

Medical Coverage Policy



**Blue Cross
Blue Shield**
of Rhode Island

Meniscal Allograft Transplantation and Collagen Meniscus Implants

Device/Equipment Drug Medical Surgery Test Other

| | | | |
|------------------------|------------------|-----------------------------|------------------|
| Effective Date: | 11/1/2011 | Policy Last Updated: | 9/18/2012 |
|------------------------|------------------|-----------------------------|------------------|

Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

Prospective review is not required.

Description:

Historically, the role of normal meniscal cartilage was greatly underappreciated, and until the mid-1980's, torn and damaged menisci was routinely excised. It is now understood that the menisci are an integral structural component of the human knee, functioning to absorb shocks, provide 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. Moreover, meniscal allograft transplantation has been investigated in patients with a previous meniscectomy or requiring total or near total meniscectomy for irreparable tears.

Meniscal allograft transplantation is a surgical procedure that has been proposed as treatment for individuals with irreparable meniscal tears, or who have undergone previous total meniscectomy. The procedure can be performed either arthroscopically or by open technique and involves grafting a donor meniscus into the knee of the patient. The goal of meniscal allograft transplantation is to restore knee function and prevent further joint degeneration by replacing the damaged or destroyed meniscus with allograft tissue having similar properties.

There are 3 general groups of patients who have been treated with meniscal allograft transplantation. Those with pain and discomfort associated with early osteoarthrosis; those who are undergoing ACL reconstruction in whom a concomitant meniscal transplant is intended to provide increased stability; and athletes with few symptoms in whom the allograft transplantation is intended to deter the development of osteoarthritis.

The following different types of allograft have been investigated:

Fresh

Fresh implants, harvested under sterile conditions, are not typically a practical option. The grafts must be used within a couple of days to maintain viability. The grafts must be appropriately sized, and there are concerns regarding infectious diseases, such as HIV.

Frozen

After sterile harvest, the meniscus can be frozen for storage until thawed for use. The freezing process may destroy donor cells and decrease the size of the graft.

Freeze Dried (Lyophilized)

In addition to freezing, the tissue may be dehydrated, permitting storage at room temperature. Before transplantation, the graft is thawed and rehydrated.

Cryopreserved

Cryopreservation freezes the graft in glycerol, preserving the cell membrane integrity and donor fibrochondrocyte viability. Of all the above options, cryopreserved grafts are most commonly used; Cryolife (Marietta, Ga.) is a commercial supplier of such grafts.

The risk of infectious disease, particularly HIV or hepatitis, continues to be a concern. Several secondary sterilization techniques have been used, with gamma irradiation the most common.¹

Meniscal allograft transplantation is typically used for patients who have had a prior meniscectomy and have symptoms related to the affected side, for the following:

- Adolescent patients should be skeletally mature with documented closure of growth plates (e.g., 15 years or older). 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); or
- Disabling knee pain with activity that is refractory to conservative treatment; or
- Absence or near absence (more than 50%) of the meniscus, established by imaging or prior surgery; or
- Documented minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge grade II or less); or
- Normal knee biomechanics, or alignment and stability achieved concurrently with meniscal transplantation.

Collagen meniscus implant:

Cleared for marketing by the FDA in 2009, the collagen meniscus implant has shown promise in terms of arthroscopic examination of tissue integration at short-term follow-up in some patients. In contrast, average improvements in clinical outcomes have been reported in the range of marginal to none when compared with control procedures at short-term follow-up. Longer follow-up 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 at longer durations. Therefore collagen meniscus implants are **not medically necessary** due to insufficient evidence to permit conclusions concerning the effect of this technology on health outcomes.

Medical Criteria:

Not applicable.

Policy:

Meniscal allograft transplantation:

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

Collagen meniscal implants:

- Collagen meniscal implants are **not medically necessary** due to insufficient peer-reviewed scientific literature providing definite conclusions concerning the effect of this technology on health outcomes.

Coverage:

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

Coding:

The following code is **medically necessary**:
29868

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

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

Publications:

Policy Update, July 2008
Provider Update, October 2009
Provider Update, January 2010
Provider Update, January 2011
Provider Update, January 2012
Provider Update, November 2012

References:

¹Blue Cross Blue Shield Association. Medical Policy Reference Manual. Meniscal Allograft Transplantation Collagen Meniscus Implants. Policy 7.01.15. Retrieved on 04/02/08; 4/20/09; 10/15/10; 3/11 from:
http://bluewebportal.bcbs.com/global_assets/special_content/medical_policy/policymanual/policy.html?pn=70115.

Noyes, FR, Barber-Westin, SD, Rankin, M. *Meniscal transplantation in symptomatic patients less than fifty years old*. Journal of Bone and Joint Surgery;2004;86-A(7):1392-1404.

Paxton ES, Stock MV, Brophy RH. *Meniscal Repair Versus Partial Meniscectomy: A Systematic Review Comparing Reoperation Rates and Clinical Outcomes*. Arthroscopy: The Journal of Arthroscopic and Related Surgery;27(9):1275-1288.

Stone KR, Adelson WS, Pelsis JR, Walgenbach AW, Turek TJ. *Long-term survival of concurrent meniscus allograft transplantation and repair of the articular cartilage; A prospective two - to 12-year follow-up report*.The Journal of Bone and Joint Surgery;92-B(7);2010;941-948.

Vundelinckx B, Bellemans J, Vanlauwe J. *Arthroscopically assisted meniscal allograft transplantation in the knee: a medium-term subjective, clinical, and radiographical outcome evaluation*.American Journal of Sports Medicine;2010;38(11):2240-7.

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.