Policy Replaced with LCD L36954 Effective February 26, 2018

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Meniscal Allografts and Other Meniscus Implants

Policy #: 158
Category: Surgery

Latest Review Date: April 2017
Policy Grade: B

Background:

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coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

Description of Procedure or Service:

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.

Meniscal Cartilage

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 (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. With this greater understanding, the surgical principles of treating torn or damaged menisci evolved to favor repair and preservation whenever possible.

Treatment

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

were asked about type of allograft preference, 68% responded fresh frozen nonirradiated allografts, with 14% responding fresh viable allografts.

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

Tissue engineering that grows new replacement host tissue is also being investigated. For example, the Collagen Meniscus Implant (Ivy Sports Medicine, formerly the ReGen Collagen Scaffold by ReGen Biologics), is a resorbable collagen matrix comprised primarily of Type I collagen from bovine Achilles tendons. The implant is provided in a semilunar shape and trimmed to size for suturing to the remaining meniscal rim. The implant provides an absorbable collagen scaffold that is replaced by the patient's own soft tissue; it is not intended to replace normal body structure. Because it requires a meniscal rim for attachment, it is intended to fill meniscus defects after a partial meniscectomy. Other scaffold materials and cell-seeding techniques are being investigated. For example, Actifit® (Orteq) is a biodegradable polyurethane scaffold that currently has market approval 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.

Policy:

Effective for dates of service on or after February 26, 2018 refer to LCD L36954

Effective for dates of service on or after April 30, 2017 and prior to February 26, 2018:
Blue Advantage will treat **meniscal allograft transplantation** as a **covered** benefit in patients who have had a prior meniscectomy and have symptoms related to the affected side, when **all** of the following criteria are met:

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

Blue Advantage will treat **meniscal allograft transplantation** as a **covered** benefit when performed in combination, either concurrently or sequentially, with autologous chondrocyte implantation or osteochondral allografting for focal articular cartilage lesions.

Blue Advantage will treat **contraindicated meniscal allograft transplantation** as a **non-covered benefit for the following:**

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

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

For coverage of collagen meniscus implant please refer to the NCD for Collagen Meniscus Implant (150.12).

Effective for dates of service on or after July 26, 2011 and prior to April 30, 2017:
Blue Advantage will treat **meniscal allograft transplantation** as a **covered** benefit in patients who have had a prior meniscectomy and have symptoms related to the affected side, when **all** of the following criteria are met:

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

Effective for dates of service on or after July 26, 2011:
Blue Advantage will treat **meniscal allograft transplantation** as a **covered** benefit when performed in combination, either concurrently or sequentially, with autologous chondrocyte implantation or osteochondral allografting for focal articular cartilage lesions.

For coverage of collagen meniscus implant please refer to the NCD for Collagen Meniscus Implant (150.12).

NOTE:

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

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

Key Points:

This evidence review has been updated regularly with searches using the MEDLINE database. The most recent literature update was performed through February 23, 2017**.**

Meniscal Allograft Transplantation

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 that is 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 done that compare meniscal allografts with other orthopedic procedures, although trials of allograft transplant versus medical therapy are possible. The outcomes of this treatment (i.e., pain, functional status) are subjective, patient-reported outcomes that are prone to placebo effects. On the other hand, the natural history of a severely damaged meniscus is predictable, with progressive joint damage, pain, and loss of function.

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

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

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

Table 1: Summary of Key Systematic Reviews of Meniscal Allograft Transplantation

Variables	Elattar (2011)	Hergan (2011)	Rosso (2015)
No. and type of studies	44 cohort and case series	14 cohort and case series with minimum 2-y follow-up	55 (2 level II, 7 level III, 46 level IV)
Population	1136 knees (1068 patients)	196 knees	1623 patients
Follow-up	4.6 y (range, 8 mo to 20 y)	53.8 mo (range, 24-167 mo)	53.6 mo (range, 12-168 mo)
Main outcome measures	Various measures of pain and function	Various measures of pain and function	Various measures of pain and function
Review Synthesis			
Pain and function	All showed clinical improvement	Alleviation of knee pain and improvement in function noted	Weighted pre-/postmeasures: [a] • 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 both objective and subjective outcome measures shown in relatively young patients without significant chondromalacia who underwent concomitant procedures 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 are 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.
a Data from 37 out of the 55 studies in the systematic review

