MEDICAL POLICY

POLICY TITLE	MENISCAL ALLOGRAFTS AND OTHER MENISCAL IMPLANTS
POLICY NUMBER	MP-1.010

Original Issue Date (Created):	**7/1/2002**
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Effective Date:	**9/1/2018** **RETIRED**

I. POLICY

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:

- Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., younger than 55 years)
- Disabling knee pain with activity that is refractory to conservative treatment
- 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.

Meniscal allograft transplantation may be considered **medically necessary** when performed in combination, either concurrently or sequentially, with treatment of focal articular cartilage lesions using any of the following procedures:

- autologous chondrocyte implantation, or
- osteochondral allografting, or
- osteochondral autografting.

Use of other meniscal implants incorporating materials such as collagen and polyurethane are considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

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Policy Guidelines

Patients should exhibit symptoms of persistent disabling knee pain that has not shown an adequate response to physical therapy and analgesic medications. Uncorrected misalignment and instability of the joint are contraindications. Therefore additional procedures, such as repair of ligaments or tendons or creation of an osteotomy for realignment of the joint, may be performed at the same time.

Severe obesity, e.g., body mass index greater than 35 kg/m^2, may affect outcomes due to the increased stress on weight-bearing surfaces of the joint. Meniscal allograft transplantation is typically recommended for young active patients who are too young for total knee arthroplasty.

Cross-references:
MP-1.022 Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions
MP-9.003 Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

II. PRODUCT VARIATIONS

TOP

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO - Refer to FEP Medical Policy Manual MP-7.01.15, Meniscal Allografts and Other Meniscus Implants. The FEP Medical Policy Manual can be found at: www.fepblue.org.

III. DESCRIPTION/BACKGROUND

TOP

Meniscal allografts and other meniscal implants (collagen or polyurethane) are intended to improve symptoms and reduce joint degeneration in patients who have had a total or partially resected meniscus.

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

Treatment
Meniscal allograft transplantation (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 3 general groups of patients who have been treated with MAT:

- young patients with a history of meniscectomy who have symptoms of pain and discomfort associated with early OA 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 OA. Due to the risks associated with this surgical procedure, prophylactic treatment for this purpose is not frequently recommended.

Issues under study include techniques for processing and storing the grafts, proper sizing of the grafts, and appropriate surgical techniques. The 4 primary ways of processing and storing allografts are: fresh viable, fresh frozen, cryopreserved, and lyophilized. Fresh viable implants, harvested under sterile conditions, are less frequently used because the grafts must be used within a couple of days to maintain viability. Alternatively, the harvested meniscus can be fresh frozen for storage until needed. Cryopreservation freezes the graft in glycerol, which aids in preserving the cell membrane integrity and donor fibrochondrocyte viability. Cryolife (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, shrinkage, poor rehydration, post-transplantation joint effusion, and synovitis; they are no longer used in the clinical setting. Several secondary sterilization techniques may be used, with gamma irradiation the most common. The dose of radiation considered effective has been shown to change the mechanical structure of the allograft; therefore, nonirradiated grafts from screened donors are most frequently used. In a survey conducted by the International Meniscus Reconstruction Experts Forum, when surgeons were asked about allograft preference, 68% preferred fresh frozen nonirradiated allografts, with 14% responding fresh viable allografts.[1]

There are several techniques for MAT; most are arthroscopically assisted or all-arthroscopic. Broadly, the techniques are either all-suture fixation or bone fixation. Within the bone fixation category, the surgeon may use either bone plugs or a bone bridge. Types of bone bridges include keyhole, trough, dove-tail, and bridge-in-slot. The technique used depends on laterality and the need for concomitant procedures. Patients with malalignment, focal chondral defects, and/or ligamentous insufficiency may need concomitant procedures (osteotomy, cartilage restoration, and/or ligament reconstruction, respectively).[2]

Tissue engineering that grows new replacement host tissue 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 composed primarily of type I collagen from bovine Achilles tendons. The implant is provided in a semilunar shape and trimmed to size for suturing to the remaining meniscal rim. The implant provides an absorbable collagen scaffold that is replaced by the patient's 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. Nonabsorbable and nonporous synthetic implants for total meniscus replacement are in development. One total meniscus replacement that is in early phase clinical testing is NUsurface® (Active Implants); it is composed of a polyethylene reinforced polycarbonate urethane.

