## Meniscal Allografts and Other Meniscus Implants

**Title:** Meniscal Allografts and Other Meniscus Implants

### Professional
- **Original Effective Date:** June 1, 2007
- **Revision Date(s):**
  - July 21, 2011
  - August 13, 2012; September 17, 2013;
  - March 4, 2015; May 13, 2015;
  - May 24, 2017
- **Current Effective Date:** March 4, 2015

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<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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</thead>
<tbody>
<tr>
<td>Individuals: • Who are undergoing partial meniscectomy</td>
<td>Interventions of interest are: • Meniscal allograft transplantation</td>
<td>Comparators of interest are: • Partial meniscectomy without meniscal allograft transplantation</td>
<td>Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life</td>
</tr>
<tr>
<td>Individuals: • Who are undergoing partial meniscectomy, and repair of malalignment, focal chondral defects, and/or ligamentous insufficiency</td>
<td>Interventions of interest are: • Meniscal allograft transplantation</td>
<td>Comparators of interest are: • Partial meniscectomy without meniscal allograft transplantation</td>
<td>Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life</td>
</tr>
<tr>
<td>Individuals: • Who are undergoing partial meniscectomy</td>
<td>Interventions of interest are: • Collagen meniscal implants</td>
<td>Comparators of interest are: • Partial meniscectomy without meniscal implant</td>
<td>Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life</td>
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**DESCRIPTION**

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

**OBJECTIVE**

The objective of this policy is to evaluate the net health outcome when meniscal allografts are used to treat patients with disabling knee pain following meniscectomy who are too young for total knee arthroplasty.

**BACKGROUND**

**Meniscal Cartilage**

Meniscal cartilage is an integral structural component of the human knee, functioning to absorb shocks and providing load sharing, joint stability, congruity, proprioception, and lubrication and nutrition of the cartilage surfaces. Total and partial meniscectomy frequently result in degenerative osteoarthritis (OA). The integrity of the menisci is particularly important in knees in which the anterior cruciate ligament (ACL) has been damaged. In these situations, the menisci act as secondary stabilizers of anteroposterior and varus-valgus translation.

**Treatment**

Meniscal allograft transplantation has been investigated in patients with a previous meniscectomy, or in patients who require a total or near total meniscectomy for irreparable tears. There are 3 general groups of patients who have been treated with meniscal allograft transplantation:
- 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. Four primary ways of processing and storing allografts are: fresh viable, fresh frozen, cryopreserved, and

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<th>Populations</th>
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<th>Comparators</th>
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<tbody>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are: Polyurethane meniscal implants</td>
<td>Comparators of interest are: Partial meniscectomy without meniscal implant</td>
<td>Relevant outcomes include: Symptoms, Functional outcomes, Quality of life</td>
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</table>
lyophilized. Fresh viable implants, harvested under sterile conditions, are less frequently used since 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 tissue may also be dehydrated (freeze-dried or lyophilized), permitting storage at room temperature. Lyophilized grafts are prone to reduced tensile strength, shrinkage, poor rehydration, post-transplantation joint effusion, and synovitis 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 allograft preference, 68% preferred fresh frozen nonirradiated allografts, with 14% responding fresh viable allografts.¹

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).²

Tissue engineering that grows new replacement host tissue for individual patients is also being investigated. For example, the ReGen Collagen Scaffold (Ivy Sports Medicine, formerly ReGen Biologics), which may also be referred to as the Menaflex™ collagen meniscus implant or CMI™, 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. In addition, 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. For example, Actifit® (Orteq) is a biodegradable polyurethane scaffold that is currently being studied in Europe. 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.
REGULATORY STATUS

Collagen Meniscus Implants
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 absorbable surgical mesh devices. The ReGen Collagen Scaffold (also known as MenaFlex™ CMI) was the only collagen meniscus implant (CMI) with FDA clearance at that time. Amid controversy about this 510(k) clearance decision, FDA reviewed it decision. 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, now called CMI®, is manufactured by Ivy Sports Medicine. CMI® is the only FDA-approved collagen meniscus product currently on the market. FDA product code: OLC.

Polyurethane Meniscal Implant
There are no FDA-approved polyurethane meniscal implants currently on the market in the United States. Actifit® is approved for marketing in Europe.
**POLICY**

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

1. Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (eg, younger than 55 years); **AND**
2. Disabling knee pain with activity that is refractory to conservative treatment; **AND**
3. Absence or near absence (more than 50%) of the meniscus, established by imaging or prior surgery; **AND**
4. Documented minimal to absent diffuse degenerative changes in the surrounding articular cartilage (eg, Outerbridge grade II or less, <50% joint space narrowing); **AND**
5. Normal knee biomechanics, or alignment and stability achieved prior to or concurrently with meniscal transplantation.

B. 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:

1. Autologous chondrocyte implantation; **OR**
2. Osteochondral allografting; **OR**
3. Osteochondral autografting.

C. Use of other meniscal implants incorporating materials such as collagen and polyurethane are considered **experimental / investigational**.

**Policy Guidelines**

1. Patients should exhibit symptoms of persistent disabling knee pain that has not shown an adequate response 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.

2. Severe obesity, eg, body mass index (BMI) greater than 35 kg/m², may affect outcomes due to the increased stress on weight bearing surfaces of the joint. Meniscal allograft transplantation is typically recommended for young active patients who are too young for total knee arthroplasty.
Rationale

The most recent literature update was performed through February 23, 2017.