Table 2: Summary of Key Trial Characteristic on Meniscal Allografts

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

FU: follow up

Table 3: Summary of Key Trial Results on Meniscal Allografts

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

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

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

At a mean of 16 years of follow-up, Van der Wal et al reported graft survival decreased to 52.5%.6 Most failures in the study by Vundelinckx et al (2010) occurred approximately 10 years postoperatively; average 105-month follow-up from the 34 remaining patients showed significant improvements in pain and function relative to preoperative levels. One question that is frequently asked is whether meniscal allografts can slow the progression to osteoarthritis. Radiographic evaluation in the study by Van der Wal et al showed a slight or moderate increase in

osteoarthritis (OA) in 42% of the patients (1 or 2 points), and no increase in OA in 58% of patients. Of 15 patients with follow-up radiographs in the study by Hommen et al, 10 (67%) had joint space narrowing, and 12 (80%) had progression of the Fairbank degenerative joint disease score in the transplanted tibiofemoral compartment.

Section Summary: Meniscal Allograft Transplantation

Evidence for the use of MAT in patients with disabling knee pain and a prior meniscectomy consists of systematic reviews of a large number of case series. The reviews conclude 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, of 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 (case series and systematic reviews of these case series) as well as the heterogeneity in surgical technique and patient characteristics across the studies.

Combined Meniscus Transplantation and Articular Cartilage Repair

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

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

Harris et al (2011) published a systematic review of combined meniscal allograft transplantation and cartilage repair/restoration in 2011 (See Tables 4 and 5). 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 with the preoperative condition. Outcomes were also found to be similar to historical outcomes, extracted from midterm and long-term follow-up studies, of procedures performed in isolation. Additional surgeries are common after combined meniscal allograft transplantation and cartilage repair/restoration procedures; nearly 50% of the patients underwent one or more subsequent surgeries.

Table 4: Summary of Key Systematic Reviews

Variables	Harris et al (2011)
No. and types of studies	6 case series
Population	N=110 patients
Intervention	Meniscal allograft combined with cartilage repair or restoration
Control	• Baseline to posttreatment • Historical controls of procedures performed in isolation
Main outcome measures	Variable outcome measures in 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 to be as good as historical controls
Review conclusion	Meniscal allograft can improve pain and function when combined with cartilage repair or restoration procedures
Review limitations	Based on case series with historical controls

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

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

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

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

Table 5: Key Trials (Case Series) on Meniscal Transplantation in Patients with Articular Cartilage Damage

Variables	Stone et al (2010)	Kempshall et al (2015)	Farr et al (2007)	Rue et al (2008)
Sample size	115	99	36	30
Population	Consecutive patients with Grade III-IV chondral damage	Prospective series Grade 3b <1 cm^2 Grade 3b >1 cm^2	Prospective series	Prospective series
Intervention	Meniscal allograft transplantation	MACI and microfracture more common if chondral damage was 3c >1 cm^2	ACI with meniscal transplantation	ACI or OAT with meniscal transplantation
Control	None	None	None	None

Main outcome measures	Allograft survival	Allograft survival KOOS, TAS, LKS, IKDC scores	Allograft survival Additional surgeries	LKS score
Length of follow-up	5.8 y	2 y	2 y	3.1 y
Results	Mean allograft survival was 9.9 y 47% required additional operations	Similar outcomes on KOOS, TAS, LKS, IKDC scores for 2 groups Allograft survival was 97.9% if 3b <1 cm^2 and 78% if 3c >1 cm^2	4 failures 68% required additional surgeries	LKS improved from 55-79 when meniscal allografts were combined with ACI and from 42-68 with OAT

ACI: autologous chondrocyte implantation; FU: follow-up; IKDC: International Knee Documentation Committee; KOOS: Knee Injury and Osteoarthritis Outcome Score; LSK: Lysholm Knee Score; MACI: matrix-assisted autologous chondrocyte implantation; OAT: osteochondral autograft transplantation; TAS: Tegner Activity Scale.

