

MENISCUS IMPLANT AND ALLOGRAFT

Policy Number: SURGERY 096.13 T2

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[Instructions for Use](#) ⓘ

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Related Policies
<ul style="list-style-type: none"> • Autologous Chondrocyte Transplantation in the Knee • Osteochondral Grafting • Unicondylar Spacer Devices for Treatment of Pain or Disability

CONDITIONS OF COVERAGE

Applicable Lines of Business/Products	This policy applies to Oxford Commercial plan membership.
Benefit Type	General benefits package
Referral Required (Does not apply to non-gatekeeper products)	No
Authorization Required (Precertification always required for inpatient admission)	Yes
Precertification with Medical Director Review Required	Yes ¹
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	Outpatient, Inpatient
Special Considerations	¹ Precertification with review by a Medical Director or their designee is required.

COVERAGE RATIONALE

Meniscus allograft transplantation (MAT) with human cadaver tissue is proven and medically necessary for replacement of major meniscus loss due to trauma or previous meniscectomy when ALL of the following criteria are met:

- Individuals who are skeletally mature with documented closure of growth plates
- Individual has significant knee pain causing functional impairment
- Individuals are missing more than half of the meniscus due to surgery or injury or has a tear that cannot be repaired
- Radiographic criteria established by a standing anteroposterior (AP) view demonstrates all of the following:
 - Normal alignment or correctable varus or valgus deformities
 - No osteophytes or marginal osteophytes
 - No irreparable articular cartilage defects
 - No significant joint space narrowing
- Ligamentous stability has been achieved prior to surgery or achieved concurrently with meniscal transplantation (e.g., concomitant anterior cruciate ligament surgery)
- Documented minimal to absent degenerative changes in surrounding articular cartilage (Outerbridge Grade II or less)
- There is no evidence of active inflammatory arthritis or systemic arthritis
- Individual who has failed conservative treatment including physical therapy and/or bracing techniques

Collagen meniscus implants (CMI) are unproven and not medically necessary for treating or evaluating and managing meniscus injuries or tears due to insufficient evidence of efficacy.

DEFINITIONS

Functional or Physical Impairment: A Physical or Functional or physiological Impairment causes deviation from the normal function of a tissue or organ. This results in a significantly limited, impaired, or delayed capacity to move, coordinate actions, or perform physical activities and is exhibited by difficulties in one or more of the following areas: physical and motor tasks; independent movement; performing basic life functions.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

CPT Code	Description
29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral <i>CPT® is a registered trademark of the American Medical Association</i>
HCPCS Code	Description
G0428	Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)

DESCRIPTION OF SERVICES

The meniscus is a disc of cartilage that cushions the knee. Each knee has two, one at the outer edge of the knee and another at the inner edge. The surface or articular cartilage is teflon-like and facilitates the gliding and sliding of the bone ends upon each other. Meniscal cartilage is an integral structural component of the human knee, functioning to absorb shocks and providing load sharing, joint stability, congruity, proprioception, and lubrication and nutrition of the cartilage surfaces.

Replacing the meniscus can be done using donor material. This type of transplant is called an Allograft. Allografts are grafts of tissues made available from a live person or a human cadaver. Allografts from cadavers avoid morbidity from harvesting tissue from a different site on the person requiring meniscus repair. The goal of meniscal allograft transplantation is to restore knee function and prevent further joint degeneration by replacing the damaged or destroyed meniscus with allograft tissue having similar properties as the damaged tissue. Meniscal allograft transplantation is a surgical procedure that involves grafting a donor meniscus into the knee of a recipient. The procedure has been proposed as treatment for a subset of patients with irreparable meniscal tears, or who have undergone previous total meniscectomy. Patient selection criteria for meniscal allograft transplantation are not well-defined and vary across studies. However, candidates are generally young, with minimal degenerative changes, have a stable knee and normal axial alignment, and have failed to respond to conservative care.

