

## Medical Policy



### 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  
 Current Effective Date: September 17, 2013

#### Institutional

Original Effective Date: June 1, 2007  
 Revision Date(s): July 21, 2011  
 August 13, 2012; September 17, 2013  
 Current Effective Date: September 17, 2013

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact [Blue Cross and Blue Shield of Kansas Customer Service](#).

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

#### DESCRIPTION

Meniscal allografts and other meniscal implants (e.g., 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.

Historically, the role of normal meniscal cartilage was greatly underappreciated, and until some 30 years ago, torn and damaged menisci were routinely excised. However, it is now known that the menisci are an integral structural component of the human knee, functioning to absorb shocks and providing load sharing, joint stability, congruity, proprioception, and lubrication and nutrition of the cartilage surfaces. Total and partial meniscectomy frequently result in degenerative osteoarthritis. The integrity of the menisci is particularly important in knees in which the anterior cruciate ligament (ACL) has been damaged. In these situations, the menisci act as secondary stabilizers of

anteroposterior and varus-valgus translation. With this greater understanding, the surgical principles of treating torn or damaged menisci evolved to favor repair and preservation whenever possible.

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 osteoarthritis 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 (e.g., suturing or anchored with bone plugs). Four primary ways of processing and storing allografts (fresh, fresh frozen, cryopreserved, and lyophilized) have been reported. Fresh 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. Another commonly used method, 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. In addition to freezing, donor tissue may be dehydrated (freeze-dried or lyophilized), permitting storage at room temperature. Lyophilized grafts have been shown to be 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.

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<sup>®</sup> (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<sup>®</sup> (Active Implants), which is composed of a polyethylene reinforced polycarbonate urethane.

### **Regulatory Status**

The ReGen Collagen Scaffold received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) in 2008. The marketing clearance was based on the decision that this collagen scaffold was substantially equivalent to existing predicate absorbable surgical mesh devices. The ReGen Collagen Scaffold (also known as Menaflex<sup>™</sup> collagen meniscus implant) was the only collagen meniscus implant with FDA clearance at this time. Amid controversy about the 510(k) clearance for the ReGen Collagen Scaffold, the FDA initiated a review of the clearance process for this device. In September 2009, the FDA issued a preliminary report on the review of the ReGen Menaflex<sup>®</sup>: Departure from Processes, Procedures, and Practices Leave the Basis for a Review Decision in Question. This preliminary report documents findings and recommendations concerning FDA's review and clearance of the ReGen Biologics, Inc., Collagen Scaffold (CS) device for meniscal repair, marketed as Menaflex<sup>™</sup>. In October 2010, the FDA announced that the device should not have been cleared for marketing, as the Menaflex<sup>™</sup> device is intended to be used for different purposes and is technologically dissimilar from devices already on the market (predicate devices).

No partial or total meniscal implant is approved or cleared for marketing in the U.S.

### **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 (e.g., younger than 55 years)
  2. Disabling knee pain with activity that is refractory to conservative treatment
  3. Absence or near absence (more than 50%) of the meniscus, established by imaging or prior surgery
  4. Documented minimal to absent diffuse degenerative changes in the surrounding articular cartilage (e.g. Outerbridge grade II or less, < 50% joint space narrowing)
  5. Normal knee biomechanics, or alignment and stability achieved concurrently with meniscal transplantation

- 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.
- C. Use of other meniscus implants is 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, e.g., body mass index (BMI) greater than 35 kg/m<sup>2</sup>, 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**

### **Meniscal Allograft Transplantation**

Meniscal allograft transplantation is considered a salvage procedure, reserved for patients with disabling knee pain following meniscectomy who are considered too young to undergo total knee arthroplasty. As a result, the population that is intended to receive these transplants is relatively limited. Also, it is not expected that clinical trials will be done that compare meniscal allografts to other orthopedic procedures, although trials of allograft transplant versus medical therapy are possible. Case series offer limited evidence on the efficacy of meniscal allograft transplant. The outcomes of this treatment, i.e., pain and 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 mainly of retrospective case series and systematic reviews of these case series. These series address 2 main issues; the first is whether meniscal allograft transplantation improves pain and function post-operatively, the second is whether this procedure reduces joint degeneration. Following is a summary of key references to date, focusing on graft survival and health outcomes with longer-term follow-up.

