Policy Number	**SUR705.034**
Policy Effective Date	**12/15/2025**

Meniscal Allografts and Other Meniscal Implants

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Related Policies (if applicable)
SUR705.020: Autografts and Allografts in the Treatment of Focal Articular Cartilage
SUR705.035: Autologous Chondrocyte Implantation (ACI) for Focal Articular Cartilage Lesions

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Coverage

Meniscal allograft transplantation of the knee **may be considered medically necessary** in individuals who have had a prior meniscectomy and have symptoms related to the affected side when **ALL** of the following criteria are met:

- Adult individuals should be too young to be considered an appropriate candidate for a total knee arthroplasty or other reconstructive knee surgery (i.e., <55 years); **and**
- Disabling knee pain with activity that is refractory to conservative treatment, including physical therapy and analgesic medications; **and**
- Absence or near absence (>50%) of the meniscus, established by imaging or prior surgery; **and**
- Documented minimal to absent diffuse degenerative changes in surrounding articular cartilage (e.g., Outerbridge grade II or less, <50% joint space narrowing) (See **Policy Guidelines**); **and**
- Normal knee biomechanics or alignment and stability achieved concurrently with meniscal transplantation; **and**

- There is no infection, inflammatory arthritis (e.g., rheumatoid arthritis [RA]), or synovial disease present; **and**
- The body mass index (BMI) is ≤35 kg/m^2 (see **Policy Guidelines**).

Meniscal allograft transplantation of the knee **may be considered medically necessary** when performed in combination, either concurrently or sequentially, with treatment of focal articular cartilage lesions using any of the following procedures:

- Autologous chondrocyte implantation; **or**
- Osteochondral allografting; **or**
- Osteochondral autografting.

Use of other meniscal implants incorporating material such as collagen **are considered experimental, investigational and/or unproven**.

For criteria to determine medical necessity of other concurrent or sequential procedures, please refer to the following medical policies:

- SUR705.035, Autologous Chondrocyte Implantation (ACI) for Focal Articular Cartilage Lesions
- SUR705.020, Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions.

Policy Guidelines

Individuals should exhibit symptoms of persistent disabling knee pain that has not adequately responded to physical therapy and analgesic medications. Uncorrected misalignment and instability of the joint are contraindications. Therefore, additional procedures, such as repair of ligaments or tendons or creation of an osteotomy for realignment of the joint, may be performed at the same time.

Severe obesity (e.g., body mass index >35 kg/m^2) may affect outcomes due to the increased stress on weight-bearing surfaces of the joint. Meniscal allograft transplantation is typically recommended for young active individuals who are too young for total knee arthroplasty.

Outerbridge Grading and Documentation Requirements

Outerbridge Grading	
Grade 0	Normal appearing cartilage
Grade I	Swelling and softening of articular cartilage
Grade II	Fissuring within softened areas
Grade III	Fibrillation
Grade IV	Destruction of articular cartilage and exposed bone

DOCUMENTATION Required for Review of Injury and Prior Treatment/Therapies:

- Progress report(s), history, and/or operative notes confirming injury and prior treatments/therapies; **and**

- Report(s) of standing x-rays documenting normal alignment and stability of the knee and the absence of inflammatory arthritis (e.g., RA); **and**
- Report(s) from knee arthroscopy showing the presence of the cartilage defect and normal cartilage surrounding the defect.

Description

Meniscal allografts and other meniscal implants (e.g., collagen) are intended to improve symptoms and reduce joint degeneration in individuals who have had a total or partial meniscus resection.

Background

Meniscal Cartilage Damage

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. Total and partial meniscectomy frequently result in degenerative osteoarthritis (OA). The integrity of the menisci is particularly important in knees in which the anterior cruciate ligament has been damaged. In these situations, the menisci act as secondary stabilizers of anteroposterior and varus-valgus translation.

Treatment

Meniscal allograft transplantation (MAT) is considered a salvage procedure, reserved for patients with disabling knee pain following meniscectomy who are considered too young to undergo total knee arthroplasty (TKA) or in patients who require a total or near total meniscectomy for irreparable tears. As a result, the population intended to receive these transplants is relatively limited. Using a large database of privately insured non-Medicare patients, Cvetanovich et al. (2015) estimated an annual incidence of MAT in the United States (U.S.) of 0.24 per 100,000. (1) It is not expected that clinical trials will be conducted to compare meniscal allografts with other orthopedic procedures, although trials comparing allograft transplant with medical therapy are possible.