REGULATORY STATUS

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

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

IV. RATIONALE TOP

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

Meniscal allograft transplantation (MAT) is considered a salvage procedure, reserved for patients with disabling knee pain following meniscectomy who are considered too young to undergo total knee arthroplasty (TKA). As a result, the population intended to receive these transplants is relatively limited. Using a large database of privately insured non-Medicare patients, a 2015 report estimated an annual incidence of MAT in the United States of 0.24 per 100,000.[3] It is not expected that clinical trials will be conducted to compare meniscal allografts with other orthopedic procedures, although trials comparing allograft transplant with medical therapy are possible. The outcomes of this treatment (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 MAT improve pain and function? and (2) Does this procedure reduce joint degeneration? Following is a summary of key references to date, focusing on graft survival and health outcomes with longer term follow-up.

MENISCAL ALLOGRAFT TRANSPLANTATION

Systematic Reviews

Several systematic reviews of available case series have found improvements in pain and function at mid-term follow-up, with failure rates at the time of follow-up that range from 7% to 35% (see Table 1). Elattar et al (2011) published a large systematic review with a total of 1136 allografts.[4] Twelve different clinical scoring systems were described, which generally showed an improvement in pain and function. Hergan et al (2011) conducted a systematic review of the literature to evaluate characteristics of patients, graft survival, and clinical outcomes.[5] Analysis found that patients with Outerbridge scores of 2 or less in any area had significantly improved posttreatment Lysholm Knee Score (LKS) and Tegner Activity Scale (TAS) scores, whereas patients with Outerbridge grade 3 or more in any area (not repaired) did not experience significant improvements in pain and function. Studies that analyzed patients undergoing concomitant procedures did not detect a difference between the subgroup compared with MAT alone. Functional outcomes were considered generally good where reported. In 2015, Rosso et al published a systematic review including 55 studies (total N=1623 patients).[6] Data from 37 studies were included in demographic and outcome analyses. These systematic reviews, which are based primarily on level IV evidence, summarize the short- to medium-term outcomes of MAT (see Table 1).

Table 1. Summary of Key Systematic Reviews of MAT

Variables	Elattar et al (2011)[4]	Hergan et al (2011)[5]	Rosso et al (2015)[6]
No. and study type	44 cohort and case series	14 cohort and case series with minimum 2-y follow-up	55 (2 level II, 7 level III, 46 level IV)
Population	1136 knees (1068 patients)	196 knees	1623 patients
Follow-up (range)	4.6 y (8 mo to 20 y)	53.8 mo (24-167 mo)	53.6 mo (12-168 mo)
Outcome measures	Pain and function	Pain and function	Pain and function
Review synthesis			
Pain and function	All showed clinical improvement	Alleviation of knee pain and improvement in function noted	Weighted pre-/postmeasures[a]: • VAS pain score decreased from 6.4 to 2.4 • LKS increased from 55.5 to 82.7
Failure rate	10.6%	7%-35%	Fresh frozen: 9.9% Cryopreserved: 18.2%
Complication rate	21.3%		10.6%
Review conclusion	Meniscal allograft improves pain and function	Improvements in objective and subjective outcome measures shown in relatively young patients without significant chondromalacia who underwent concomitant repair for cartilage defects, limb malalignment, and/or limb instability	Agreement in literature on MAT indications: • All studies showed clinical improvement at short- and mid-term follow-ups • Complication and failure rates acceptable • Potential chondro-protective effect of MAT remains unclear
Review limitations	Based primarily on case series	Based primarily on case series and qualitative review only	Based primarily on case series

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

Case Series

Several case series with longer term follow-up are discussed next. Series characteristics and results are provided in Tables 2 and 3. Verdonk et al (2005) published a large case series with long-term follow-up from 95% of their first 105 fresh cultured (viable) meniscal allografts.[7] The indication for transplantation was moderate-to-severe pain in patients who had undergone previous total meniscectomy, not old enough to be considered for a knee joint replacement, and with good alignment of the lower limb and a stable joint (some were corrected concomitantly). In the study by Hommen et al (2007), concomitant procedures were performed in 75% of the patients, including anterior cruciate ligament reconstruction or revision (n=10), high tibial osteotomy (n=2), and lateral retinaculum release (n=3).[8]

