Medical Coverage Policy | Meniscal Allograft Transplantation and Collagen Meniscus Implants

EFFECTIVE DATE: 10|02|2003
POLICY LAST UPDATED: 07|18|2017

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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products:

Meniscal allograft transplantation:

Meniscal allograft transplantation may be considered medically necessary in patients who have had a prior meniscectomy and have symptoms related to the affected side.
Meniscal allograft transplantation may be considered medically necessary when performed in combination, either concurrently or sequentially, with treatment of focal articular cartilage lesions.

Collagen meniscal implants:

Collagen meniscal implants are not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable surgery coverage/benefits.

BACKGROUND
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 meniscus resection.

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

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

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.

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 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 MenaFlexTM CMI) was the only collagen meniscus implant (CMI) with FDA clearance at that time. Amid controversy about this 510(k) clearance decision, FDA reviewed its decision. In October 2010, FDA rescinded the approval, stating that MenaFlexTM 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.

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.

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.

CODING

BlueCHiP for Medicare and Commercial Products:

The following CPT code may be considered medically necessary when reported with a diagnosis code listed below:
29868 Arthroscopy, knee, surgical; Meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral
ICD-10 Diagnosis Codes that may support medical necessity:


ICD10-Codes_29868
.pdf

The following HCPCS code is **not medically necessary**:
G0428 Collagen Meniscus Implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)

RELATED POLICIES

None

PUBLISHED

Provider Update, September 2017
Provider Update, January 2017
Provider Update, April 2015
Provider Update, February 2014
Provider Update, November 2012
Provider Update, January 2012
Provider Update, January 2011
Provider Update, January 2010
Provider Update, October 2009

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