| 7.01.15 | Meniscal Allografts and Other Meniscal Implants | | |
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| **Original Policy Date:** | June 30, 2015 | **Effective Date:** | July 1, 2023 |
| **Section:** | 7.0 Surgery | **Page:** | Page 1 of 18 |

## Policy Statement

I. Meniscal allograft transplantation 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:
   A. Adult individuals should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., less than 55 years)
   B. Disabling knee pain with activity that is refractory to conservative treatment
   C. Absence or near absence (greater than 50%) of the meniscus, established by imaging or prior surgery
   D. Documented minimal to absent diffuse degenerative changes in the surrounding articular cartilage (e.g., Outerbridge grade II or less, less than 50% joint space narrowing)
   E. Normal knee biomechanics or alignment and stability achieved concurrently with meniscal transplantation

II. Meniscal allograft transplantation 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:
   A. Autologous chondrocyte implantation
   B. Osteochondral allografting
   C. Osteochondral autografting

III. Use of other meniscal implants incorporating materials such as collagen are considered **investigational**.

**NOTE**: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

## 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 greater than 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.

### Coding

There is a CPT category I code specific to this procedure when performed arthroscopically:

- **29868**: Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral

There is no CPT code for implantation of the ReGen Collagen Scaffold, but the American Academy of Orthopaedic Surgeons' Coding, Coverage and Reimbursement Committee has recommended that CPT code 29868 for meniscal transplantation is appropriate for this procedure.

## Description

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

## Related Policies

- Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions
- Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## 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 with FDA clearance at that time. Amid controversy about this 510(k) clearance, 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). CMI is the only FDA-approved collagen meniscus product currently on the market.

FDA product code: OLC.

## Rationale

**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. 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 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 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, posttransplantation 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, nonirradiated 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 nonirradiated 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. Other scaffold materials and cell-seeding techniques are being investigated. Nonabsorbable 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.

### Literature Review
Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, 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 quality and credibility. To be relevant, studies must represent 1 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

## 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 patients who are undergoing partial meniscectomy.

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

#### *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 patients 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.

### Review of Evidence

### 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 1 136 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 posttreatment 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=1 623 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 Systematic Reviews of Meniscal Allograft Transplantation**

| Variables | Elattar et al (2011)[4,] | Herganet al (2011)[5,] | Rosso et al (2015)[6,] |
|---|---|---|---|
| **No. and study type** | 44 cohort and case series | 14 cohort and case series with minimum 2-y follow-up | 55 (2 level II, 7 level III, 46 level IV) |
| **Population** | 1 136 knees (1068 patients) | 196 knees | 1 623 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-/postmeasures[a]:<br>• VAS pain score decreased from 6.4 to 2.4<br>• 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% |

| Variables | Elattar et al (2011)[4,] | Herganet al (2011)[5,] | Rosso et al (2015)[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 for cartilage defects, limb malalignment, and/or limb instability | Agreement in literature on MAT indications:<br>• All studies showed clinical improvement at short- and mid-term follow-ups<br>• Complication and failure rates acceptable<br>• 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; VAS: visual analog scale.
[a] Data from 37 of the 55 studies in the systematic review.

### Randomized Controlled Trials

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 the preference group), receiving MAT (n=6) or personalized physical therapy (n=9). The Knee Injury and Osteoarthritis Outcome Score (KOOS), International Knee Documentation Committee score, 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 the MAT group for KOOS composite score (mean difference, 12; p=.03) and KOOS subscales of pain (mean difference, 15; p=.02) and activities of daily living (mean difference, 18; p=.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 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,] | Vundelinckxet al (2010)[11,] |
|---|---|---|---|
| **Sample size** | 105 | 57 | 34/49 |
| **Mean age (range), y** | 35 (16 to 50) | 39 (26 to 55) | 33 (14 to 47) |

| Variables | Verdonk et al (2005)[8,] | Van der Wal et al (2009)[10,] | Vundelinckxet al (2010)[11,] |
|---|---|---|---|
| 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.