At the time of a 1997 TEC Assessment, data regarding meniscal allograft transplantation were of poor quality. (1) For example, none of the studies presented clear comparisons of preoperative findings to postoperative results, and each study assessed outcomes differently. While definitive data were not available, poor results were reported in patients with Outerbridge grade III or IV osteoarthritis, or in those with unstable knees. In terms of graft viability, the largest case series

had been collected by CryoLife, a commercial supplier of cryopreserved allografts. However, these data were not available in the published peer-reviewed literature. As summarized by Johnson and Bealle in a 1999 report, among 1,023 transplants, CryoLife reported graft survival of 93% when the meniscus is transplanted with a bone plug for fixation, compared to 67% without such fixation. (2) The method of determining graft viability, with either serial magnetic resonance imaging (MRI) scans or second-look arthroscopy, was not reported. Additional patient outcome information was posted on their company website, based on responses to patient questionnaires. (3)

A number of systematic reviews of the available case series have been published. In 2007, Matava conducted a systematic review of the available literature; none of the 15 studies identified could be classified as Level I or Level II (prospective controlled comparisons), 3 studies qualified as Level III (retrospective comparisons), and the 12 remaining studies were retrospective case series. (4) The primary indication for meniscal allograft transplantation in these studies was complete or near-complete meniscectomy with pain in the involved compartment, and before the development of moderate to severe arthrosis (less than 2 to 3 mm of joint space narrowing and/or limited chondral wear) in a young (less than 50 years of age) active patient. Lower extremity malalignment and/or ligamentous instability have been associated with meniscal transplantation failure and thus were treated (e.g., osteotomy or anterior cruciate ligament [ACL] repair) before or at the time of the transplantation. Twelve studies used validated outcome measures, with second-look arthroscopy conducted in some of the patients in 11 studies. "Success" rates were usually over 60% (ranging from 13% to 100%), with more recent series reporting short-term favorable outcomes (based on pain, function, and patient satisfaction) in about 85% of their patient cohorts (generally 20 to 30 patients per cohort). Up to 26% reoperation rates for allograft tears in addition to other complications were reported. Matava et al. noted that fresh frozen or cryopreserved grafts were associated with the highest success rates and the least risk for biomechanical degradation or disease transmission.

Elattar et al. performed a systematic review of 44 case series and cohort studies with 1,136 grafts in 1,068 patients (mean age of 34.8 years). (5) The follow-up period ranged from 8 months to 20 years, with an overall average of 4.6 years. Twelve different clinical scoring systems were described; the Lysholm and the International Knee Documentation Committee (IKDC) were the most commonly used. The average overall Lysholm score increased from 44 at baseline to 77 at the latest follow-up, the Tegner activity score increased from 3 to 5, while the mean visual analog scale (VAS) score for pain decreased from 4.8 to 1.7. Most of the studies found only slight or no loss of the joint space in a majority of patients, while some studies reported an increase in joint space in some patients. Magnetic resonance imaging indicated frequent good healing and incorporation of the graft, although tears, shrinkage, and/or extrusion were not uncommon. With failure defined as (sub)total destruction/removal of the graft, the overall mean failure rate per trial was 10.6%. The overall complication rate was 21.3%.

Hergen and colleagues conducted another systematic review of the literature to evaluate characteristics of patients, graft survival, and clinical outcomes. (6) Fourteen English language studies with a minimum of 2 years' follow-up were included; all but one provided Level IV evidence (case series). A total of 196 knees in 9 studies were assessed for joint space narrowing after meniscal allograft transplantation. Patients with Outerbridge scores of 2 or less in any area had significantly improved post-treatment Lysholm and Tegner scores, whereas patients with

Outerbridge grade 3 or greater in any area (not repaired) did not have significant improvements in post-treatment Lysholm and Tegner scores. Reported failures of the meniscal allografts at 2 years or earlier ranged from 7% to 35%. 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.