At a mean follow-up of 16 years, van der Wal et al (2009)[9] reported graft survival decreased to 52.5%, while most failures in the study by Vundelinckx et al (2010) occurred approximately 10 years postoperatively.[10] That said, at an average of 105-month follow-up, the 34 remaining patients assessed in the Vundelinckx study showed significant improvements in pain and function relative to preoperative levels. Radiographic evidence reported by van der Wal et al also showed a slight or moderate increase in osteoarthritis (OA) in 42% of patients (1 or 2 points), and no increase in the other 58%. Of 15 patients with follow-up radiographs in the Hommen study, 10 (67%) had joint space narrowing and 12 (80%) had progression of the Fairbank degenerative joint disease score in the transplanted tibiofemoral compartment.

Table 2. Summary of Key Case Series Characteristics for MAT

Variables	Verdonk et al (2005)[7]	Van der Wal et al (2009)[9]	Vundelinckx et al (2010)[10]
Sample size	105	57	34/49
Mean age (range), y	35 (16-50)	39 (26-55)	33 (14-47)
Population	Previous total meniscectomy	Previous total meniscectomy	Patients with intact allograft
Intervention	MAT	MAT	MAT
Control	None	None	None
Length of FU (range)	3-15 y	14 y (9-18 y)	105 mo

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

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

Outcomes	Verdonk et al (2005)[7]			Van der Wal et al (2009)[9]			Vundelinckx et al (2010)[10]		
	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.

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 have found that MAT is associated with reductions in pain and improvements in function. Longer term studies have indicated that these improvements are maintained in a substantial percentage of patients, up

to 10 years and beyond. Adverse events, such as graft failure and the need for additional procedures, occur frequently. The strength of the evidence, including accurate estimates of the magnitude of benefit and the complication rates, are limited by the type of data available (case series and systematic reviews of these case series) as well as the heterogeneity in surgical techniques and patient characteristics across the studies.

MAT PLUS 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 MAT in knees with chondral damage consists of 1 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 MAT plus cartilage repair or restoration (see Table 4).[11] Patients underwent MAT with autologous chondrocyte implantation (ACI; n=73), osteochondral allograft (n=20), osteochondral autograft (n=17), or microfracture (n=3). All studies showed improvement in clinical outcomes at final follow-up compared with the preoperative condition. Outcomes were similar to historical outcomes, extracted from mid-term and long-term follow-up studies, of procedures performed in isolation. Additional surgeries are common (nearly 50%) after MAT plus cartilage repair or restoration procedures.

Table 4. Summary of Key Systematic Reviews

Variables	Harris et al (2011)[11]
No. and study type	6 case series
Population	110
Intervention	MAT combined with cartilage repair or restoration
Control	• Baseline to posttreatment • Historical controls of procedures performed in isolation
Outcome measures	Pain and function
Review synthesis	• Outcomes improved from baseline to posttreatment • 4/6 studies found outcomes equivalent to procedures performed in isolation • 2/6 studies found combined surgery not as good as historical controls
Review conclusion	MAT can improve pain and function when combined with cartilage repair or restoration procedures
Review limitations	Based on case series with historical controls

MAT: meniscal allograft transplantation.

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

The following studies are those published more recently and subsequent to the systematic review (see Table 5). Kempshall et al (2015) looked at MAT concomitant with cartilage repair procedures on (1) patients with more knee cartilage damage (grade 3b >1 cm^2) and (2) patients with less knee cartilage damage (grade 3b <1 cm^2). Functional outcomes following the

procedures were similar between the 2 groups. However, implant survival (using graft failure as an end point) was lower among those with greater cartilage damage.[15]

Ogura et al (2016) retrospectively reviewed patients who had undergone ACI and MAT.[16] Seventeen patients were followed for a mean of 7.9 years. Significant improvements in clinical outcomes (visual analog scale for pain, Western Ontario and McMaster Universities Arthritis Index, 36-Item Short-Form Health Survey, and modified Cincinnati Knee Rating Scale scores) were reported in 65% of the patients. Of the 6 procedures considered failures, 4 underwent TKA and 2 underwent revision surgery.

