BlueCross BlueShield of Alabama

**Name of Policy:**

# Meniscal Allografts and Other Meniscus Implants

Policy #: 158
Category: Surgery

Latest Review Date: May 2018
Policy Grade: B

## Background/Definitions:

*As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.*

*The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:*

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

*Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:*

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *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 that patient's illness, injury or disease.*

## Description of Procedure or Service:

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 resection of the meniscus.

**Meniscal Cartilage**

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 United States of 0.24 per 100,000. 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 osteoarthrosis that is localized to the meniscus-deficient compartment;
- patients undergoing ACL 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 the most appropriate surgical techniques. The four 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 (Marietta, GA) 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, graft shrinkage, poor rehydration, post-transplantation joint effusion, and synovitis and 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 type of allograft preference, 68% responded fresh frozen nonirradiated allografts, with 14% responding fresh viable allografts.

There are several techniques for MAT; most are arthroscopic-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).

Tissue engineering that grows new replacement host tissue is also being investigated. For example, the Collagen Meniscus Implant (Ivy Sports Medicine, formerly the ReGen Collagen Scaffold by ReGen Biologics), is a resorbable collagen matrix comprised 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 own 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. Non-absorbable and non-porous synthetic implants for total meniscus replacement are in development. One total meniscus replacement that is in early phase clinical testing is NUsurface® (Active Implants), which 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.

## Policy:

**Effective for dates of service on or after April 30, 2017:**

**Meniscal allograft transplantation meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage in patients who have had a prior meniscectomy and have symptoms related to the affected side, when **all** of the following criteria are met:

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

**Meniscal allograft transplantation meets Blue Cross and Blue Shield of Alabama's** medical criteria for coverage and is considered **medically necessary** when performed in combination, either concurrently or sequentially, with autologous chondrocyte implantation or osteochondral allografting or osteochondral autografting for focal articular cartilage lesions.

**Meniscal allograft transplantation is contraindicated and does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the following:**

- Uncorrected misalignment and instability of the joint
- Severe obesity, e.g., body mass index (BMI) >35kg/$m^2$, may affect outcomes due to the increased stress on weight bearing surfaces of the joint

**Other meniscal implants** incorporating materials such as collagen and polyurethane **do not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational.**

*Conservative therapy is the use of structured physician-directed modalities which may include: prescription strength analgesics/anti-inflammatory medications if not contraindicated; participation in therapeutic physical medicine modality(ies) and/or manipulations when rendered by an eligible provider (including active exercise).

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**Effective for dates of service on or after July 26, 2011 through April 30, 2017:**

**Meniscal allograft transplantation meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage in patients who have had a prior meniscectomy and have symptoms related to the affected side, when **all** of the following criteria are met:

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

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**Other meniscal implants** incorporating materials such as collagen and polyurethane **do not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational.**

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

## Key Points:

This evidence review has been updated regularly with searches using the MEDLINE database. The most recent literature update was performed through February 5, 2018.

Evidence reviews 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, and ability to function- including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to 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 a 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.
The primary literature consists of retrospective case series and systematic reviews of these case series. Two main issues are investigated; (1) does meniscal allograft transplantation improve pain and function? and (2) does this procedure reduce joint degeneration?

**Meniscal Allograft Transplantation**

Systematic Reviews

Several systematic reviews of the available case series have found improvements in pain and function at mid-term follow-up, with failure rates at the time of follow-up that range from 7% to 35% (Table 1). Elattar et al (2011) published a large systematic review with a total of 1136 allografts. Twelve different clinical scoring systems were described; which generally showed an improvement in pain and function. Hergen et al (2011) conducted another systematic review of the literature to evaluate characteristics of patients, graft survival, and clinical outcomes. Analysis found that patients with Outerbridge scores of two or less in any area had significantly improved posttreatment Lysholm Knee Score (LKS) and Tegner Activity Scale scores, whereas

patients with Outerbridge Grade 3 or greater in any area (not repaired) did not. Studies that analyzed patients undergoing concomitant procedures did not detect a difference between the subgroup in comparison with meniscal allograft transplantation alone. Functional outcomes were considered generally good where reported. In 2015, Rosso et al published a systematic review including 55 studies (total N=1623 patients). Data from 37 studies were included in demographic and outcome analyses. These systematic reviews, which are based primarily on Level IV evidence, summarize the short- to medium-term outcomes of meniscal allograft transplant (see Table 1).Several case series with longer term follow-up are detailed in Tables 2 and 3.