There are 3 general groups of patients who have been treated with MAT:

- Young patients with a history of meniscectomy who have symptoms of pain and discomfort associated with early osteoarthritis that is localized to the meniscus-deficient compartment;
- Patients undergoing anterior cruciate ligament reconstruction in whom a concomitant meniscal transplant is intended to provide increased stability;
- Young athletes with few symptoms in whom the allograft transplantation is intended to deter the development of osteoarthritis. Due to the risks associated with this surgical procedure, prophylactic treatment for this purpose is not frequently recommended.

Issues under study include techniques for processing and storing the grafts, proper sizing of the grafts, and appropriate surgical techniques. The 4 primary ways of processing and storing allografts are fresh viable, fresh frozen, cryopreserved, and lyophilized. Fresh viable implants,

harvested under sterile conditions, are less frequently used because the grafts must be used within a couple of days to maintain viability. Alternatively, the harvested meniscus can be fresh frozen for storage until needed. Cryopreservation freezes the graft in glycerol, which aids in preserving the cell membrane integrity and donor fibrochondrocyte viability. CryoLife is a commercial supplier of such grafts. Donor tissues may also be dehydrated (freeze-dried or lyophilized), permitting storage at room temperature. Lyophilized grafts are prone to reduced tensile strength, shrinkage, poor rehydration, post-transplantation joint effusion, and synovitis; these are no longer used in the clinical setting. Several secondary sterilization techniques may be used, with gamma irradiation the most common. The dose of radiation considered effective has been shown to change the mechanical structure of the allograft; therefore, non-irradiated grafts from screened donors are most frequently used. In a survey conducted by the International Meniscus Reconstruction Experts Forum, when surgeons were asked about allograft preference, 68% preferred fresh frozen non-irradiated allografts, with 14% responding fresh viable allografts. (2)

There are several techniques for MAT; most are arthroscopically assisted or all-arthroscopic. Broadly, the techniques are either all-suture fixation or bone fixation. Within the bone fixation category, the surgeon may use either bone plugs or a bone bridge. Types of bone bridges include keyhole, trough, dove-tail, and bridge-in-slot. The technique used depends on laterality and the need for concomitant procedures. Patients with malalignment, focal chondral defects, and/or ligamentous insufficiency may need concomitant procedures (osteotomy, cartilage restoration, and/or ligament reconstruction, respectively). (3)

Tissue engineering that grows new replacement host tissue is also being investigated. For example, the Collagen Meniscus Implant (CMI®) (by Stryker, formerly the ReGen Collagen Scaffold® by ReGen Biologics), is a resorbable collagen matrix composed primarily of type I collagen from bovine Achilles tendons. The implant is provided in a semilunar shape and trimmed to size for suturing to the remaining meniscal rim. The implant provides an absorbable collagen scaffold that is replaced by the patient's soft tissue; it is not intended to replace normal body structure. Because it requires a meniscal rim for attachment, it is intended to fill meniscus defects after a partial meniscectomy. A second collagen meniscus implant, RejuvaKnee™ has similar characteristics to CMI; however, the bovine collagen is sourced from the meniscus as opposed to the Achilles tendon. Other scaffold materials and cell-seeding techniques are being investigated. Non-absorbable and nonporous synthetic implants for total meniscus replacement are in development. One total meniscus replacement that is in early phase clinical testing is NUsurface® (Active Implants); it is composed of a polyethylene reinforced polycarbonate urethane.

Outcome Measures

The outcomes of this treatment (i.e., pain, functional status) are subjective, patient-reported outcomes that are prone to placebo effects. On the other hand, the natural history of a severely damaged meniscus is predictable, with progressive joint damage, pain, and loss of function.

Regulatory Status

Collagen Meniscus Implants

In 2008, the ReGen Collagen Scaffold was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing absorbable surgical mesh devices. The ReGen Collagen Scaffold (also known as MenaFlex™ CMI) was the only collagen meniscus implant (CMI) with FDA clearance at that time. Amid controversy about this 510(k) clearance decision, the FDA reviewed its decision. In October 2010, the FDA rescinded the approval, stating that MenaFlex™ is intended for different purposes and is technologically dissimilar from the predicate devices identified in the approval process. The manufacturer appealed the rescission and won its appeal in 2014. The product, now called CMI, was manufactured by Ivy Sports Medicine (now Stryker). A second collagen meniscus implant, RejuvaKnee™ (Collagen Matrix, Inc [now Regenity]), was declared substantially equivalent to CMI by the FDA in 2024.

FDA product code: OLC.

Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life (QOL), and ability to function--including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Meniscal Allograft Transplantation

Clinical Context and Therapy Purpose

The purpose of meniscal allograft transplantation (MAT) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as partial meniscectomy without MAT, in individuals who are undergoing partial meniscectomy.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals who are undergoing partial meniscectomy.

Interventions
The therapy being considered is MAT. Meniscal allografts and other meniscal implants (e.g., collagen) are intended to improve symptoms and reduce joint degeneration in individuals who have had a total or partial meniscus resection.