Zaffagnini et al (2016) reviewed 147 patients undergoing arthroscopic bone plug-free MAT, with 48% of patients having concomitant procedures (mostly high tibial osteotomy and ACL reconstruction).[17] Two survival analyses were conducted, one with the end point of surgical failure (need for revision procedures related to initial MAT) and the other with the end point of clinical failure (same revision procedures as surgical failure or LKS less than 65 at final follow-up). Mean overall survival time with the surgical failure end point was 9.7 years (95% confidence interval [CI], 9.1 to 10.3 years) and mean overall survival with the clinical failure end point was 8.0 years (95% CI, 7.1 to 8.8 years). Logistic regression analysis did not reveal any variables (including concomitant procedures) affecting the surgical or clinical failure end points.

Table 5. Series of MAT with Articular Cartilage Repair

Variables	Stone et al (2010)[12]	Kempshall et al (2015)[15]	Ogura et al (2016)[16]	Zaffagnini et al (2016)[17]
Sample size	115	99	17	147
Population	Consecutive patients with grade III-IV chondral damage	Prospective series • Grade 3b <1 cm^2 • Grade 3b >1 cm^2	Retrospective series	Retrospective series
Intervention	MAT	MACI and microfracture more common if chondral damage was 3c >1 cm^2	ACI with MAT	MAT
Control	None	None	None	None
Outcome measures	MAT survival	• MAT survival • KOOS, TAS, LKS, IKDC scores	• MAT survival • MCKRS, WOMAC, VAS, SF-36	• MAT survival • KOOS, LKS, VAS
Length of FU	5.8 y	2 y	5-10 y	4 y
Results	• Mean MAT survival, 9.9 y • 47% required additional surgery	• Similar outcomes on KOOS, TAS, LKS, IKDC scores for 2 groups • MAT survival 97.9% if 3b <1 cm^2 and 78% if 3c >1 cm^2	• Mean MAT survival rate, 75% at 5- and 10-y follow-up • 67% (12/18) required additional surgery	• Mean MAT survival range, 8-9.7 y • 17% required additional surgery

ACI: autologous chondrocyte implantation; FU: follow-up; IKDC: International Knee Documentation Committee; KOOS: Knee Injury and Osteoarthritis Outcome Score; LSK: Lysholm Knee Score; MACI: matrix-assisted autologous chondrocyte implantation; MAT: meniscal allograft transplantation; MCKRS: modified Cincinnati Knee Rating Scale; OAT: osteochondral autograft transplantation; SF-36: 36-Item Short-Form Health Survey; TAS: Tegner Activity Scale; VAS: visual analog scale; WOMAC: Western Ontario and McMaster Universities Arthritis Index.

Section Summary: MAT Plus Articular Cartilage Repair

There is a limited amount of low-quality evidence on combined MAT and articular cartilage repair. The available literature has reported reductions in pain and improvements in functioning following these procedures, though studies have reported graft failures and the need for additional surgeries.

COLLAGEN MENISCUS IMPLANTS

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

Systematic Reviews

Two systematic reviews, 1 published in 2012 (Harston et al[18]) and 1 published in 2015 (Warth et al[19]) are summarized in Table 6. A third, by Zaffagnini et al (2015),[20] focused only on studies assessing postoperative magnetic resonance imaging evaluations, which included 6 studies, none was an RCT and all which were included in the Warth review. We do not discuss the Zaffagnini review further.

