Meniscal Allografts and Other Meniscal Implants

Policy # 00083
Original Effective Date: 06/05/2002
Current Effective Date: 05/30/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions is addressed separately in medical policy 00006.

Note: Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions is addressed separately in medical policy 00091.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider meniscal allograft transplantation of the knee as a treatment for individuals with significant partial (more than 50%) or complete loss of the meniscus, as documented by previous operative reports, magnetic resonance imaging (MRI), or diagnostic arthroscopy, to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility will be considered for meniscal allograft transplantation (MAT) of the knee as a treatment for individuals with significant partial (more than 50%) or complete loss of the meniscus, as documented by previous operative reports, magnetic resonance imaging (MRI), or diagnostic arthroscopy, when **ALL** of the following criteria are met:

- Age 55 or younger and skeletally mature; **AND**
- Knee pain refractory to conservative treatment (see Policy Guidelines); **AND**
- Ligamentous stability either prior to surgery or achieved concurrently with meniscal transplantation; **AND**
- Normal alignment without varus or valgus deformities; **AND**
- Mild to moderate articular damage (Outerbridge grade II or less).

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Note:
Grade Description of Outerbridge Scale:
Grade 0 normal articular cartilage
Grade I softening or blistering of joint cartilage
Grade II cartilage fragmentation or fissuring on the surface <1cm diameter
Grade III cartilage fragmentation or fissuring > 1cm diameter
Grade IV cartilage erosion down to subchondral bone

When Services Are Considered Not Medically Necessary

The use of meniscal allograft transplantation of the knee when patient selection criteria are not met is considered to be **not medically necessary****, including but not limited to the following:

- Treatment for asymptomatic individuals with partial or complete loss of the meniscus;
- Use of other meniscal implants incorporating materials such as collagen and polyurethane.

Policy Guidelines

Documentation Requirements

Operative report of a prior arthroscopic procedure and/or magnetic resonance imaging (MRI) of the knee performed within the past twelve (12) months – The provider shall submit a detailed and specific imaging report that correlates with clinical findings of the requested procedure. In the absence of the detailed report, the provider will be required to submit a report from an independent radiologist. The results of all imaging studies should correlate with the clinical findings in support of the requested procedure.

Conservative management offered by the provider or other health professionals for this condition(s) should include a combination of strategies to reduce inflammation, alleviate pain, and improve function, including requirements for physical therapy and at least one complementary conservative management strategy.

Physical therapy requirement at least one of:

- Physical therapy
- Physician or physical therapist-supervised therapeutic home exercise program which includes flexibility and muscle strengthening exercises.

- Exception to the physical therapy requirement in unusual circumstances (for instance intractable pain so severe that physical therapy is not possible) when clearly documented in the medical record.

Complementary conservative management requirement at least one of:

- Activity modification
- Prescription strength anti-inflammatory medications and analgesics
- Intraarticular corticosteroid injection(s)

Documentation of compliance with a plan of therapy that includes elements from these areas is required where conservative management is appropriate.

Reporting of symptom severity
Severity of pain and its impact on function is a key factor in determining the need for intervention. For purposes of this guideline, significant pain and functional impairment refers to pain ≥ 4 on the VAS scale associated with difficulty performing at least two (2) age-appropriate daily activities.

Background/Overview

Meniscal Cartilage Damage
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. The integrity of the menisci is particularly important in knees in which the anterior cruciate ligament has been damaged. In these situations, the menisci act as secondary stabilizers of anteroposterior and varus-valgus translation.

Treatment
Meniscal allograft transplantation (MAT) is considered a salvage procedure, reserved for patients with disabling knee pain following meniscectomy who are considered too young to undergo total knee arthroplasty or in patients who require a total or near total meniscectomy for irreparable tears. As a result, the population intended to receive these transplants is relatively limited. Using a large database of privately insured non-Medicare patients, Cvetanovich et al (2015) estimated an annual incidence of MAT in the U.S. of 0.24 per 100000. It is not expected that clinical trials will be

conducted to compare meniscal allografts with other orthopedic procedures, although trials comparing allograft transplant with medical therapy are possible.

There are three 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 osteoarthritis that is localized to the meniscus-deficient compartment
- patients undergoing anterior cruciate ligament 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 appropriate surgical techniques. The four 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 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, posttransplantation 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 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. 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.