Comparators
Comparators of interest include partial meniscectomy without MAT.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and quality of life (Table 1).

Table 1. Outcomes of Interest for Individuals Undergoing Partial Meniscectomy

Outcomes	Details
Symptoms	Outcomes of interest include pain measured using various scales and questionnaires [Timing: 1-10 years]
Functional outcomes	Outcomes of interest include knee function and range of motion [Timing: 1-10 years]

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Several systematic reviews of available case series have reported reductions in pain and improvements in function at mid-term follow-up, with failure rates at the time of follow-up ranging from 7% to 35% (Table 2). Elattar et al. (2011) published a large systematic review with a total of 1136 allografts. (4) Twelve different clinical scoring systems were described, which generally showed reductions in pain and improvements in function. Hergan et al. (2011) conducted a systematic review of the literature to evaluate the characteristics of patients, graft survival, and clinical outcomes. (5) The analysis found that patients with Outerbridge scores of II

or less in any area had significantly improved post-treatment Lysholm Knee Score (LKS) and Tegner Activity Scale (TAS) scores, whereas patients with Outerbridge grade III or more in any area (not repaired) did not. Studies that analyzed patients undergoing concomitant procedures did not detect a difference between subgroups compared with MAT alone. Functional outcomes were considered generally good where reported. Rosso et al. (2015) published a systematic review evaluating 55 studies (N=1623 patients). (6) Data from 37 studies were included in demographic and outcome analyses. Collectively, these systematic reviews, which are based primarily on level IV evidence, summarize the short- to medium-term outcomes of MAT (Table 2).

Table 2. Summary of Key Systematic Reviews of Meniscal Allograft Transplantation

Variables	**Elattar et al. (2011) (4)**	**Herganet et al. (2011) (5)**	**Rosso et al. (2015) (6)**
Number and study type	44 cohort and case series	14 cohort and case series with minimum 2-year follow-up	55 (2 level II, 7 level III, 46 level IV)
Population	1136 knees (1068 patients)	196 knees	1623 patients
Follow-up (range)	4.6 y (8 mo to 20 y)	4.5 y (2 y to 14 y)	4.5 y (1 y to 14 y)
Outcome measures	Pain and function	Pain and function	Pain and function
Review Synthesis			
Pain and function	All showed clinical improvement	Alleviation of knee pain and improvement in function noted	Weighted pre-/post-measures[a]: • VAS pain score decreased from 6.4 to 2.4 • LKS increased from 55.5 to 82.7
Failure rate	10.6%	7% to 35%	• Fresh frozen: 9.9% • Cryopreserved: 18.2%
Complication rate	21.3%		10.6%
Review conclusion	MAT improves pain and function	Improvements in objective and subjective outcome measures shown in relatively young patients without significant chondromalacia who underwent concomitant repair	Agreement in literature on MAT indications: • All studies showed clinical improvement at short- and mid-term follow-ups

		procedures for cartilage defects, limb malalignment, and/or limb instability	• Complication and failure rates acceptable • Potential chondro-protective effect of MAT remains unclear
Review limitations	Based primarily on case series	Based primarily on case series and qualitative review only	Based primarily on case series

LKS: Lysholm Knee Score; MAT: meniscal allograft transplantation; mo: months; VAS: visual analog scale; y: years.

[a] Data from 37 of the 55 studies in the systematic review.

Randomized Controlled Trials (RCT)

Smith et al. (2018) reported on the results of a small RCT that randomized 21 patients with a symptomatic meniscal deficient knee to MAT (n=10) or personalized physical therapy (n=11). (7) Another 15 patients who were screened for the RCT decided instead to choose their treatment (referred to as preference group), receiving MAT (n=6) or personalized physical therapy (n=9). The Knee Injury and Osteoarthritis Outcome Score (KOOS), International Knee Documentation Committee (IKDC) score, Lysholm Knee Scoring Scale (LKS) score, and complications were collected at baseline, 4 and 8 months, and 1 year after the interventions. Trialists reported pooled results from the RCT and preference group, with statistically significant differences in favor of MAT group for KOOS composite score (mean difference, 12; p=0.03) and KOOS subscales of pain (mean difference, 15; p=0.02) and activities of daily living (mean difference, 18; p=0.005). However, pooling data from the RCT and preference group precluded a meaningful interpretation of data.

