BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Meniscal Allografts and Other Meniscus Implants

Policy #: 158
Latest Review Date: April 2024
Category: Musculoskeletal

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **meniscal allograft transplantation** as a **covered benefit** 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 (e.g., younger than 55 years).
- Disabling knee pain with activity that is refractory to conservative therapy * i.e., physical therapy, analgesic medications.
- 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 (Outerbridge Grade II or less, <50% joint space narrowing).
- Normal knee biomechanics, or alignment and stability achieved concurrently with meniscal transplantation.

Blue Advantage will treat **meniscal allograft transplantation** as a **covered benefit** when performed in combination, either concurrently or sequentially, with autologous chondrocyte implantation or osteochondral allografting or osteochondral autografting for focal articular cartilage lesions.

Blue Advantage will treat **meniscal allograft transplantation** as contraindicated and as a **non-covered benefit** for the following:

- Uncorrected misalignment and instability of the joint
- Severe obesity, e.g., body mass index (BMI) >35kg/m2, may affect outcomes due to the increased stress on weight-bearing surfaces of the joint

Blue Advantage will treat **other meniscal implants incorporating materials such as collagen and polyurethane** as a **non-covered benefit** and as **investigational**.

*Conservative therapy is the use of structured physician-directed modalities which may include: prescription-strength analgesics/anti-inflammatory medications if not contraindicated; participation in therapeutic physical medicine modality(ies) and/or manipulations when rendered by an eligible provider (including active exercise).

For coverage of collagen meniscus implant please refer to the NCD for Collagen Meniscus Implant (150.12).

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue

Advantage administers benefits based on the members' contracts and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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

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, 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 100,000. It is not expected that clinical trials will be conducted to compare meniscal allografts with other orthopedic procedures, although trials comparing allograft transplants 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 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. 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 and 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, 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 being 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. In a survey conducted by the International Meniscus Reconstruction Experts Forum, when surgeons were asked about the type of allograft preference, 68% responded to fresh frozen nonirradiated allografts, with 14% responding to 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 (CMI®) (by Stryker, formerly the ReGen Collagen Scaffold® by ReGen Biologics), is a resorbable collagen matrix comprised 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. Non-absorbable and non-porous synthetic implants for total meniscus replacement are in development. One total meniscus replacement that is in early phase clinical testing is NUsurface® (Active Implants), which is composed of a polyethylene-reinforced polycarbonate urethane.

Outcome Measures
The outcomes of this treatment (i.e., 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.

KEY POINTS:
The most recent literature update was performed through February 20, 2024.

Summary of Evidence
For individuals who are undergoing partial meniscectomy who receive MAT, the evidence includes systematic reviews of mostly case series and an RCT. The relevant outcomes are

symptoms, functional outcomes, and QOL. 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 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 a meaningful improvement in the net health outcome.

For individuals who are undergoing partial meniscectomy with a concomitant procedure to repair malalignment, focal chondral defects and/or ligamentous insufficiency, who receive MAT, the evidence includes one systematic review of case series as well as several case series published after the systematic review. The relevant outcomes are symptoms, functional outcomes, and QOL. 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, and who receive CMIs, the evidence includes two systematic reviews primarily of case series. The relevant outcomes are symptoms, functional outcomes, and QOL. 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 the effects of the technology on health outcomes.

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. The Forum's statements included guidance on indications, graft procurement and preparation, surgical technique, and rehabilitation.

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 the meniscus deficient
MAT is not recommended for asymptomatic meniscus-deficient patients.

Potentially poorer outcomes are 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 is 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 United Kingdom's National Institute for Health and Care Excellence (2012) stated that evidence on "partial replacement of the meniscus of the knee using a biodegradable scaffold raised 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.

