Meniscus Implant and Allograft

Policy Number: CS078.L
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Instructions for Use

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Related Community Plan Policies

- Articular Cartilage Defect Repairs
- Unicondylar Spacer Devices for Treatment of Pain or Disability

Commercial Policy

- Meniscus Implant and Allograft

Application

This Medical Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Indiana	Meniscus Implant and Allograft (for Indiana Only)
Kentucky	Meniscus Implant and Allograft (for Kentucky Only)
Louisiana	Meniscus Implant and Allograft (for Louisiana Only)
New Jersey	Meniscus Implant and Allograft (for New Jersey Only)
Tennessee	Meniscus Implant and Allograft (for Tennessee Only)

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
- Disabling knee pain causing Functional Impairment that is refractory to conservative treatment
- Absence of 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
- Normal knee biomechanics, or alignment and stability achieved concurrently with meniscal transplantation
- Minimal to absent degenerative changes in surrounding articular cartilage (Outerbridge Grade II or less)
- No evidence of active inflammatory arthritis or systemic arthritis

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

Definitions

Collagen Meniscal Implant (CMI): Resorbable and biocompatible Type I collagen matrix that was developed to restore the segmental loss of meniscal tissue in the knee. It consists of a porous cross-linked matrix scaffold that allows for the ingrowth of the body's own cells. (Warth and Rodkey, 2015).

Functional or Physical Impairment: A functional or physical 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. (World Health Organization and World Bank (WHO), 2011).

Meniscal Allograft Transplantation (MAT): Transplant of the meniscus of the knee, which separates the thigh bone (femur) from the lower leg bone (tibia). The worn or damaged meniscus is removed and is replaced with a new one from a donor. The meniscus to be transplanted is taken from a cadaver, and, as such, is known as an allograft. (AAOS, 2021).

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 federal, state, or contractual requirements 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 and Guidelines may apply.

CPT Code	Description
29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral

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HCPCS Code	Description
G0428	Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)

Description of Services

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. 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.

The Collagen Meniscal Implant (CMI) (Stryker Corp.) 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 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.

Collagen Meniscus Implants (CMIs)

There is insufficient evidence to demonstrate the efficacy of collagen meniscus implants for treating meniscus injuries or tears. Robust randomized controlled trial studies are needed along with long-term outcomes to establish the safety and efficacy of this procedure.

Veronesi et al. (2021) conducted a systematic review to collect and evaluate the available evidence on biosynthetic scaffolds for meniscus regeneration both in vivo and in clinical studies. Three databases were searched: A total of 46 in vivo preclinical studies and 30 clinical studies were identified. Sixteen natural, 15 synthetic, and 15 hybrid scaffolds were studied in vivo. Among them, only two scaffolds were evaluated in clinical studies: The Collagen Meniscus Implant was evaluated in 11 studies, and the polyurethane-based scaffold Actifit® was evaluated in 19 studies. Although positive outcomes were described in the short- to mid-term, the number of concurrent procedures and the lack of randomized trials are the major limitations of the available clinical literature. According to the authors, current solutions offer a significant but incomplete clinical improvement and the regeneration potential is still unsatisfactory. Authors Rodkey et al., 2008; Bulgheroni et al., 2015; and Zaffagnini et al., 2011 which were previously cited in this policy are included in the Veronesi et al., 2021 systematic review.

Grassi et al. (2021) assessed the clinical outcomes and failures of lateral CMI implantation at a minimum 10-year follow-up. This study included 24 consecutive patients who underwent lateral CMI implantation for partial lateral meniscal defects and who were part of a previous study with a 2-year follow-up (cited as Zaffagnini et al., 2015). Outcome measures at the latest follow-up included the Lysholm score, Knee injury and Osteoarthritis Outcome Score, visual analog scale (VAS) for pain, Tegner activity level, and EuroQol 5-Dimensions score. Data regarding complications and failures were collected, and patients were asked about their satisfaction with the procedure. Included in the final analysis were 19 patients (16 male, 3 female) with a mean age at surgery of 37.1 ± 12.6 years and a mean follow-up of 12.4 ± 1.5 years (range, 10-14 years). Five failures (26%) were reported: 1 CMI removal because of implant breakage and 4 joint replacements (2 unicompartmental knee arthroplasties and 2 total knee arthroplasties). The implant survival rate was 96% at 2 years, 85% at 5 years, 85% at 10 years, 77% at 12 years, and 64% at 14 years. Lysholm scores at the final follow-up were rated as "excellent" in 36% (5 of 14 nonfailures), "good" in 43% (6 of 14), and "fair" in 21% (3 of 14). The VAS score was 3.1 ± 3.1, with only 16% (3 of 19 patients) reporting that they were pain-free; the median Tegner score was 3 (interquartile range, 2-5). All clinical scores decreased from the 2-year follow-up; however, with the exception of the Tegner score, they remained significantly higher compared with the preoperative status. Overall, 79% of patients were willing to undergo the same procedure. The authors concluded that lateral CMI implantation for partial lateral meniscal defects provided good long-term results, with a 10-year survival rate of 85% and a 14-year survival rate of 64%. At the final follow-up, 58% of the patients had "good" or "excellent" Lysholm scores. However, there was a general decrease in outcome scores between the short- and the long-term follow-up. According to the authors, although this represents the first study to assess the long-term outcome of lateral meniscal replacement using a scaffold, several limitations are present. Four patients were lost to follow-up, thus creating a possible selection bias. Another limitation is the limited number of patients, which did not allow the performance of sophisticated statistical subanalyses to identify outcomes and failure predictors. According to the authors, additional factors such as a surgical learning curve, the time from meniscectomy to scaffold implantation and the cartilage status, and the time of the index surgery could be relevant and should be investigated in studies with a larger sample size.

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 was 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.

Harston et al. (2012) conducted a systematic review to examine 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 osteoarthrosis prevention efficacy and appropriate patient selection.

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."

Meniscus Allograft Transplantation (MAT)

In a systematic review, Waugh et al. (2019) assessed the clinical effectiveness of MAT after meniscal injury and subsequent meniscectomy. Thirty-seven papers from 19 studies of MAT were included in the review. Cohort size in the included studies ranged from 30 to 313, with a total of 1731 people undergoing at least one MAT. There was considerable evidence from observational studies, of improvement in symptoms after meniscal allograft transplantation, but the authors found only one small pilot trial with a randomized comparison with a control group that received non-surgical care. MAT has not yet been proven to be chondroprotective. The authors concluded that the benefits of MAT include symptomatic relief and restoration of at least some previous activities, which will be reflected in utility values and hence in quality-adjusted life years, and in the longer term, prevention or delay of osteoarthritis, and avoidance or postponement of some knee replacements.

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 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 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.

Clinical Practice Guidelines

American Academy of Orthopaedic Surgeons (AAOS)

The AAOS published an information statement regarding the use of musculoskeletal tissue allografts (AAOS, 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)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

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. Refer to the following website for more information: http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm. (Accessed June 30, 2021)

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. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K170364. (Accessed June 30, 2021)

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Policy History/Revision Information

Date	Summary of Changes
06/01/2022	Application *Nebraska* • Updated language to indicate this Medical Policy applies to the state of Nebraska (retired state-specific policy version) Supporting Information • Archived previous policy version CS078.K

Instructions for Use

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

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.