Table 6. Summary of Key Systematic Reviews for CMI

Variables	Harston et al (2012)[18]	Warth et al (2015)[19]
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	
Outcome measures	• LKS, TAS, pain scales • 8/11 studies provided postoperative imaging data	• LKS, TAS, pain scales • 11/13 studies provided postoperative imaging data
Length of FU	6-135 mo	3-152 mo
Review synthesis	• 66%-70% patients receiving CMI had satisfactory outcomes • 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 showed 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	• Mostly level IV evidence • No meta-analysis due to differing methodologies and data reporting across studies

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

The quality of the studies included in the systematic reviews was generally rated as low. Tables 7 and 8 summarize select studies (2 RCTs, 2 cohort) included in the systematic reviews. A large RCT from the manufacturers of MenaFlex (Rodkey et al, 2008) was conducted under a Food and Drug Administration (FDA) investigational device exemption (IDE).[21] Only TAS scores in the chronic arm (but not the acute arm) differed significantly between the CMI and partial meniscectomy only groups. Kaplan-Meier analysis suggested a modest 10% increase in survival in the chronic CMI group.

An independent research group published results from an RCT comparing high tibial valgus osteotomy alone and osteotomy plus CMI (Linke et al, 2006).[22] Arthroscopy in the CMI group showed 35% complete healing, 30% partial healing requiring resection of the posterior part of the implant, and 35% with only small remains of the CMI left. Complications included

implantation in insufficiently vascularized tissue, sutures cutting into the implant, inadequate fixation to the rim, destruction of the implant in an unstable knee joint or with premature loading postoperatively, allergic reaction to the xenogenic collagen implant, avulsion of the implant with joint blocking, and infection. Pain and function scores did not differ significantly between the CMI and control groups.

Zaffagnini et al (2011) compared outcomes of 18 patients who chose to CMI with 18 patients who chose partial medial meniscectomy, with a minimum 10-year follow-up.[23] The 2 groups were comparable at baseline. No significant differences were found in the LKS and Yulish scores. Independent and blinded radiographic evaluation showed significantly less medial joint space narrowing in the CMI group (0.48 mm) than in the partial meniscectomy group (2.13 mm). This study had a potential for selection bias.

Retrospective Studies

A retrospective review by Bulgheroni (2015) of 34 patients (17 CMI, 17 partial medial meniscectomy) found no significant difference between the groups for pain and function scores at an average of 9.6 year-follow-up.[24]

Table 7. Summary of Key Study Characteristics for CMI

Variables	Rodkey et al (2008)[21]	Linke et al (2006)[22]	Zaffagnini et al (2011)[23]	Bulgheroni et al 2014)[24]
Study design	RCT	RCT	Controlled cohort	Retrospective cohorts
Sample size	311	60	36	34
Population	Acute and chronic partial meniscectomy		Patient choice	Matched controls
Intervention	CMI	Osteotomy plus CMI	CMI	CMI
Control	Partial meniscectomy alone	Osteotomy alone	Partial meniscectomy alone	Partial meniscectomy alone
Length of FU (range)	59 mo (16-92 mo)	8-18 mo	133 mo (120-152 mo)	9.6 y

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

Table 8. Summary of Key Study Results for CMI

Outcomes	Rodkey et al (2008)[21]			Linke et al (2006)[22]			Zaffagnini et al (2011)[23]			Bulgheroni et al (2014)[24]		
	CMI	Ctrl	p	CMI	Ctrl	p	CMI	Ctrl	p	CMI	Ctrl	p
Survival rate	90%[a]	80%[a]		65%			89%					
VAS pain	19/100[a]	21/100[a]		2.2/10	1.5/10	*NS*	1.2/10	3.3/10	<0.004	14.7/100	13.5/100	*NS*
LKS	79[a]	78[a]	*NS*	93.6	91.0	*NS*	≈86	≈80	*NS*	94.1	95.5	*NS*
IKDC						*NS*			<0.001[b]	85.7	88.1	*NS*
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; TAS: Tegner Activity Scale; VAS: visual analog scale.
[a] Chronic only.
[b] Higher scores reported by CMI group vs control group.

Section Summary: Collagen Meniscus Implants

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

POLYURETHANE MENISCAL IMPLANT

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

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

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

In contrast with the results from the Actifit Study Group, a controlled pragmatic trial (2015) found no benefit of inserting an Actifit at the time of high tibial osteotomy compared with those left with a meniscus defect.[29]

A case series by Schuttler et al (2016) evaluated the use of Actifit to treat patients with symptomatic segmented medial meniscus deficiency (N=18).[30] Results from a subset of these patients followed for 4 years (n=16) showed that significant reductions in pain and improvements in function were maintained.