**Table 1. Summary of Key Systematic Reviews of MAT**

| Variables | Elattar et al (2011) | Hergan et al (2011) | Rosso et al (2015) |
|---|---|---|---|
| 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 | 1136 knees (1068 patients) | 196 knees | 1623 patients |
| Follow-up (range) | 4.6 y (8 mo to 20 y) | 53.8 mo (24-167 mo) | 53.6 mo (12-168 mo) |
| 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%-35% | Fresh frozen: 9.9%<br>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 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). Another 15 patients who were screened for the RCT decided instead to choose their treatment (referred to as preference group) received 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 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 2 and 3. 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. The indication for transplantation was moderate-to-severe pain in a patient who had undergone a previous total meniscectomy, not old enough to be considered for a knee joint replacement, and had good alignment of the lower limb and a stable joint (some were corrected concomitantly). Concomitant procedures to improve alignment and stability of the knee are frequently reported. In the study by Hommen et al (2007), concomitant procedures were performed in 75% of the patients, including anterior cruciate ligament (ACL) reconstruction or revision (n=10), high tibial osteotomy (n=2), and lateral retinaculum release (n=3).

At a mean of 16 years of follow-up, Van der Wal et al reported graft survival decreased to 52.5%.6 Most failures in the study by Vundelinckx et al (2010) occurred approximately 10 years postoperatively; average 105-month follow-up from the 34 remaining patients showed significant improvements in pain and function relative to preoperative levels. One question that is frequently asked is whether meniscal allografts can slow the progression to osteoarthritis. Radiographic evaluation in the study by Van der Wal et al showed a slight or moderate increase in osteoarthritis (OA) in 42% of the patients (1 or 2 points), and no increase in OA in 58% of patients. Of 15 patients with follow-up radiographs in the study by Hommen et al, 10 (67%) had joint space narrowing, and 12 (80%) had progression of the Fairbank degenerative joint disease score in the transplanted tibiofemoral compartment.

**Table 2. Summary of Key Case Series Characteristics for MAT**

| Variables | Verdonk et al (2005) | Van der Wal et al (2009) | Vundelinckx et al (2010) |
|---|---|---|---|
| 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) | 3-15 y | 14 y (9-18 y) | 105 mo |

FU: follow-up; MAT: meniscal allograft transplantation.

**Table 3. Summary of Key Case Series Outcomes for Meniscal Allograft Transplantation**

| Outcomes | Verdonk et al (2005) | | | Van der Wal et al (2009) | | | Vundelinckx et al (2010) | | |
|---|---|---|---|---|---|---|---|---|---|
| | Base | FU | p | Base | FU | p | Base | FU | p |
| 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%<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.

**Combined Meniscus Transplantation and Articular Cartilage Repair**

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.

The evidence available for the efficacy of meniscus transplantation in knees with chondral damage consists of one prospective comparative study, case series, most of which are retrospective and systematic reviews of case series.

Systematic Reviews

Harris et al (2011) published a systematic review of MAT plus cartilage repair or restoration (see Table 4). Patients underwent MAT with autologous chondrocyte implantation (ACI; 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 4. Summary of Key Systematic Reviews**

| Variables | Harris et al (2011) |
|---|---|
| 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 meniscal allograft transplantation in patients with significant (Grade III and IV) chondral damage is by Stone et al who found that the mean allograft survival was 9.9 years. Other prospective studies have reported on graft survival and functional outcomes when meniscal allograft transplantation is combined with articular cartilage repair (Table 5).