These systematic reviews generally summarize the short- to medium-term outcomes of meniscal allograft transplant. A few case series report on longer-term outcomes, these are summarized below. Verdonk and colleagues published the largest case series, and in 2005 reported long-term follow-up from 95% of their first 105 fresh cultured (viable) meniscal allografts performed from 1989–2001. (7) The indication for transplantation was moderate-to-severe pain in a younger patient (mean of 35 years, range: 16- to 50-years-old) who had undergone a previous total meniscectomy, was 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). Postoperative clinical evaluation was conducted yearly; 2 subjects were lost to follow-up as a result of death unrelated to the transplant (these were carried forward). With failure defined as moderate or severe pain (occasional or persistent) or poor knee function (modified Hospital for Special Surgery score of less than 80), 70% of the viable allografts (39 medial, 61 lateral) survived at 10 years, the mean survival time was estimated at 11.6 years.

This group also published follow-up of at least 10 years with radiological imaging from their first 42 allografts (27 medial, 15 lateral, treated from 1989 to 1993). (8) Of the 41 patients, 7 (17%) were followed up at the time of total knee replacement (failures); these were characterized by progression in joint space width narrowing (by 1 or 2 grades) and Fairbank changes (by 1 or 2 grades). Twenty-five allografts were evaluated in 2004 (average of 12 years' follow-up). Of the 32 cases evaluated (76% follow-up), joint space remained stable in 41% and Fairbank changes did not progress in 28%. MRI scans showed absence of further femoral cartilage degeneration in 8 of 17 knees (47%) evaluated.

In a 2009 study by van der Wal and colleagues, minimum 9-year follow-up was conducted by telephone for 57 patients (63 allografts) who had previously received a cryopreserved meniscal allograft. (9) The mean interval between total meniscectomy and meniscal allograft transplantation was 16 years (range, 2–33 years), and the mean age of the patients was 39 years (range, 26–55 years) at the time of transplantation. Eleven patients could not be contacted (2 had died), although 3 were known to have had total knee arthroplasty (TKA) and were included as failures. Thus, follow-up information was available for 49 of the 57 patients (86%) at an average 14 years (range, 9–18 years) after the procedure. Overall, 29% of the grafts had failed, with 21% converted to TKA at a mean follow-up of 11 years (range, 6–17 years). Failure rates were somewhat greater for medial (35%) than for lateral allografts (25%), with 67% of the failed medial allografts in an ACL-insufficient knee (an exclusion criterion later in the series). A long-term survival rate of 52.5% was observed after 16 years of follow-up. Lysholm functional scores were available preoperatively, at short term (3 years), and at long-term follow-up for 81% of the patients; these improved from a mean of 36 (poor) to 79 points (fair) at short-term, declining to 61 points (fair for men and poor for women) at long-term follow-up. Lysholm scores were similar for those patients who had retained the meniscal allograft (61.1 points, range of 21-91, n=33) and those who had converted to TKA (61.3 points, range of 18-100, n=10).

In 2010, Vundelinckx et al. reported 5- to 15-year follow-up from 49 patients (69%) who had received meniscal allograft transplantation. (10) Five of the patients were considered failures (10%), as they underwent TKA because of persistent pain, 8 patients were contacted but chose not to join the study, and 2 patients were lost to follow-up. The 34 patients who participated in the follow-up study had a mean age of 33 years (range, 14 to 47 years) at the time of transplantation. At an average 105-month follow-up, there was a significant decrease in the visual analog scale (VAS) for pain (7 to 3.4) and increase in the Knee Injury and Osteoarthritis Outcome Score (KOOS, 35.8 to 60.2), Lysholm (39.7 to 71.8), and total Short Form (SF)-36 Health Survey (51.5 to 75.2) relative to preoperative levels. There was no increase in Tegner activity level. The more severe the osteoarthritis was at follow-up, the less the improvement in the KOOS and Lysholm scores. Radiographic evaluation showed an overall increase in osteoarthritis compared to baseline (0.58 points on the Kellgren-Lawrence classification), with a slight or moderate increase in osteoarthritis in 42% of the patients (1 or 2 points), and no increase in osteoarthritis in 58% of patients. Kaplan-Meier analysis showed that a majority of the failures occurred approximately 10 years' post-operatively.