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 | <.001 |
| LKS score | | | | 36 | 61 | <.05 | 39.7 | 71.8 | <.001 |
| KOOS score | | | | | | | 35.8 | 60.2 | <.001 |
| Graft survival rate | | 70% | | | • 11 y: 71%<br>• 16 y: 52.5% | • | | 90% | |
| Mean survival | | 11.6 y | | | | | | | |

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

### Section Summary: Meniscal Allograft Transplantation

Evidence for the use of MAT 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 MAT 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 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 and repair of malalignment, focal chondral defects and/or ligamentous insufficiency.

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

#### *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 MAT. Patients with malalignment, focal chondral defects, and/or ligamentous insufficiency may require additional surgery combined with MAT. When MAT is combined with osteotomy or articular cartilage repair in a single procedure, MAT should be performed first.

*Comparators*
Comparators of interest include partial meniscectomy without MAT.

*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.

### Review of Evidence
### Systematic Reviews
Harris et al (2011) published a systematic review of MAT plus cartilage repair or restoration (Table 5).[12,] Patients underwent MAT 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 MAT 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,] |
|---|---|
| **No. and study type** | 6 case series |
| **Population** | 110 |
| **Intervention** | MAT combined with cartilage repair or restoration |
| **Control** | • Baseline to posttreatment<br>• Historical controls of procedures performed in isolation |
| **Outcome measures** | Pain and function |
| **Review synthesis** | • Outcomes improved from baseline to posttreatment<br>• 4/6 studies found outcomes equivalent to procedures performed in isolation<br>• 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 MAT 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 MAT 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 endpoint) was lower among those with greater cartilage damage.

Ogura et al (2016) retrospectively reviewed patients who had undergone autologous chondrocyte implantation and MAT.[17] Seventeen patients were followed for a mean of 7.9 years. Significant improvements in clinical outcomes (visual analog scale 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, 1 with the endpoint of surgical failure (need for revision procedures related to initial MAT) and the other with the endpoint 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 endpoint was 9.7 years (95% confidence interval [CI], 9.1 to 10.3 years) and mean overall survival with the clinical failure endpoint 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 endpoints.

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

| 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<br>• Grade 3b <1 cm2<br>• Grade 3b >1 cm2 | Retrospective series | Retrospective series |
| **Intervention** | MAT | MACI and microfracture more common if chondral damage was 3c >1 cm2 | ACI with MAT | MAT |
| **Control** | None | None | None | None |
| **Outcome measures** | MAT survival | • MAT survival<br>• KOOS, TAS, LKS, IKDC scores | • MAT survival<br>• MCKRS, WOMAC, VAS, SF-36 | • MAT survival<br>• KOOS, LKS, VAS |
| **Length of FU** | 5.8 y | 2 y | 5 to 10 y | 4 y |
| **Results** | Mean MAT survival, 9.9 y<br>47% required additional surgery | • Similar outcomes on KOOS, TAS, LKS, IKDC scores for 2 groups<br>• MAT survival 97.9% if 3b <1 cm2 and 78% if 3c >1 cm2 | • Mean MAT survival rate, 75% at 5- and 10-y follow-up<br>• 67% (12/18) required additional surgery | • Mean MAT survival range, 8 to 9.7 y<br>• 17% required additional surgery |

ACI: autologous chondrocyte implantation; FU: follow-up; IKDC: International Knee Documentation Committee; KOOS: Knee Injury and Osteoarthritis Outcome Score; LKS: 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.

### Section Summary: Meniscal Allograft Transplantation Plus 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 meniscal implants (CMIs) 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 with who are undergoing partial meniscectomy.

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

#### *Populations*

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

#### *Interventions*

The therapy being considered is CMIs. A CMI 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.

### Review of Evidence

### 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 an 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) published the results of a systematic review that included multiple scaffold implantations including CMI.[22,] No studies in addition to those previously summarized by Warth et al (2015)[20,] were cited in this systematic review and Houck et al (2018) is not discussed further.