Meniscal allograft transplantation (MAT) is considered a salvage procedure, reserved for patients with disabling knee pain following meniscectomy who are considered too young to undergo total knee arthroplasty (TKA). As a result, the population intended to receive these transplants is relatively limited. Using a large database of privately insured non-Medicare patients, a 2015 report 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. The outcomes of this treatment (ie, 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.

The primary literature consists of retrospective case series and systematic reviews of these case series. Two main issues are investigated: (1) Does MAT improve pain and function? and (2) Does this procedure reduce joint degeneration? Following is a summary of key references to date, focusing on graft survival and health outcomes with longer term follow-up.

Meniscal Allograft Transplantation
Systematic Reviews

Several systematic reviews of 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% (see 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. Hergan et al (2011) conducted a systematic review of the literature to evaluate characteristics of patients, graft survival, and clinical outcomes. Analysis found that patients with Outerbridge scores of 2 or less in any area had significantly improved posttreatment Lysholm Knee Score (LKS) and Tegner Activity Scale (TAS) scores, whereas patients with Outerbridge grade 3 or more in any area (not repaired) did not experience significant improvements in pain and function. Studies that analyzed patients undergoing concomitant procedures did not detect a difference between the subgroup compared with MAT 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 MAT (see Table 1).

Table 1. Summary of Key Systematic Reviews of MAT

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<tbody>
<tr>
<td>No. and study type</td>
<td>44 cohort and case series</td>
<td>14 cohort and case series with minimum 2-y follow-up</td>
<td>55 (2 level II, 7 level III, 46 level IV)</td>
</tr>
<tr>
<td>Population</td>
<td>1136 knees (1068 patients)</td>
<td>196 knees</td>
<td>1623 patients</td>
</tr>
<tr>
<td>Follow-up (range)</td>
<td>4.6 y (8 mo to 20 y)</td>
<td>53.8 mo (24-167 mo)</td>
<td>53.6 mo (12-168 mo)</td>
</tr>
<tr>
<td>Outcome measures</td>
<td>Pain and function</td>
<td>Pain and function</td>
<td>Pain and function</td>
</tr>
</tbody>
</table>
--- | --- | --- | ---
Review synthesis |  |  |  
Pain and function | All showed clinical improvement | Alleviation of knee pain and improvement in function noted | Weighted pre-/postmeasures⁴: • VAS pain score decreased from 6.4 to 2.4 • LKS increased from 55.5 to 82.7 
Failure rate | 10.6% | 7%-35% | Fresh frozen: 9.9% Cryopreserved: 18.2% 
Complication rate | 21.3% | 10.6% |  
Review conclusion | Meniscal allograft 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: • All studies showed clinical improvement at short- and mid-term follow-ups • Complication and failure rates acceptable • Potential chondro-protective effect of MAT remains unclear 
Review limitations | Based primarily on case series | Based primarily on case series and qualitative review only | Based primarily on case series 

LKS: Lysholm Knee Score; MAT: meniscal allograft transplantation; VAS: visual analog scale.  
⁴ Data from 37 of the 55 studies in the systematic review.

Case Series
Several case series with longer term follow-up are discussed next. Series characteristics and results 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.⁷ 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).⁸

At a mean follow-up of 16 years, van der Wal et al (2009)⁹ reported graft survival decreased to 52.5%, while most failures in the study by Vundelinckx et al (2010) occurred approximately 10 years postoperatively.¹⁰ That said, at an average of 105-month follow-up, the 34 remaining patients assessed in the Vundelinckx study showed significant improvements in pain and function relative to preoperative levels. Radiographic evidence reported by van der Wal et al also showed a slight or moderate increase in osteoarthritis (OA) in 42% of patients (1 or 2 points), and no increase in the other 58%. Of 15 patients with follow-up radiographs in the Hommen study, 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

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<thead>
<tr>
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<tbody>
<tr>
<td>Sample size</td>
<td>105</td>
<td>57</td>
<td>34/49</td>
</tr>
<tr>
<td>Mean age (range), y</td>
<td>35 (16-50)</td>
<td>39 (26-55)</td>
<td>33 (14-47)</td>
</tr>
<tr>
<td>Population</td>
<td>Previous total meniscectomy</td>
<td>Previous total meniscectomy</td>
<td>Patients with intact allograft</td>
</tr>
<tr>
<td>Intervention</td>
<td>MAT</td>
<td>MAT</td>
<td>MAT</td>
</tr>
<tr>
<td>Control</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>
### Table 3. Summary of Key Case Series Results for Meniscal Allograft Transplantation

<table>
<thead>
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<tbody>
<tr>
<td><strong>Length of FU (range)</strong></td>
<td>3-15 y</td>
<td>14 y (9-18 y)</td>
<td>105 mo</td>
</tr>
</tbody>
</table>

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

### Table 4. Summary of Key Systematic Reviews

<table>
<thead>
<tr>
<th>Variables</th>
<th>Harris et al (2011)(^11)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No. and study type</strong></td>
<td>6 case series</td>
</tr>
<tr>
<td><strong>Population</strong></td>
<td>110</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td>MAT combined with cartilage repair or restoration</td>
</tr>
</tbody>
</table>

\(^7\) Verdonk et al (2005); \(^9\) Van der Wal et al (2009); \(^10\) Vundelinckx et al (2010); \(^11\) Harris et al (2011)
Variables | Harris et al (2011)\textsuperscript{11}
--- | ---
Control | • Baseline to posttreatment  
• Historical controls of procedures performed in isolation
Outcome measures | Pain and function
Review synthesis | • Outcomes improved from baseline to posttreatment  
• 4/6 studies found outcomes equivalent to procedures performed in isolation  
• 2/6 studies found combined surgery not as good as historical controls
Review conclusion | MAT can improve pain and function when combined with cartilage repair or restoration procedures
Review limitations | Based on case series with historical controls

MAT: meniscal allograft transplantation.