Section Summary

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

Collagen Meniscus Implants

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

Two systematic reviews, 1 published in 2012 (Harston et al) and 1 published in 2015 (Warth et al) are summarized in Table 6. A third systematic review by Zaffagnini (2015) focused only on studies that included postoperative MRI evaluations. Six studies were included; none was an RCT and all 6 were also included in the Warth review.

Table 6: Summary of Key Systematic Reviews of Collagen Meniscus Implant

Variables	Harston et al (2012)	Warth et al (2015)
Search date	May 2011	March 2014
No. of studies	11	13
Population	520	674
Intervention	• 321 patients received a CMI • 41.1% patients had concomitant procedures	• 439 patients received CMI • 32.3% patients had concomitant procedures
Control	Partial meniscectomy alone	
Main outcome measures	• LKS, TAS, pain scales • 8 of 11 studies provided postoperative imaging data	• LKS, TAS, pain scales • 11 of 13 studies provided postoperative imaging data

Length of FU	6-135 mo	3-152 mo
Review synthesis	• Approximately 66%-70% of patients receiving CMI had satisfactory outcomes • Outcomes in studies with control or comparison groups reported improvements in both groups • Reduced CMI size at last follow-up reported in 6 (54.5%) of 11 studies	• CMI has shown superior clinical outcomes vs partial meniscectomy alone • Several studies reported that meniscus scaffold decreased in volume over time • Second-look arthroscopy showed presence of newly formed meniscus-like tissue in area of the scaffold
Review limitations	• Based on low-quality evidence • Additional well-designed long-term prospective studies are needed	• Mostly level IV studies • Unable to conduct meta-analysis due to differing methodologies and data reporting across studies

CMI: collagen meniscus implant; FU: follow-up; LSK: Lysholm Knee Score; TAS: Tegner Activity Scale.

Table 7: Summary of Key Trial Characteristics on the Collagen Meniscus Implant

Variables	Rodkey et al (2008)	Link et al (2006)	Zaffagnini et al (2011)	Bulgheroni et al (2014)
Study design	RCT	RCT	Controlled cohort	Retrospective cohorts
Sample size	311	60	36	34
Population	Acute and chronic partial meniscectomy		Patient choice	Matched controls
Intervention	CMI	Osteotomy plus CMI	CMI	CMI
Control	Partial Meniscectomy alone	Osteotomy alone	Partial Meniscectomy alone	Partial Meniscectomy alone
Length of follow-up	59 (16-92) mo	8-18 mo	133 (120-152) mo	9.6 y

CMI: collagen meniscus implant; RCT: randomized controlled trial.

Table 8. Summary of Key Trial Results on the Collagen Meniscus Implant

Outcomes	Rodkey et al (2008)			Linke et al (2006)			Zaffagnini et al (2011)			Bulgheroni et al (2014)		
	CMI	Ctrl	p	CMI	Ctrl	p	CMI	Ctrl	p	CMI	Ctrl	p
Survival rate	90%a	80%a		65%			89%					
VAS pain	19/100a	21/100a		2.2/10	1.5/10	NS	1.2/10	3.3/10	<0.004	14.7/100	13.5/100	*NS*
LKS	79a	78a	*NS*	93.6	91.0	*NS*	86	80	*NS*	94.1	95.5	*NS*
IKDC						N			<0.001	85.7	88.1	*NS*

				S			[b]			
TAS	42%a	29%a	*<0.02*	75	50	<0.026	6 5-6	6 5-6	*NS*

CMI: collagen meniscus implant; Ctrl: control; IKDC: International Knee Documentation Committee; LSK: Lysholm Knee Score; RCT: randomized controlled trial; TAS: Tegner Activity Scale; VAS: visual analog scale.
a Chronic only.
b Higher scores reported by CMI group vs control group.

Research 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 an FDA investigational device exemption (IDE). Only Tegner activity scores in the chronic arm (but not the acute arm) were significantly different 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 initial results from a randomized trial that compared high tibial valgus osteotomy alone versus osteotomy plus CMI (Linke et al, 2006). Arthroscopy in the CMI group showed complete healing in 35%, partial healing in 30% requiring resection of the posterior part of the implant, and 35 % of patients with only small remains of the collagen implant 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 were not significantly different between the CMI and control groups.