The rationale for meniscal allograft transplant is to prevent the development of arthritis resulting from the loss of the meniscal function following trauma or meniscectomy. Donor menisci are obtained from genetically unrelated individuals, usually through organ procurement programs, coroners' offices, hospitals, and morgues. The allografts may be implanted fresh from cadaver donor, although this presents problems regarding the timing of the surgery and also increases the risk of disease transmission. Fresh menisci can be maintained in culture for 2 weeks, which allows time for infectious disease testing while preserving cell viability. Cryopreservation, in which the graft is treated with a cryoprotectant and frozen, preserves fibrochondrocytes and does not distort the graft. Fresh freezing is another technique used in the preservation of the allograft; however, this process kills the cells and can damage the collagen net of the graft. (Hayes, 2011)

The Collagen Meniscal Implant (CMI) (formerly marketed as Menaflex) is an implant derived from bovine collagen used to treat acute or chronic advanced meniscal loss or damage with the intent of relieving symptoms and preventing joint degeneration. The CMI is a flexible, sickle-shaped disc that mimics the shape of the native meniscus and is attached arthroscopically to native tissue with suture. The porous, collagen-glycosaminoglycan matrix of the CMI is meant to serve as a temporary template to support migration of the host's cells to the meniscal deficiency, restoring meniscal volume and function. (Hayes, 2017)

Collagen Meniscus Implants

In the new Hayes technology brief (2017) the authors reported that studies for collagen meniscus implants commonly included small total enrollment, differences in duration of follow-up between groups, lack of blinding/masking, retrospective design; and less frequently included incomplete reporting, and in comparative studies, differences in group characteristics, duration of followup, and attrition. The overall quality of the evidence was rated as low due to poor quality studies, and inconsistent findings.

A poor-quality retrospective cohort study compared outcomes after Collagen Meniscus Implant (CMI) during concomitant ACL reconstruction with partial medial meniscectomy. (Bulgheroni et al., 2015). The results suggest that outcomes are not significantly different between CMI and partial medial meniscectomy. Among patients with chronic pattern, patients treated with CMI had significantly lower postoperative pain than patients treated with partial medial meniscectomy; however, no difference was noted in patients with acute pattern or overall. Study limitations include small size, retrospective design with preoperative outcome scores obtained postoperatively, limited number of study centers, possible bias in selection of control group, and lack of blinding.

Grassi et al (2014) performed a systematic review to summarize and evaluate the clinical outcomes of the collagen meniscus implant (CMI) and its complication and failure rates. These data were then used to evaluate the results of the CMI at different follow-up time periods and investigate possible differences in the behavior of lateral and medial CMI. All studies evaluating medial or lateral CMI using the Lysholm score, visual analogue scale (VAS) for pain, Tegner activity scale and subjective or objective International Knee Documentation Committee (IKDC) scores were included in the systematic review. Eleven studies were included in the systematic review. The pooled number of patients involved in CMI surgery were 396. The Lysholm score and VAS for pain showed an improvement at six months up to ten years. No noticeable differences were present comparing short-term values of Lysholm score between medial and lateral CMI. The Tegner activity level reached its peak at 12 months after surgery and showed a progressive decrease through five and ten years post CMI implantation, however always remaining above the pre-operative level. Only a few knees were rated as "nearly abnormal" or "abnormal" at IKDC grading at all follow-up evaluations. The reviewers concluded the CMI could produce good and stable clinical results, particularly regarding knee function and pain, with low rates of complications and reoperations.

Rodkey et al. (2008) conducted a randomized controlled trial (RCT) that included 311 patients with an irreparable injury of the medial meniscus or a previous partial medial meniscectomy. There were two study arms, one consisting of 157 patients who had had no prior surgery on the involved meniscus (the acute arm of the study) and one consisting of 154 patients who had had one, two, or three prior meniscal surgical procedures (the chronic arm). Patients were randomized either to receive the collagen meniscus implant (CMI) or to serve as a control subject treated with a partial meniscectomy only. Patients underwent frequent clinical follow-up examinations over two years and completed validated outcomes questionnaires over seven years. Patients who received the CMI followed a different post-op protocol, receiving a specific rehabilitation protocol and the requirement of a second-look arthroscopy with biopsy one year after implant placement. In the acute group, seventy-five patients received a CMI and eighty-two were controls. In the chronic group, eighty-five patients received the implant and sixty-nine were controls. The mean duration of follow-up was fifty-nine months. The 141 repeat arthroscopies done at one year showed that the CMIs had resulted in significantly increased meniscal tissue compared with that seen after the original index partial meniscectomy. The implant supported meniscus-like matrix production and integration as it was assimilated and resorbed. In the chronic group, the patients who had received an implant regained significantly more of their lost activity than did the controls and they underwent significantly fewer non-protocol re-operations. No differences were detected between the two treatment groups in the acute arm of the study. The investigators concluded that new biomechanically competent meniscus-like tissue forms after placement of a CMI, and use of the implant appears safe. The CMI supports new tissue ingrowth that appears to be adequate to enhance meniscal function as evidenced by improved clinical outcomes in patients with a chronic meniscal injury. According to the investigators, the implant was not found to have any benefit for patients with an acute injury.