The largest and longest study to report on MAT in patients with significant (grade III and IV) chondral damage is that by Stone et al who reported mean allograft survival of 9.9 years (see Table 5).\textsuperscript{12} Other prospective studies have reported on graft survival and functional outcomes when MAT has been combined with articular cartilage repair.\textsuperscript{13,14}

The following studies are those published more recently and subsequent to the systematic review (see Table 5). Kempshall et al (2015) looked at MAT concomitant with cartilage repair procedures on (1) patients with more knee cartilage damage (grade 3b $>1\text{ cm}^2$) and (2) patients with less knee cartilage damage (grade 3b $<1\text{ cm}^2$). Functional outcomes following the procedures were similar between the 2 groups. However, implant survival (using graft failure as an end point) was lower among those with greater cartilage damage.\textsuperscript{15}

Ogura et al (2016) retrospectively reviewed patients who had undergone ACI and MAT.\textsuperscript{16} 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 TKA 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 ACL reconstruction).\textsuperscript{17} Two survival analyses were conducted, one with the end point of surgical failure (need for revision procedures related to initial MAT) and the other with the end point of clinical failure (same revision procedures as surgical failure or LKS less than 65 at final follow-up). Mean overall survival time with the surgical failure end point was 9.7 years (95% confidence interval [CI], 9.1 to 10.3 years) and mean overall survival with the clinical failure end point was 8.0 years (95% CI, 7.1 to 8.8 years). Logistic regression analysis did not reveal any variables (including concomitant procedures) affecting the surgical or clinical failure end points.

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

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<tbody>
<tr>
<td>Sample size</td>
<td>115</td>
<td>99</td>
<td>17</td>
<td>147</td>
</tr>
</tbody>
</table>
| Population | Consecutive patients with grade III-IV chondral damage | Prospective series  
• Grade 3b $<1\text{ cm}^2$  
• Grade 3b $>1\text{ cm}^2$ | Retrospective series | Retrospective series |
| Intervention | MAT | MACI and microfracture  
more common if chondral damage was 3c $>1\text{ cm}^2$ | ACI with MAT | MAT |
| Control | None | None | None | None |
--- | --- | --- | --- | ---
Outcome measures | MAT survival | MAT survival • KOOS, TAS, LKS, IKDC scores | MAT survival • MCKRS, WOMAC, VAS, SF-36 | MAT survival • KOOS, LKS, VAS
Length of FU | 5.8 y | 2 y | 5-10 y | 4 y
Results | • Mean MAT survival, 9.9 y • 47% required additional surgery | • Similar outcomes on KOOS, TAS, LKS, IKDC scores for 2 groups • 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 • 67% (12/18) required additional surgery | • Mean MAT survival range, 8-9.7 y • 17% required additional surgery

Section Summary: MAT Plus Articular Cartilage Repair
There is a limited amount of 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
A 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 focused on controlled trials comparing health outcomes for CMI versus partial meniscectomy alone. The literature to date consists of case series, a large RCT sponsored by a CMI manufacturer, a smaller RCT from Germany, and a small prospective comparative cohort study.

Systematic Reviews
Two systematic reviews, 1 published in 2012 (Harston et al) and 1 published in 2015 (Warth et al) 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 was an RCT and all which were included in the Warth review. We do not discuss the Zaffagnini review further.

Table 6. Summary of Key Systematic Reviews for CMI

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<tbody>
<tr>
<td>Search date</td>
<td>May 2011</td>
<td>March 2014</td>
</tr>
<tr>
<td>No. of studies</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>Population</td>
<td>520</td>
<td>674</td>
</tr>
<tr>
<td>Intervention</td>
<td>• 321 patients received a CMI • 41.1% patients had concomitant procedures</td>
<td>• 439 patients received CMI • 32.3% patients had concomitant procedures</td>
</tr>
<tr>
<td>Control</td>
<td>Partial meniscectomy alone</td>
<td>Partial meniscectomy alone</td>
</tr>
<tr>
<td>Outcome measures</td>
<td>• LKS, TAS, pain scales • 8/11 studies provided postoperative imaging data</td>
<td>• LKS, TAS, pain scales • 11/13 studies provided postoperative imaging data</td>
</tr>
<tr>
<td>Length of FU</td>
<td>6-135 mo</td>
<td>3-152 mo</td>
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</table>
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 (FDA) investigational device exemption (IDE). 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.

An independent research group published results from an RCT comparing high tibial valgus osteotomy alone and osteotomy plus CMI (Linke et al, 2006). 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.

Zaffagnini et al (2011) compared outcomes of 18 patients who chose to CMI with 18 patients who chose partial medial meniscectomy, with a minimum 10-year follow-up. 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 a potential for selection bias.