Hommen et al. reported 10-year follow-up on 20 of 22 (91%) consecutive patients who received cryopreserved meniscus allografts. (11) Twenty-four concomitant procedures were performed in 15 of the patients, including anterior cruciate ligament (ACL) reconstruction or revision (n=10), high tibial osteotomy (n=2), and lateral retinaculum release (n=3). Forty additional surgical procedures were performed on 17 patients (85%) after transplantation; these included manipulation under anesthesia, arthroscopic synovectomy for postoperative arthrofibrosis, and additional meniscus-related procedures. The 10-year graft survival/success rate was 45%, with 5 allograft failures identified on second-look surgery, 5 allografts with grade III tears identified on MRI, and 4 patients reporting no improvement. Of 15 patients with follow-up radiographs, 10 (67%) had narrowing (from 5.2 mm at baseline to 4.0 mm at follow-up) and 12 (80%) had progression of the Fairbank degenerative joint disease score (0.5 at baseline to 1.3 at follow-up) in the transplanted tibiofemoral compartment. Twenty-year follow-up was reported for 5 patients who had received a deep frozen meniscal allograft along with other procedures on the knee. (12) At 20-year follow-up, MRI revealed shrinkage of the transplants with very small rims of the meniscus; the remaining meniscal tissue showed degenerative changes. The average Lysholm score at 20-year follow-up was 74 points (individual scores of 97, 95, 88, 70, and 21).

**Conclusions.** For patients who have disabling knee pain and a prior meniscectomy, a large number of case series report that meniscal allograft transplantation is associated with improvements in pain and function. Longer-term studies indicate that the improvements are maintained in a substantial percentage of patients up to 10 years or longer. Adverse events, such as graft failure and the need for additional procedures, occur frequently. The strength of these conclusions, including accurate estimates of the magnitude of benefit and the complication rates, are limited by the type of evidence available, which is case series and systematic reviews of these case series.

### **Combined Meniscus Transplantation and Articular Cartilage Repair**

The evidence available for this question consists of case series, most of which are retrospective, and systematic reviews of case series.

Harris et al. published a systematic review of combined meniscal allograft transplantation and cartilage repair/restoration in 2010. (13) Six level-IV studies (case series) with a total of 110 patients were included in the review. Patients underwent meniscal allograft transplantation with either 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 to the preoperative condition. Outcomes were also compared with historical outcomes, extracted from midterm and long-term follow-up studies, of individual procedures performed in isolation. Four of the 6 studies found outcomes equivalent to procedures performed in isolation, while 2 studies found that outcomes with combined surgery were not as good as the historical controls. Across the 6 studies, 13 failures (12%) were reported; these included 11 isolated meniscal allograft transplantation failures, 1 combined meniscal allograft and ACI failure, and 1 isolated ACI failure. Three knees with failed meniscal allograft transplantation were converted to TKA. Nearly 50% of the patients underwent 1 or more subsequent surgeries after combined meniscal allograft transplantation and cartilage repair/restoration procedures.

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. in 2010, who described combined meniscal allograft transplantation with focal articular cartilage repair in 115 consecutive patients (119 transplants), with a mean follow-up of 5.8 years (range, 2 months to 12.3 years). (14) Fifty-three (46%) of the patients were older than age 50 years at the time of surgery, and the mean time from injury to surgery was 14.2 years (2 months to 39.7 years). The intraoperative Outerbridge classification was grade III in 22 knees (18.5%) and grade IV in 97 knees (81.5%). There was a mean of 5 concomitant procedures performed, which included articular cartilage paste grafting (n=67) and microfracture (n=69). Thirteen patients (11%) were lost to follow-up. A total of 56 knees (47%) required up to 5 subsequent operations after the original meniscal allograft transplantation. Subsequent procedures included partial meniscectomy in 23 knees (19.3%), repair of the allograft in 11 knees (9.2%), and revision meniscal allograft transplantation in 8 knees (6.7%). Fourteen of these 42 revisions (33%) ultimately failed. Out of the 119 meniscal allograft transplantations, 25 (20.1%) failed, with 18 progressing to joint replacement. The mean survival of the allograft was 9.9 years (range, 2 months to 12.3 years).