Case Series

The following studies were published subsequent to the systematic review. Kempshall et al (2015) looked at MAT concomitant with cartilage repair procedures on (1) patients with knees that had cartilage damage at the grade 3b >1 cm2 level, and (2) patients with knees that had less cartilage damage (grade 3b <1 $cm^2$). Functional outcomes following the procedures were similar between the two groups. However, implant survival (using graft failure as endpoint) was lower among patients with greater cartilage damage (see Table 5).

Ogura et al (2016) retrospectively reviewed of patients who had undergone autologous chondrocyte implantation and MAT. Seventeen patients were followed for a mean of 7.9 years. Significant improvements in clinical outcomes (VAS pain, WOMAC, SF-36, and modified Cincinnati Knee Rating Scale scores) were reported in 65% of the patients. Of the 6 procedures considered failures, 4 underwent TKA and 2 underwent revision surgery.

Zaffagnini et al (2016) reviewed 147 patients undergoing arthroscopic bone plug free MAT, with 48% of the patients having concomitant procedures (majority high tibial osteotomy and ACL reconstruction). Two survival analyses were conducted, one with the end point of surgical failure (need for revision procedures related to initial MAT: TKA, meniscectomy due to graft tear, or revision MAT) and the other with the end point of clinical failure (same revision procedures as surgical failure or LKS less than 65 at final follow-up). Mean overall survival time with surgical failure end point was 9.7 years (95% CI, 9.1 to 10.3 years) and mean overall survival with clinical failure end point was 8.0 years (95% CI, 7.1 to 8.8 years). Logistic regressions did not reveal any variables (including concomitant procedures) affecting surgical or clinical failure end points.

**Table 5. Series of MAT with Articular Cartilage Repair**

| Variables | Stone et al (2010) | Kempshall et al (2015) | Ogura et al (2016) | Zaffagnini et al (2016) |
|---|---|---|---|---|
| Sample size | 115 | 99 | 17 | 147 |
| Population | Consecutive patients with grade III-IV chondral damage | Prospective series<br>• Grade 3b <1 $cm^2$<br>• 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<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 | 5-10 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 $cm^2$ and 78% if 3c >1 $cm^2$ | • Mean MAT survival rate, 75% at 5- and 10-y follow-up<br>• 67% (12/18) required additional surgery | • Mean MAT survival range, 8-9.7 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; LSK: Lysholm Knee Score; MACI: matrix-assisted autologous chondrocyte implantation; MAT: meniscal allograft transplantation; MCKRS: modified Cincinnati Knee Rating Scale; OAT: osteochondral autograft transplantation; 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

There is a limited amount of low-quality evidence on combined meniscal allograft transplant and articular cartilage repair. The available literature reports improvements in pain and functioning following these procedures, though there are reports of graft failure and the need for additional procedures.

## Collagen Meniscus Implants

The collagen meniscus implant (CMI) is sutured into place on a meniscal rim and is intended for use with a partial meniscectomy. Therefore, the literature search focuses on controlled trials that compare health outcomes with a collagen meniscus implant versus partial meniscectomy alone. The literature to date consists of case series, a large randomized controlled trial (RCT) that was sponsored by the manufacturer, a smaller RCT from Germany, and a small prospective comparative cohort study.

Two systematic reviews, one by Harston et al (2012) and the other by Warth et al (2015), are summarized in Table 6. A third, by Zaffagnini et al (2015), 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 review. We do not discuss the Zaffagnini review further. Houck et al (2018) published the results of a systematic review that included multiple scaffold implantations including CMI. No studies in addition to those

previously summarized by Warth were cited in this systematic review and Houck is not discussed further.

**Table 6. 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<br>• 41.1% patients had concomitant procedures | • 439 patients received CMI<br>• 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 | 6-135 mo | 3-152 mo |
| Review synthesis | • 66%-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; LSK: Lysholm Knee Score; TAS: Tegner Activity Scale.

