Cohere Medical Policy - Bone Xenograft

Clinical Guidelines for Medical Necessity Review

Version: 3
Cohere Health UMC Approval Date: July 24, 2025
Last Annual Review: July 24, 2025
Revision: Not applicable
Next Annual Review: July 24, 2026

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.

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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: Musculoskeletal Care
Policy Name: Cohere Medical Policy - Bone Xenograft
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Bone Xenograft

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
    - The medical necessity of each individual request
    - Why prior imaging or procedures were inconclusive, or why additional/follow-up studies are needed
    - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the

patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

Xenografts are bone grafts derived from non-human animal sources, most commonly bovine (cow) or porcine (pig) bone. These grafts are used to repair bone defects, fractures, or to augment bone in various orthopedic procedures. Xenograft implantation into the articular surface is a cartilage repair procedure to replace naturally occurring damage resulting from trauma or disease.[1-4]

Medical Necessity Criteria

Indications

Bone Xenograft Implantation is considered appropriate if **ANY** of the following is **TRUE**:

- This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Non-Indications

Bone Xenograft Implantation is not considered appropriate if **ANY** of the following is **TRUE**:

- This is not applicable, as there are no indications.

Level of Care Criteria

None

Procedure Codes (CPT/HCPCS)

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

Medical Evidence

A systematic review and meta-analysis, conducted by Oettl et al. (2025), examined the safety and efficacy of xenograft augmentation in rotator cuff repair. The review sought to compare the outcomes of xenograft repair with standard rotator cuff repair techniques. The authors found no statistically significant differences between the two approaches in strength measurements and range of motion, though xenograft augmentation was associated with slightly higher complication rates and functional scores.[5]

In their study of osteochondral regeneration, Rastegar et al. (2022) examined the regenerative effect of decellularized osteochondral extracellular matrix xenografts in combination with biological products in an osteochondral defect. The objective of this study was to prepare decellularized osteochondral scaffolds from sheep and implant the xenograft into a rabbit model with an osteochondral defect. The decellularization was performed by multistate methods and resulted in approximately 98% cell elimination. The authors concluded that xenograft decellularized extracellular matrix and biological factor platforms represent a promising approach to human osteochondral regeneration.[6]

Anderson et al. (2022) reviewed studies related to NeoCart, a third-generation autologous chondrocyte (ACI) therapeutic. Phased clinical trials, which began in 2003, 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.[2]

Amid et al. (2020) conducted a systematic review to evaluate the chemical and structural features of various xenograft bone substitutes. Of the 25 studies included in the final review, 19 were examinations of bovine xenografts. The authors found that the porosity, crystallinity, Ca/P (calcium-to-phosphorus) ratio, and osteogenesis of the xenografts varied significantly–a heterogeneity they attributed to disparate preparation methods.[7]

Elder et al. (2018) evaluated an antigen removal procedure as part of a larger effort to develop an osteochondral xenograft for articulate cartilage repair. The antigen removal protocol extracted nearly 90% of DNA from cartilage and bone and 80% of glycosaminoglycan from cartilage. The authors concluded that this procedure for producing an osteochondral xenograft shows promise for the treatment of osteochondral lesions in human knees.[8]

Sutherland et al. (2015) examined the use of cartilage matrices, including their promise as a biomaterial for enhanced cartilage regeneration. These materials provide for enhanced cartilage regeneration due to their ability to provide stem cells with physical attachment sites, as well as mechanical and chemical signals.[1]

Moyad et al. (2011) reviewed the literature regarding cartilage injuries in the adult knee and the workup and management techniques in current use. Previously, 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.[9]

No current, peer-reviewed studies were found to unequivocally support the use of xenograft implantation into the articular surface.

References

1. Sutherland AJ, Converse GL, Hopkins RA, et al. 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 DE, Gridley A, Crawford DC. Next generation cartilage repair and the pre-arthroplasty patient. *Oper Tech Sports Med*. 2022 Dec 1;30(4):150956

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

5. Oettl FC, Tuengler T, Kraus M, Dagli MM, Inclan P, Rodeo SA. Efficacy and safety of xenograft augmentation in rotator cuff repair: a systematic review and meta-analysis. JSES Rev Rep Tech. 2024;5(2):222-230. Published 2024 Dec 14. doi:10.1016/j.xrrt.2024.11.004

6. Rastegar Adib F, Bagheri F, Sharifi AM. Osteochondral regeneration in rabbits using xenograft decellularized ECM in combination with different biological products: Platelet-rich fibrin, amniotic membrane extract, and mesenchymal stromal cells. *J Biomed Mater Res B Appl Biomater*. 2022;110(9):2089-2099. doi:10.1002/jbm.b.35063

7. Amid R, Kheiri A, Kheiri L, et al. Structural and chemical features of xenograft bone substitutes: A systematic review of in vitro studies. *Biotechnol Appl Biochem*. 2021;68(6):1432-1452. doi: 10.1002/bab.2065

8. Elder S, Chenault H, Gloth P, et al. Effects of antigen removal on a porcine osteochondral xenograft for articular cartilage repair. *J Biomed Mater Res A*. 2018;106(8):2251-2260. doi: 10.1002/jbm.a.36411

9. Moyad TF. Cartilage injuries in the adult knee: Evaluation and management. *Cartilage*. 2011;2(3):226-236. doi: 10.1177/1947603510383973

Policy Revision History/Information

Original Date: October 6, 2023		
Review History		
Version 2	04/26/2024	Policy criteria reviewed and updated per medical literature
Version 3	07/24/2025	Annual Review The name of this policy has been changed from "Xenograft Implantation" to "Bone Xenograft" to reflect that the policy is limited to bone grafts. Added procedure description (page 4). The medical evidence section has been updated to include Oettl et al. (2025) Reference added (Oettl et al.)