

## Medical Coverage Policy | Meniscal Allograft Transplantation and Collagen Meniscus Implants



**EFFECTIVE DATE:** 11|01|2011  
**POLICY LAST UPDATED:** 12|03|2013

### OVERVIEW

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

### PRIOR AUTHORIZATION

Prior authorization is not required

### POLICY STATEMENT

**BlueCHiP for Medicare and Commercial:**

**BlueCHiP for Medicare and Commercial:**

Meniscal allograft transplantation:

Meniscal allograft transplantation is considered medically necessary.

Collagen meniscal implants:

Collagen meniscal implants are not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

### MEDICAL CRITERIA

None.

### BACKGROUND

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

Meniscal allograft transplantation has been investigated in patients with a previous meniscectomy, or in patients who require a total or near total meniscectomy for irreparable tears. There are 3 general groups of patients who have been treated with meniscal allograft transplantation:

- young patients with a history of meniscectomy who have symptoms of pain and discomfort associated with early osteoarthrosis that is localized to the meniscus-deficient compartment

- patients undergoing ACL reconstruction in whom a concomitant meniscal transplant is intended to provide increased stability
- young athletes with few symptoms in whom the allograft transplantation is intended to deter the development of osteoarthritis. Due to the risks associated with this surgical procedure, prophylactic treatment for this purpose is not frequently recommended

Issues under study include techniques for processing and storing the grafts, proper sizing of the grafts, and the most appropriate surgical techniques (e.g., suturing or anchored with bone plugs). Four primary ways of processing and storing allografts (fresh, fresh frozen, cryopreserved, and lyophilized) have been reported. Fresh implants, harvested under sterile conditions, are less frequently used since the grafts must be used within a couple of days to maintain viability. Alternatively, the harvested meniscus can be fresh frozen for storage until needed. Another commonly used method, cryopreservation, freezes the graft in glycerol, which aids in preserving the cell membrane integrity and donor fibrochondrocyte viability. Cryolife (Marietta, GA) is a commercial supplier of such grafts. In addition to freezing, donor tissue may be dehydrated (freeze-dried or lyophilized), permitting storage at room temperature. Lyophilized grafts have been shown to be prone to reduced tensile strength, graft shrinkage, poor rehydration, post-transplantation joint effusion, and synovitis and are no longer used in the clinical setting. Several secondary sterilization techniques may be used, with gamma irradiation the most common. The dose of radiation considered effective has been shown to change the mechanical structure of the allograft; therefore, non-irradiated grafts from screened donors are most frequently used.

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

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

Meniscal allograft transplantation is associated with a high number of complications, including tears of the transplanted meniscus, displacement, or arthrofibrosis. Careful selection of patients and surgical technique appear to be critical for success of this procedure. (4, 11) These major interventions are considered salvage procedures and are not recommended to be performed casually or by surgeons without extensive experience and expertise in complex knee reconstruction.

Therefore, meniscal allograft transplant may be considered medically necessary for patients with prior meniscectomy who have disabling knee pain, and who are too young to be considered for total knee arthroscopy.

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

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

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

## COVERAGE

### BlueCHiP for Medicare and Commercial:

Benefits may vary between groups/contracts. Please refer to the appropriate evidence of coverage, subscriber agreement, or benefit booklet for applicable surgery coverage/benefits

## CODING

### BlueCHiP for Medicare and Commercial:

The following code is **medically necessary**:

**29868**

The following code is **not medically necessary**:

**G0428**

## RELATED POLICIES

None

## PUBLISHED

Provider Update Feb 2014

Provider Update Nov 2012

Provider Update Jan 2012

Provider Update Jan 2011

Provider Update Jan 2010

Provider Update Oct 2009

Provider Update Jul 2008

## REFERENCES

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Meniscal Allograft Transplantation. TEC Assessments 1997; Volume 12, Tab14.
2. Johnson DL, Bealle D. Meniscal allograft transplantation. Clin Sports Med 1999; 18(1):93-108.
3. CryoLife Web site. Available online at: [www.cryolife.com](http://www.cryolife.com). Last accessed February 2013.
4. Matava MJ. Meniscal allograft transplantation: a systematic review. Clin Orthop Relat Res 2007; 455:142-57.
5. Elattar M, Dhollander A, Verdonk R et al. Twenty-six years of meniscal allograft transplantation: is it still experimental? A meta-analysis of 44 trials. Knee Surg Sports Traumatol Arthrosc 2011; 19(2):147-57.
6. Hergan D, Thut D, Sherman O et al. Meniscal allograft transplantation. Arthroscopy 2011; 27(1):101-12.
7. Verdonk PC, Demurie A, Almqvist KF et al. Transplantation of viable meniscal allograft. Survivorship analysis and clinical outcome of one hundred cases. J Bone Joint Surg Am 2005; 87(4):715-24.
8. Verdonk PC, Verstraete KL, Almqvist KF et al. Meniscal allograft transplantation: long-term clinical results with radiological and magnetic resonance imaging correlations. Knee Surg Sports Traumatol Arthrosc 2006; 14(8):694-706.
9. van der Wal RJ, Thomassen BJ, van Arkel ER. Long-term clinical outcome of open meniscal allograft transplantation. Am J Sports Med 2009; 37(11):2134-9.
10. Vundelinckx B, Bellemans J, Vanlauwe J. Arthroscopically assisted meniscal allograft transplantation in the knee: a medium-term subjective, clinical, and radiographical outcome evaluation. Am J Sports Med 2010; 38(11):2240-7.

**CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS**

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

