Clinical Review Criteria
Allogeneic Meniscal Transplant

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Criteria
For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
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</thead>
<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
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<tr>
<td>National Coverage Determinations (NCD)</td>
<td>None</td>
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<tr>
<td>Local Coverage Article</td>
<td>None</td>
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<tr>
<td>KPWA Medical Policy</td>
<td>Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, “Allogenic Meniscal Transplant,” for medical necessity determinations. Use the Non-Medicare criteria below.</td>
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For Non-Medicare Members
Kaiser Permanente has elected to use the MCG* Meniscal Allograft Transplant (A-0216) for medical necessity determinations. This service is not covered per MCG guidelines.

*MCG Manuals are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:
• Last 6 months of clinical notes from requesting provider &/or specialist (Orthopedics/podiatry)

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
The knee meniscus is a fibrocartilagenous crescent-shaped structure that plays an important part in the biomechanics of the joint. It functions as load bearing, shock absorption, stabilization of the joint as well as lubrication. Partial or complete loss of the meniscus alters the joint function, and predisposes the articular cartilage to degenerative changes. In the past, total or subtotal meniscectomy was routinely performed for patients with meniscal tears. More recently, repair of the meniscus has become the standard treatment for tears. If unreparable, arthroscopic partial meniscectomy of only the torn segments is recommended (Yoldas 2003). Subtotal or complete meniscectomy is however performed when the entire meniscus is torn and irreparable. Meniscectomy leads to deterioration of the articular cartilage, and narrowing of the knee joint. Allograft meniscal transplantation, has become an option for these patients, and is believed to prevent progression of degenerative changes of the knee.

The first meniscal allograft was performed in 1984 by Milachowski and Wirth. The technique of the transplantation has evolved over the years, and different graft types were used. These include meniscus prosthesis, scaffolds, genetically engineered tissue, meniscus xenografts, meniscus autografts, and meniscus allografts. The allografts
used are fresh, fresh-frozen, lyophilized, or cryopreserved menisci. Fresh menisci are thought to be superior as the architecture is unchanged, and chondrocytes and other cells are still viable. However, fresh grafts are logistically difficult to obtain. Fresh-frozen and cryopreserved menisci are reported to have good results but are associated with storage and availability problems. The Lyophilized and freeze dried menisci can be stored for a long time, but have the disadvantage of the decay of ground substance and destruction of the architecture in the freeze dried menisci, and shrinkage in the lyophilized. Cryopreservation may maintain fibrochondrocytes for 2-4 weeks but is very expensive in cost. The success of the transplantation depends on the revascularization and the cell proliferation for the restitution of the lost ground substance. Sizing of the meniscus before transplantation is also important to have a good geometrical fit in the joint, and a proper function.

The indications of the transplantation are not well defined. Persistent pain after meniscectomy is a common indication. Some authors believe that a knee with minimal or no arthritic changes is the ideal for transplantation, and others indicate it only for knees with degenerative changes. Some investigators in the US (Felix N, and Paulos L 2003), indicate meniscal transplantation for those <40 years old, with pain and swelling not responding to conservative treatment, minimal degenerative changes, stable knee, and axial alignment. In other countries e.g. Germany (Peters 2003) the indications include total meniscectomy with early arthritis, loss of anterior cruciate ligament, concomitant osteotomy, and prophylactic transplantation. It is contraindicated in patients with severe degenerative changes in the joint, instability, malalignment, and history of infection of the joint.

Medical Technology Assessment Committee (MTAC)

Allogenic Meniscal Transplant

07/14/2004: MTAC REVIEW

Evidence Conclusion: The results of the studies reviewed are promising but do not provide sufficient evidence, on the effectiveness of the meniscal allograft transplantation in restoring the knee function and preventing degenerative osteoarthritis. The prospective study, the two case series appraised, as well as the other published case series and reports were small, included heterogeneous patients at different ages, and with different indications for the meniscal transplantation. None of the studies used a consistent protocol. The grafts used were fresh, deep-frozen, cryopreserved, or lyophilized allografts. The duration from the meniscectomy to the transplant varied among patients from few months to more than 30 years. In several reports and within studies some patients received an anterior cruciate ligament repair, together with the meniscal transplant. In others, patients underwent different procedures after the transplantation. The rehabilitation programs varied between and within studies, as well as the duration of follow-up. Overall the results of the studies show that meniscal transplantation may alleviate pain and improve the knee function. However, there is insufficient data to determine which patients will benefit most, and if benefits observed would be maintained over time, and whether the transplantation will prevent degenerative changes from occurring within the joint.

Articles: The search yielded 75 articles many of which were review articles. There were no meta-analyses or randomized controlled trials. One prospective cohort study and several case series reports with limited number of patients were identified. The prospective cohort study and two case series reports were selected for critical appraisal. Selection for the case series reports for review was based on the population size, duration of follow-up, and/or primary outcomes. Evidence tables were created for the following studies: Wirth CJ, Peters G, Milachowski KA, et al. Long-term results of meniscal allograft transplantation. Am J Sports Med 2002;30:174-181. See Evidence Table van Arkel ERA, and de Boer HH. Survival analysis of human meniscal transplantations. J Bone Joint Surg 2002;84-B:227-31. See Evidence Table Rath E, Richmond JC, Yassir W et al. Meniscal allograft transplantation. Two-to eight-year results. Am J Sports Med 2001;29:174-181. See Evidence Table

The use of allogeneic meniscal transplant in the treatment of knee pain and swelling does not meet the Kaiser Permanente Medical Technology Assessment Criteria.
<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>06/14/2016</td>
<td>Revised Medicare language and added date that code was taken off the non-covered services list</td>
</tr>
<tr>
<td>09/08/2015</td>
<td>Revised LCD Non-Covered Services (L34886)</td>
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**Codes**

CPT: 29868