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| MEDICAL POLICY | Knee: Meniscal Allograft Transplantation and Other Meniscal Implants |
| Effective Date: 11/1/2021 | Medical Policy Number: 150 |
|  11/1/2021 | Technology Assessment Committee Approved Date: 3/10; 9/15 Medical Policy Committee Approved Date: 9/04; 9/05; 9/07; 11/09 ; 3/12; 7/13; 6/14; 6/15; 6/16; 8/17; 1/19; 2/2020; 8/2020; 10/2021 |
| Medical Officer | Date |

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Meniscal Allograft Transplantation

I. Meniscal allograft transplantation may be **medically necessary and covered** when **all** of the following criteria are met (A. – G.):

- A. Age 55 years or younger; **and**
- B. Body mass index (BMI) of <35; **and**
- C. Symptoms from acute or chronic trauma interfere with age-appropriate activities of daily living; **and**
- D. Symptoms have failed to improve after 3 months of conservative treatment, including physical therapy, as part of pre-operative planning for surgery; **and**

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| <p>E. The meniscus is shown by imaging (e.g., MRI or arthroscopy) to be absent or near absent; and</p> <p>F. Documented minimal to absent degenerative changes in surrounding articular cartilage (Outerbridge Grade 2 or less AND radiographic evidence of normal joint spacing; please see Policy Guidelines section for Outerbridge scale information); and</p> <p>G. Stable and aligned knee with intact meniscus and functional ligaments (intact or reconstructed).</p> <p>Note: Corrective procedures (e.g. ligament or tendon repair, osteotomy for realignment) may be performed concurrently or sequentially.</p> <p>II. Meniscal allograft transplantation is considered investigational and not covered when criterion I. above is not met.</p> <p>Other Meniscal Implants</p> <p>III. Use of collagen meniscal implants (e.g., CMI or CMI XL) are considered not medically necessary and not covered.</p> <p>IV. Use of meniscal implants that incorporate other materials (e.g., polyurethane) are considered investigational and not covered.</p> <p>Link to Policy Summary</p> |
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POLICY GUIDELINES

Outerbridge Scale to Determine Severity of Cartilage Defects of the Knee

This scale was originally created to classify the macroscopic changes of chondromalacia of the patella.¹ Later, the scale was slightly modified to allow for grading of all cartilage lesions.²

- Grade 1: Softening and swelling of the cartilage.
- Grade 2: Fragmentation and fissuring in an area half an inch or less in diameter.
- Grade 3: Fragmentation and fissuring in an area more than half an inch in diameter.
- Grade 4: Erosion of cartilage down to the bone.

CPT/HCPCS CODES

| All Lines of Business | |
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| No Prior Authorization Required | |
| 29868 | Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral |

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| Not Covered | |
| G0428 | Collagen meniscus implant procedure for filling meniscal defects (e.g., cmi, collagen scaffold, menaflex) |
| Unlisted Codes | |
| All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then prior-authorization is required. | |
| 27599 | Unlisted procedure, femur or knee |
| 29999 | Unlisted procedure, arthroscopy |

DESCRIPTION

Meniscal Allograft Transplantation (MAT)

The meniscus (or menisci) refers to the lateral and medial crescent shaped fibrocartilage located between the tibia and femur, which provide structural integrity and shock-absorption to the knee. The meniscus aids in the stability and to some degree, alignment of the knee.

Meniscal allograft transplantation (MAT) is a surgical technique that involves grafting a donor meniscus into the knee of a recipient to aid in restoring knee function in individuals with destroyed or absent menisci. Allograft tissue from a cadaver is matched by size to the recipient, inserted into the knee joint and anchored to supporting structures by hardware, soft tissue or bony tissue fixation. The procedure may be performed using an arthroscopic approach or an open procedure.

