FEP Medical Policy Manual

FEP 7.01.15 Meniscal Allografts and Other Meniscal Implants

Annual Effective Policy Date: July 1, 2024

Original Policy Date: December 2011

Related Policies:

7.01.48 - Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

Meniscal Allografts and Other Meniscal Implants

Description

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

OBJECTIVE

The objective of this evidence review is to determine the net health outcome when meniscal allografts are used to treat individuals with disabling knee pain following meniscectomy who are too young for total knee arthroplasty.

POLICY STATEMENT

Meniscal allograft transplantation may be considered **medically necessary** in individuals who have had a prior meniscectomy and have symptoms related to the affected side when all of the following criteria are met:

- Adult individuals should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (eg, <55 years).
- Disabling knee pain with activity that is refractory to conservative treatment.
- Absence or near absence (>50%) of the meniscus, established by imaging or prior surgery.
- Documented minimal to absent diffuse degenerative changes in the surrounding articular cartilage (eg, 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.

Use of other meniscal implants incorporating materials such as collagen are considered **investigational**.

POLICY GUIDELINES

Individuals should exhibit symptoms of persistent disabling knee pain that has not adequately responded 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 (eg, body mass index >35 kg/m^2) may affect outcomes due to the increased stress on weight-bearing surfaces of the joint. Meniscal allograft transplantation is typically recommended for young active individuals who are too young for total knee arthroplasty.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Plans may consider requiring prior approval or preauthorization for meniscal allograft.

FDA REGULATORY STATUS

Collagen Meniscus Implants

In 2008, the ReGen Collagen Scaffold was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing absorbable surgical mesh devices. The ReGen Collagen Scaffold (also known as MenaFlex™ CMI) was the only collagen meniscus implant with FDA clearance at that time. Amid controversy about this 510(k) clearance, the FDA reviewed its decision. In October 2010, the FDA rescinded the approval, stating that MenaFlex 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, was manufactured by Ivy Sports Medicine (now Stryker). CMI is the only FDA-approved collagen meniscus product currently on the market.

FDA product code: OLC.

RATIONALE

Summary of Evidence

For individuals who are undergoing partial meniscectomy who receive meniscal allograft transplantation (MAT), the evidence includes systematic reviews of mostly case series and a randomized controlled trial (RCT). 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 a long-term effect (>10 years). Reviews have also reported acceptable complication and failure rates. There remains no evidence that MAT can delay or prevent the development of knee osteoarthritis. A limitation of the evidence is its reliance primarily on case series. Because the results of the single RCT, which enrolled a very small number of patients, pooled data from randomized and nonrandomized groups, results cannot be interpreted in a meaningful way. The evidence is sufficient to determine that the technology results in an 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 MAT, the evidence includes a 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 an improvement in the net health outcome.

For individuals who are undergoing partial meniscectomy who receive collagen meniscal implants (CMIs), 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 CMI, but the quality of the selected studies (RCTs, observational studies) was low. Radiologic evaluations have shown reductions in the size of the implant in a large portion of patients. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

International Meniscus Reconstruction Experts Forum

In 2015, the International Meniscus Reconstruction Experts Forum published consensus statements on the practice of MAT (Table 1).[2,] The Forum's statements included guidance on indications, graft procurement and preparation, surgical technique, and rehabilitation.

Table 1. Select Consensus Statements on the Practice of Meniscal Allograft Transplantation

Statements
Indications for MAT: • Unicompartmental pain post-meniscectomy • In combination with anterior cruciate ligament reconstruction when meniscus deficient • In combination with articular cartilage repair if meniscus deficient
MAT not recommended for asymptomatic meniscus deficient patient.
Potentially poorer outcomes expected in patients with moderate to severe OA (Kellgren-Lawrence grade ≥3).
Non-irradiated fresh frozen or fresh viable grafts are recommended.
Mechanical axis alignment should be performed prior to MAT; if mechanical axis deviation present, consider realignment osteotomy.
Based on current evidence, the superiority of 1 surgical technique over another (all-suture vs bone) is not established.
Outcome scores should include: • Disease-specific: Western Ontario Meniscal Evaluation Tool • Region-specific: Knee injury and Osteoarthritis Outcome Score • Activity: Marx Activity Rating Scale • Quality of life/utility: EuroQoL 5 dimensions questionnaire

MAT: meniscal allograft transplantation; OA: osteoarthritis.

National Institute for Health and Care Excellence

In 2012, the guidance from the National Institute for Health and Care Excellence stated that the evidence on "partial replacement of the meniscus of the knee using a biodegradable scaffold raises no major safety concerns," but evidence for any advantage of the procedure over standard surgery was limited.[27,]

American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons (2009) updated its position in 2014, still recommending MAT for active people younger than 55 years of age, with the goal of replacing the meniscus cushion before the articular cartilage is damaged.[28,] The website also notes that "synthetic (artificial) meniscal tissue has been tried, but there is conflicting information at this time."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services (2010) issued a national noncoverage determination for the collagen meniscus implant.[29,] A number of concerns regarding the efficacy and safety were raised by the Centers for Medicare & Medicaid Services analysis, which compared data reported to the U.S. Food and Drug Administration and published data. Concerns included an increased number of reoperations and a higher serious adverse event rate than in the control group. Centers for Medicare & Medicaid Services concluded that the collagen meniscus implant does not improve health outcomes in the Medicare population and that collagen meniscus implant is not reasonable and necessary for the treatment of meniscal injury or tear.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
June 2013	Replace policy	Policy updated with literature review; references 17, 21-24 added; title and investigational statement changed from "collagen€š to "other€š
June 2014	Replace policy	Policy updated with literature review, adding reference 23. No change to policy statement.
June 2015	Replace policy	Policy updated with literature review through January 28, 2015; Rationale extensively revised; references 9, 16 and 20 added; no change to the policy statements.
June 2017	Replace policy	Policy updated with literature review through February 23, 2017; references 1, 6, 16-17, 19, 27, and 30 added. Policy statements unchanged.
June 2018	Replace policy	Policy updated with literature review through February 5, 2018; references 7 and 22 added; note 28 updated. Multiple references were deleted. "Polyurethane€š removed from the policy; statements otherwise unchanged
September 2019	Replace policy	Policy updated with literature review through May 13, 2019; no references added. Policy statements unchanged.
September 2020	Replace policy	Policy updated with literature review through May 23, 2020; no references added. Policy statements unchanged.
June 2021	Replace policy	Policy updated with literature review through February 17, 2021; no references added. Policy statements unchanged.
June 2022	Replace policy	Policy updated with literature review through February 20, 2022; no references added. Policy statements unchanged.
June 2023	Replace policy	Policy updated with literature review through February 17, 2023; no references added. Minor editorial refinements to policy statements; intent unchanged.
June 2024	Replace policy	Policy updated with literature review through February 20, 2024; no references added. Policy statements unchanged.