



MEDICAL POLICY

Date Reviewed: 01/23/04, 08/25/06, 04/20/07, 02/15/08, 01/23/09, 02/05/10, 01/14/11

Subject: Allograft Procedures of the Knee (Allograft Anterior Cruciate Ligament Reconstruction, Meniscal Allografting, Meniscal Transplant, Osteochondral Allografting)

Description: Allografting (the use of tissue from another individual) includes several types of cartilage and/or ligament transplant procedures used to treat individuals with symptomatic cartilage and/or ligament injuries or diseases. The procedure involves transplantation of either a piece of cartilage that remains attached to the donor bone, a donor meniscus, or a donor ligament. Donor tissue may be either fresh, frozen, freeze dried (lyophilized), or cryopreserved (frozen in glycerol). The procedure is usually performed arthroscopically, but an open procedure may occasionally be necessary.

Indications of Coverage:

The use of an anterior cruciate ligament allograft is considered medically necessary when one of the following conditions have been met (**Note: review benefits to determine whether tendon grafts are a covered benefit. This criteria does not address the medical necessity of the procedure, only the medical necessity of the allograft.**):

History of a prior, failed anterior cruciate ligament reconstruction

Multiple ligament reconstruction in the same treatment setting

Use of an autologous graft (graft material taken from the patient at another anatomical site) is contraindicated

Osteochondral allograft transplant is considered medically necessary when all of the following criteria have been met (**Note: for the purposes of review, osteochondral grafts are considered cartilage grafts, not bone grafts. Review benefits to determine whether cartilage grafts are a covered benefit.**):

Documentation of a symptomatic focal (not widespread) chondral (involving the cartilage) lesion surrounded by normal, healthy cartilage **OR** non-repairable stage III or IV osteochondritis dissecans (unstable lesions where the cartilage is damaged and synovial fluid exists between the fragment and underlying bone).

Arthroscopic procedures have failed or are contraindicated due to the size, shape, or location of the lesion.

The patient is not currently a candidate for total or partial (unicompartmental) knee replacement.

Meniscal allografting is considered medically necessary when all of the following criteria are met (**Note: review benefits to determine whether cartilage grafts are a covered benefit**):

The patient is between the ages of 18 and 50 and is not a candidate for total knee arthroplasty (replacement)

Severe knee pain that is unresponsive to conservative therapy, including anti-inflammatory medications, physical therapy, joint injections, and bracing, for a minimum of six months that results in functional limitations

Preoperative imaging studies (for example, MRI, diagnostic arthroscopy) documents the absence of a minimum of 50% of the meniscus

The absence of degenerative changes (for example, arthritis) in the joint is documented

Normal knee alignment and stability is documented (anterior cruciate ligament is intact and without damage)

Limitations of Coverage:

Review contract and endorsements (including transplant benefit language to see whether allograft tendon, ligament, and/or cartilage/chondrocyte transplantation is a covered benefit. Many policies do not have a benefit for tendon, ligament, and/or cartilage/chondrocyte transplantation.) for exclusions and prior authorization or benefit requirements.

If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.

If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

Osteochondral allografting is considered investigational for any joint other than the knee as there is insufficient peer-reviewed scientific literature supporting the effectiveness of the procedure for other joints.

Osteochondral allografts are considered not medically necessary when any of the following conditions are described:

Uncorrected instability or misalignment of the joint

Patients who will not comply with post-operative physical therapy

Advanced degenerative disease of the joint

Steroid-induced osteonecrosis of the joint to be treated

Documentation Required:

Office notes

Procedure report

Documentation of the contraindication to autologous graft tissue and/or documentation of the failure of previous procedures.

Rationale: There are few studies comparing the use of allograft and autograft for reconstruction of the ACL, but these are sufficient to recommend ligament allograft transplantation in limited situations. There is also limited literature regarding osteochondral allografting, but the literature does show an increase in function and a decrease in pain in individuals undergoing osteochondral allografting who meet rigorous selection criteria.

Meniscal allograft procedures have been used to treat patients with meniscal tears that cannot be surgically repaired and in patients who have previously undergone total meniscectomy procedures. These transplants have been performed with the meniscus alone or with bone plugs attached to the graft that help to hold the donor meniscus in place. Outcome studies are generally of poor quality and the results differ dramatically; however, the American Academy of Orthopedic Surgeons has suggested that the procedure may be of benefit in selected individuals and the quality and results of the studies regarding meniscal allograft transplantation are improving. Continuing research to evaluate long-term function of the graft is still needed.

References: American Academy of Orthopaedic Surgeons. Meniscal Transplants. Reviewed and updated Feb 2009. Available at: orthoinfo.aaos.org/topic.cfm?topic=A00381&return_link=0. Accessed: 5 Jan 11.

Gross A, Shasha N, Aubin P. Long-Term Followup of the Use of Fresh Osteochondral Allografts for Posttraumatic Knee Defects. *Clin Orthop Rel Res*. 2005 Jun; (435):79-87.

Ghazavi MT, Pritzker KP, Davis AM, Gross AE. Fresh osteochondral allografts for post-traumatic osteochondral defects of the knee. *J Bone Joint Surg Br*. 1997 Nov; 79(6):1008-13.

Hommen JP, Applegate GR, Del Pizzo W. Meniscus allograft transplantation: ten-year results of cryopreserved allografts. *Arthroscopy*. 2007 Apr; 23(4):388-93.

Matava MJ. Meniscal allograft transplantation: a systematic review. *Clin Orthop Relat Res*. 2007 Feb; 455:142-57.

Noyes FR, Barber-Westin SD, Rankin M. Meniscal transplantation in symptomatic patients less than fifty years old. *J Bone Joint Surg Am*. 2005; 87 Suppl 1(Pt.2):149-165.

Strickland, SM, MacGillivray, JD, Warren, RF. Anterior cruciate ligament reconstruction with allograft tendons. *Orthop Clin North Am*. 2003 Jan; 34(1):41-7.

Verdonk PC, Demurie A, Almqvist KF, Veys EM, Verbruggen G, Verdonk R. Transplantation of viable meniscal allograft. Survivorship analysis and clinical outcome of one hundred cases. *J Bone Joint Surg Am*. 2005 Apr; 87(4):715-24.

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Approved by the Medical Director