Meniscal Allografts and Collagen Meniscus Implants

Medical Benefit
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The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is required.* Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Description
Meniscal allografts and collagen meniscus implants are intended to improve symptoms and reduce joint degeneration in patients who have had a total or partial resection of the meniscus.

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 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 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 (ReGen Biologics), which may also be referred to as the Menaflex™ collagen meniscus implant or CMI™, is a resorbable collagen matrix comprised primarily of bovine type I collagen. 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.

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 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).

Related Protocols:
Autologous Chondrocyte Implantation and Other Cell-based Treatments of Focal Articular Cartilage Lesions
Osteochondral Autografts and Allografts in Treatment of Focal Articular Cartilage Lesions

Corporate Medical Guideline
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 is considered medically necessary when performed in combination, either
concurrently or sequentially, with autologous chondrocyte implantation or osteochondral allografting or osteochondral autografting for focal articular cartilage lesions.

Collagen meniscus implants are considered investigational.

Policy Guideline

Patients should exhibit symptoms of persistent disabling knee pain that has not shown an adequate response to physical therapy and analgesic medications. Uncorrected misalignment and instability of the joint are contraindications. Therefore 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, e.g., body mass index (BMI) 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.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


