



## **Cohere Medicare Advantage Policy – Xenograft Implantation**

*Clinical Policy for Medical Necessity Review*

**Version:** 3  
**Revision Date:** May 22, 2025

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## Policy Information:

**Specialty Area:** Musculoskeletal Care

**Policy Name:** Cohere Medicare Advantage Policy - Xenograft Implantation

**Type:** ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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# Medical Necessity Criteria

## ***Service: Xenograft Implantation***

### **Related CMS Documents**

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no NCDs and/or LCDs for xenograft implantation.

### **Description**

A xenograft is a category of graft derived from a non-human animal.<sup>1</sup> Xenograft implantation into the articular surface is a bone and cartilage repair procedure to replace naturally occurring damage resulting from trauma or disease.<sup>2</sup>

### **Medical Necessity Criteria**

#### **Indications**

**Xenograft implantation** is considered appropriate if **ALL** of the following are **TRUE**<sup>3-4</sup>:

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

#### **Non-Indications**

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

- This is not applicable as there are no indications.

### **Level of Care Criteria**

Inpatient and Outpatient

### **Procedure Codes (CPT/HCPCS)**

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

**Disclaimer:** S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

## Medical Evidence

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.<sup>6</sup>

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.<sup>2</sup>

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.<sup>5</sup>

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.<sup>7</sup>

Sutherland et al. (2015) examined the use of cartilage matrixes, 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.<sup>1</sup>

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.<sup>8</sup>

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

## References

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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.
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7. 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.
8. Moyad TF. Cartilage injuries in the adult knee: Evaluation and management. *Cartilage.* 2011;2(3):226–236. doi: 10.1177/1947603510383973



# Clinical Guideline Revision History/Information

Original Date: May 27, 2024		
Review History		
Version 2	6/10/2024	422.101 Disclaimer added
Version 3	05/22/2025	<p>Annual Review.</p> <p>Reformatted policy to align with 2025 format.</p> <p>Removed the Harms and Benefits section.</p> <p>Literature review - Medical Evidence section updated to support non-coverage based on a lack of evidence (Rastegar et al. 2022; Elder et al 2018; Moyad et al 2011).</p>