Outcome Measures
The outcomes of this treatment (ie, pain, functional status) are subjective, patient-reported outcomes that are prone to placebo effects. On the other hand, the natural history of a severely damaged meniscus is predictable, with progressive joint damage, pain, and loss of function.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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 the FDA clearance at that time. Amid controversy about this 510(k) clearance decision, 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 CMIÒ, is manufactured by Ivy Sports Medicine. CMIÒ is the only FDA-approved collagen meniscus product currently on the market. FDA product code: OLC.

Rationale/Source

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.

For individuals who are undergoing partial meniscectomy who receive meniscal allograft transplantation, the evidence includes systematic reviews of mostly case series and a randomized controlled trial. The 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 meniscal allograft transplantation can delay or prevent the development of knee osteoarthritis. A limitation of the evidence is its reliance primarily on case series. Because the single randomized controlled trial, 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 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 a systematic review of case series as well as case series published after the systematic review. The 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 two systematic reviews primarily of case series. The 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 selected studies (randomized controlled trials, 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 the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

International Meniscus Reconstruction Experts Forum

The International Meniscus Reconstruction Experts Forum (2015) published consensus statements on the practice of MAT (see Table 1). 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 MAT

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
The guidance from the National Institute for Health and Care Excellence (2012) 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.

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 old, with the goal of replacing the meniscus cushion before the articular cartilage is damaged. 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. 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 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.

Ongoing and Unpublished Clinical Trials
Currently, ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01712191[a]	Treatment of the Medial Meniscus with the Treatment of the Medial Meniscus with the NUSurface® Meniscus Implant	150	Mar 2016 (completed)
NCT01059409	The Clinical and Medico-economical Evaluation of Meniscal Allografts in the Sequelae of Total or Sub-total Meniscectomy	120	Sep 2017 (ongoing)
NCT02136901[a]	The VENUS Clinical Study (Verifying the Effectiveness of the NUSurface® System): A Multi-center, Prospective, Randomized, Interventional Superiority Clinical Study	37	Jun 2020

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Policy History

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05/16/2002	Medical Policy Committee review
06/05/2002	Managed Care Advisory Council approval
06/24/2002	Format revision. No substance change to policy
06/01/2004	Medical Director review
06/15/2004	Medical Policy Committee review
06/28/2004	Managed Care Advisory Council approval
07/12/2006	Medical Director review
07/19/2006	Medical Policy Committee review. Format changes and FDA information added.
07/02/2008	Medical Director review
07/16/2008	Medical Policy Committee review. Coverage eligibility unchanged.
07/02/2009	Medical Director review
07/22/2009	Medical Policy Committee review. Coverage changed from investigational to eligible with criteria.
07/01/2010	Medical Policy Committee approval
07/21/2010	Medical Policy Implementation Committee approval. Policy statement added; collagen implant considered investigational; collagen meniscus implant added to policy title.
07/07/2011	Medical Policy Committee review.
07/20/2011	Medical Policy Implementation Committee approval. Meniscal allograft transplantation when performed in combination, either concurrently or sequentially, with autologous chondrocyte implantation, osteochondral allografting or osteochondral autografting for focal articular cartilage lesions is now considered eligible for coverage instead of investigational.

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06/28/2012	Medical Policy Committee review.
07/27/2012	Medical Policy Implementation Committee approval. No change to coverage.
06/27/2013	Medical Policy Committee review
07/17/2013	Medical Policy Implementation Committee approval. Title and investigational statement changed from "collagen" to "other" and included polyurethane as an example of other meniscal implants in the investigational statement.
07/10/2014	Medical Policy Committee review
07/16/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/25/2015	Medical Policy Committee review
07/15/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Updated rationale and references.
08/04/2016	Medical Policy Committee review
08/17/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
08/03/2017	Medical Policy Committee review
08/23/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/03/2018	Medical Policy Committee review
05/16/2018	Medical Policy Implementation Committee approval. Coverage section adopts both BCBSA and AIM Guidelines.
05/02/2019	Medical Policy Committee review
05/15/2019	Medical Policy Implementation Committee approval. Policy coverage and Policy Guidelines sections changed to track AIM Guidelines.
04/02/2020	Medical Policy Committee review
04/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2021

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	29868
HCPCS	G0428
ICD-10 Diagnosis	M23.000-M23.369, Q68.6, S83.200A-S23.32XA

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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