Zaffagnini et al (2011) compared outcomes of 18 patients who chose to receive a CMI versus 18 patients who chose a partial medial meniscectomy, with a minimum ten-year follow-up. The two groups were comparable at baseline. No significant differences were found in the LSK and Yulish scores. Independent and blinded radiographic evaluation showed significantly less medial joint space narrowing in the implant group than in the partial meniscectomy group (0.48 vs. 2.13 mm, respectively). This study is limited by the potential for selection bias. A retrospective review by Bulgheroni (2014) of 34 patients (17 partial medical meniscectomy and 17 CMI) found no significant difference between the groups for pain and function scores at an average of 9.6 year follow-up.

Section Summary: Collagen Meniscus Implants
Evidence for the use of CMI for patients undergoing partial meniscectomies consists of 2 systematic reviews, the most recent including 674 patients. The reviews reported overall positive results with the CMI, but the quality of the included studies (RCTs and observational studies) was low. Radiologic evaluations show destruction and/or absorption of the implant in a very large portion of patients.

Polyurethane Meniscal Implant
A polyurethane meniscal implant (Actifit) is currently on the market in Europe. There are no FDA-approved polyurethane meniscal implants to date.

Evidence on the polyurethane meniscal implant (PMI) includes a prospective multicenter series from the Actifit Study Group, an independently conducted pragmatic trial, and a case series (see Tables 9 and 10). Verdonk et al (2012) reported positive results in two-year clinical outcomes in

patients who received a PMI at the time of partial meniscectomy (34 medial, 18 lateral). In 2016, Dhollander et al presented updated data on 44 patients in this cohort. Significant improvements in VAS pain, IKDC, and KOOS were maintained through 5-year follow-up (see Table 10). Interpretations of these results are 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 post-meniscectomy syndrome. Using last observation carried forward for missing data, clinical outcomes were found to improve over the course of the study. This study is also limited by the lack of a control group. In contrast with the results from the Actifit Study Group, a controlled pragmatic trial found no benefit of inserting an Actifit at the time of high tibial osteotomy compared with benefit in patients who were left with a meniscus defect.

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 for a subset of patients followed for 4 years (n=16) have shown that significant improvements in pain and function have been maintained.

Table 9: Summary of Key Trial Characteristics on the Polyurethane Meniscal Implant

Variables	Verdonk (2012) Dhollander (2016)	Bouyarmane (2014)	Gelber (2015)	Schuttler (2016)
	Actifit Study Group			
Study design	Prospective multicenter series	Prospective multicenter series	Pragmatic comparative trial	Case series
Sample size	52	54	60	18
Inclusion	Undergoing partial meniscectomy	Postmeniscectomy syndrome	Symptomatic varus knees with defect >25 mm	Symptomatic segmented medial meniscus deficiency
Intervention	FU of subjects from Verdonk et al (2011)26	PMI of the lateral meniscus	HTO with PMI	FU of subjects from Efe et al (2012)32
Control	None	None	HTO without PMI	None
Main outcome measures	Clinical outcomes	Clinical outcomes	Clinical outcomes	Clinical and radiographic outcomes
Length of FU	5 y	24 mo	31.2 mo	48 mo

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

Table 10. Summary of Key Trial Results on the Polyurethane Meniscal Implant

Outcomes	Verdonk (2012) Dhollander (2016)		Bouyarmane (2014)		Gelber (2015)		Schuttler (2016)	
	Actifit Study Group							
	Pre	**Post**	**Pre**	**Post**	**Pre**	**Post**	**Pre**	**Post**
VAS pain	56.2/100	19.3/100a	5.5/10	2.9/10a	5.9	4.7b	5.2	1.0a
IKDC	38.7	66.9a	47.0	67.0a	56.7	50.3c		
KOOS pain	48.3	77.2a					47	89a
KOOS ADL	54.4	80.2					53	94a
KSS function							61	98a
KSS knee							65	90a

ADL: activities of daily living; IKDC: International Knee Documentation Committee; KOOS: Knee Injury and Osteoarthritis Outcome Score; KSS: Knee Society Score; VAS: visual analog score.
a $p<0.001$.
b $p<0.006$.