Retrospective Studies
A retrospective review by Bulgheroni (2015) of 34 patients (17 CMI, 17 partial medial meniscectomy) 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

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<tbody>
<tr>
<td>Study design</td>
<td>RCT</td>
<td>RCT</td>
<td>Controlled cohort</td>
<td>Retrospective cohorts</td>
</tr>
<tr>
<td>Sample size</td>
<td>311</td>
<td>60</td>
<td>36</td>
<td>34</td>
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<tr>
<td>Population</td>
<td>Acute and chronic</td>
<td>Patient choice</td>
<td>Matched controls</td>
<td></td>
</tr>
<tr>
<td></td>
<td>partial meniscectomy</td>
<td></td>
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<td></td>
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<tr>
<td>Intervention</td>
<td>CMI</td>
<td>Osteotomy plus</td>
<td>CMI</td>
<td>CMI</td>
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<tr>
<td></td>
<td></td>
<td>CMI</td>
<td></td>
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</tbody>
</table>
Control Partial meniscectomy 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

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<tr>
<td></td>
<td>CMI</td>
<td>Ctrl</td>
<td>p</td>
<td>CMI</td>
</tr>
<tr>
<td>Survival</td>
<td>90%</td>
<td>80%</td>
<td>a</td>
<td>65%</td>
</tr>
<tr>
<td>VAS pain</td>
<td>19/100</td>
<td>21/100</td>
<td>a</td>
<td>2.2/1</td>
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<td></td>
<td>10</td>
<td>10</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>NS</td>
<td></td>
<td></td>
<td>NS</td>
</tr>
<tr>
<td>LKS</td>
<td>79a</td>
<td>78a</td>
<td>NS</td>
<td>93.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IKDC</td>
<td>NS</td>
<td></td>
<td>b</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>TAS</td>
<td>42%</td>
<td>29%</td>
<td>&lt;0.026</td>
<td>75</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 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.

Polyurethane Meniscal Implant

A polyurethane meniscal implant (PMI; Actifit) is currently on the market in Europe. There are no FDA-approved PMIs to date.

Evidence on the PMI includes a multicenter series from the Actifit Study Group, an independently conducted pragmatic trial, and a case series (see Tables 9 and 10). Verdonk et al (2011, 2012) reported positive results in 2-year clinical outcomes in patients who received a PMI at the time of partial meniscectomy (34 medial, 18 lateral).25,26 In 2016, Dhollander et al presented updated data on 44 patients in this cohort.27 Significant improvements in VAS pain, International Knee Documentation Committee, and Knee Injury and Osteoarthritis Outcome Score were maintained through 5-year follow-up (see Table 10). Interpretation of these results is limited by the absence of a control group undergoing partial meniscectomy without the scaffold.

Another report from the Actifit Study Group, by Bouyarmane et al (2014), evaluated the Actifit biodegradable polyurethane scaffold for the lateral meniscus in patients with postmeniscectomy syndrome.28 Using last observation carried forward for missing data, clinical outcomes were found to improve during the study. This study also lacked a control group.

In contrast with the results from the Actifit Study Group, a controlled pragmatic trial (2015) found no benefit of inserting an Actifit at the time of high tibial osteotomy compared with those left with a meniscus defect.29
A case series by Schuttler et al (2016) evaluated the use of Actifit to treat patients with symptomatic segmented medial meniscus deficiency (N=18). Results from a subset of these patients followed for 4 years (n=16) showed that significant reductions in pain and improvements in function were maintained.

### Table 9. Summary of Key Study Characteristics for PMI

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Prospective multicenter series</td>
<td>Prospective multicenter series</td>
<td>Pragmatic comparative trial</td>
<td>Case series</td>
<td></td>
</tr>
<tr>
<td>Sample size</td>
<td>52</td>
<td>54</td>
<td>60</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Inclusion</td>
<td>Undergoing partial meniscectomy</td>
<td>Postmeniscectomy syndrome</td>
<td>Symptomatic varus knees with defect &gt;25 mm</td>
<td>Symptomatic segmented medial meniscus deficiency</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>None</td>
<td>None</td>
<td>HTO without PMI</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Outcome measures</td>
<td>Clinical outcomes</td>
<td>Clinical outcomes</td>
<td>Clinical outcomes</td>
<td>Clinical and radiographic outcomes</td>
<td></td>
</tr>
<tr>
<td>Length of FU</td>
<td>5 y</td>
<td>24 mo</td>
<td>31.2 mo</td>
<td>48 mo</td>
<td></td>
</tr>
</tbody>
</table>

FU: follow-up; HTO: high tibial osteotomy; PMI: polyurethane meniscal implant.

### Table 10. Summary of Key Study Results on for PMI

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS pain</td>
<td>Pre 56.2/100</td>
<td>Post 19.3/100&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Pre 5.5/10</td>
<td>Post 2.9/10&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Pre 5.9</td>
</tr>
<tr>
<td>IKDC</td>
<td>38.7</td>
<td>66.9&lt;sup&gt;a&lt;/sup&gt;</td>
<td>47.0</td>
<td>67.0&lt;sup&gt;a&lt;/sup&gt;</td>
<td>56.7</td>
</tr>
<tr>
<td>KOOS pain</td>
<td>48.3</td>
<td>77.2&lt;sup&gt;a&lt;/sup&gt;</td>
<td>47</td>
<td>89&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>KOOS ADLs</td>
<td>54.4</td>
<td>80.2</td>
<td>53</td>
<td>94&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>KSS function</td>
<td>61</td>
<td>98&lt;sup&gt;a&lt;/sup&gt;</td>
<td>65</td>
<td>90&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
</tr>
</tbody>
</table>

ADLs: activities of daily living; IKDC: International Knee Documentation Committee; KOOS: Knee Injury and Osteoarthritis Outcome Score; KSS: Knee Society Score; VAS: visual analog score.