Case Series

The characteristics and results of several case series with longer-term follow-up are provided in Tables 3 and 4. Verdonk et al. (2005) published a large case series with long-term follow-up from 95% of their first 105 fresh cultured (viable) meniscal allografts. (8) The indication for transplantation was moderate-to-severe pain in patients who had undergone previous total meniscectomy, not old enough to be considered for a knee joint replacement, and with good alignment of the lower limb and a stable joint (some were corrected concomitantly). In the study by Hommen et al. (2007), concomitant procedures were performed in 75% of the patients, including anterior cruciate ligament reconstruction or revision (n=10), high tibial osteotomy (n=2), and lateral retinaculum release (n=3). (9)

At a mean follow-up of 16 years, van der Wal et al. (2009) (10) reported graft survival decreased to 52.5%, while most failures in the study by Vundelinckx et al. (2010) (11) occurred approximately 10 years postoperatively. That said, at an average of 105 months of follow-up, the 34 remaining patients assessed in the Vundelinckx et al. (2010) study showed significant

reductions in pain and improvements in function relative to preoperative levels. Radiographic evidence reported by van der Wal et al. (2009), also showed a slight or moderate increase in osteoarthritis (OA) in 42% of patients (1 or 2 points) and no increase in the other 58%. Of 15 patients with follow-up radiographs in the Hommen et al. (2007) study, 10 (67%) had joint space narrowing, and 12 (80%) had a progression of the Fairbank degenerative joint disease score in the transplanted tibiofemoral compartment.

Table 3. Summary of Case Series Characteristics for Meniscal Allograft Transplantation

Variables	Verdonk et al. (2005) (8)	van der Wal et al. (2009) (10)	Vundelinckx et al. (2010) (11)
Sample size	105	57	34/49
Mean age (range), y	35 (16-50)	39 (26-55)	33 (14-47)
Population	Previous total meniscectomy	Previous total meniscectomy	Patients with intact allograft
Intervention	MAT	MAT	MAT
Control	None	None	None
Length of FU (range)	3 to 15 y	14 y (9 to 18 y)	105 mo

FU: follow-up; MAT: meniscal allograft transplantation; y: year; mo: months.

Table 4. Summary of Case Series Outcomes for Meniscal Allograft Transplantation

Outcomes	Verdonk et al. (2005) (8)			van der Wal et al. (2009) (10)			Vundelinckx et al. (2010) (11)		
	Base	FU	p-value	Base	FU	p-value	Base	FU	p-value
VAS score							7.0	3.4	<0.001
LKS score				36	61	<0.05	39.7	71.8	<0.001
KOOS score							35.8	60.2	<0.001
Graft survival rate		70%			• 11 y: 71% • 16 y: 52.5%			90%	
Mean survival		11.6 y							

Base: baseline; FU: follow-up; LKS: Lysholm Knee Score; KOOS: Knee Injury and Osteoarthritis Outcome Score; VAS: visual analog scale; y: year(s).

Section Summary: Meniscal Allograft Transplantation

Evidence for the use of meniscal allograft transplantation in patients with disabling knee pain and a prior meniscectomy consists of systematic reviews of a large number of case series and an RCT. The reviews have found that meniscal allograft transplantation is associated with reductions in pain and improvements in function. Longer term studies have indicated that these improvements are maintained in a substantial percentage of patients, up to 10 years and beyond. Because the results of a single RCT, which enrolled a very small number of patients, pooled data from randomized and nonrandomized groups, results cannot be interpreted in a

meaningful way. Adverse events, such as graft failure and the need for additional procedures, occur frequently. The strength of the evidence, including accurate estimates of the magnitude of benefit and the complication rates, are limited by the type of data available (case series and systematic reviews of these case series) as well as the heterogeneity in surgical techniques and patient characteristics across the studies.

Meniscal Allograft Transplantation Plus Articular Cartilage Repair

Clinical Context and Therapy Purpose

The purpose of meniscal allograft transplantation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as partial meniscectomy without meniscal allograft transplantation, in individuals who are undergoing partial meniscectomy and repair of malalignment, focal chondral defects and/or ligamentous insufficiency.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are undergoing partial meniscectomy and repair of malalignment, focal chondral defects and/or ligamentous insufficiency.

Interventions

The therapy being considered is meniscal allograft transplantation. Individuals with malalignment, focal chondral defects, and/or ligamentous insufficiency may require additional surgery combined with meniscal allograft transplantation. When meniscal allograft transplantation is combined with osteotomy or articular cartilage repair in a single procedure, meniscal allograft transplantation should be performed first.

Comparators

Comparators of interest include partial meniscectomy without meniscal allograft transplantation.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and quality of life.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Harris et al. (2011) published a systematic review of meniscal allograft transplantation plus cartilage repair or restoration (Table 5). (12) Patients underwent meniscal allograft transplantation with autologous chondrocyte implantation (n=73), osteochondral allograft (n=20), osteochondral autograft (n=17), or microfracture (n=3). All studies showed improvement in clinical outcomes at final follow-up compared with the preoperative condition. Outcomes were similar to historical outcomes, extracted from mid-term and long-term follow-up studies, of procedures performed in isolation. Additional surgeries are common (nearly 50%) after meniscal allograft transplantation plus cartilage repair or restoration procedures.

