Xenograft Implantation

Clinical Guidelines for Medical Necessity Review

Version: 1.0
Effective Date: October 6, 2023

Important Notices

Notices & Disclaimers:

GUIDELINES SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION MAKING OF END USERS.

Cohere Health, Inc. ("**Cohere**") has published these clinical guidelines to determine medical necessity of services (the "**Guidelines**") for informational purposes only, and solely for use by Cohere's authorized "**End Users**". These Guidelines (and any attachments or linked third party content) are not intended to be a substitute for medical advice, diagnosis, or treatment directed by an appropriately licensed healthcare professional. These Guidelines are not in any way intended to support clinical decision making of any kind; their sole purpose and intended use is to summarize certain criteria Cohere may use when reviewing the medical necessity of any service requests submitted to Cohere by End Users. Always seek the advice of a qualified healthcare professional regarding any medical questions, treatment decisions, or other clinical guidance. The Guidelines, including any attachments or linked content, are subject to change at any time without notice.

Other Notices:

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Guideline Information:

Specialty Area: Diseases & Disorders of the Musculoskeletal System (M00-M99)
Guideline Name: Xenograft Implantation - Single Service

Literature review current through: October 6, 2023
Document last updated: October 6, 2023
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

Table of Contents

Medical Necessity Criteria

Service: Xenograft Implantation

General Guidelines

- **Units, Frequency, & Duration:** The service is experimental/ investigational.
- **Criteria for Subsequent Requests:** The service is experimental/ investigational.
- **Recommended Clinical Approach**[1]: Xenograft implantation has been proposed as a type of bone, cartilage, or soft-tissue graft used to replace natural existing tissue damaged by trauma or disease. While there are several different types of bone grafts currently in use or under study, the xenograft is a category that is obtained by a non-human animal or plant species[2].
- **Exclusions:** This policy addresses xenograft implantation. There may be unique clinical scenarios where this procedure is considered medically necessary and supported by the medical literature (i.e., "off-label use").

Medical Necessity Criteria

Indications

➔ **Xenograft implantation** is considered appropriate if **ALL** of the following are **TRUE**[3-4]:

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

Non-Indications

➔ **Xenograft implantation** is not considered appropriate if **ALL** of the following are **TRUE**:

- ◆ The procedure is considered experimental/investigational for use as a bone graft in an articular surface.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (HCPCS/CPT)

HCPCS/CPT Code	Code Description
0737T	Xenograft implantation into the articular surface

Medical Evidence

Moyad et al. (2011) reviewed the literature regarding cartilage injuries in the adult knee and the workup and management techniques in current use. In the past, autologous chondrocyte implantation often resulted in complications from hypertrophy of the periosteal graft. Porcine tissue xenografts have been studied and found to have lower complication rates.

Anderson et al. (2022) reviewed studies related to NeoCart, a third-generation autologous chondrocyte (ACI) therapeutic. Phased clinical trials began in 2003, and it was found that the control microfracture procedure demonstrated the most pain relief and functional improvement depending on the size of the patient's lesion. The study was terminated in Phase III, and the therapy was not approved for use.

Sutherland et al. (2015) examined the use of cartilage matrix including its promise as a biomaterial for enhanced cartilage regeneration. Such materials provide for enhanced cartilage regeneration due to ability to provide stem cells with physical attachment sites, as well as mechanical and chemical signals.

References

1. Sutherland AJ, Converse GL, Hopkins RA, Detamore MS. The bioactivity of cartilage extracellular matrix in articular cartilage regeneration. Adv Healthc Mater. 2015;4(1):29-39. doi:10.1002/adhm.201400165
2. Anderson D., Gridley A., Crawford D. *Next Generation Cartilage Repair and the Pre-Arthroplasty Patient.* Operative Techniques in Sports Medicine, (2022), 30(4). Elsevier.org. 2022.
3. Murphy MP, Koepke LS, Lopez MT, et al. Articular cartilage regeneration by activated skeletal stem cells. Nat Med. 2020;26(10):1583-1592. doi:10.1038/s41591-020-1013-2
4. Bracey DN, Cignetti NE, Jinnah AH, et al. Bone xenotransplantation: A review of the history, orthopedic clinical literature, and a single-center case series. Xenotransplantation. 2020;27(5):e12600. doi:10.1111/xen.12600

Clinical Guideline Revision History/Information

Original Date: October 6, 2023	
Review History	