<sup>a</sup> p<0.001.
<sup>b</sup> p<0.006.
<sup>c</sup> Not significant.

**Section Summary: Polyurethane Meniscal Implant**

Evidence for the use of PMIs for patients undergoing meniscectomy consists of several case series. Long-range follow-up have shown significant improvements in pain and functional outcomes maintained up through 5 years. There are currently no PMIs approved for marketing in the United States, though these products are available in Europe.

**SUMMARY OF EVIDENCE**

For individuals who are undergoing partial meniscectomy who receive meniscal allograft transplantation, the evidence includes systematic reviews of mostly case series. 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 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. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are undergoing partial meniscectomy and concomitant repair of malalignment, focal chondral defects, and/or ligamentous insufficiency who receive meniscal allograft transplantation, the evidence includes 1 systematic review of case series as well as case series published after the systematic review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review concluded that pain and function improved following the procedure. One of the series published after the review showed that patients with more severe cartilage damage experienced favorable outcomes similar to patients with less cartilage damage. Another series published subsequently reported an overall 9.7-year survival of the implant. A limitation of the evidence is its reliance primarily on case series. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are undergoing partial meniscectomy who receive collagen meniscal implants, the evidence includes 2 systematic reviews primarily of case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The reviews reported overall positive results with the collagen meniscus implant, but the quality of the included studies (randomized controlled trials, observational studies) is low. Radiologic evaluations have shown 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.

For individuals who are undergoing partial meniscectomy who receive polyurethane meniscal implants, the evidence includes a multicenter case series from the Actifit Study Group, an independently conducted pragmatic trial, and a small case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. Overall improvements in pain and function have been seen following the implantation. The longest follow-up among these studies is 5 years. The studies had small sample sizes and were of low quality. Currently, no polyurethane meniscal implants have been approved by the Food and Drug Administration for use in the United States. The evidence is insufficient to determine the effects of the technology on health outcomes.

**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. The input considered combined meniscal allograft transplantation (MAT) and focal cartilage repair procedures to be medically necessary in 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 with a prior meniscectomy who have disabling knee pain. Contraindications were noted as uncorrected instability, uncorrected malalignment, and the presence of significant articular disease.

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 11). The Forum’s statements included guidance on indications, graft procurement and preparation, surgical technique, and rehabilitation.

Table 11. Select IMREF Consensus Statements on the Practice of MAT

<table>
<thead>
<tr>
<th>Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for MAT:</td>
</tr>
<tr>
<td>• Unicompartmental pain post-meniscectomy</td>
</tr>
<tr>
<td>• In combination with ACL reconstruction when meniscus deficient</td>
</tr>
<tr>
<td>• In combination with ACR if meniscus deficient</td>
</tr>
<tr>
<td>MAT not recommended for asymptomatic meniscus deficient patient.</td>
</tr>
<tr>
<td>Potentially poorer outcomes expected in patients with moderate to severe OA (Kellgren-Lawrence grade ≥3).</td>
</tr>
<tr>
<td>Non-irradiated fresh frozen or fresh viable grafts are recommended.</td>
</tr>
<tr>
<td>Mechanical axis alignment should be performed prior to MAT; if mechanical axis deviation present, consider realignment osteotomy.</td>
</tr>
<tr>
<td>Based on current evidence, superiority of 1 surgical technique over another (all-suture vs bone) is not established.</td>
</tr>
<tr>
<td>Outcome scores should include:</td>
</tr>
<tr>
<td>• Disease-specific: WOMAT</td>
</tr>
<tr>
<td>• Region-specific: KOOS</td>
</tr>
<tr>
<td>• Activity: Marx Activity Rating Scale</td>
</tr>
<tr>
<td>• QOL/utility: EQ-5D</td>
</tr>
</tbody>
</table>


U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS
Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS
Currently ongoing and unpublished trials that might influence this review are listed in Table 12.

Table 12. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>Treatment of the Medial Meniscus with the Treatment of the Medial Meniscus with the NUSurface® Meniscus Implant</td>
<td>150</td>
<td>Jun 2017</td>
</tr>
</tbody>
</table>
### CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

#### CPT/HCPCS

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>29868</td>
<td>Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral</td>
</tr>
<tr>
<td>G0428</td>
<td>Collagen meniscus implant procedure for filling meniscal defects (eg, CMI, collagen scaffold, Menaflex)</td>
</tr>
</tbody>
</table>

- Effective in 2005, there is a CPT category I code specific to this procedure when performed arthroscopically: 29868.
- There is no CPT code for implantation of the ReGen Collagen Scaffold, but the American Academy of Orthopedic Surgeons’ Coding, Coverage and Reimbursement Committee feels that the meniscal transplantation CPT code 29868 is appropriate for this procedure.