Table 5. Summary of Systematic Reviews for Meniscal Allograft Transplantation Plus Articular Cartilage Repair

Variables	Harris et al. (2011) (12)
Number and study type	6 case series
Population	110
Intervention	MAT combined with cartilage repair or restoration
Control	• Baseline to posttreatment • Historical controls of procedures performed in isolation
Outcome measures	Pain and Function
Review synthesis	• Outcomes improved from baseline to posttreatment • 4/6 studies found outcomes equivalent to procedures performed in isolation • 2/6 studies found combined surgery not as good as historical controls
Review conclusion	MAT can improve pain and function when combined with cartilage repair or restoration procedures
Review limitations	Based on case series with historical controls

MAT: meniscal allograft transplantation.

The largest and longest study to report on meniscal allograft transplantation in patients with significant (grade III and IV) chondral damage is that by Stone et al. (2010) who reported mean allograft survival of 9.9 years (Table 6). (13) Other prospective studies have reported on graft survival and functional outcomes when meniscal allograft transplantation has been combined with articular cartilage repair. (14, 15)

Case Series

The following studies were published subsequent to the systematic review (Table 6). Kempshall et al. (2015) looked at MAT concomitant with cartilage repair procedures in 1) patients with more knee cartilage damage (grade 3b >1 cm^2) and 2) patients with less knee cartilage damage (grade 3b <1 cm^2). (16) Functional outcomes following the procedures were similar between the 2 groups. However, implant survival (using graft failure as an end point) was lower among those with greater cartilage damage.

Ogura et al. (2016) retrospectively reviewed patients who had undergone autologous chondrocyte implantation (ACI) and MAT. (17) Seventeen patients were followed for a mean of 7.9 years. Significant improvements in clinical outcomes (visual analog scale [VAS] for pain, Western Ontario and McMaster Universities Arthritis Index, 36-Item Short-Form Health Survey, and modified Cincinnati Knee Rating Scale scores) were reported in 65% of the patients. Of the 6 procedures considered failures, 4 underwent total knee arthroplasty and 2 underwent revision surgery.

Zaffagnini et al. (2016) reviewed 147 patients undergoing arthroscopic bone plug-free MAT, with 48% of patients having concomitant procedures (mostly high tibial osteotomy and anterior cruciate ligament reconstruction). (18) Two survival analyses were conducted, one with the end point of surgical failure (need for revision procedures related to initial MAT) and the other with the end point of clinical failure (same revision procedures as a surgical failure or LKS less than 65 at final follow-up). Mean overall survival time with the surgical failure end point was 9.7 years (95% confidence interval [CI], 9.1 to 10.3 years) and mean overall survival with the clinical failure end point was 8.0 years (95% CI, 7.1 to 8.8 years). Logistic regression analysis did not reveal any variables (including concomitant procedures) affecting the surgical or clinical failure end points.

Table 6. Case Series of Meniscal Allograft Transplantation Plus Articular Cartilage Damage

Variables	Stone et al. (2010) (13)	Kempshall et al. (2015) (16)	Ogura et al. (2016) (17)	Zaffagnini et al. (2016) (18)
Sample size	115	99	17	147
Population	Consecutive patients with grade III-IV chondral damage	Prospective series • Grade 3b <1 cm^2 • Grade 3b >1 cm^2	Retrospective series	Retrospective series
Intervention	MAT	MACI and microfracture more common if chondral damage was 3c >1 cm^2	ACI with MAT	MAT
Control	None	None	None	None
Outcome measures	MAT survival	• MAT survival • KOOS, TAS, LKS, IKDC scores	• MAT survival • MCKRS, WOMAC, VAS, SF-36	• MAT survival • KOOS, LKS, VAS
Length of FU	5.8 y	2 y	5 to 10 y	4 y
Results	• Mean MAT survival, 9.9 y	• Similar outcomes on KOOS, TAS, LKS, IKDC	• Mean MAT survival rate, 75% at 5- and 10-y follow-up	• Mean MAT survival range, 8 to 9.7 y

	• 47% required additional surgery	scores for 2 groups • MAT survival was 97.9% if 3b <1 cm^2 and 78% if 3c >1 cm^2	• 67% (12/18) required additional surgery	• 17% required additional surgery

ACI: autologous chondrocyte implantation; FU: follow-up; IKDC: International Knee Documentation Committee; KOOS: Knee Injury and Osteoarthritis Outcome Score; LSK: Lysholm Knee Score; MACI: matrix-assisted autologous chondrocyte implantation; MAT: meniscal allograft transplantation; MCKRS: modified Cincinnati Knee Rating Scale; SF-36: 36-Item Short-Form Health Survey; TAS: Tegner Activity Scale; VAS: visual analog scale; WOMAC: Western Ontario and McMaster Universities Arthritis Index; y: year.

