Allograft Transplantation of the Knee

Effective Date: 01/01/2024
Revision Date: Click or tap to enter a date.
Review Date: Click or tap to enter a date.
Policy Number: WI.PA-1010
Line of Business: Medicare

Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies
None

Related Documents
Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/Transmittals.

There are no NCDs and/or LCDs for allograft transplantation of the knee.

Description
This policy focuses on reconstruction of the meniscus and ligament structures of the knee.
Allografts may be used as an alternative to autografts for ligament reconstruction or meniscal transplantation of the knee. Allograft tissue is procured from genetically unrelated cadaver donors and processed, stored and utilized according to US Food & Drug Administration (FDA) and the American Association of Tissue Banks (AATB) standards. The advantages of allografts include no donor site morbidity, shorter surgical time, smaller incisions and greater availability. Allograft transplants are not rejected by the body as with other organ transplants.

**Knee Ligaments**

Reconstruction with allograft tendons may be performed for the anterior cruciate ligament (ACL), posterior cruciate ligament (PCL), medial or lateral collateral ligaments (MCL, LCL). These ligaments are strong fibrous bands of tissue that attach to the femur, fibula patella and tibia bones providing strength and stability to the joint. Allografts are commonly used for ACL reconstruction.

Resorbable implant for ACL repair is a resorbable implant made of degradable material (bovine collagen) that allows healing of a torn ACL biomechanically stabilized by traditional suturing procedures at the torn ends of the tendon. Purportedly, the implant acts like a bridge scaffold. After suture stabilization, the individual’s blood is injected into the implant to form a protective clot to stimulate tissue healing to eventually replace the device. The device is intended to protect the biological healing process from the surrounding intraarticular environment and not intended to replace biomechanical fixation via suturing. As the ACL heals, the implant is absorbed by the body, within approximately 8 weeks. An example of an FDA-approved ACL resorbable implant is the BEAR (Bridge-Enhanced ACL Repair).

**Meniscus**

Meniscal allograft transplantation (MAT) is a surgical technique for restoring knee function for an individual with a destroyed or absent menisci. The meniscus (or menisci) refers to the lateral and medial crescent shaped cartilaginous tissues that are located at the junction of the tibia and femur which provide structural integrity to the knee and absorbs shock. Allograft tissue is matched by size to the individual, inserted into the knee joint and anchored to supporting structures by hardware, soft tissue or bony tissue fixation. The procedure may be performed using an arthroscopic approach or by open incision and may be done alone or in tandem with other reconstructive knee procedures.

Collagen meniscus implants (CMI), also known as collagen scaffolds or Menaflex, are implantable porous meniscus scaffolds composed of collagen fibers, enriched with glycosaminoglycan, used as a template and support for generation of new tissue to replace the lost menisci. An example of an FDA-approved CMI is the Collagen Meniscus Implant XL.

**Coverage Determination**

*iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.*
In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

Allograft Transplantation of the Knee

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

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<td>Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)</td>
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**Change Summary**

- 01/01/2024  New Policy.