Cohere Medicare Advantage Policy - Xenograft Implantation

Clinical Guidelines for Medical Necessity Review

Version: 2
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Important Notices

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Other Notices:

Guideline Information:

Specialty Area: Disorders of the Musculoskeletal System
Guideline Name: Cohere Medicare Advantage Policy - Xenograft Implantation

Date of last literature review: 6/10/2024
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Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Xenograft Implantation

Benefit Category

Not applicable.

Recommended Clinical Approach

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.[1] While there are several different types of bone grafts currently in use or under study, the xenograft is a category that is obtained from a non-human animal or plant species.[2]

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of xenograft implantation procedures. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, adverse reactions, and infection.

The potential clinical harms of using these criteria may include:

- Inadequate management of conditions such as knee arthritis requiring tissue repair due to inappropriate denials. At this time there is no evidence to support the use of autologous or Xenograft tissue for the management of knee arthritis. Moyad et al note autologous chondrocyte implantation can result in complications from hypertrophy of the periosteal graft.[5] Anderson et al report that clinical trials for autologous chondrocyte implantation were terminated in Phase III as therapy was determined not to be not appropriate.[2] Without evidence to support its use in patients, there is not harm from inappropriate denials.
- Adverse effects from delayed or denied treatment, which can worsen patient outcomes, such as increased pain and reduced mobility. In this

case, Xenograft has not been found to be appropriate therefore there are no adverse effects from denied treatment.
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:
- At this time there is no evidence to support the use of autologous or Xenograft tissue for the management of knee arthritis. Moyad et al note autologous chondrocyte implantation can result in complications from hypertrophy of the periosteal graft.[5] Anderson et al report that clinical trials for autologous chondrocyte implantation were terminated in Phase III as therapy was determined not to be not appropriate.[2]
- Reduction in complications and adverse effects from unnecessary procedures. There are complications with knee procedures which can include infection, bleeding, injury to neurovascular structures, ongoing pain, knee stiffness, damage to the articular cartilage and progression of the knee arthritis.
- Enhanced overall patient satisfaction by preventing unproved procedures.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

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

Level of Care Criteria

None

Procedure Codes (CPT/HCPCS)

CPT/HCPCS 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.[5]

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.[2]

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.[1]

References

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Clinical Guideline Revision History/Information

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