Section Summary: Meniscal Allograft Transplantation Plus and Articular Cartilage Repair
There is limited low-quality evidence on combined MAT and articular cartilage repair. The available literature has reported reductions in pain and improvements in functioning following these procedures, though studies have reported graft failures and the need for additional surgeries.

Collagen Meniscus Implants
Clinical Context and Therapy Purpose
The purpose of collagen meniscus implants is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as partial meniscectomy without a meniscal implant, in individuals who are undergoing partial meniscectomy.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals who are undergoing partial meniscectomy.

Interventions
The therapy being considered is collagen meniscal implants. A collagen meniscus implant is sutured into place on a meniscal rim and is intended for use with a partial meniscectomy.

Comparators
Comparators of interest include partial meniscectomy without a meniscal implant.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and quality of life.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Two systematic reviews, one by Harston et al. (2012) (19) and the other by Warth et al. (2015), (20) are summarized in Table 7. A third systematic review by Zaffagnini et al. (2015) (21) focused only on studies assessing postoperative magnetic resonance imaging evaluations, which included 6 studies, none of which was a RCT and all of which were included in the Warth et al. (2015) review. We do not discuss the Zaffagnini et al. (2015) review further. Houck et al. (2018) and Han et al. (2025) published results of systematic reviews that included multiple scaffold implantations including collagen meniscus implants. (22, 23) No new studies comparing CMI to meniscectomy were identified in these reviews and they are not further discussed.

Table 7. Summary of Key Systematic Reviews for CMI

Variables	Harston et al. (2012) (19)	Warth et al. (2015) (20)
Search date	May 2011	March 2014
No. of studies	11	13
Population	520	674
Intervention	• 321 patients received a CMI • 41.1% patients had concomitant procedures	• 439 patients received CMI • 32.3% patients had concomitant procedures
Control	Partial meniscectomy alone	
Outcome measures	• LKS, TAS, pain scales • 8/11 studies provided postoperative imaging data	• LKS, TAS, pain scales • 11/13 studies provided postoperative imaging data
Length of FU	6 to 135 mo	3 to 152 mo
Review synthesis	• 66% to 70% patients receiving CMI had satisfactory outcomes • Outcomes in studies with control or comparison groups reported improvement in both groups • Reduced CMI size at last follow-up reported in 6 (54.5%) of 11 studies	• CMI showed superior clinical outcomes vs partial meniscectomy alone • Several studies reported that meniscus scaffold decreased in volume over time • Second-look arthroscopy showed presence of newly formed meniscus-like tissue in area of the scaffold
Review limitations	• Based on low-quality evidence	• Mostly level IV evidence

		• No meta-analysis due to differing methodologies and data reporting across studies

CMI: collagen meniscus implant; FU: follow-up; LSK: Lysholm Knee Score; mo: month(s); No: number; TAS: Tegner Activity Scale.

The quality of the studies included in the systematic reviews was generally rated as low. Tables 8 and 9 summarize select studies (2 RCTs, 2 cohorts) included in the systematic reviews. A large RCT from the manufacturers of MenaFlex (Rodkey et al. [2008] [24]) was conducted under a U.S. Food and Drug Administration (FDA) investigational device exemption. Only TAS scores in the chronic arm (but not the acute arm) differed significantly between the CMI and partial meniscectomy only groups. Kaplan-Meier analysis suggested a modest 10% increase in survival in the chronic CMI group.

Randomized Controlled Trials

An independent research group published results from an RCT, reported by Linke et al. (2006), comparing high tibial valgus osteotomy alone with osteotomy plus CMI. (25) Arthroscopy in the CMI group showed 35% complete healing, 30% partial healing requiring resection of the posterior part of the implant, and 35% with only small remains of the CMI left. Complications included implantation in insufficiently vascularized tissue, sutures cutting into the implant, inadequate fixation to the rim, destruction of the implant in an unstable knee joint or with premature loading postoperatively, allergic reaction to the xenogenic collagen implant, avulsion of the implant with joint blocking, and infection. Pain and function scores did not differ significantly between the CMI and control groups.

Observational Studies

Zaffagnini et al. (2011) compared outcomes of 18 patients who chose CMI with 18 patients who chose partial medial meniscectomy, with a minimum 10-year follow-up. (26) The two groups were comparable at baseline. No significant differences were found in the LKS and Yulish scores. Independent and blinded radiographic evaluation showed significantly less medial joint space narrowing in the CMI group (0.48 mm) than in the partial meniscectomy group (2.13 mm). This study had the potential for selection bias.