Farr et al. in 2007 described outcomes from a prospective series of 36 patients who underwent autologous chondrocyte implantation (ACI) together with meniscal transplantation. (15) Four patients (11%) were considered failures before 2 years, and 3 were lost to follow-up (8%), resulting in 29 evaluable patients at an average of 4.5 years after surgery. The Lysholm score improved from an average of 58 to 78; maximum pain decreased an average 33% (from 7.6 to 5.1). Excluding the 4 failures, 68% of their patients required additional surgeries; 52% had 1 additional surgery, and 16% required 2 or more additional surgeries. The most common procedures were trimming of periosteal overgrowth or degenerative rims of the transplanted meniscus. Another report described average 3.1 years of follow-up from a prospective series of 30 patients (31 procedures) who had undergone combined meniscal allograft transplantation with ACI (52%) or osteochondral allograft (OA) transplantation (48%). (16) The Lysholm score improved in both the ACI (from 55 to 79) and allograft (from 42 to 68) groups; 48% of patients (60% ACI and 36% OA) were considered to be normal or nearly normal at the latest follow-up. Patients treated with OA were on average older (average 37 vs. 23 years) and with larger

lesions (5.5 cm<sup>2</sup> vs. 3.9 cm<sup>2</sup>). Two patients were considered failures (7%) and 5 (17%) underwent subsequent surgery.

Conclusions. 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, together with substantial rates of graft failure and high rates of additional procedures.

### **Collagen Meniscus Implants**

The collagen meniscus implant 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.

A systematic review of the Menaflex collagen meniscus implant was published in 2012. (17) Included were 11 studies with a total of 520 subjects, 321 of whom received a collagen meniscus implant (CMI). Research quality was generally rated as low, with widely ranging scores. Of all the patients who received a CMI, 41.1% had concomitant procedures such as anterior cruciate ligament (ACL) reconstruction or repair (n=122), high tibial osteotomy (n=33), microfracture or the femoral condyle or patella (n=5), or autologous chondrocyte implantation (ACI, n=19). The last follow-up was at a mean of 46.6 months (range, 6-135 months). Meniscus-like fibro-cartilaginous tissue ingrowth was observed, although the collagen meniscus implant and regenerated tissue were smaller than the original implant. Approximately 66-70% of patients who received a collagen meniscus implant had satisfactory outcomes, but in studies that had either control or comparison groups, outcomes improved in both groups. These results reinforce the need for controlled trials, which are described below.

Data provided to the FDA in support of the 510(k) application for the Menaflex collagen meniscus implant included a prospective, randomized multicenter clinical trial (26 surgeon-investigators from 16 sites) that was conducted under an investigational device exemption (IDE) and published in 2008. (18) The study involved 311 patients, 18 to 60 years of age, who had an irreparable injury to or previous partial loss of 1 medial meniscus, randomized and analyzed separately for those with no prior surgery (acute group, n=157) and those who had from 1 to 3 prior meniscal procedures (chronic group, n=154). Patients within the acute and chronic arms were randomized to receive the collagen meniscus implant or be treated with a partial meniscectomy only. Control patients (partial meniscectomy only) underwent standard physical therapy only. Patients underwent frequent clinical follow-up examinations over 2 years and completed validated outcomes questionnaires for up to 7 years (Lysholm functional score, Tegner activity scale and pain on a VAS).

At an average follow-up of 59 months (range, 16–92 months), there were no differences between the implant and control groups for pain, Lysholm, and self-assessment scores. Only Tegner activity scores in the chronic arm were significantly different, with patients in the implant group reporting regaining 42% of their lost activity level, compared to a 29% regain in activity reported by controls (p=0.02). Implant patients in the chronic group underwent significantly

fewer non-protocol reoperations (8 vs. 15, respectively) compared to controls, although the report did not indicate whether procedures other than a “re-look” were performed during the 1-year protocol scheduled reoperation. No differences were detected between the 2 treatment groups in the acute arm of the study, with 5 reoperations in each group. Kaplan-Meier analysis, which was estimated at 5 years due to the low number of patients at risk, suggested a modest increase in survival in the chronic group who had received a collagen implant compared to controls (approximately 90% vs. 80%, respectively).

In 2006, a German research group published initial results from a randomized trial that compared high tibial valgus osteotomy alone with osteotomy plus a collagen meniscus implant in 60 patients with subtotal loss of the medial meniscus. (19) Arthroscopy on the first 23 of 30 patients with a collagen implant at 8–18 months' post-surgery showed complete healing in 8 patients (35%), partial healing in 7 (30%; requiring resection of the posterior part of the implant), and poor results with only small remains of the collagen implant left in 8 patients (35%). 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. Assessment of pain and function (Lysholm, International Knee Documentation Committee [IKDC], subjective pain scores) showed slight and non-significant differences in comparison with the 16 patients treated with correction osteotomy only. Longer follow-up on all 60 patients is reported to be continuing.

