

## Corporate Medical Policy

### Meniscal Allografts and Collagen Meniscus Implants

<b>File Name:</b>	meniscal_allografts_and_collagen_meniscus_implants
<b>Origination:</b>	9/1993
<b>Last CAP Review:</b>	7/2011
<b>Next CAP Review:</b>	7/2012
<b>Last Review:</b>	7/2011

#### Description of Procedure or Service

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

Historically, the role of normal meniscal cartilage was greatly underappreciated, and until some 30 years ago, torn and damaged menisci were routinely excised. However, it is now known that the menisci are an integral structural component of the human knee, functioning to absorb shocks and providing joint stability, congruity, and nutrition. In addition, total and partial meniscectomy are associated with altered load bearing across the joint, frequently resulting in degenerative osteoarthritis. The integrity of the menisci are 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 their repair and preservation whenever possible.

Meniscal allograft transplantation has been investigated in patients with a previous meniscectomy or requiring 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 osteoarthritis that is localized to the meniscus-deficient compartment
- those who are 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 the most appropriate surgical techniques (e.g., suturing or anchored with bone plugs). Four primary ways of processing and storing allografts (fresh, fresh frozen, cryopreserved, and lyophilized) have been reported. Fresh implants, harvested under sterile conditions, are less frequently used since the grafts must be used within a couple of days to maintain viability. Alternatively, the harvested meniscus can be fresh frozen for storage until needed. Another commonly used method, cryopreservation, freezes the graft in glycerol, which aids in preserving the cell membrane integrity and donor fibrochondrocyte viability. Cryolife (Marietta, Ga.) is a commercial supplier of such grafts. In addition to freezing, donor tissue may be dehydrated (freeze dried or lyophilized), permitting storage at room temperature. Lyophilized grafts have been shown to be prone to reduced tensile strength, graft shrinkage, poor rehydration, post-transplantation joint effusion, and synovitis, and are no longer used in the clinical setting. Several secondary sterilization techniques may be used, with gamma irradiation the most common. The dose of

# Meniscal Allografts and Collagen Meniscus Implants

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.

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 this time. Amid controversy about the 510(K) clearance for the ReGen Collagen Scaffold, the FDA initiated a review of the clearance process for this device. In September 2009, the FDA issued a preliminary report on the review of the ReGen Menaflex®: Departure from Processes, Procedures, and Practices Leave the Basis for a Review Decision in Question. This preliminary report documents findings and recommendations concerning FDA's review and clearance of the ReGen Biologics, Inc., Collagen Scaffold (CS) device for meniscal repair, marketed as Menaflex™.

In October 2010, the FDA announced that the device should not have been cleared for marketing, as the Menaflex™ device is intended to be used for different purposes and is technologically dissimilar from devices already on the market (predicate devices). To correct this error, the FDA will begin a process to rescind the product's marketing clearance and determine the appropriate marketing pathway for the device.

**\*\*\*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

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**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.**

**BCBSNC will not cover collagen meniscal implants. They are considered investigational. BCBSNC does not cover investigational services.**

## Benefits Application

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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 Collagen Meniscus Implants are covered

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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

# Meniscal Allografts and Collagen Meniscus Implants

(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 Collagen Meniscus Implants are not covered**

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Collagen meniscus implants are considered investigational.

## **Policy Guidelines**

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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/m<sup>2</sup>), may affect outcomes due to the increased stress on weight bearing surfaces of the joint. Meniscal allograft transplantation is typically recommended for young active patients who are too young for total knee arthroplasty.

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. Careful selection of patients and surgical technique appear to be critical for success of this procedure.

The collagen meniscus implant, for which the FDA decided to rescind the clearance for marketing in 2010, is considered investigational. In addition to FDA approval, mid-to long-term follow-up with a larger number of subjects is needed to determine whether implantation of a collagen scaffold is able to slow joint degeneration, reduce pain, or otherwise improve the net health outcome.

## **Billing/Coding/Physician Documentation Information**

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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](http://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

# Meniscal Allografts and Collagen Meniscus Implants

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

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### **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

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). Retrieved 3/2/07 from

[http://www.guideline.gov/summary/summary.aspx?doc\\_id=4393&nbr=003311&string=meniscal+AND+allograft+AND+transplantation](http://www.guideline.gov/summary/summary.aspx?doc_id=4393&nbr=003311&string=meniscal+AND+allograft+AND+transplantation)

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 May 21, 2010 from [http://www.accessdata.fda.gov/cdrh\\_docs/pdf8/K082079.pdf](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 on May 10, 2011 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

# Meniscal Allografts and Collagen Meniscus Implants

## Policy Implementation/Update Information

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### 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.
- 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/m<sup>2</sup>), may affect outcomes due to the increased stress on weight bearing surfaces of the joint. Meniscal allograft transplantation is typically recommended for young active patients who are too young for total knee arthroplasty. 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.

## Meniscal Allografts and Collagen Meniscus Implants

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 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)

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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.