(2):E12.

Government Agency, Medical Society, and Other Authoritative Publications:

1. North American Spine Society (NASS). Coverage Policy Recommendations. Guidelines. Available at: https://www.spine.org/Research-Clinical-Care/Quality-Improvement/Clinical-Guidelines. Accessed on June 2, 2023.
2. U.S. Food and Drug Administration (FDA). Overview of Device Regulation. Available at: http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/default.htm. Accessed on June 2, 2023.

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References and Index sections.
Reviewed	08/11/2022	MPTAC review. Updated Rationale and References sections.
Reviewed	08/12/2021	MPTAC review. Updated Rationale, Background, References and Index sections.
Reviewed	08/13/2020	MPTAC review. Updated Description, Rationale and References sections.
Reviewed	08/22/2019	MPTAC review. Updated Rationale and References sections.
Reviewed	09/13/2018	MPTAC review. Updated Rationale and References sections.
Reviewed	11/02/2017	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” References updated.
Reviewed	11/03/2016	MPTAC review. Updated Description, Rationale and References sections.
Reviewed	11/05/2015	MPTAC review. Updated Rationale and Reference sections. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Updated Description and References.
Reviewed	11/14/2013	MPTAC review. Updated Rationale, References and Websites.
Reviewed	11/08/2012	MPTAC review. References updated.
Reviewed	11/17/2011	MPTAC review. References updated.
Reviewed	11/18/2010	MPTAC review. Rationale and References updated.
New	11/19/2009	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.