A retrospective review by Bulgheroni et al. (2015) of 34 patients (17 CMI, 17 partial medial meniscectomies) found no significant differences between the groups for pain and function scores at an average of 9.6 years of follow-up. (27)

Table 8. Summary of Study Characteristics for Collagen Meniscus Implants

Variables	Rodkey et al. (2008) (24)	Linke et al. (2006) (25)	Zaffagnini et al. (2011) (26)	Bulgheroni et al. (2015) (27)
Study design	RCT	RCT	Controlled cohort	Retrospective cohorts
Sample size	311	60	36	34

Population	Acute and chronic partial meniscectomy		Patient choice	Matched controls
Intervention	CMI	Osteotomy plus CMI	CMI	CMI
Control	Partial meniscectomy alone	Osteotomy alone	Partial meniscectomy alone	Partial meniscectomy alone
Length of FU (range)	59 mo (16-92 mo)	8-18 mo	133 mo (120-152 mo)	9.6 y

CMI: collagen meniscus implant; FU: follow-up; mo: month; RCT: randomized control trial; y: year.

Table 9. Summary of Study Results for Collagen Meniscus Implants

Outcomes	**Rodkey et al. (2008) (24)**			**Linke et al. (2006) (25)**			**Zaffagnini et al. (2011) (26)**			**Bulgheroni et al. (2015) (27)**		
	CMI	Ctrl	p	CMI	Ctrl	p	CMI	Ctrl	p	CMI	Ctrl	p
Survival rate	90%[a]	80%[a]		65%			89%					
VAS pain	19/100[a]	21/100[a]		2.2/10	1.5/10	*NS*	1.2/10	3.3/10	<0.004	14.7/100	13.5/100	*NS*
LKS score	79[a]	78[a]	*NS*	93.6	91.0	*NS*	≈86	≈80	*NS*	94.1	95.5	*NS*
IKDC score						*NS*			<0.001[b]	85.7	88.1	*NS*
TAS score	42%[a]	29%[a]	<0.02				75	50	<0.026	mean, 6 (SD, 5-6)	mean, 6 (SD, 5-6)	*NS*

CMI: collagen meniscus implant; Ctrl: control; IKDC: International Knee Documentation Committee; LSK: Lysholm Knee Score; *NS*: Not significant; SD: standard deviation; TAS: Tegner Activity Scale; VAS: Visual Analog Scale.

[a] Chronic only.

[b] Higher scores reported by CMI group versus control group.

Section Summary: Collagen Meniscus Implants

Evidence for the use of collagen meniscus implants in patients undergoing partial meniscectomies consists of systematic reviews, the largest including 674 patients. The reviews reported overall positive results with collagen meniscus implants, but the quality of the included studies (RCTs and observational studies) was low. Radiologic evaluation showed destruction and/or absorption of the implant in a very large portion of patients.

Summary of Evidence

For individuals who are undergoing partial meniscectomy who receive meniscal allograft transplantation, the evidence includes systematic reviews of mostly case series and a randomized controlled trial (RCT). Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic reviews concluded that most studies have shown statistically significant improvements in pain and function following the procedure. The benefits have also been shown to have a long-term effect (>10 years). Reviews have also reported acceptable complication and failure rates. There remains no evidence that meniscal allograft transplantation can delay or prevent the development of knee osteoarthritis. A limitation of the evidence is its reliance primarily on case series. Because the results of the single RCT, which enrolled a very small number of patients, pooled data from randomized and nonrandomized groups, results cannot be interpreted in a meaningful way. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are undergoing partial meniscectomy and concomitant repair of malalignment, focal chondral defects, and/or ligamentous insufficiency who receive meniscal allograft transplantation, the evidence includes a systematic review of case series as well as case series published after the systematic review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review concluded that pain and function improved following the procedure. One of the series published after the review showed that patients with more severe cartilage damage experienced favorable outcomes similar to patients with less cartilage damage. Another series published subsequently reported an overall 9.7-year survival of the implant. A limitation of the evidence is its reliance primarily on case series. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing partial meniscectomy who receive collagen meniscal implants, the evidence includes several systematic reviews primarily of case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The reviews reported overall positive results with the CMI, but the quality of the selected studies (RCTs, observational studies) was low. Radiologic evaluations have shown reductions in the size of the implant in a large portion of patients. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons (AAOS) published guidelines on acute isolated meniscal pathology in 2024. (28) These guidelines do not include information on meniscal allografts or implants.

International Meniscus Reconstruction Experts Forum

In 2015, the International Meniscus Reconstruction Experts Forum published consensus statements on the practice of MAT (Table 10). (2) The Forum's statements included guidance on indications, graft procurement and preparation, surgical technique, and rehabilitation.