Section Summary: Polyurethane Meniscal Implant

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

Summary of Evidence

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.

For individuals who are undergoing partial meniscectomy, who receive meniscal allograft transplantation, the evidence includes systematic reviews of mostly case series. Relevant outcomes include symptoms, function, and quality of life (for example: VAS pain, Lysholm Knee score, Tegner Activity Scale, SF-36). The systematic reviews conclude that a majority of the studies have shown statistically significant improvements in pain and function following the procedure. The benefits have also been shown to be long-term, past 10 years. The reviews also report 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 these conclusions is the reliance on mostly case series. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are undergoing partial meniscectomy with a concomitant procedure to repair malalignment, focal chondral defects and/or ligamentous insufficiency, who receive meniscal allograft transplantation, the evidence includes one systematic review of case series as well as several case series published after the systematic review. Relevant outcomes include symptoms, function, and quality of life (for example: VAS pain, Lysholm Knee score, Tegner Activity Scale, SF-36). The systematic review concluded that pain and function improved following the procedure. One of the studies published after the review showed that patients with more severe cartilage damage experienced favorable outcomes similar to patients with less cartilage damage. Another study published after the review reported an overall 9.7 year survival of the implant. A limitation of these conclusions is the reliance on mostly case series. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are undergoing partial meniscectomy, who receive collagen meniscal implants, the evidence includes two systematic reviews of mostly case series. Relevant outcomes include symptoms, function, and quality of life (for example: VAS pain, Lysholm Knee score, Tegner Activity Scale, SF-36). The reviews reported overall positive results with the CMI, but the quality of the included studies (RCTs and observational studies) is low. Radiologic evaluations showed reduced size of the implant in a large portion of patients. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 include symptoms, and quality of life (for example: VAS pain, Lysholm Knee score, Tegner Activity Scale, SF-36). Overall improvements in pain and function were 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. There are currently no FDA-approved polyurethane meniscal implants in the U.S. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

International Meniscus Reconstruction Experts Forum

In 2015, the International Meniscus Reconstruction Experts Forum published consensus statements on the practice of meniscal allograft transplantation (MAT) (see Table 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

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

ACL: anterior cruciate ligament; ACR: articular cartilage repair; EQ-5D: EuroQoL 5 dimensions questionnaire; IMREF: International Meniscus Reconstruction Experts Forum; KOOS: Knee injury and Osteoarthritis Outcome Score; MAT: meniscal allograft transplantation; MRI: magnetic resonance imaging; OA: osteoarthritis; QOL: quality of life; WOMAT: Western Ontario Meniscal Evaluation Tool.

National Institute for Health and Care Excellence

The 2012 guidance from the United Kingdom's National Institute for Health and Care Excellence (NICE) stated that evidence on partial replacement of the meniscus of the knee using a biodegradable scaffold raised no major safety concerns, but evidence for any advantage of the procedure over standard surgery was limited. NICE recommended that this procedure only be used with special arrangements for clinical governance, consent and audit or research.

American Academy of Orthopaedic Surgeons

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. 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".

U.S. Preventive Services Task Force Recommendations
Not applicable.

Key Words:

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

Approved by Governing Bodies:

In 2008, the ReGen Collagen Scaffold (CS) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA determined that this device was substantially equivalent to existing predicate absorbable surgical mesh devices. The ReGen Collagen Scaffold (also known as MenaFlex™ CMI) was the only collagen meniscus implant (CMI) with FDA clearance at that time. Amid controversy about the 510(k) clearance, FDA initiated a review of the clearance process. In October 2010, FDA rescinded the approval, stating that MenaFlex™ is intended for different purposes and is technologically dissimilar from the predicate devices identified in the approval process. The manufacturer appealed the rescission, and won its appeal in 2014. The product is now called CMI® and manufactured by Ivy Sports Medicine. CMI® is the only FDA-approved collagen meniscus product currently on the market.

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

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

Current Codes:

CPT coding:

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

HCPCS:

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

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This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.