The quality of the studies included in the systematic reviews was generally rated as low. Tables 7 and 8 summarize select studies (2 RCTs, 2 cohort) included in the systematic reviews. A large RCT from the manufacturers of MenaFlex (Rodkey et al [2008]) was conducted under a 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. 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 to receive a CMI versus 18 patients who chose a partial medial meniscectomy, with a minimum ten-year follow-up. The two groups were comparable at baseline. No significant differences were found in the LSK and Yulish scores. Independent and blinded radiographic evaluation showed significantly less medial joint space narrowing in the implant group than in the partial meniscectomy group (0.48 vs. 2.13 mm, respectively). This study is limited by the potential for selection bias. A retrospective review by Bulgheroni (2014) of 34 patients (17 partial medical meniscectomy and 17 CMI) found no significant difference between the groups for pain and function scores at an average of 9.6 year follow-up.

**Table 7. Summary of Key Study Characteristics for CMI**

| Variables | Rodkey et al (2008) | Linke et al (2006) | Zaffagnini et al (2011) | Bulgheroni et al (2015) |
|---|---|---|---|---|
| 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; RCT: randomized controlled trial.

**Table 8. Summary of Key Study Results for CMI**

| Outcomes | Rodkey et al (2008) | | | Linke et al (2006) | | | Zaffagnini et al (2011) | | | Bulgheroni et al (2015) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 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 | 6 5-6 | 6 5-6 | *NS* |

CMI: collagen meniscus implant; Ctrl: control; IKDC: International Knee Documentation Committee; LSK: Lysholm Knee Score; TAS: Tegner Activity Scale; VAS: visual analog scale.

[a] Chronic only.

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

Section Summary: Collagen Meniscus Implants

Evidence for the use of CMI for patients undergoing partial meniscectomies consists of 2 systematic reviews, the most recent including 674 patients. The reviews reported overall positive results with the CMI, but the quality of the included studies (RCTs and observational studies) was low. Radiologic evaluations show 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 an 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 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 with a concomitant procedure to repair malalignment, focal chondral defects and/or ligamentous insufficiency, who receive meniscal allograft transplantation, the evidence includes one systematic review of case series as well as several case series published after the systematic review. Relevant outcomes include symptoms, function, and quality of life (for example: VAS pain, Lysholm Knee score, Tegner Activity Scale, SF-36). The systematic review concluded that pain and function improved following the procedure. One of the studies published after the review showed that patients with more severe cartilage damage experienced favorable outcomes similar to patients with less cartilage damage. Another study published after the review reported an overall 9.7 year survival of the implant. A limitation of these conclusions is the reliance on mostly case series. 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, who receive collagen meniscal implants, the evidence includes two systematic reviews of mostly case series. Relevant outcomes include symptoms, function, and quality of life (for example: VAS pain, Lysholm Knee score, Tegner Activity Scale, SF-36). The reviews reported overall positive results with the CMI, but the quality of the included studies (RCTs and observational studies) is low. Radiologic evaluations showed reduced size of the implant in a large portion of patients. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Practice Guidelines and Position Statements**
International Meniscus Reconstruction Experts Forum
In 2015, the International Meniscus Reconstruction Experts Forum published consensus statements on the practice of meniscal allograft transplantation (MAT) (see Table 9). The Forum's statements included guidance on indications, graft procurement and preparation, surgical technique, and rehabilitation.

**Table 9. Select Consensus Statements on the Practice of MAT**

| 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, 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

The 2012 guidance from the United Kingdom's National Institute for Health and Care Excellence (NICE) stated that evidence on partial replacement of the meniscus of the knee using a biodegradable scaffold raised no major safety concerns, but evidence for any advantage of the procedure over standard surgery was limited.

American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons updated its 2009 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. 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.

## Key Words:

Meniscal allograft transplantation (MAT), anterior cruciate ligament (ACL), ReGen Collagen Scaffold, Menaflex, Collagen Meniscal Implant (CMI)

## Approved by Governing Bodies:

In 2008, the ReGen Collagen Scaffold (CS) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA determined that this device was substantially equivalent to existing predicate 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 the 510(k) clearance, FDA initiated a review of the clearance process. In October 2010, 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 is now called CMI® and manufactured by Ivy Sports Medicine. CMI® is the only FDA-approved collagen meniscus product currently on the market.

## Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational and will be reviewed for medical necessity

## Current Codes:

CPT coding:

| | |
|---|---|
| **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) |

## References:


1. Amendola A. Knee osteotomy and meniscal transplantation: indications, technical considerations, and results. Sports Med Arthrosc 2007; 15(1):32-38.
2. American Academy of Orthopaedic Surgeons. OrthoInfo: Meniscal transplant surgery. 2014; https://orthoinfo.aaos.org/en/treatment/meniscal-transplant-surgery/.
3. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Meniscal Allograft Transplantation. TEC Assessments 1997; Volume 12, Tab14.
4. Bouyarmane H, Beaufils P, Pujol N et al. Polyurethane scaffold in lateral meniscus segmental defects: Clinical outcomes at 24months follow-up. Orthop Traumatol Surg Res 2014; 100(1):153-157.
5. Bulgheroni E, Grassi A, Bulgheroni P, et al. Long-term outcomes of medial CMI implant versus partial medial meniscectomy in patients with concomitant ACL reconstruction. Knee Surg Sports Traumatol Arthrosc. Jul 2014.
6. Bulgheroni P, Murena L, Ratti C et al. Follow-up of collagen meniscus implant patients: clinical, radiological, and magnetic resonance imaging results at 5 years. Knee 2010; 17(3):224-229.
7. Chang HC, Teh KL, Leong KL, et al. Clinical evaluation of arthroscopic-assisted allograft meniscal transplantation. Ann Acad Med Singapore, April 2008; 37(4): 266-267.
8. Cole BJ, Dennis MG, Lee SJ, et al. Prospective evaluation of allograft meniscus transplantation: A minimum 2-year follow-up. Am J Sports Med 2006; 34(6): 919-927.
9. Cole BJ, et al. Allograft meniscal transplantation: Background, techniques, and results. Instructional Course Lectures, January 2003; 52: 383-396.
10. Cryolife Web site, available online at: www.cryolife.com.

11. Cvetanovich GL, Yanke AB, McCormick F, et al. Trends in meniscal allograft transplantation in the United States, 2007 to 2011. Arthroscopy. Jun 2015; 31(6):1123-1127.
12. DeLee. Meniscal allografts. DeLee and Drez's Orthopedic Sports Medicine, 2nd edition.
13. Dhollander A, Verdonk P, Verdonk R. Treatment of painful, irreparable partial meniscal defects with a polyurethane scaffold: midterm clinical outcomes and survival analysis. Am J Sports Med. Oct 2016; 44(10):2615-2621.
14. Elattar M, Dhollander A, Verdonk R et al. Twenty-six years of meniscal allograft transplantation: is it still experimental? A meta-analysis of 44 trials. Knee Surg Sports Traumatol Arthrosc 2011; 19(2):147-157.
15. Eriksson E. Meniscus transplantation. Knee Surg Sports Traumatol Arthrosc 2006; 14(8):693.
16. Farr J, Rawal A, Marberry KM. Concomitant meniscal allograft transplantation and autologous chondrocyte implantation: minimum 2-year follow-up. Am J Sports Med 2007; 35(9):1459-1466.
17. Frank RM, Cole BJ. Meniscus transplantation. Curr Rev Musculoskelet Med. Dec 2015; 8(4):443-450.
18. Gelber PE, Isart A, Erquicia JI, et al. Partial meniscus substitution with a polyurethane scaffold does not improve outcome after an open-wedge high tibial osteotomy. Knee Surg Sports Traumatol Arthrosc. Jan 2015; 23(1):334-339.
19. Getgood A, LaPrade RF, Verdonk P, et al. International Meniscus Reconstruction Experts Forum (IMREF) 2015 Consensus Statement on the Practice of Meniscal Allograft Transplantation. Am J Sports Med. Aug 25 2017; 45(5):1195-1205.
20. Graf KW, et al. Long term results after combined medial meniscal allograft transplantation and anterior cruciate ligament reconstruction: Minimum 8.5 year follow-up study. Arthroscopy, February 2004; 20(2): 129-140.
21. Greis PE, et al. Meniscal injury: II Management. Journal of the American Academy of Orthopedic Surgeons, May 2002; 10(3): 177-187.
22. Harris JD, Cavo M, Brophy R et al. Biological knee reconstruction: a systematic review of combined meniscal allograft transplantation and cartilage repair or restoration. Arthroscopy 2011; 27(3):409-418.
23. Harston A, Nyland J, Brand E et al. Collagen meniscus implantation: a systematic review including rehabilitation and return to sports activity. Knee Surg Sports Traumatol Arthrosc 2012; 20(1):135-146.
24. Health Technology Assessment. Meniscal allograft. October 22, 2002.
25. Heckmann TP, Barber-Westin SD and Noyes FR. Meniscal repair and transplantation: Indications, techniques, rehabilitation, and clinical outcome. J Orthop Sports Phys Ther, October 2006; 36(10): 795-814.
26. Hergan D, Thut D, Sherman O et al. Meniscal allograft transplantation. Arthroscopy 2011; 27(1):101-112.
27. Hirschmann MT, Keller L, Hirschmann A et al. One-year clinical and MR imaging outcome after partial meniscal replacement in stabilized knees using a collagen meniscus implant. Knee Surg Sports Traumatol Arthrosc 2013; 21(3):740-747.
28. Hommen JP, Applegate GR and Del Pizzo W. Meniscus allograft transplantation: ten-year results of cryopreserved allografts. Arthroscopy 2007; 23(4): 388-393.