#### ICD-9 Diagnoses

<table>
<thead>
<tr>
<th>Code</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>717.0</td>
<td>Internal derangement of knee; old bucket handle tear of medial meniscus</td>
</tr>
<tr>
<td>717.1</td>
<td>Internal derangement of knee; derangement of anterior horn of medial meniscus</td>
</tr>
<tr>
<td>717.2</td>
<td>Internal derangement of knee; derangement of posterior horn of medial meniscus</td>
</tr>
<tr>
<td>717.3</td>
<td>Internal derangement of knee; other and unspecified derangement of medial meniscus</td>
</tr>
<tr>
<td>717.40</td>
<td>Derangement of lateral meniscus; unspecified</td>
</tr>
<tr>
<td>717.41</td>
<td>Derangement of lateral meniscus; bucket handle tear of lateral meniscus</td>
</tr>
<tr>
<td>717.42</td>
<td>Derangement of lateral meniscus; derangement of anterior horn of lateral meniscus</td>
</tr>
<tr>
<td>717.43</td>
<td>Derangement of lateral meniscus; derangement of posterior horn of lateral meniscus</td>
</tr>
<tr>
<td>717.49</td>
<td>Derangement of lateral meniscus; other</td>
</tr>
<tr>
<td>717.5</td>
<td>Internal derangement of knee; derangement of meniscus, not elsewhere classified</td>
</tr>
<tr>
<td>836.0</td>
<td>Dislocation of knee; tear of medial cartilage or meniscus of knee, current</td>
</tr>
<tr>
<td>836.1</td>
<td>Dislocation of knee; tear of lateral cartilage or meniscus of knee, current</td>
</tr>
<tr>
<td>836.2</td>
<td>Dislocation of knee; other tear of cartilage or meniscus of knee, current</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

*a Denotes industry-sponsored or cosponsored trial.
ICD-10 Diagnoses (Effective October 1, 2015)

M23.000 Cystic meniscus, unspecified lateral meniscus, right knee
M23.001 Cystic meniscus, unspecified lateral meniscus, left knee
M23.003 Cystic meniscus, unspecified medial meniscus, right knee
M23.004 Cystic meniscus, unspecified medial meniscus, left knee
M23.011 Cystic meniscus, anterior horn of medial meniscus, right knee
M23.012 Cystic meniscus, anterior horn of medial meniscus, left knee
M23.021 Cystic meniscus, posterior horn of medial meniscus, right knee
M23.022 Cystic meniscus, posterior horn of medial meniscus, left knee
M23.031 Cystic meniscus, other medial meniscus, right knee
M23.032 Cystic meniscus, other medial meniscus, left knee
M23.041 Cystic meniscus, anterior horn of lateral meniscus, right knee
M23.042 Cystic meniscus, anterior horn of lateral meniscus, left knee
M23.051 Cystic meniscus, posterior horn of lateral meniscus, right knee
M23.052 Cystic meniscus, posterior horn of lateral meniscus, left knee
M23.061 Cystic meniscus, other lateral meniscus, right knee
M23.062 Cystic meniscus, other lateral meniscus, left knee
M23.200 Derangement of unspecified lateral meniscus due to old tear or injury, right knee
M23.201 Derangement of unspecified lateral meniscus due to old tear or injury, left knee
M23.203 Derangement of unspecified medial meniscus due to old tear or injury, right knee
M23.204 Derangement of unspecified medial meniscus due to old tear or injury, left knee
M23.206 Derangement of unspecified meniscus due to old tear or injury, right knee
M23.207 Derangement of unspecified meniscus due to old tear or injury, left knee
M23.211 Derangement of anterior horn of medial meniscus due to old tear or injury, right knee
M23.212 Derangement of anterior horn of medial meniscus due to old tear or injury, left knee
M23.221 Derangement of posterior horn of medial meniscus due to old tear or injury, right knee
M23.222 Derangement of posterior horn of medial meniscus due to old tear or injury, left knee
M23.231 Derangement of other medial meniscus due to old tear or injury, right knee
M23.232 Derangement of other medial meniscus due to old tear or injury, left knee
M23.241 Derangement of anterior horn of lateral meniscus due to old tear or injury, right knee
M23.242 Derangement of anterior horn of lateral meniscus due to old tear or injury, left knee
M23.251 Derangement of posterior horn of lateral meniscus due to old tear or injury, right knee
M23.252 Derangement of posterior horn of lateral meniscus due to old tear or injury, left knee
M23.261 Derangement of other lateral meniscus due to old tear or injury, right knee
M23.262 Derangement of other lateral meniscus due to old tear or injury, left knee
M23.300 Other meniscus derangements, unspecified lateral meniscus, right knee
M23.301 Other meniscus derangements, unspecified lateral meniscus, left knee
M23.304 Other meniscus derangements, unspecified medial meniscus, left knee
M23.306 Other meniscus derangements, unspecified meniscus, right knee
M23.307 Other meniscus derangements, unspecified meniscus, left knee
M23.311 Other meniscus derangements, anterior horn of medial meniscus, right knee
M23.312 Other meniscus derangements, anterior horn of medial meniscus, left knee
M23.321 Other meniscus derangements, posterior horn of medial meniscus, right knee
M23.322 Other meniscus derangements, posterior horn of medial meniscus, left knee
M23.331 Other meniscus derangements, other medial meniscus, right knee
M23.332 Other meniscus derangements, other medial meniscus, left knee
M23.341 Other meniscus derangements, anterior horn of lateral meniscus, right knee
M23.342 Other meniscus derangements, anterior horn of lateral meniscus, left knee
M23.351 Other meniscus derangements, posterior horn of lateral meniscus, right knee
M23.352 Other meniscus derangements, posterior horn of lateral meniscus, left knee
M23.361 Other meniscus derangements, other lateral meniscus, right knee
M23.362 Other meniscus derangements, other lateral meniscus, left knee
Q68.6 Discoid meniscus