Collagen Meniscus Implants (CMIs)

Collagen meniscus implants (CMIs) have been proposed as an alternative treatment to MAT for individuals with a damaged knee meniscus. For example, CMI (previously known as Menaflex™) is an implant derived from bovine collagen used to treat acute or chronic advanced meniscal loss or damage with the intent of relieving symptoms and preventing joint degeneration.³ The goal of the CMI scaffold is to support ingrowth and regeneration of new meniscal tissue and is designed to be reabsorbed in 12–18 months.⁴

Polyurethane Scaffolds

Polyurethane scaffold implantation, also purported as an alternative to MAT, is designed to provide mechanical support to the knee joint and slowly degrade as the scaffold is replaced by regenerated tissue.⁵

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of meniscal allografting and meniscal implants as treatments for damaged or degraded menisci. Below is a summary of the available evidence identified through July 2021.

Meniscus Allograft Transplantation (MAT)

Due to the large body of evidence on meniscal allograft transplantation (MAT), the evidence review below focused primarily on recent systematic reviews and RCTs.

Systematic Reviews

- In 2019, Novaretti and colleagues conducted a systematic review evaluating the long-term survival and outcomes of meniscal allograft transplantation (MAT) at 10-year follow-up.⁶ Independent investigators systematically searched the literature through January 2018, identified eligible studies, assessed study quality and extracted data. In total, 11 studies evaluating 658 patients were included for review. Mean survivorship rates were 73.5% at 10-year and 60.3% at 15-year follow-up, with 2 studies reporting 19- and 24-year survivorship of 50% and 15.1%, respectively. Postoperative Knee injury and Osteoarthritis Outcome Score subset scores were as follows: Pain: 61.6 to 76.3; Symptoms: 57.9 to 61.8; Function in Daily Living: 68.5 to 79.9; Sport and Recreation: 33.9 to 49.3; Quality of Life: 37.3 to 45.9. Postoperative International Knee Documentation Committee scores ranged from 46 to 77. Limitations included the lack of high-quality evidence and the small sample sizes for several studies included for review. On the basis of level IV evidence, investigators concluded that MAT can yield good long-term survivorship rates at long-term follow-up, with functional outcomes of “fair” and “improved” when compared with preoperative scores.
- In 2019, Lee and colleagues conducted a systematic review and meta-analysis evaluating clinical outcomes of MAT with or without other procedures.⁷ Independent investigators systematically searched the literature through January 2018, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 24 studies were included for review. No significant differences in Lysholm scores (95% CI, –5.92 to 1.55; P = .25), Tegner activity scores (95% CI, –0.54 to 0.22; P = .41), International Knee Documentation Committee subjective scores (95% CI, –5.67 to 3.37; P = .62), and visual analog scale scores (95% CI, –0.15 to 0.94; P = .16) were observed between isolated MAT and combined MAT. Most studies reported no significant difference for patient-reported outcomes between the 2 groups. Results for survivorship and failure rates were mixed. Four studies reported that additional procedures did not affect MAT failure or survivorship. However, 3 studies reported that ligament surgery, realignment osteotomy, and osteochondral autograft transfer were risk factors of failure. Investigators concluded that there appears to be no significant difference between postoperative PROs in terms of isolated MAT and combined MAT, yet called for additional research to validate the clinical outcomes of MAT. No conclusions regarding differences in complication, reoperation and survivorship could be drawn between the two groups.

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- Additional systematic reviews reported improvements in patients’ progression of osteoarthritis, functional outcomes, quality of life and survivorship at long-term follow-up, despite noting a lack of high-quality evidence available for review.⁸⁻¹⁰

Randomized Controlled Trials (RCTs)

No RCTs evaluating the efficacy of MAT were identified after the publication of the systematic reviews described above.

Meniscus Implants

Systematic Reviews

- In 2017 (updated 2019; archived 2020), Hayes published a systematic review that evaluated the efficacy of the collagen meniscal implant (CMI) Menaflex for meniscal repair, including eight clinical studies, two of which were RCTs.³ Seven of the eight studies were considered to be of poor- to very poor quality. Evidence from the included comparative studies in patients with medial meniscus repair with CMI did not clearly demonstrate that outcomes were significantly better with medial CMI than other surgical techniques. No comparative studies were identified that used CMI for lateral meniscus repair. Overall there was a lack of comparative data between CMI and any given procedure or with control groups.