Table 9. Summary of Key Study Characteristics for PMI

Variables	Verdonk et al (2012)[25] Dhollander et al (2016)[27]	Bouyarmane et al (2014)[28]	Gelber et al (2015)[29]	Schuttler et al (2016)[30]
	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)[25]	PMI of the lateral meniscus	HTO with PMI	FU of subjects from Efe et al (2012)[31]
Control	None	None	HTO without PMI	None
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 Study Results on for PMI

Outcomes	Verdonk et al (2012)[26] Dhollander et al (2016)[27]		Bouyarmane et al (2014)[28]		Gelber et al (2015)[29]		Schuttler et al (2016)[30]	
	Actifit Study Group							
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
VAS pain	56.2/100	19.3/100[a]	5.5/10	2.9/10[a]	5.9	4.7[b]	5.2	1.0[a]
IKDC	38.7	66.9[a]	47.0	67.0[a]	56.7	50.3[c]		
KOOS pain	48.3	77.2[a]					47	89[a]
KOOS ADLs	54.4	80.2					53	94[a]
KSS function							61	98[a]
KSS knee							65	90[a]

ADLs: activities of daily living; IKDC: International Knee Documentation Committee; KOOS: Knee Injury and Osteoarthritis Outcome Score; KSS: Knee Society Score; VAS: visual analog score.
[a] p<0.001.
[b] p<0.006.
[c] Not significant.

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

SUMMARY OF EVIDENCE
For individuals who are undergoing partial meniscectomy who receive meniscal allograft transplantation, the evidence includes systematic reviews of mostly case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic reviews concluded that most studies have shown statistically significant improvements in pain and function following the procedure. The benefits have also been shown to have long-term effect (>10 years). Reviews have also reported acceptable complication and failure rates. There remains no evidence that meniscal allograft transplantation can delay or prevent the development of knee osteoarthritis. A limitation of the evidence is its reliance primarily on case series. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

For individuals who are undergoing partial meniscectomy who receive collagen meniscal implants, the evidence includes 2 systematic reviews primarily of case series. Relevant outcomes

are symptoms, functional outcomes, and quality of life. The reviews reported overall positive results with the collagen meniscus implant, but the quality of the included studies (randomized controlled trials, observational studies) is low. Radiologic evaluations have shown reduced size of the implant in a large portion of patients. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

CLINICAL INPUT FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS

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

2011 Input

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

2008 Input

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

PRACTICE GUIDELINES AND POSITION STATEMENTS

International Meniscus Reconstruction Experts Forum

In 2015, the International Meniscus Reconstruction Experts Forum published consensus statements on the practice of meniscal allograft transplantation (MAT) (see Table 11).[1] 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; OA: osteoarthritis; QOL: quality of life; WOMAT: Western Ontario Meniscal Evaluation Tool.

National Institute for Health and Care Excellence

The 2012 guidance from the U.K.s National Institute for Health and Care Excellence (NICE) stated that the evidence on "partial replacement of the meniscus of the knee using a biodegradable scaffold raises no major safety concerns," but evidence for any advantage of the procedure over standard surgery was limited.[32] NICE recommended that "this procedure should 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 stated in 2009 that a MAT 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.[33] The website also notes that "synthetic (artificial) meniscal tissue has been tried, but there is conflicting information at this time."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

In May 2010, the Centers for Medicare and Medicaid Services (CMS) issued a national noncoverage determination for the collagen meniscus implant (CMI).[34] A number of concerns regarding the efficacy and safety were raised in the CMS analysis that compared data reported to the Food and Drug Administration and published data. Concerns included an increased number of reoperations and a higher serious adverse event rate than in the control group. CMS concluded

that the CMI does not improve health outcomes in the Medicare population and determined that the CMI is not reasonable and necessary for the treatment of meniscal injury or tear.

Ongoing and Unpublished Clinical Trials
Currently ongoing and unpublished trials that might influence this review are listed in Table 12.