S83.200A Bucket-handle tear of unspecified meniscus, current injury, right knee, initial encounter
S83.200D Bucket-handle tear of unspecified meniscus, current injury, right knee, subsequent encounter
S83.200S Bucket-handle tear of unspecified meniscus, current injury, right knee, sequela
S83.201A Bucket-handle tear of unspecified meniscus, current injury, left knee, initial encounter
S83.201D Bucket-handle tear of unspecified meniscus, current injury, left knee, subsequent encounter
S83.201S Bucket-handle tear of unspecified meniscus, current injury, left knee, sequela
S83.203A Other tear of unspecified meniscus, current injury, right knee, initial encounter
S83.203D Other tear of unspecified meniscus, current injury, right knee, subsequent encounter
S83.203S Other tear of unspecified meniscus, current injury, right knee, sequela
S83.204A Other tear of unspecified meniscus, current injury, left knee, initial encounter
S83.204D Other tear of unspecified meniscus, current injury, left knee, subsequent encounter
S83.204S Other tear of unspecified meniscus, current injury, left knee, sequela
S83.206A Unspecified tear of unspecified meniscus, current injury, right knee, initial encounter
S83.206D Unspecified tear of unspecified meniscus, current injury, right knee, subsequent encounter
S83.206S Unspecified tear of unspecified meniscus, current injury, right knee, sequela
S83.207A Unspecified tear of unspecified meniscus, current injury, left knee, initial encounter
S83.207D Unspecified tear of unspecified meniscus, current injury, left knee, subsequent encounter
S83.207S Unspecified tear of unspecified meniscus, current injury, left knee, sequela
S83.211A Bucket-handle tear of medial meniscus, current injury, right knee, initial encounter
S83.211D Bucket-handle tear of medial meniscus, current injury, right knee, subsequent encounter
S83.211S Bucket-handle tear of medial meniscus, current injury, right knee, sequela
S83.212A Bucket-handle tear of medial meniscus, current injury, left knee, initial encounter
S83.212D Bucket-handle tear of medial meniscus, current injury, left knee, subsequent encounter
S83.212S Bucket-handle tear of medial meniscus, current injury, left knee, sequela
S83.221A Peripheral tear of medial meniscus, current injury, right knee, initial encounter
S83.221D Peripheral tear of medial meniscus, current injury, right knee, subsequent encounter
S83.221S Peripheral tear of medial meniscus, current injury, right knee, sequela
S83.222A Peripheral tear of medial meniscus, current injury, left knee, initial encounter
S83.222D Peripheral tear of medial meniscus, current injury, left knee, subsequent encounter
S83.222S Peripheral tear of medial meniscus, current injury, left knee, sequela
S83.231A Complex tear of medial meniscus, current injury, right knee, initial encounter
S83.231D Complex tear of medial meniscus, current injury, right knee, subsequent encounter
S83.231S Complex tear of medial meniscus, current injury, right knee, sequela
S83.232A Complex tear of medial meniscus, current injury, left knee, initial encounter
S83.232D Complex tear of medial meniscus, current injury, left knee, subsequent encounter
S83.232S Complex tear of medial meniscus, current injury, left knee, sequela
S83.241A Other tear of medial meniscus, current injury, right knee, initial encounter
S83.241D Other tear of medial meniscus, current injury, right knee, subsequent encounter
S83.241S Other tear of medial meniscus, current injury, right knee, sequela
S83.242A Other tear of medial meniscus, current injury, left knee, initial encounter
S83.242D Other tear of medial meniscus, current injury, left knee, subsequent encounter
S83.242S Other tear of medial meniscus, current injury, left knee, sequela
S83.251A Bucket-handle tear of lateral meniscus, current injury, right knee, initial encounter
S83.251D Bucket-handle tear of lateral meniscus, current injury, right knee, subsequent encounter
S83.251S Bucket-handle tear of lateral meniscus, current injury, right knee, sequela
S83.252A Bucket-handle tear of lateral meniscus, current injury, left knee, initial encounter
S83.252D Bucket-handle tear of lateral meniscus, current injury, left knee, subsequent encounter
S83.252S Bucket-handle tear of lateral meniscus, current injury, left knee, sequela
S83.261A Peripheral tear of lateral meniscus, current injury, right knee, initial encounter
S83.261D Peripheral tear of lateral meniscus, current injury, right knee, subsequent encounter
S83.261S Peripheral tear of lateral meniscus, current injury, right knee, sequela
S83.262A Peripheral tear of lateral meniscus, current injury, left knee, initial encounter
S83.262D Peripheral tear of lateral meniscus, current injury, left knee, subsequent encounter
S83.262S  Peripheral tear of lateral meniscus, current injury, left knee, sequela
S83.271A  Complex tear of lateral meniscus, current injury, right knee, initial encounter
S83.271D  Complex tear of lateral meniscus, current injury, right knee, subsequent encounter
S83.271S  Complex tear of lateral meniscus, current injury, right knee, sequela
S83.272A  Complex tear of lateral meniscus, current injury, left knee, initial encounter
S83.272D  Complex tear of lateral meniscus, current injury, left knee, subsequent encounter
S83.272S  Complex tear of lateral meniscus, current injury, left knee, sequela
S83.281A  Other tear of lateral meniscus, current injury, right knee, initial encounter
S83.281D  Other tear of lateral meniscus, current injury, right knee, subsequent encounter
S83.281S  Other tear of lateral meniscus, current injury, right knee, sequela
S83.282A  Other tear of lateral meniscus, current injury, left knee, initial encounter
S83.282D  Other tear of lateral meniscus, current injury, left knee, subsequent encounter
S83.282S  Other tear of lateral meniscus, current injury, left knee, sequela
S83.31X A  Tear of articular cartilage of right knee, current, initial encounter
S83.31XD  Tear of articular cartilage of right knee, current, subsequent encounter
S83.31XS  Tear of articular cartilage of right knee, current, sequela
S83.32XA  Tear of articular cartilage of left knee, current, initial encounter
S83.32XD  Tear of articular cartilage of left knee, current, subsequent encounter
S83.32XS  Tear of articular cartilage of left knee, current, sequela