29. Houck DA, Kraeutler MJ, Belk JW, et al. Similar clinical outcomes following collagen or polyurethane meniscal scaffold implantation: a systematic review. Knee Surg Sports Traumatol Arthrosc. Jan 16 2018.
30. Johnson DL and Bealle D. Meniscal allograft transplantation. Clinics in Sports Medicine, January 1999, Vol. 18, No. 1, pp. 93-108.
31. Johnson DL and Selby JB. Meniscal transplantation: Indications and results. August 2001, Medscape General Medicine 3(4), www.medscape.com/viewarticle/408541_print.
32. Kempshall PJ, Parkinson B, Thomas M, et al. Outcome of meniscal allograft transplantation related to articular cartilage status: advanced chondral damage should not be a contraindication. Knee Surg Sports Traumatol Arthrosc. Jan 2015; 23(1):280-289.
33. Klimkiewicz JJ, et al. Meniscal allograft transplantation: Current indications for treatment, July 2000, Medscape General Medicine 2(4): www.medscape.com/viewarticle/408526_print.
34. Linke RD, Ulmer M, Imhoff AB. Replacement of the meniscus with a collagen implant (CMI). Oper Orthop Traumatol 2006; 18(5-6):453-462.
35. Lubowitz JH, Verdonk PC, Reid JB 3rd et al. Meniscus allograft transplantation: a current concepts review. Knee Surg Sports Traumatol Arthrosc 2007; 15(5):476-492.
36. Matava MJ. Meniscal allograft transplantation: A systematic review. Clin Orthop Relat Res 2007; 455: 142-157.
37. National Institute for Health and Clinical Excellence. IPG430 Partial replacement of the meniscus of the knee using a biodegradable scaffold: guidance. 2012. www.guidance.nice.org.uk/IPG430/Guidance/pdf/English. Last accessed February, 2014.
38. Noyes FR, Barber-Westin SD, Rankin M. Meniscal transplantation in symptomatic patients less than fifty years old. J Bone Joint Surg Am 2004; 86-A(7):1392-404.
39. Noyes FR, Barber-Westin SD, Rankin M. Meniscal transplantation in symptomatic patients less than fifty years old. J Bone Joint Surg Am 2005; 87 Suppl 1(Pt 2):149-165.
40. Ogura T, Bryant T, Minas T. Biological knee reconstruction with concomitant autologous chondrocyte implantation and meniscal allograft transplantation: mid- to long-term outcomes. Orthop J Sports Med. Oct 2016;4(10):2325967116668490.
41. Peters G. The current state of meniscal allograft transplantation and replacement. Knee, March 2003; 10(1): 19-31.
42. Rath E, et al. Meniscal allograft transplantation: Two-to-eight year results. American Journal of Sports Medicine, July 2001.
43. Rodkey WG, DeHaven KE, Montgomery WH 3rd et al. Comparison of the collagen meniscus implant with partial meniscectomy: A prospective randomized trial. J Bone Joint Surg Am 2008; 90(7):1413-1426.
44. Rosso F, Bisicchia S, Bonasia DE, et al. Meniscal allograft transplantation: a systematic review. Am J Sports Med. Apr 2015; 43(4):998-1007.
45. Rue JP, Yanke AB, Busam ML et al. Prospective evaluation of concurrent meniscus transplantation and articular cartilage repair: minimum 2-year follow-up. Am J Sports Med 2008; 36(9):1770-1778.
46. Ryu RK, et al. Meniscal allograft replacement: A 1 year to 6 year experience. Arthroscopy, November 2002; 18(9): 989-994.
47. Schuttler KF, Haberhauer F, Gesslein M, et al. Midterm follow-up after implantation of a polyurethane meniscal scaffold for segmental medial meniscus loss: maintenance of good