Zaffagnini et al. performed a prospective cohort study that compared outcomes of 18 patients who chose to receive a collagen meniscus implant (with 18 patients who chose a partial medial meniscectomy after a minimum 10-year follow-up. (20) Reconstruction of the ACL and focal cartilage repair (microfracture) procedures were performed as needed. The 2 groups (non-consecutive patients meeting the inclusion and exclusion criteria) were comparable at baseline for this prospective cohort study. All patients followed a rehabilitation protocol for 6 months until they returned to full unrestricted activity as tolerated. At a mean of 133 months after surgery (range, 120 to 152 months), 33 patients (92%) were available for follow-up. The implanted group showed a lower VAS for pain (1.2 vs. 3.3) and higher objective IKDC score (7A and 10B vs. 4B and 12C), Tegner index (75 vs. 50), and Short Form (SF)-36 Health Survey (53.9 vs. 44.1 – all respectively). No significant differences were found in the Lysholm 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). MRI of the implanted knees showed 11 cases of myxoid degeneration signal, 4 knees with a normal signal but reduced size, and 2 knees that had no recognizable implant. Two patients in each group (12%) required additional surgeries.

Hirschmann et al. reported 1-year clinical and magnetic resonance imaging (MRI) outcomes in a prospective series of 67 patients who received a collagen meniscus implant after partial meniscectomy. (21) Thirty-seven percent of patients received the implant for persistent joint pain while 63% received it for prophylaxis. Clinical failure of the implant occurred in 3 patients. Of the 60 patients (90%) who had a complete clinical and radiological follow-up, MRI showed complete or partial absorption of the implant in 95% and preservation in 5%. A majority of patients (72%) showed extrusion of the implant (more than 3 mm). Clinical outcomes improved compared to just prior surgery, but without a control group undergoing partial meniscectomy alone, interpretation of results is limited.

Conclusions. The two randomized controlled trials of collagen meniscus implants as an adjunct to partial meniscectomy did not report improvements for the implant group on the majority of outcome measures. Case series and one small prospective cohort studies report improvements in outcomes, but these studies are not adequately rigorous to determine efficacy. Further clinical trials with longer follow-up are needed to determine whether outcomes are improved by collagen meniscal transplant. In addition, recent actions by the FDA have been undertaken to rescind marketing clearance of this device.

### **Polyurethane Meniscal Scaffold**

The Actifit Study Group reported on 1-year tissue ingrowth and 2-year clinical outcomes from a prospective multi-center series of 52 patients who received a polyurethane scaffold at the time of partial meniscectomy. (22, 23) MRI at 3 months showed evidence of tissue ingrowth in 81.4% of patients. Out of 44 second-look arthroscopies at 1 year, 43 (97.7%) showed integration of the scaffold with the native meniscus. Biopsy specimens taken at this time showed vital material with no signs of cell death, necrosis, or adverse reaction to the scaffold material. Nine treatment failures (17.3%) occurred during the study and 5 adverse events were considered to be related to the scaffold. Two-year clinical follow-up in 39 patients (75%) found significant improvements from the pre-surgery baseline in VAS for pain, IKDC, Lysholm, and Knee Injury and Osteoarthritis Outcome Score (KOOS). Interpretation of these results is limited by the absence of a control group undergoing partial meniscectomy without the scaffold. However, the progressive improvement in clinical outcomes observed over the 2-years of follow-up does provide indirect support for successful integration of the scaffold.

Controlled trials are needed to determine the efficacy of the polyurethane meniscal scaffold with greater certainty. It is also noted that the Actifit meniscal scaffold is not currently approved for marketing in the U.S.

### **Clinical Input Received through 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.

### **2008**

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 of the reviewers considered meniscal allograft 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.

**2011**

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 and focal cartilage repair procedures to be medically necessary in patients younger than 55 years of age who have failed conservative treatment. The reviewers agreed that the collagen meniscus implant is investigational, although some considered the implant to be both investigational and medically necessary for some patients.