An assessment by the California Technology Assessment Forum (CTAF), (Tice, 2010) concluded that the collagen meniscus implant does not meet CTAF criteria. The CTAF assessment found that the pivotal randomized clinical trial (citing Rodkey et al, 2008) failed to demonstrate any improvement in pain or symptoms in either arm of the trial and the trial has substantial risk for selection bias, confounding, and reporting bias because of the large number of patients lost to follow-up after randomization and the lack of blinding for subjective outcomes. In addition, no data on osteoarthritis were presented. The CTAF assessment concluded that the trial "presents evidence that the collagen meniscus implant offers no important clinical benefits, requires longer and more intensive post-operative rehabilitation, and some uncertainty remains about the potential for long-term harm from the device."

The data from the Rodkey study was used by the U.S. Food and Drug Administration (FDA) in the 510(k) application process for the Menaflex collagen meniscus implant. An FDA executive summary of the Rodkey data indicated that patients who received the collagen meniscus implant (CMI) followed a different post-op protocol than the control group and control patients were not required to undergo a planned second-look arthroscopy since it was assumed that there was no tissue regrowth in these patients. The FDA also indicated that more meniscal tissue was removed from the CMI patients than in the control patients. The FDA noted that the re-look arthroscopy results for CMI group showed that 16% of evaluated devices were not firmly attached to the host rim and 18% of knee compartments were determined to be worse than during the operative procedure at the time of the re-look arthroscopic procedure. According to the FDA summary, the Tegner Index is meant to complement other functional scores (Lysholm knee score) for patients with ligamentous injuries, however, the investigators reported the Tegner Index in isolation and there was no pre-specified hypothesis for its use in the study design, thus, it is unclear how this endpoint should be interpreted given that there is no defined clinical significance for the Tegner Score when used in isolation. In addition, the FDA executive summary stated that at the 3 to 7 year annual follow-up time points, there is approximately 50% of the data available. It is not clear how the missing data has impacted the presentation of the safety and effectiveness endpoints at time-points later than 24 months. The primary endpoint was a 24-month endpoint.

Harston et al (2012) examined collagen meniscus implant (CMI) effectiveness for improving patient function, symptoms, and activity level. Study methodologies, rehabilitation, and return to sports guidelines were also reviewed. A total of 11 studies with 520 subjects met inclusion criteria. The authors concluded that knee function, symptoms, and activity level generally improved following CMI use, but poor research report quality was common. They stated that additional well-designed long-term prospective studies are needed to better determine knee osteoarthritis prevention efficacy and appropriate patient selection.

Zaffagnini et al. (2011) conducted a cohort study that included 33 nonconsecutive patients (men; mean age, 40 years) with meniscal injuries. Study participants received medial collagen meniscus implant (MCMCI) or served as a control patient treated with partial medial meniscectomy (PMM). The choice of treatment was decided by the patient. All patients were clinically evaluated at time 0 and at 5 years and a minimum of 10 years after surgery by Lysholm, visual analog scale (VAS) for pain, objective International Knee Documentation Committee (IKDC) knee form, and Tegner activity level scores. The MCMCI group, compared with the PMM one, showed significantly lower VAS for pain and higher objective IKDC, Tegner index, and SF-36 for Physical Health Index scores. Radiographic evaluation showed significantly less medial joint space narrowing in the MCMCI group than in the PMM group. The MRI evaluation of the MCMCI patients revealed 11 cases of myxoid degeneration signal: 4 had a normal signal with reduced size, and 2 had no recognizable implant. The investigators concluded that pain, activity level, and radiological outcomes are significantly improved with use of the MCMCI at a minimum 10-year follow-up compared with PMM alone. According to the investigators, randomized controlled trials on a larger population are necessary to confirm MCMCI benefits at long term.