Table 10. Select Consensus Statements on the Practice of Meniscal Allograft Transplantation

Statement
Indications for Meniscal Allograft Transplantation: • Unicompartmental pain post-meniscectomy; • In combination with anterior cruciate ligament reconstruction when meniscus deficient; • In combination with articular cartilage repair if meniscus deficient.
Meniscal Allograft Transplantation not recommended for asymptomatic meniscus deficient patient.
Potentially poorer outcomes expected in patients with moderate to severe OA (Kellgren-Lawrence grade ≥3).
Non-irradiated fresh frozen or fresh viable grafts are recommended.
Mechanical axis alignment should be performed prior to meniscal allograft transplantation; if mechanical axis deviation present, consider realignment osteotomy.
Based on current evidence, the superiority of 1 surgical technique over another (all-suture versus bone) is not established.
Outcome scores should include: • Disease-specific: Western Ontario Meniscal Evaluation Tool • Region-specific: Knee injury and Osteoarthritis Outcome Score • Activity: Marx Activity Rating Scale • Quality of life/utility: EuroQoL 5 dimensions questionnaire

OA: osteoarthritis.

National Institute for Health and Care Excellence (NICE)

In 2012, the guidance from the NICE stated that the evidence on "partial replacement of the meniscus of the knee using a biodegradable scaffold raises no major safety concerns," but evidence for any advantage of the procedure over standard surgery was limited. (29)

Medicare National Coverage

The Centers for Medicare & Medicaid Services (2010) issued a national noncoverage determination for the collagen meniscus implant. (30) A number of concerns regarding the efficacy and safety were raised by the Centers for Medicare & Medicaid Services analysis, which compared data reported to the U.S. Food and Drug Administration and published data. Concerns included an increased number of reoperations and a higher serious adverse event rate than in the control group. Centers for Medicare & Medicaid Services concluded that the collagen meniscus implant does not improve health outcomes in the Medicare population and that collagen meniscus implant is not reasonable and necessary for the treatment of meniscal injury or tear.

Ongoing and Unpublished Clinical Trials

No relevant currently ongoing or unpublished trials that might influence this policy were identified.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	29868
HCPCS Codes	G0428

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/15/2025	Document updated with literature review. The following changes were made to Coverage: Removed the following: Meniscal allograft transplantation of the knee is considered not medically necessary as a treatment for symptomatic patients with partial or complete loss of the meniscus when criteria listed above are not met or as a treatment for asymptomatic patients with partial or complete loss of the meniscus. Note 1 moved to Policy Guidelines. References 23 and 31 added; others updated.
06/15/2024	Reviewed. No changes.

12/01/2023	Document updated with literature review. The following editorial change was made to coverage: Changed “patients” to “individuals”. No new references added; others updated.
10/15/2022	Reviewed. No changes.
09/01/2021	Document updated with literature review. Editorial changes made to Coverage without change to intent. Reference 29 added, others updated or removed.
07/01/2020	Document updated with literature review. Coverage unchanged. References 31-33 were added.
10/01/2018	Document updated with literature review. Coverage unchanged. References 1-3, 6, 7, 17, 18, 20-22 were added; numerous removed.
07/15/2017	Reviewed. No changes.
09/15/2016	Document updated with literature review. The following criteria changed to: 1) Absence or near absence (> 50%) of the meniscus, established by imaging or prior surgery; and 2) Minimal to absent diffuse degenerative changes in surrounding articular cartilage (Outerbridge grade O, I, or II, < 50% joint space narrowing.
02/01/2015	Document updated with literature review. The following was added: 1) additions to criterion regarding the type of surgery planned, biomechanics, conservative therapies; 2) documentation required for review of procedures; 3) meniscal allograft transplantation (MAT) may be considered medically necessary when performed in combination, either concurrently or sequentially, with autologous chondrocyte implantation, osteochondral allografting, or osteochondral autografting for focal articular cartilage lesions; AND 4) use of other meniscal implants such as collagen and polyurethane are considered experimental, investigational and/or unproven. Description and Rationale substantially revised and reorganized. Title changed from Meniscal Allograft Transplantation. Policy number has been changed from SUR703.011.
02/15/2010	Revised/updated entire document. Coverage added to allow for adolescents ≥ 15 years of age when meeting criteria. This policy is no longer scheduled for routine literature review and update.
08/15/2007	Revised/updated entire document
12/01/2003	Revised/updated entire document
01/01/2000	Revised/updated entire document
07/01/1999	Revised/updated entire document
05/01/1996	Medical policy number changed
04/01/1996	Revised/updated entire document
07/01/1994	New medical document