

Corporate Medical Policy

Meniscal Allografts and Other Meniscal Implants

File Name:	meniscal_allografts_and_other_meniscal_implants
Origination:	9/1993
Last CAP Review:	6/2020
Next CAP Review:	6/2021
Last Review:	6/2020

Description of Procedure or Service

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

Meniscal cartilage 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. 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.

Meniscal allograft transplantation (MAT) is considered a salvage procedure, reserved for patients with disabling knee pain following meniscectomy who are considered too young to undergo total knee arthroplasty or in patients who require a total or near total meniscectomy for irreparable tears. As a result, the population intended to receive these transplants is relatively limited. Using a large database of privately insured non-Medicare patients, Cvetanovich et al (2015) estimated an annual incidence of MAT in the United States of 0.24 per 100,000. It is not expected that clinical trials will be conducted to compare meniscal allografts with other orthopedic procedures, although trials comparing allograft transplant with medical therapy are possible.

There are 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 osteoarthritis that is localized to the meniscus-deficient compartment
- patients undergoing ACL reconstruction in whom a concomitant meniscal transplant is intended to provide increased stability
- young athletes with few symptoms in whom the allograft transplantation is intended to deter the development of osteoarthritis; due to the risks associated with this surgical procedure, prophylactic treatment 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 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 since the grafts must be used within a couple of days to maintain viability. Alternatively, the harvested meniscus can be fresh frozen for storage until needed. Cryopreservation freezes the graft in glycerol, which aids in preserving the cell membrane integrity and donor fibrochondrocyte viability. Cryolife (Marietta, Ga.) is a commercial supplier of such grafts.

Meniscal Allografts and Other Meniscal Implants

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 allograft preference, 68% preferred fresh frozen nonirradiated allografts, with 14% responding fresh viable allografts.

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).

Tissue engineering that grows new replacement host tissue is also being investigated. For example, the Collagen Meniscus Implant (Ivy Sports Medicine, formerly the ReGen Collagen Scaffold by ReGen Biologics), is a resorbable collagen matrix comprised primarily of type I collagen from bovine Achilles tendons. The implant is provided in a semilunar shape and trimmed to size for suturing to the remaining meniscal rim. The implant provides an absorbable collagen scaffold that is replaced by the patient's own soft tissue; it is not intended to replace normal body structure. Because it requires a meniscal rim for attachment, it is intended to fill meniscus defects after a partial meniscectomy. Other scaffold materials and cell-seeding techniques are being investigated. Non-absorbable and non-porous synthetic implants for total meniscus replacement are in development. One total meniscus replacement that is in early phase clinical testing is NUsurface® (Active Implants), which is composed of a polyethylene reinforced polycarbonate urethane.

Regulatory Status

The ReGen Collagen Scaffold received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) in 2008. The marketing clearance was based on the decision that this collagen scaffold was substantially equivalent to existing predicate absorbable surgical mesh devices. The ReGen Collagen Scaffold (also known as Menaflex™ collagen meniscus implant) was the only collagen meniscus implant with FDA clearance at that time. Amid controversy about the 510(k) clearance for the ReGen Collagen Scaffold, the FDA initiated a review of the clearance process. In October 2010, the FDA rescinded the approval, stating that Menaflex™ is intended for different purposes and is technologically dissimilar from the predicate 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.

Related Policies

Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions
Autologous Chondrocyte Implantation

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

Meniscal Allografts and Other Meniscal Implants

BCBSNC will cover meniscal allograft transplantation when it is determined to be medically necessary because the medical criteria and guidelines shown below have been met.

Use of other meniscal implants incorporating materials such as collagen is considered investigational. BCBSNC does not cover investigational services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Meniscal Allografts and Other Meniscal Implants are covered

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:

- The patient is skeletally mature and not considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., age greater than 15 and less than 55)
- 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 degenerative changes in the surrounding articular cartilage (Outerbridge Grade II or less, < 50% joint space narrowing)
- Normal knee biomechanics, or alignment and stability achieved concurrently with meniscal transplantation.

Meniscal allograft transplantation may be considered medically necessary when performed in combination, either concurrently or sequentially, with autologous chondrocyte implantation, osteochondral allografting or osteochondral autografting for focal articular cartilage lesions.

When Meniscal Allografts and Other Meniscal Implants are not covered

Use of other meniscal implants incorporating materials such as collagen is considered **investigational**.

Policy Guidelines

Patients should exhibit symptoms of persistent disabling knee pain lasting at least 6 months that has not shown an adequate response to physical therapy and analgesic medications.

Uncorrected misalignment and instability of the joint are contraindications. 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 (body mass index greater than 35 kg/m²), may affect outcomes due to the increased stress on weight bearing surfaces of the joint. Meniscal allograft transplantation is typically recommended for young active patients who are too young for total knee arthroplasty.