**Table 7. Summary of Systematic Reviews for Collagen Meniscus Implants**

| 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 | • 439 patients received CMI |

| Variables | Harston et al (2012)[19,] | Warth et al (2015)[20,] |
|---|---|---|
| | • 41.1% patients had concomitant procedures | • 32.3% patients had concomitant procedures |
| **Control** | Partial meniscectomy alone | |
| **Outcome measures** | • LKS, TAS, pain scales<br>• 8/11 studies provided postoperative imaging data | • LKS, TAS, pain scales<br>• 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<br>• Outcomes in studies with control or comparison groups reported improvements in both groups<br>• Reduced CMI size at last follow-up reported in 6 (54.5%) of 11 studies | • CMI showed superior clinical outcomes vs partial meniscectomy alone<br>• Several studies reported that meniscus scaffold decreased in volume over time<br>• 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<br>• No meta-analysis due to differing methodologies and data reporting across studies |

CMI: collagen meniscus implant; FU: follow-up; LKS: Lysholm Knee Score; 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][23,]) was conducted under a U.S. Food and Drug Administration 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.[24,] 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.[25,] The 2 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.[26,]

**Table 8. Summary of Study Characteristics for Collagen Meniscus Implants**

| Variables | Rodkey et al (2008)[23,] | Linke et al (2006)[24,] | Zaffagnini et al (2011)[25,] | Bulgheroni et al 2015)[26,] |
|---|---|---|---|---|
| **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 to 92 mo) | 8 to 18 mo | 133 mo (120 to 152 mo) | 9.6 y |

CMI: collagen meniscus implant; FU: follow-up; RCT: randomized controlled trial.

**Table 9. Summary of Study Results for Collagen Meniscus Implants**

| Outcomes | Rodkey et al (2008)[23,] | | | Linke et al (2006)[24,] | | | Zaffagnini et al (2011)[25,] | | | Bulgheroni et al (2015)[26,] | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | CMI | Ctrl | p-value | CMI | Ctrl | p-value | CMI | Ctrl | p-value | CMI | Ctrl | p-value |
| **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 | <.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* | | | <.001[b] | 85.7 | 88.1 | *NS* |
| **TAS score** | 42%[a] | 29%[a] | <.02 | | | | 75 | 50 | <.026 | mean, 6 (SD, 5-6) | mean, 6 (SD, 5-6) | *NS* |

CMI: collagen meniscus implant; Ctrl: control; IKDC: International Knee Documentation Committee; LKS : Lysholm Knee Score; NS: not significant; TAS: Tegner Activity Scale; VAS: visual analog scale.
[a] Chronic only. [b] Higher scores reported by CMI group vs. control group.

### Section Summary: Collagen Meniscal Implants

Evidence for the use of CMI in patients undergoing partial meniscectomies consists of 2 systematic reviews, the most recent including 674 patients. The reviews reported overall positive results with CMI, 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.

### Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

### 2011 Input

In response to requests, input was received from 1 physician specialty society (3 reviewers) and 3 academic medical centers while this policy was under review in 2011. Input considered combined meniscal allograft transplantation (MAT) and focal cartilage repair procedures to be medically necessary for patients younger than 55 years of age who have failed conservative treatment. Reviewers agreed that the collagen meniscus implant is investigational, although some considered it to be both investigational and medically necessary for some patients.

### 2008 Input

In response to requests, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2008. Although long-term effects on joint space narrowing were unknown, all reviewers considered MAT to be beneficial in selected patients, with evidence of short to intermediate pain relief when performed in younger patients who had a prior meniscectomy and disabling knee pain. Contraindications noted were uncorrected instability, uncorrected malalignment, and the presence of significant articular disease.

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### 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**

| Statements |
|---|
| **Indications for MAT:**<br>• **Unicompartmental pain post-meniscectomy**<br>• **In combination with anterior cruciate ligament reconstruction when meniscus deficient**<br>• **In combination with articular cartilage repair if meniscus deficient** |
| **MAT 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 MAT; if mechanical axis deviation present, consider realignment osteotomy.** |
| **Based on current evidence, the superiority of 1 surgical technique over another (all-suture vs bone) is not established.** |
| **Outcome scores should include:**<br>• **Disease-specific: Western Ontario Meniscal Evaluation Tool**<br>• **Region-specific: Knee injury and Osteoarthritis Outcome Score**<br>• **Activity: Marx Activity Rating Scale**<br>• **Quality of life/utility: EuroQoL 5 dimensions questionnaire** |

MAT: meniscal allograft transplantation; OA: osteoarthritis.