Table 12. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01712191[a]	Treatment of the Medial Meniscus with the Treatment of the Medial Meniscus with the NUSurface® Meniscus Implant	150	Jun 2017
NCT01059409	The Clinical and Medico-economical Evaluation of Meniscal Allografts in the Sequelae of Total or Sub-total Meniscectomy	120	Sep 2017
NCT02136901[a]	The VENUS Clinical Study (Verifying the Effectiveness of the NUSurface® System): A Multi-center, Prospective, Randomized, Interventional Superiority Clinical Study	37	Feb 2019

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

V. DEFINITIONS

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ALLOGRAFT refers to transplant tissue obtained from a member of one's own species.

ANTERIOR CRUCIATE LIGAMENT (ACL) refers to the cross-shaped ligaments in the front of the knee.

ARTHROTOMY refers to cutting into a joint.

MENISCECTOMY refers to removal of the meniscus cartilage of the knee.

OSTEOARTHRITIS is a type of arthritis marked by progressive cartilage deterioration in the synovial joints and vertebrae.

OUTERBRIDGE CLASSIFICATION refers to classification of chondral damage to the articular surface of the patella according to the following five grades: Grade 0- normal cartilage; Grade I- cartilage with softening and swelling; Grade II- a partial-thickness defect with fissures on the surface that do not reach subchondral bone or exceed 1.5 cm in diameter; Grade III- fissuring to the level of subchondral bone in an area with a diameter more than 1.5 cm; Grade IV- exposed subchondral bone.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require

preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement**.**

Investigational; therefore not covered:

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

Covered when medically necessary:

CPT Codes®								
29868								

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ICD-10-CM Diagnosis Codes	Description
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

POLICY TITLE	MENISCAL ALLOGRAFTS AND OTHER MENISCAL IMPLANTS
POLICY NUMBER	MP-1.010

ICD-10-CM Diagnosis Codes	Description
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
M23.211	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 of 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
M23.311	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 derangement, anterior horn of lateral meniscus, 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
M23.311	Other meniscus derangements, anterior horn of medial meniscus, right knee

POLICY TITLE	MENISCAL ALLOGRAFTS AND OTHER MENISCAL IMPLANTS
POLICY NUMBER	MP-1.010

ICD-10-CM Diagnosis Codes	Description
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 derangement, anterior horn of lateral meniscus, right knee
M23.342	Other meniscus derangement, 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
M25.561	Pain in right knee
M25.562	Pain in left knee
Q68.2	Congenital deformity of knee
Q68.6	Discoid meniscus
Q74.1	Congenital malformation of knee
S83.011A	Lateral subluxation of right patella, initial encounter
S83.012A	Lateral subluxation of left patella, initial encounter
S83.014A	Lateral dislocation of right patella, initial encounter
S83.015A	Lateral dislocation of left patella, initial encounter
S83.091A	Other subluxation of right patella, initial encounter
S83.092A	Other subluxation of left patella, initial encounter
S83.094A	Other dislocation of right patella, initial encounter
S83.095A	Other dislocation of left patella, initial encounter

POLICY TITLE	MENISCAL ALLOGRAFTS AND OTHER MENISCAL IMPLANTS
POLICY NUMBER	MP-1.010

ICD-10-CM Diagnosis Codes	Description
S83.111A	Anterior subluxation of proximal end of tibia, right knee, initial encounter
S83.112A	Anterior subluxation of proximal end of tibia, left knee, initial encounter
S83.114A	Anterior dislocation of proximal end of tibia, right knee, initial encounter
S83.115A	Anterior dislocation of proximal end of tibia, left knee, initial encounter
S83.121A	Posterior subluxation of proximal end of tibia, right knee, initial encounter
S83.122A	Posterior subluxation of proximal end of tibia, left knee, initial encounter
S83.124A	Posterior dislocation of proximal end of tibia, right knee, initial encounter
S83.125A	Posterior dislocation of proximal end of tibia, left knee, initial encounter
S83.131A	Medial subluxation of proximal end of tibia, right knee, initial encounter
S83.132A	Medial subluxation of proximal end of tibia, left knee, initial encounter
S83.134A	Medial dislocation of proximal end of tibia, right knee, initial encounter
S83.135A	Medial dislocation of proximal end of tibia, left knee, initial encounter
S83.141A	Lateral subluxation of proximal end of tibia, right knee, initial encounter
S83.142A	Lateral subluxation of proximal end of tibia, left knee, initial encounter
S83.144A	Lateral dislocation of proximal end of tibia, right knee, initial encounter
S83.145A	Lateral dislocation of proximal end of tibia, left knee, initial encounter
S83.191A	Other subluxation of right knee, initial encounter
S83.192A	Other subluxation of left knee, initial encounter
S83.194A	Other dislocation of right knee, initial encounter
S83.195A	Other dislocation of left knee, initial encounter
S83.211A	Bucket-handle tear of medial meniscus, current injury, right knee, initial encounter
S83.212A	Bucket-handle tear of medial meniscus, current injury, left knee, initial encounter
S83.221A	Peripheral tear of medial meniscus, current injury, right knee, initial encounter
S83.222A	Peripheral tear of medial meniscus, current injury, left knee, initial encounter

