

## FEP 7.01.15 Meniscal Allografts and Other Meniscal Implants

**Effective Date:** July 15, 2018

**Related Policies:**

7.01.48 Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

## Meniscal Allografts and Other Meniscal Implants

### Description

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

### 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. 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 (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 In October 2010, FDA rescinded the approval, stating that MenaFlex™ is intended for different purposes and is technologically dissimilar from the predicate devices identified in the approval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®, is manufactured by Ivy Sports Medicine. CMI® is the only FDA-approved collagen meniscus product currently on the market. FDA product code: OLC.

### POLICY STATEMENT

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 (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

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- osteochondral allografting, or
- osteochondral autografting.

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

### POLICY GUIDELINES

Patients 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<sup>2</sup>) 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.

### BENEFIT APPLICATION

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

### RATIONALE

#### Summary of Evidence

For individuals who are undergoing partial meniscectomy who receive meniscal allograft transplantation, the evidence includes systematic reviews of mostly case series and an 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 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 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 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. 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 selected studies (RCTs, observational studies) was low.

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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

In 2015, the International Meniscus Reconstruction Experts Forum published consensus statements on the practice of meniscal allograft transplantation (MAT) (see Table 1).<sup>2</sup> 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:
<ul style="list-style-type: none"> <li>• Unicompartmental pain post-meniscectomy</li> <li>• In combination with anterior cruciate ligament reconstruction when meniscus deficient</li> <li>• In combination with articular cartilage repair if meniscus deficient</li> </ul>
MAT not recommended for asymptomatic meniscus deficient patient.
Potentially poorer outcomes expected in patients with moderate to severe OA (Kellgren-Lawrence grade $\geq 3$ ).
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, superiority of 1 surgical technique over another (all-suture vs bone) is not established.
Outcome scores should include:
<ul style="list-style-type: none"> <li>• Disease-specific: Western Ontario Meniscal Evaluation Tool</li> <li>• Region-specific: Knee injury and Osteoarthritis Outcome Score</li> <li>• Activity: Marx Activity Rating Scale</li> <li>• Quality of life/utility: EuroQoL 5 dimensions questionnaire</li> </ul>
MAT: meniscal allograft transplantation; OA: osteoarthritis.

##### National Institute for Health and Care Excellence

The 2012 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.<sup>27</sup>

##### American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons updated its 2009 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.<sup>28</sup> 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

In 2010, the Centers for Medicare & Medicaid Services (CMS) issued a national noncoverage determination for the collagen meniscus implant (CMI).<sup>29</sup> A number of concerns regarding the efficacy and safety were raised by the CMS 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. CMS concluded that the CMI does not improve

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health outcomes in the Medicare population and that CMI is not reasonable and necessary for the treatment of meniscal injury or tear.

### REFERENCES

1. 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. PMID 25682330
2. 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. PMID 27562342
3. Frank RM, Cole BJ. Meniscus transplantation. *Curr Rev Musculoskelet Med*. Dec 2015;8(4):443-450. PMID 26431702
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*. Feb 2011;19(2):147-157. PMID 21161170
5. Hergan D, Thut D, Sherman O, et al. Meniscal allograft transplantation. *Arthroscopy*. Jan 2011;27(1):101-112. PMID 20884166
6. Rosso F, Bisicchia S, Bonasia DE, et al. Meniscal allograft transplantation: a systematic review. *Am J Sports Med*. Apr 2015;43(4):998-1007. PMID 24928760
7. 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. PMID 29305451
8. 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*. Apr 2005;87(4):715-724. PMID 15805198
9. Hommen JP, Applegate GR, Del Pizzo W. Meniscus allograft transplantation: ten-year results of cryopreserved allografts. *Arthroscopy*. Apr 2007;23(4):388-393. PMID 17418331
10. van der Wal RJ, Thomassen BJ, van Arkel ER. Long-term clinical outcome of open meniscal allograft transplantation. *Am J Sports Med*. Nov 2009;37(11):2134-2139. PMID 19542303
11. 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*. Nov 2010;38(11):2240-2247. PMID 20724642
12. 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*. Mar 2011;27(3):409-418. PMID 21030203
13. 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*. Jul 2010;92(7):941-948. PMID 20595111
14. Farr J, Rawal A, Marberry KM. Concomitant meniscal allograft transplantation and autologous chondrocyte implantation: minimum 2-year follow-up. *Am J Sports Med*. Sep 2007;35(9):1459-1466. PMID 17435058
15. 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*. Sep 2008;36(9):1770-1778. PMID 18483199
16. 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. PMID 25432522
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. PMID 27803938
18. 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. PMID 26860105
19. 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*. Jan 2012;20(1):135-146. PMID 21695465
20. Warth RJ, Rodkey WG. Resorbable collagen scaffolds for the treatment of meniscus defects: a systematic review. *Arthroscopy*. May 2015;31(5):927-941. PMID 25595693
21. 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. PMID 24993568

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22. 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. PMID 29340746
23. 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.* Jul 2008;90(7):1413-1426. PMID 18594088
24. Linke RD, Ulmer M, Imhoff AB. [Replacement of the meniscus with a collagen implant (CMI)] [German]. *Oper Orthop Traumatol.* Dec 2006;18(5-6):453-462. PMID 17171330
25. 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.* May 2011;39(5):977-985. PMID 21297005
26. 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.* Nov 2015;23(11):3221-3227. PMID 24990662
27. National Institute for Health and Care Excellence (NICE). Partial replacement of the meniscus of the knee using a biodegradable scaffold: guidance [IPG430]. 2012; <https://www.nice.org.uk/guidance/IPG430>. Accessed March 16, 2018.
28. American Academy of Orthopaedic Surgeons. OrthoInfo: Meniscal transplant surgery. 2014; <https://orthoinfo.aaos.org/en/treatment/meniscal-transplant-surgery/>. Accessed March 16, 2018.
29. Centers for Medicare and Medicaid Services (CMS). Decision Memo for COLLAGEN MENISCUS IMPLANT (CAG-00414N). 2010; <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=235&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&Keyword=Collagen+Meniscus+Implant&KeywordLookUp=Title&KeywordSearchType=And&id=235&bc=gAAAACAACAAAAA%3d%3d&>. Accessed March 16, 2018.

### POLICY HISTORY

Date	Action	Description
December 2011	New Policy	
June 2013	Revise Policy	Policy updated with literature review; references 17, 21-24 added; title and investigational statement changed from "collagen" to "other"
June 2014	Revise Policy	Policy updated with literature review, adding reference 23. No change to policy statement.
June 2015	Revise 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	Revise 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	Revise Policy	Policy updated with literature review through February 5, 2018; references 7 and 22 added; note 28 updated. Multiple references were deleted. "Polyurethane" removed from the policy; statements otherwise unchanged.

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