Cohere Medicare Advantage Policy - Xenograft Implantation

Clinical Policy for Medical Necessity Review

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Policy Information:

Specialty Area: Musculoskeletal Care
Policy Name: Cohere Medicare Advantage Policy - Xenograft Implantation
Type: [**X**] Adult (18+ yo) | [**X**] 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

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.[2]

Medical Necessity Criteria

Indications

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

- 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

Not applicable.

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Procedure Codes (CPT/HCPCS)

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

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

Evaluation of Clinical Harms and Benefits

Refer to the Medical Evidence section for various citations and references to studies conducted to date that are inconsistent, inadequately powered, or otherwise do not allow for solid scientific conclusions. Potential harms and benefits of applying an “unproven and not medically necessary” designation to this procedure might include, but are not limited to, the following:

Potential Harms of applying the clinical criteria in this policy include, but are not limited to, denying opportunities to improve health outcomes for individuals and populations suffering from pain secondary to bone defects from trauma or degenerative conditions. For example, restricting access to this procedure may increase patient and population dependence on excessive pain medication, including opioids, reduced functionality leading to additional medical problems, and a decrease in economic opportunity.

Potential Benefits include safeguarding patients and populations from unproven technologies, procedures, and medical treatments until the proposed treatments' safety, efficacy, and anticipated results are thoroughly validated via peer-reviewed scientific literature. This safeguards patients from failed xenograft implantations, which can lead to pain, inflammation, and the displacement of the materials used in the grafts, which in turn may require additional surgeries.

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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.[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.[5]

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.[7]

Sutherland et al. (2015) examined the use of cartilage matrices, including their promise as a biomaterial for enhanced cartilage regeneration. These

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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.[8]

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

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Clinical Guideline Revision History/Information

Original Date: May 27, 2024		
Review History		
Version 2	06/10/2024	422.101 Disclaimer added
Version 3	05/22/2025	Annual Review. Reformatted policy to align with 2025 format. Removed the Harms and Benefits section. 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).
Version 4	07/01/2025	Added Harms and Benefits section.

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