For individuals who are undergoing partial meniscectomy who receive meniscal allograft transplantation, the evidence includes systematic reviews of mostly case series and a randomized

Meniscal Allografts and Other Meniscal Implants

controlled trial (RCT). Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic reviews concluded that most studies have shown statistically significant improvements in pain and function following the procedure. The benefits have also been shown to have long-term effect (>10 years). Reviews have also reported acceptable complication and failure rates. There remains no evidence that meniscal allograft transplantation can delay or prevent the development of knee osteoarthritis. A limitation of the evidence is its reliance primarily on case series. Because the single RCT, which enrolled a very small number of patients, pooled data from randomized and nonrandomized groups, results cannot be interpreted in a meaningful way. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are undergoing partial meniscectomy and concomitant repair of 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 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 two 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 29868, G0428

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

For Policy Titled Meniscal Allograft Transplantation

BCBSA Medical Policy Reference Manual 12/95

Clinics in Sports Medicine, D. L. Johnson, January 18, 1999 (1): 93-108

MPAG Review 3/99

Specialty Matched Consultant Advisory Panel - 9/2000

Meniscal Allografts and Other Meniscal Implants

Medical Policy Advisory Group - 10/2000

BCBSA Medical Policy Reference Manual, 8/15/01; 7.01.15

Specialty Matched Consultant Advisory Panel - 5/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.15, 4/29/03

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.15, 11/9/04

BCBSA TEC Assessment. Meniscal Allograft Transplantation. August 1997; 12(14): 1-8
National Guideline Clearinghouse. Meniscal allograft transplantation (October 2002). R

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.15, 11/13/08

For Policy retitled Meniscal Allograft and Collagen Meniscus Implantation

Food and Drug Administration (FDA). 501(k) Summary for ReGen Collagen Scaffold (CS), dated 12/15/08. Retrieved from http://www.accessdata.fda.gov/cdrh_docs/pdf8/K082079.pdf

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.15, 10/6/09

Specialty Matched Consultant Advisory Panel review 7/2010

Harris JD, Cavo M, Brophy R et al. Biological knee reconstruction: a systematic review of combined meniscal allograft transplantation and cartilage repair or restoration. *Arthroscopy* 2011; 27(3):409-18.

Food and Drug Administration (FDA) News Release. FDA Determines Knee Device Should Not Have Been Cleared for Marketing. Oct. 14, 2010. Retrieved from <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm229384.htm>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.15, 3/10/11

Specialty Matched Consultant Advisory Panel review 7/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.15, 3/8/12

Specialty Matched Consultant Advisory Panel review 7/2012

For Policy re-titled Meniscal Allografts and Other Meniscal Implants

National Institute for Health and Clinical Excellence.(NICE) IPG430 Partial replacement of the meniscus of the knee using a biodegradable scaffold: guidance. 2012. Retrieved from <http://guidance.nice.org.uk/IPG430>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.15, 3/14/13

Medical Director review 4/2013

Specialty Matched Consultant Advisory Panel review 7/2013

Medical Director review 7/2013

Bouyarmane H, Beaufile P, Pujol N et al. Polyurethane scaffold in lateral meniscus segmental defects: Clinical outcomes at 24months follow-up. *Orthop Traumatol Surg Res* 2014; 100(1):153- 7.

Meniscal Allografts and Other Meniscal Implants

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.15, 3/13/14

Specialty Matched Consultant Advisory Panel review 7/2014

Medical Director review 7/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.15, 3/12/15

Specialty Matched Consultant Advisory Panel review 6/2015

Specialty Matched Consultant Advisory Panel 6/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.15, 4/13/2017

Specialty Matched Consultant Advisory Panel 6/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.15, 4/12/2018

Specialty Matched Consultant Advisory Panel 6/2018

Specialty Matched Consultant Advisory Panel 7/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.15, 7/11/2019

Specialty Matched Consultant Advisory Panel 6/2020

Policy Implementation/Update Information

For Policy Titled Meniscal Allograft Transplantation

9/93 Evaluated: Investigational

7/96 Reaffirmed: National Association reviewed 12/95. No changes.

3/99 Reaffirmed

6/99 Reformatted, Description of procedure changed, Medical Term Definitions added.

10/00 Specialty Matched Consultant Advisory Panel. No change recommended in criteria. System coding changes. Medical Policy Advisory Group review. No change in criteria. Approve.

9/01 Independent consultant review. No changes.

3/02 System coding changes. Added code 0014T.

5/03 Specialty Matched Consultant Advisory Panel review. No change in criteria. Code S9085 deleted from HCPCS 12/31/01 and removed from Billing/Coding section.

5/04 Benefits Application and Billing/Coding section updated for consistency.

6/2/2005 Specialty Matched Consultant Advisory Panel review on 5/23/2005. No changes made to policy statement. References added. SUR6470 added as key word. When not covered section updated for consistent policy language. Code 0014T and description removed (code deleted). CPT code 29868 added.