**Summary**

Meniscal allograft transplantation, performed in combination with other surgical interventions, appears to improve symptoms in some patients with a prior meniscectomy who are considered too young to undergo total knee replacement. Evidence consisting primarily of retrospective case series indicates that this procedure may produce short- to intermediate-term pain relief in selected patients. Although short- to intermediate-term results are promising, the literature does not permit conclusions concerning the effect of meniscal transplantation on the long-term progression of degenerative changes and joint space narrowing.

Meniscal allograft transplantation is associated with a high number of complications, including tears of the transplanted meniscus, displacement, or arthrofibrosis. Careful selection of patients and surgical technique appear to be critical for success of this procedure. (4, 11) These major interventions are considered salvage procedures and are not recommended to be performed casually or by surgeons without extensive experience and expertise in complex knee reconstruction. Therefore, meniscal allograft transplant may be considered medically necessary for patients with prior meniscectomy who have disabling knee pain, and who are too young to be considered for total knee arthroscopy.

Similar types of evidence are available for meniscal allograft transplantation in combination with treatment of focal articular lesions, with case series reporting short- to intermediate-term improvement in pain and functioning. Based on the available evidence and clinical input, meniscal allograft transplantation may be considered medically necessary when performed in combination with treatment of focal articular cartilage lesions in patients younger than 55 years with disabling knee pain that has not shown an adequate response to physical therapy and analgesic medications.

The collagen meniscus implant, for which the FDA decided to rescind the clearance for marketing in 2010, is considered investigational. Current RCTs do not report improvements in outcomes for the majority of pain and functional status measures. In addition to FDA approval, mid-to long-term follow-up from controlled studies with a larger number of subjects is needed to determine whether implantation of a collagen scaffold is able to slow joint degeneration, reduce pain, or otherwise improve the net health outcome.

There are no randomized controlled trials for the polyurethane meniscal scaffold, and this product is not approved for marketing in the U.S. at this time. Therefore, synthetic meniscal implants are considered investigational.

## Practice Guidelines and Position Statements

The 2012 guidance from the United Kingdom's National Institute for Health and Clinical 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. (24) Therefore, NICE recommends that this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

The American Academy of Orthopaedic Surgeons (AAOS) stated in 2009 that a meniscal transplant may be recommended for active people younger than 55-years-old, with the goal of replacing the meniscus cushion before the articular cartilage is damaged. (25) The hope is that the transplant will also delay the development of arthritis, but long-term results are not yet available. The website also notes that "synthetic (artificial) meniscal tissue has been tried, but there is conflicting information at this time".

## 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

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

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

- Effective in 2005, there is a CPT category I code specific to this procedure when performed arthroscopically:
- There is no CPT code for implantation of the ReGen Collagen Scaffold G0428 – collagen meniscus implant procedure for filling meniscal defect (e.g., CMI, collagen scaffold, Menaflex), 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.

### DIAGNOSIS

717.0 Internal derangement of knee; old bucket handle tear of medial meniscus

717.1 Internal derangement of knee; derangement of anterior horn of medial meniscus

717.2 Internal derangement of knee; derangement of posterior horn of medial meniscus

717.3 Internal derangement of knee; other and unspecified derangement of medial meniscus

- 717.40 Derangement of lateral meniscus; unspecified
- 717.41 Derangement of lateral meniscus; bucket handle tear of lateral meniscus
- 717.42 Derangement of lateral meniscus; derangement of anterior horn of lateral meniscus
- 717.43 Derangement of lateral meniscus; derangement of posterior horn of lateral meniscus
- 717.49 Derangement of lateral meniscus; other
- 717.5 Internal derangement of knee; derangement of meniscus, not elsewhere classified
- 836.0 Dislocation of knee; tear of medial cartilage or meniscus of knee, current
- 836.1 Dislocation of knee; tear of lateral cartilage or meniscus of knee, current
- 836.2 Dislocation of knee; other tear of cartilage or meniscus of knee, current

### **ICD-10 Diagnosis** *(Effective October 1, 2014)*

- 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 tar 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
- S83.31xA 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**