**REVISIONS**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>07-21-2011</td>
<td>Updated the Description section.</td>
</tr>
<tr>
<td></td>
<td>In the Policy section:</td>
</tr>
<tr>
<td></td>
<td>- Removed “Meniscal transplantation is experimental / investigational due to the lack of long-term studies.”</td>
</tr>
<tr>
<td></td>
<td>- Added:</td>
</tr>
<tr>
<td></td>
<td>A.  Meniscal allograft transplantation may be considered medically necessary in patients who have had a prior meniscectomy and have symptoms related to the affected side, when all the following criteria are met:</td>
</tr>
<tr>
<td></td>
<td>1.  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).</td>
</tr>
<tr>
<td></td>
<td>2.  Disabling knee pain with activity that is refractory to conservative treatment.</td>
</tr>
<tr>
<td></td>
<td>3.  Absence or near absence (more than 50%) of the meniscus, established by imaging or prior surgery.</td>
</tr>
<tr>
<td></td>
<td>4.  Documentation minimal to absent diffuse degenerative changes in the surrounding articular cartilage (e.g., Outerbridge grade II or less, &lt; 50% joint space narrowing).</td>
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<td>5.  Normal knee biomechanics, or alignment and stability achieved concurrently with Meniscal transplantation.</td>
</tr>
<tr>
<td></td>
<td>B.  Meniscal allograft transplantation may be considered medically necessary when performed in combination, either concurrently or sequentially, with autologous chondrocyte implantation, osteochondral allografting or osteochondral autografting for focal articular cartilage lesions.</td>
</tr>
<tr>
<td></td>
<td>C.  Collagen meniscus implants are considered experimental / investigational.</td>
</tr>
</tbody>
</table>
Policy Guidelines
Patients should exhibit symptoms of persistent disabling knee pain that has not shown an adequate response 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 (BMI) greater than 35 kg/m², may affect outcomes due to the increased stress on weight bearing surfaces of the joint.
Meniscal allograft transplantation is typically recommended for young active patients who are too young for a total knee arthroplasty.

Rationale section

Added Rationale section.
In the Diagnosis section:
- Added 717.1-717.5; 836.0-836.2

Added Revisions section.
Added Reference section.

08-13-2012 Rationale section updated.
Reference section updated.

09-17-2013 In the Medical Policy Title, replaced "collagen" with "other" to read "Meniscal Allografts and Other Meniscus Implants"

Updated Description section.
In Policy section:
- In Item C, replaced "collagen" with "Use of" to read "Use of other meniscal implants..."

Updated Rationale section.

In Coding section:
- Updated coding nomenclature.
- Added HCPCS code G0428.
- Added ICD-10 Diagnosis codes. (Effective October 1, 2014)
Reference section updated.

03-04-2015 In Policy section:
- In Item A #5, added "prior to or", to read, "Normal knee biomechanics, or alignment and stability achieved prior to or concurrently with meniscal transplantation."
- In item B, added "treatment of focal articular cartilage lesions using any of the following procedures:" to read, "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:"
- In item B #1, removed "for focal articular cartilage lesions", to read, "Osteochondral autografting."
- In Item C, added "incorporating materials such as collagen and polyurethane are," to read, "Use of other meniscal implants incorporating materials such as collagen and polyurethane are considered experimental / investigational."

Updated Rationale section.

In Coding section:
- In CPT/HCPCS bullet points, removed ",G0428 –collagen meniscus implant procedure for filling meniscal defect (e.g., CMI, collagen scaffold, Menaflex)," to read, "There is no CPT code for implantation of the ReGen Collagen Scaffold but the American Academy of Orthopedic Surgeons' ...

Updated References section.

05-13-2015 Updated Rationale section.
Updated References section.
REFERENCES


Other References
2. Blue Cross and Blue Shield of Kansas, Medical Advisory Committee, April 2007.
3. Blue Cross and Blue Shield of Kansas, Orthopedic Liaison Committee, CB, May 2011.