Bulgheroni et al. (2010) investigated the clinical outcomes and any progression of knee osteoarthritis in 34 patients who underwent arthroscopic placement of a collagen meniscus implant. Lysholm and Tegner activity scores at 2 and 5 years after surgery improved significantly compared to the preoperative score. These patients showed good to excellent clinical results after 5 years from a CMI placement. In most of cases, the CMI-new tissue complex had a slight reduction in size, compared to a normal medial meniscus, but the new tissue had no apparent negative effects. According to the investigators, 5 years after the implant, the regenerated tissue still was not completely similar to a normal meniscus. This study is limited by a small sample size and lack of a control group.

A technology assessment conducted by Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). (2010) concluded that the collagen meniscal implant for irreparable medical meniscus injury did not meet technology assessment criteria. The published evidence did not support improvement in health outcomes or that clinical improvement was attainable outside of the investigational setting. Although promising, long-term data supporting safety, efficacy and improved clinical outcomes, including prevention of osteoarthritis, are not yet available to support widespread use of this bioactive scaffold for meniscal regeneration.

Meniscus Allograft Transplantation

Elattar et al. (2011) conducted a meta-analysis of published trials reporting outcomes of meniscal allograft transplantation to establish its safety and reproducibility. The outcomes of 678 medial and 458 lateral grafts in 613 male, 265 female and 190 non-defined patients with a mean age of 34.8 years were included in the meta-analysis. According to the authors, all studies reported a continuously satisfactory outcome with restoration of working capacity in these active patients. The authors stated that meniscal allograft transplantation can be considered as safe and reliable for the treatment of refractory post-meniscectomy symptoms in selected patients.

Hergan et al. (2011) performed a systematic review evaluating meniscal allograft transplantation (MAT). Included in the review were 14 studies with at least 2 years' follow-up, studies with validated outcome measures, and studies in which the allograft meniscal horns were secured with bony fixation. Thirteen of the articles provided Level IV evidence,

and one article (Stollsteimer et al. 2000) provided Level III evidence. The authors concluded that good early and midterm results of cryopreserved or fresh-frozen, nonirradiated MAT can be achieved in a relatively young patient with only mild chondromalacia (lower than Outerbridge grade 3) who is not overweight and has a stable, mechanically aligned lower extremity, if the allograft is sized radiographically by use of anteroposterior and lateral films and the allograft meniscal horns have bony attachments and are fixed by bony techniques. Similar results can be expected if the transplant is performed alone or with a concomitant cartilage repair procedure; however, significant cartilage defects (Outerbridge grade 2 or greater) on both the femoral and tibial sides in the same compartment requiring autologous cartilage implantation result in a high failure rate. Good outcomes of MAT can be expected when performing a concomitant ligament reconstruction or malalignment procedure on the knee, unless greater than 3 concomitant procedures are performed. There is no significant difference in outcome between medial and lateral MAT. According to the authors, despite a growing body of knowledge on the topic, there remains a lack of consensus regarding optimal allograft sizing technique, allograft fixation techniques, tissue processing, indications, and long-term efficacy. The authors stated that a prospective, randomized trial comparing MAT in a meniscectomized knee with a control group is needed to determine the best technique and patient selection criteria.

Crook et al. (2009) reviewed the current literature to consolidate the evidence surrounding the use of human meniscal allograft transplantation. No Level I or II studies were identified. Many studies had small study groups with limited follow-up and patient selection and description of patient factors varied greatly. This made comparing data difficult. Four types of graft are used--fresh, fresh-frozen, cryopreserved and freeze-dried (lyophilised) graft. Cryopreserved and fresh-frozen allografts are deemed most suitable. Most authors advocate the use of non-irradiated grafts from screened donors to reduce transmission of infection. Patients have an improved outcome if they have less severe degenerative changes within the knee prior to transplantation. The authors concluded that no statistically significant studies looking at isolated meniscal transplantations have been found. The evidence suggests that MAT provides improvement of pain and function in the short and intermediate term. The effect on future joint degeneration is still unknown. The authors stated that the ideal patient group includes patients less than 40 years of age with knee pain, proven meniscal injury and a normally aligned, stable joint without severe degenerative changes.