Meniscal Allografts and Other Meniscal Implants

- 6/18/07 References updated. Specialty Matched Consultant Advisory Panel review 5/18/07. No changes to policy coverage criteria. (adn)
- 3/30/09 Description section expanded for clarity. Policy statement changed to read, "BCBSNC will cover Meniscal Allograft Transplantation when it is determined to be medically necessary because the medical criteria and guidelines shown below have been met." 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: The patient is skeletally mature and not considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., age greater than 15 and less than 55), 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 degenerative changes in the surrounding articular cartilage (Outerbridge Grade II or less), Normal knee biomechanics, or alignment and stability achieved concurrently with meniscal transplantation. The following statement was added to the Not Covered section: Meniscal Allograft Transplantation is considered investigational when performed in combination, either concurrently or sequentially, with autologous chondrocyte implantation or osteochondral allografting. The following was added to the Policy Guidelines section: "Patients should exhibit symptoms of persistent disabling knee pain lasting at least 6 months that have not shown an adequate response to physical therapy and analgesic medications. Uncorrected misalignment and instability of the joint are contraindications. 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 (body mass index greater than 35 kg/m²), may affect outcomes due to the increased stress on weight bearing surfaces of the joint. Meniscal allograft transplantation is typically recommended for young active patients who are too young for total knee arthroplasty. Meniscal Allograft Transplantation performed in combination with other surgical interventions, appears to improve symptoms in some patients with a prior meniscectomy who are considered too young to undergo total knee replacement. Evidence consisting primarily of retrospective case series indicates that this procedure may produce short to intermediate-term pain relief in selected patients. The literature does not permit conclusions concerning the effect of meniscal transplantation on the progression of degenerative changes and joint space narrowing. Meniscal Allograft Transplantation is associated with a high number of complications, including tears of the transplanted meniscus, displacement, or arthrofibrosis, and careful selection of patients and surgical technique appear to be critical for success of this procedure." (adn)
- 7/6/09 Specialty Matched Consultant Advisory Panel review 5/21/09. No change to policy statement.

For Policy retitled Meniscal Allograft and Collagen Meniscus Implantation

- 8/17/10 Policy renamed from "Meniscal Allograft Transplantation" to "Meniscal Allografts and Collagen Meniscus Implants". Revised Description section. Removed Medical Policy number. New statements added to Policy section that state: "BCBSNC will not cover collagen meniscus implants. They are considered investigational. BCBSNC does not cover investigational services." New statement added to "Not Covered" section that states: "Collagen meniscus implants are considered investigational." Policy Guidelines section updated to include information regarding collagen meniscus implants. New code G0428 added to Billing section. References updated. Specialty Matched Consultant Advisory Panel review 7/2010.(mco)
- 5/24/11 Description section updated. Policy Guidelines updated. Information regarding FDA rescinding approval for Menaflex™ collagen meniscus implant added. Added the following statement to the "When Covered" section: "Meniscal allograft transplantation may be

Meniscal Allografts and Other Meniscal Implants

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.” Combined meniscal allograft transplantation and cartilage repair or restoration is no longer considered investigational. References updated. (mco)

8/16/11 Specialty Matched Consultant Advisory Panel review 7/2011. No changes to Policy Statements. (mco)

5/1/12 References updated. No changes to Policy Statements. (mco)

8/7/12 Specialty Matched Consultant Advisory Panel review 7/2012. No changes to Policy Statements. (mco)

For Policy re-titled Meniscal Allografts and Other Meniscal Implants

5/14/13 Policy re-titled from “Meniscal Allografts and Collagen Meniscus Implants” to “Meniscal Allografts and Other Meniscal Implants.” References updated. Description section and Policy Guidelines updated. Policy statement and “When not Covered” statement revised to state: “Use of other meniscal implants incorporating materials such as collagen and polyurethane are considered investigational. BCBSNC does not cover investigational services.” Medical Director review 4/2013. (mco)

8/13/13 Specialty Matched Consultant Advisory Panel review 7/2013. Medical Director review 7/2013. No changes to Policy Statements. (mco)

4/29/14 References updated. No changes to Policy Statements. (mco)

8/12/14 Specialty Matched Consultant Advisory Panel review 7/2014. Medical Director review 7/2014. No changes to Policy Statements. (mco)

4/28/15 Reference added. (sk)

7/28/15 Specialty Matched Consultant Advisory Panel review. (sk)

8/30/16 Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 6/29/2016. (sk)

7/28/17 Reference added. Description section, Regulatory section, and Policy Guidelines section updated. Specialty Matched Consultant Advisory Panel review 6/28/2017. (sk)

7/13/18 Reference added. Description section, Regulatory section, and Policy Guidelines section updated. “Polyurethane” removed from the policy. Specialty Matched Consultant Advisory Panel review 6/27/2018. (sk)

8/27/19 Specialty Matched Consultant Advisory Panel review 7/30/2019. Reference added. (sk)

6/30/20 Specialty Matched Consultant Advisory Panel review 6/17/2020. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.