KEY WORDS:
Meniscal allograft transplantation (MAT), anterior cruciate ligament (ACL), ReGen Collagen Scaffold, Menaflex, Collagen Meniscal Implant (CMI)

APPROVED BY GOVERNING BODIES:

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 predicate 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 the 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 is now called CMI® and is manufactured by Ivy Sports Medicine. CMI® is the only FDA-approved collagen meniscus product currently on the market.

BENEFIT APPLICATION:

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODES:

CPT Codes:

29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral

HCPCS:

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

REFERENCES:

1. American Academy of Orthopaedic Surgeons. OrthoInfo: Meniscal transplant surgery. 2014; https://orthoinfo.aaos.org/en/treatment/meniscal-transplant-surgery/.
2. Bulgheroni E, Grassi A, Bulgheroni P, et al. Long-term outcomes of medial CMI implant versus partial medial meniscectomy in patients with concomitant ACL reconstruction. Knee Surg Sports Traumatol Arthrosc. Jul 2014.
3. Cvetanovich GL, Yanke AB, McCormick F, et al. Trends in meniscal allograft transplantation in the United States, 2007 to 2011. Arthroscopy. Jun 2015; 31(6):1123-1127.
4. Elattar M, Dhollander A, Verdonk R et al. Twenty-six years of meniscal allograft transplantation: is it still experimental? A meta-analysis of 44 trials. Knee Surg Sports Traumatol Arthrosc 2011; 19(2):147-157.

5. Farr J, Rawal A, Marberry KM. Concomitant meniscal allograft transplantation and autologous chondrocyte implantation: minimum 2-year follow-up. Am J Sports Med 2007; 35(9):1459-1466.
6. Frank RM, Cole BJ. Meniscus transplantation. Curr Rev Musculoskelet Med. Dec 2015; 8(4):443-450.
7. Getgood A, LaPrade RF, Verdonk P, et al. International Meniscus Reconstruction Experts Forum (IMREF) 2015 Consensus Statement on the Practice of Meniscal Allograft Transplantation. Am J Sports Med. Aug 25 2017; 45(5):1195-1205.
8. Harris JD, Cavo M, Brophy R et al. Biological knee reconstruction: a systematic review of combined meniscal allograft transplantation and cartilage repair or restoration. Arthroscopy 2011; 27(3):409-418.
9. Harston A, Nyland J, Brand E et al. Collagen meniscus implantation: a systematic review including rehabilitation and return to sports activity. Knee Surg Sports Traumatol Arthrosc 2012; 20(1):135-146.
10. Hergan D, Thut D, Sherman O et al. Meniscal allograft transplantation. Arthroscopy 2011; 27(1):101-112.
11. Hommen JP, Applegate GR and Del Pizzo W. Meniscus allograft transplantation: ten-year results of cryopreserved allografts. Arthroscopy 2007; 23(4): 388-393.
12. Houck DA, Kraeutler MJ, Belk JW, et al. Similar clinical outcomes following collagen or polyurethane meniscal scaffold implantation: a systematic review. Knee Surg Sports Traumatol Arthrosc. Jan 16 2018.
13. IOM (Institute of Medicine). 2011. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press.
14. Kempshall PJ, Parkinson B, Thomas M, et al. Outcome of meniscal allograft transplantation related to articular cartilage status: advanced chondral damage should not be a contraindication. Knee Surg Sports Traumatol Arthrosc. Jan 2015; 23(1):280-289.
15. Linke RD, Ulmer M, Imhoff AB. Replacement of the meniscus with a collagen implant (CMI). Oper Orthop Traumatol 2006; 18(5-6):453-462.
16. National Institute for Health and Clinical Excellence. IPG430 Partial replacement of the meniscus of the knee using a biodegradable scaffold: guidance. 2012. www.guidance.nice.org.uk/IPG430/Guidance/pdf/English. Last accessed March, 2018.
17. Ogura T, Bryant T, Minas T. Biological knee reconstruction with concomitant autologous chondrocyte implantation and meniscal allograft transplantation: mid- to long-term outcomes. Orthop J Sports Med. Oct 2016;4(10):2325967116668490.
18. Rodkey WG, DeHaven KE, Montgomery WH 3rd et al. Comparison of the collagen meniscus implant with partial meniscectomy: A prospective randomized trial. J Bone Joint Surg Am 2008; 90(7):1413-1426.
19. Rosso F, Bisicchia S, Bonasia DE, et al. Meniscal allograft transplantation: a systematic review. Am J Sports Med. Apr 2015; 43(4):998-1007.
20. Rue JP, Yanke AB, Busam ML et al. Prospective evaluation of concurrent meniscus transplantation and articular cartilage repair: minimum 2-year follow-up. Am J Sports Med 2008; 36(9):1770-1778.