The results of the reviewed studies indicate that meniscal allografts can be successfully implanted and may produce short to intermediate relief in selected patients. Many patients reported good or satisfactory results with respect to function and pain for both normal daily living and moderate sports activities (Stollsteimer et al., 2000; Rue et al., 2008; Sekiya et al., 2006; Cole et al., 2006; Noyes et al., 2005; Vundelinckx et al., 2010; LaPrade et al., 2010). Short-term functional results from clinical analysis and patient self-assessment appear to be encouraging. However, none of the studies provide strong evidence that meniscal transplantation can slow or stop the degenerative process seen in meniscectomized knees, and none provided a comparison with other treatment options. Some of the studies also reported shrinking or extrusion of the allograft with time. Results of the few long-term studies indicated deterioration of the transplants over a long-term period when compared with short-term analysis (Verdonk et al., 2005; van der Wal et al., 2009). Moreover, differences in patient selection, concomitant procedures, allograft selection and treatment, surgical technique, graft fixation, rehabilitation protocol, and length of follow-up make results difficult to interpret and compare. Issues that remain to be addressed include patient selection criteria, optimal treatment for the allografts (irradiated or non-irradiated), and long-term outcomes. (Hayes 2017)

There is insufficient evidence to establish definitive patient selection criteria for meniscal allograft transplantation (Hayes, Archived 2017). Meniscal allograft transplantation is not recommended for patients age > 50 years, since procedures such as arthroplasty or osteotomy offer a more predictable outcome for these patients. Meniscal allograft transplantation is contraindicated in patients with large areas of significant articular degeneration (Outerbridge grade 3 or 4) or bony architectural changes, including osteophytes. The condition of the meniscus should be firmly established by previous operative reports, magnetic resonance imaging (MRI), or diagnostic arthroscopy (Hayes, Archived 2017). Other contraindications include systemic inflammatory disease, obesity (body mass index > 30), immunodeficiency, previous infection of the knee, and skeletal immaturity. (Crook et al., 2009; Monllau et al., 2010)

Meniscal allograft transplantation may be indicated in patients who are considered too young or active for arthroplasty if they have all of the following (Friel and Cole, 2010; Monllau et al., 2010):

- Disabling knee pain refractory to conservative treatment
- Ligamentous stability prior to surgery or achieved concurrently with meniscal transplantation
- Documented mild to moderate articular damage (Outerbridge grade I-II)
- Normal alignment without varus or valgus deformities

It is evident that meniscal allograft transplantation is a viable option for the treatment of symptomatic individuals provided rigid inclusion criteria are met. Those with appropriate indications should expect to do well postoperatively in terms of predictable reduction in pain and an ability to increase activity levels. Further study will clarify the long-term results of meniscal allografts as well as their role in preventing the progression of secondary osteoarthritis in the involved compartment.

Professional Societies

The American Academy of Orthopedic Surgeons

The American Academy of Orthopedic Surgeons published an information statement regarding the use of musculoskeletal tissue allografts (AAOS, Updated 2011). The AAOS supports the following:

- The use of musculoskeletal allograft as a therapeutic alternative to autograft use for appropriate patients. Allograft tissues should be acquired from facilities that demonstrate compliance, use well-accepted banking methodology and good tissue practices. The AAOS urges all tissue banks to follow rigorous national guidelines and standards.
- The AAOS strongly favors on-site inspection and recommends the use of tissue banks by the American Association of Tissue Banks (AATB). The AAOS supports informed consent, for both the donor family and the recipient of human tissue, in accordance with local, state and federal laws and regulations.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Transplantation of meniscal allografts is a surgical procedure and, as such, is not subject to regulation by the FDA. However, the FDA does regulate certain aspects of tissue banking, and tissues are subject to FDA registration and requirements for good tissue practices and infectious disease screening and testing, as well as to the good manufacturing practice requirements applicable to drugs and devices. According to current rules, FDA premarket review or marketing approval is not required for minimally processed tissues transplanted from one person to another for their normal structural functions; these criteria apply to meniscal allografts. See the following website for more information: <http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm>. (Accessed May 10, 2018)

Collagen meniscus implants, also known as collagen scaffold, or Menaflex, are bioresorbable, primarily bovine type 1 collagen. This product was designed as a tissue-engineered scaffold to support the generation of new meniscus-like tissue. The Collagen Meniscal Implant (CMI), the ReGen Collagen Scaffold (CS), and the Menaflex device are different names for the same device. The collagen meniscus implant and polyurethane meniscus implant do not have FDA approval at this time.

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2019T0543K]

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
01/01/2019	<ul style="list-style-type: none">• Simplified coverage rationale (no change to guidelines)• Added definition of "Functional or Physical Impairment"• Archived previous policy version SURGERY 096.12 T2

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

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