clinical and MRI outcome. Knee Surg Sports Traumatol Arthrosc. May 2016; 24(5):1478-1484.
48. Sekiya JK, Ellingson CI. Meniscal allograft transplantation. J Am Acad Orthop Surg 2006; 14(3):164-174.
49. Sekiya JK, et al. Clinical outcomes after combined meniscal allograft transplantation and anterior cruciate ligament reconstruction. American Journal of Sports Medicine, November-December 2003.
50. Sekiya JK, West RV, Groff YJ, et al. Clinical outcomes following isolated lateral meniscal allograft transplantation. Arthroscopy, July 2006; 22(7): 771-780.
51. Smith NA, Parsons N, Wright D, et al. A pilot randomized trial of meniscal allograft transplantation versus personalized physiotherapy for patients with a symptomatic meniscal deficient knee compartment. Bone Joint J. Jan 2018; 100-B(1):56-63.
52. Stollsteimer GT, et al. Meniscal allograft transplantation: A 1-to5-year follow up of 22 patients, Arthroscopy, May 2000; 16(4): 343-347.
53. Stone KR, Adelson WS, Pelsis JR et al. Long-term survival of concurrent meniscus allograft transplantation and repair of the articular cartilage: a prospective two- to 12-year follow-up report. J Bone Joint Surg Br 2010; 92(7):941-948.
54. van Arkel ER, et al. Survival analysis of human meniscal transplantations, Journal of Bone and Joint Surgery, British Volume, March 2002; 84(2): 227-231.
55. van der Wal RJ, Thomassen BJ, van Arkel ER. Long-term clinical outcome of open meniscal allograft transplantation. Am J Sports Med 2009; 37(11):2134-2139.
56. Verdonk P, Beaufils P, Bellemans J et al. Successful treatment of painful irreparable partial meniscal defects with a polyurethane scaffold: two-year safety and clinical outcomes. Am J Sports Med 2012; 40(4):844-853.
57. Verdonk PC, Demurie A, Almqvist KF et al. Transplantation of viable meniscal allograft. Survivorship analysis and clinical outcome of one hundred cases. J Bone Joint Surg Am 2005; 87(4):715-724.
58. Verdonk PC, Verstraete KL, Almqvist KF, et al. Meniscal allograft transplantation: Long-term clinical results with radiological and magnetic resonance imaging correlations. Knee Surg Sports Traumatol Arthrosc 2006; 14(8): 694-706.
59. Verdonk R, et al. Harvest and conservation of meniscal allografts, Scandinavian Journal of Medicine and Science in Sports, June 1999; 9(3): 158-159.
60. Verdonk R, Verdonk P, Huysse W et al. Tissue ingrowth after implantation of a novel, biodegradable polyurethane scaffold for treatment of partial meniscal lesions. Am J Sports Med 2011; 39(4):774-782.
61. Verdonk R. Meniscal transplantation, Acta Orthopaedica Belgica, April 2002; 68(2): 118-127.
62. von Lewinski G, Milachowski, KA, et al. Twenty-year results of combined meniscal allograft transplantation, anterior cruciate ligament reconstruction and advancement of the medial collateral ligament. Knee Surg Sports Traumatol Arthrosc, September 2007; 15(9): 1072-1082.
63. Vundelinckx B, Bellemans J, Vanlauwe J. Arthroscopically assisted meniscal allograft transplantation in the knee: a medium-term subjective, clinical, and radiographical outcome evaluation. Am J Sports Med 2010; 38(11):2240-2247.
64. Warth RJ, Rodkey WG. Resorbable collagen scaffolds for the treatment of meniscus defects: a systematic review. Arthroscopy. May 2015; 31(5):927-941.