21. Smith NA, Parsons N, Wright D, et al. A pilot randomized trial of meniscal allograft transplantation versus personalized physiotherapy for patients with a symptomatic meniscal deficient knee compartment. Bone Joint J. Jan 2018; 100-B(1):56-63.
22. Stone KR, Adelson WS, Pelsis JR et al. Long-term survival of concurrent meniscus allograft transplantation and repair of the articular cartilage: a prospective two- to 12-year follow-up report. J Bone Joint Surg Br 2010; 92(7):941-948.
23. van der Wal RJ, Thomassen BJ, van Arkel ER. Long-term clinical outcome of open meniscal allograft transplantation. Am J Sports Med 2009; 37(11):2134-2139.
24. Verdonk PC, Demurie A, Almqvist KF et al. Transplantation of viable meniscal allograft. Survivorship analysis and clinical outcome of one hundred cases. J Bone Joint Surg Am 2005; 87(4):715-724.
25. Vundelinckx B, Bellemans J, Vanlauwe J. Arthroscopically assisted meniscal allograft transplantation in the knee: a medium-term subjective, clinical, and radiographical outcome evaluation. Am J Sports Med 2010; 38(11):2240-2247.
26. Warth RJ, Rodkey WG. Resorbable collagen scaffolds for the treatment of meniscus defects: a systematic review. Arthroscopy. May 2015; 31(5):927-941.
27. Zaffagnini S, Grassi A, Marcheggiani Muccioli GM, et al. Survivorship and clinical outcomes of 147 consecutive isolated or combined arthroscopic bone plug free meniscal allograft transplantation. Knee Surg Sports Traumatol Arthrosc. May 2016; 24(5):1432-1439.
28. Zaffagnini S, Grassi A, Marcheggiani Muccioli GM, et al. MRI evaluation of a collagen meniscus implant: a systematic review. Knee Surg Sports Traumatol Arthrosc. Nov 2015; 23(11):3228-3237.
29. Zaffagnini S, Marcheggiani Muccioli GM, Lopomo N et al. Prospective Long-Term Outcomes of the Medial Collagen Meniscus Implant Versus Partial Medial Meniscectomy: A Minimum 10-Year Follow-Up Study. Am J Sports Med 2011; 39(5):977-985.

POLICY HISTORY:

Adopted for Blue Advantage, March 2005
Available for comment May 12-June 27, 2005
Medical Policy Group, May 2006
Medical Policy Group, August 2008
Medical Policy Group, January 2009
Available for comment January 24-March 10, 2009
Medical Policy Group, November 2009
Available for comment January 26-March 11, 2010
Medical Policy Group, October 2010
Medical Policy Group, November 2010
Medical Policy Group, May 2011
Available for comment June 8 – July 25, 2011
Medical Policy Group, April 2012

Medical Policy Group, March 2014
Medical Policy Group, March 2015
Medical Policy Group, April 2017
Available for comment April 28 through June 11, 2017
Medical Policy Group, February 2018
Medical Policy Group, April 2020: Reinstated policy effective March 24, 2020.
Medical Policy Group, April 2021
Medical Policy Group: April 2022
Medical Policy Group, April 2023
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, April 2024
UM Committee, April 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.