07-21-2011	<p>Updated the Description section.</p> <p>In the Policy section:</p> <ul style="list-style-type: none"> <li>▪ Removed "Meniscal transplantation is experimental / investigational due to the lack of long-term studies."</li> <li>▪ Added:                             <ul style="list-style-type: none"> <li>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:                                     <ol style="list-style-type: none"> <li>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).</li> </ol> </li> </ul> </li> </ul>
------------	---

	<p>2. Disabling knee pain with activity that is refractory to conservative treatment.</p> <p>3. Absence or near absence (more than 50%) of the meniscus, established by imaging or prior surgery.</p> <p>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).</p> <p>5. Normal knee biomechanics, or alignment and stability achieved concurrently with Meniscal transplantation.</p> <p>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.</p> <p>C. Collagen meniscus implants are considered experimental / investigational.</p> <p><u>Policy Guidelines</u></p> <p>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.</p> <p>Severe obesity, e.g., body mass index (BMI) greater than 35 kg/m<sup>2</sup>, 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.</p>
	<p>Added Rationale section.</p>
	<p>In the Diagnosis section:</p> <ul style="list-style-type: none"> <li>▪ Added 717.1-717.5; 836.0-836.2</li> </ul>
	<p>Added Revisions section.</p>
	<p>Added Reference section.</p>
<p>08-13-2012</p>	<p>Rationale section updated.</p>
	<p>Reference section updated.</p>
<p>09-17-2013</p>	<p>In the Medical Policy Title, replaced "collagen" with "other" to read "Meniscal Allografts and Other Meniscus Implants"</p> <p>Updated Description section.</p> <p>In Policy section:</p> <ul style="list-style-type: none"> <li>▪ In Item C, replaced "collagen" with "Use of" to read "Use of other meniscal implants..."</li> </ul> <p>Updated Rationale section.</p> <p>In Coding section:</p> <ul style="list-style-type: none"> <li>▪ Updated coding nomenclature.</li> <li>▪ Added HCPCS code G0428.</li> <li>▪ Added ICD-10 Diagnosis codes. <i>(Effective October 1,2 014)</i></li> </ul> <p>Reference section updated.</p>

**REFERENCES**

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Meniscal Allograft Transplantation. TEC Assessments 1997; Volume 12, Tab14.
2. Johnson DL, Bealle D. Meniscal allograft transplantation. Clin Sports Med 1999; 18(1):93-108.
3. CryoLife Web site. Available online at: [www.cryolife.com](http://www.cryolife.com). Last accessed February 2013.
4. Matava MJ. Meniscal allograft transplantation: a systematic review. Clin Orthop Relat Res 2007; 455:142-57.
5. 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):147-57.
6. Hergan D, Thut D, Sherman O et al. Meniscal allograft transplantation. Arthroscopy 2011; 27(1):101-12.
7. 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):715-24.
8. 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.
9. 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):2134-9.
10. 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):2240-7.
11. Hommen JP, Applegate GR, Del Pizzo W. Meniscus allograft transplantation: ten-year results of cryopreserved allografts. Arthroscopy 2007; 23(4):388-93.
12. von Lewinski G, Milachowski KA, Weismeier K 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 2007; 15(9):1072-82.
13. 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):409-18.
14. 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):941-8.
15. 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):1459-66.
16. 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):1770-8.
17. 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):135-46.
18. 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):1413-26.

19. Linke RD, Ulmer M, Imhoff AB. [Replacement of the meniscus with a collagen implant (CMI)]. *Oper Orthop Traumatol* 2006; 18(5-6):453-62.
20. 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):977-85.
21. 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* 2012 [Epub ahead of print].
22. 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):774-82.
23. 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):844-53.
24. National Institute for Health and Clinical Excellence. IPG430 Partial replacement of the meniscus of the knee using a biodegradable scaffold: guidance. 2012. Available online at: <http://guidance.nice.org.uk/IPG430/Guidance/pdf/English>. Last accessed January, 2013.
25. American Academy of Orthopaedic Surgeons. Meniscal transplant surgery. *Your Orthopaedic Connection* 2009. Available online at: [http://orthoinfo.aaos.org/topic.cfm?topic=A00381&return\\_link=0](http://orthoinfo.aaos.org/topic.cfm?topic=A00381&return_link=0). Last accessed January, 2013.

### Other References

1. Blue Cross and Blue Shield of Kansas, Orthopedic Liaison Committee, January 2007; February 2013.
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.