65. Wirth CJ, et al. Long-term results of meniscal allograft transplantation. American Journal of Sports Medicine, March 2002; 30(2): 174-181.
66. Yoldas EA, et al. Arthroscopically assisted meniscal allograft transplantation with and without combined anterior cruciate ligament reconstruction. Knee Surgery, Sports Traumatology, Arthroscopy, May 2003; 11(3): 173-182.
67. Zaffagnini S, Grassi A, Marcheggiani Muccioli GM, et al. Survivorship and clinical outcomes of 147 consecutive isolated or combined arthroscopic bone plug free meniscal allograft transplantation. Knee Surg Sports Traumatol Arthrosc. May 2016; 24(5):1432-1439.
68. Zaffagnini S, Grassi A, Marcheggiani Muccioli GM, et al. MRI evaluation of a collagen meniscus implant: a systematic review. Knee Surg Sports Traumatol Arthrosc. Nov 2015; 23(11):3228-3237.
69. Zaffagnini S, Marcheggiani Muccioli GM, Lopomo N et al. Prospective Long-Term Outcomes of the Medial Collagen Meniscus Implant Versus Partial Medial Meniscectomy: A Minimum 10-Year Follow-Up Study. Am J Sports Med 2011; 39(5):977-985.

## Policy History:

Medical Policy Group, May 2004 **(1)**
Medical Policy Administration Committee, May 2004
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Medical Policy Group, May 2006 **(1)**
Medical Policy Group, August 2008 **(1)**
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Medical Policy Group, October 2010 (1) Added info regarding Menaflex having clearance rescinded from the FDA (see Approved by Governing Bodies)
Medical Policy Group, November 2010 Updated References
Medical Policy Group, May 2011; Updates to Policy, Key Points, & References
Medical Policy Administration Committee June 2011
Available for comment June 8 – July 25
Medical Policy Group, March 2012 **(3)**: 2012 Updates: Key Points, & References
Medical Policy Panel, March 2013
Medical Policy Group, September 2013 **(1):** Change in Title replacing collagen with other; replaced the word collagen with other in investigational policy statement, no change in coverage; update to Key Points, Governing Bodies and References
Medical Policy Administration Committee, September 2013
Medical Policy Panel, March 2014
Medical Policy Group, March 2014 **(3):** 2014 Updates to Key Points & References; no change in policy statement
Medical Policy Panel, March 2015

Medical Policy Group, March 2015 (**2)**: 2015 Updates to Key Points and References, removed coverage statement from policy section - effective for dates of service prior to March 24, 2010, no change in policy statement
Medical Policy Panel, April 2017
Medical Policy Group, April 2017 **(7):** 2017 Updates to Description, Key Points, Approved by Governing Bodies & References. Policy statement updated- removed "six months" time frame for conservative therapy and added definition of conservative therapy; removed old policy statements effective March 24, 2010 – July 25, 2011 and dates prior to July 26, 2011.
Medical Policy Administration Committee; May 2017
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Medical Policy Panel, April 2018
Medical Policy Group, May 2018 **(7)**: Updates to Description, Key Points and References. Previous Coding Section removed. No change in Policy Statement.

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