POLICY TITLE	MENISCAL ALLOGRAFTS AND OTHER MENISCAL IMPLANTS
POLICY NUMBER	MP-1.010

ICD-10-CM Diagnosis Codes	Description
S83.231A	Complex tear of medial meniscus, current injury, right knee, initial encounter
S83.232A	Complex tear of medial meniscus, current injury, left knee, initial encounter
S83.241A	Other tear of medial meniscus, current injury, right knee, initial encounter
S83.242A	Other tear of medial meniscus, current injury, left knee, initial encounter
S83.251A	Bucket-handle tear of lateral meniscus, current injury, right knee, initial encounter
S83.252A	Bucket-handle tear of lateral meniscus, current injury, left knee, initial encounter
S83.261A	Peripheral tear of lateral meniscus, current injury, right knee, initial encounter
S83.262A	Peripheral tear of lateral meniscus, current injury, left knee, initial encounter
S83.271A	Complex tear of lateral meniscus, current injury, right knee, initial encounter
S83.272A	Complex tear of lateral meniscus, current injury, left knee, initial encounter
S83.281A	Other tear of lateral meniscus, current injury, right knee, initial encounter
S83.282A	Other tear of lateral meniscus, current injury, left knee, initial encounter
S83.31XA	Tear of articular cartilage of right knee, current, initial encounter
S83.32XA	Tear of articular cartilage of left knee, current, initial encounter
Z47.89	Encounter for other orthopedic aftercare

IX. REFERENCES

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X. POLICY HISTORY

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MP 1.010	**CAC 12/2/03**
	CAC 5/31/05
	CAC 6/28/05
	CAC 5/30/06 Consensus
	CAC 6/26/07
	CAC 5/27/08
	CAC 1/27/09
	CAC 1/26/10 Minor revisions; An additional investigational indication was added for meniscal allotransplantation when performed in combination, either concurrently or sequentially, with autologous chondrocyte implantation or osteochondral allografting. Added information about collagen meniscal implants, considered investigational. Policy was retitled.
	CAC 7/26/11 Adopt BCBSA. Meniscal allograft transplantation now 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. Medicare and FEP variations were added.
	CAC 1/29/13 Consensus review. References updated; no changes to policy statements**.** FEP variation revised to refer to the FEP manual. Codes reviewed 11/27/12
	CAC 1/28/14 Consensus review. Title and investigational statement changed from "collagen" to "other". References updated. Rationale added. Codes reviewed.
	CAC 1/27/15 Consensus. No change to policy statements. Policy guidelines added. References and rationale added. 12/30/14 Coding reviewed. Updated the ICD 9 and 10 ranges.
	06/04/15 Admin coding update. Coding corrections made and code duplications

	removed.
	CAC 1/26/16 Consensus review. No changes to the policy statements. References and rationale updated. Coding reviewed.
	Admin update 1/1/17: Product variation section reformatted.
	CAC 3/28/17 Consensus review. No change to the policy statements. References reviewed. Coding reviewed.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	1/17/18 Consensus review. Policy statements unchanged. Description/Background, Rationale and Reference sections updated.
	6/21/18 Retirement due to management by Turning Point.

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