### National Institute for Health and Care Excellence

In 2012, the guidance from the National Institute for Health and Care Excellence 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.[27,]

### American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons (2009) updated its position in 2014, still recommending MAT for active people younger than 55 years old, with the goal of replacing the meniscus cushion before the articular cartilage is damaged.[28,] The website also notes that "synthetic (artificial) meniscal tissue has been tried, but there is conflicting information at this time."

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

The Centers for Medicare & Medicaid Services (2010) issued a national noncoverage determination for the collagen meniscus implant.[29,] 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

Currently ongoing and unpublished trials that might influence this review are listed in Table 11.

**Table 11. Summary of Ongoing Trials**

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| *Ongoing* | | | |
| **NCT02483988** | The SUN Clinical Trial (Safety Utilizing NUsurface Meniscus Implant). A Multi-Center, Single-arm, Prospective, Open-label, Non-randomized, Observational Clinical Study | 115 | Jun 2023 |
| *Unpublished* | | | |
| **NCT02108496[a]** | The VENUS Clinical Study (Verifying the Effectiveness of the NUSurface® System): A Multi-centered, Prospective, Randomized, Interventional Superiority Clinical Study | 127 | May 2022 (completed) |
| **NCT01712191[a]** | Treatment of the Medial Meniscus with the NUSurface® Meniscus Implant | 150 | Mar 2016 (completed) |

NCT: national clinical trial. [a] Denotes industry-sponsored or cosponsored trial.

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## Documentation for Clinical Review

**Please provide the following documentation:**

- History and physical and/or consultation notes including:
  - Description of the knee structure (e.g., articular cartilage defects [including grade] and surrounding articular cartilage degenerative changes)
  - Knee biomechanics (i.e., stability and alignment) on physical exam
  - Reason patient is not a candidate for total knee arthroplasty
  - Prior treatment (surgical and non-surgical) and patient response(s)
  - Type and reason for requested procedure including all materials/tissue to be used
- Progress notes specific to the condition and request (if applicable)
- Diagnostic radiology reports (including Outerbridge classification)

**Post Service (in addition to the above, please include the following):**

- Operative report(s)

## Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

| Type | Code | Description |
|---|---|---|
| CPT® | 29868 | Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral |
| HCPCS | G0428 | Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex) |

## Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

| Effective Date | Action |
|---|---|
| 06/30/2015 | BCBSA Medical Policy adoption |
| 05/01/2017 | Policy revision without position change |
| 06/01/2017 | Policy revision without position change |
| 06/01/2018 | Policy revision without position change |
| 11/01/2019 | Policy revision without position change |
| 07/01/2023 | Policy reactivated. Previously archived from 04/01/2020 to 06/30/2023. |

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

## Appendix A

| POLICY STATEMENT | |
|---|---|
| **BEFORE** | **AFTER**<br>**Blue font: Verbiage Changes/Additions** |
| **Reactivated Policy**<br><br>**Policy Statement:**<br>N/A | **Meniscal Allografts and Other Meniscal Implants 7.01.15**<br><br>**Policy Statement:**<br>I. Meniscal allograft transplantation 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:<br>A. Adult individuals should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., less than 55 years)<br>B. Disabling knee pain with activity that is refractory to conservative treatment<br>C. Absence or near absence (greater than 50%) of the meniscus, established by imaging or prior surgery<br>D. Documented minimal to absent diffuse degenerative changes in the surrounding articular cartilage (e.g., Outerbridge grade II or less, less than 50% joint space narrowing)<br>E. Normal knee biomechanics or alignment and stability achieved concurrently with meniscal transplantation<br><br>II. Meniscal allograft transplantation 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:<br>A. Autologous chondrocyte implantation<br>B. Osteochondral allografting<br>C. Osteochondral autografting<br><br>III. Use of other meniscal implants incorporating materials such as collagen are considered **investigational**. |