Limitations of individual studies included one or more of the following:

- small sample size
 - differences in duration of follow-up within the study
 - lack of blinding/masking
 - retrospective design
 - incomplete reporting
 - differences in characteristics and attrition between treatment and control groups (comparative studies only)
 - inconsistent findings in comparisons with partial meniscectomy
- In 2018, Houck et al., published the results of a systematic review of clinical outcomes following CMI (Menaflex) or polyurethane meniscal scaffold (Actifit) implantation, including 19 studies (N=658 patients [347 Actifit, 311 CMI]).¹¹ Seventeen of the 19 studies included were case series, which ranged from 8-54 patients. The two comparative studies included evaluated CMI and were also included in the Hayes review above. Treatment failure occurred in 9.9% of patients receiving the Actifit scaffold (mean follow-up of 40 months) and 6.7% of patients receiving CMI (mean follow-up of 44 months). Although the review concluded that “patients undergoing meniscal scaffold implantation with either CMI or Actifit scaffold can both be expected to experience improvement in clinical outcomes when used in association with concomitant procedures such as anterior cruciate ligament reconstruction and high tibial osteotomy”, the paucity of studies comparing either implant to other conventional treatments warrants caution.

This review cited the same limitations of the individual studies as the Hayes review above. In addition, the following limitations were indicated:

- considerable differences in preoperative VAS scores between the implants, making it difficult to compare.
- failure rate ranged from 0 to 31.8% and treatment failure definitions differed between studies.
- not all studies for each implant type evaluated patients using the same outcome measures, and therefore sample sizes were limited for certain outcomes.
- minimum and maximum follow-up of patients was not defined in many of the included studies.

Randomized Controlled Trials

Only two randomized controlled trials (RCTs) for procedures using collagen meniscal implants (CMIs) have been identified and included in the systematic reviews above. The largest RCT identified was published in 2008 by Rodkey et al. and evaluated CMIs in two groups of patients: those with prior meniscal surgery (chronic group, n=157) and those with no prior surgery (acute group, n=154).⁴ Each of these groups was randomized to receive either treatment with a CMI or a partial meniscectomy only. Mean follow-up was 59 months (range: 16 - 92 months). In the chronic group, participants who received the collagen implant regained a significantly higher degree of pre-surgery activity and underwent significantly fewer reoperations than did the controls. However, no significant differences were reported between the two treatment groups in the acute arm of the study. In addition, post-operative pain scores, Lysholm scores, and patient self-assessment scores were similar in all groups, regardless of treatment or chronicity. This indicates a lack of superiority over conventional procedures such as partial meniscectomy. Additional limitations of this trial included:

- lack of long-term follow-up in all patients (duration of follow-up was less than two years for 5.5% of patients)
- lack of blinding, which could lead to patient reporting bias
- postoperative rehabilitation protocols were very different between the CMI and control groups
- control patients did not have a follow-up arthroscopy to confirm that they had not regenerated competent meniscal tissue
- possible recall bias (overestimation) in the scoring of preinjury activity levels
- there was unsuitably high radiograph variability in the views and techniques used at the 16 different study sites that the consulting radiologist was unable to make any definitive statements

No additional RCTs evaluating CMI have been identified since the publications of the systematic reviews above. No RCTs were identified that

Nonrandomized Studies

The following study was identified that was not included in either of the systematic reviews above. In 2016, Waterman et al. published the results of a cohort study in which 230 active duty military personnel underwent treatment with CMI.¹² Fifty-one complications occurred in 46 patients (21.1%)

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and 50 patients (22%) ultimately underwent knee-related military discharge at a mean of 2.5 years post-CMI. The authors concluded that while there were low reoperation and revision rates, an unsuitably high number of patients who received implants were unable to return to military duty due to persistent knee problems.

CLINICAL PRACTICE GUIDELINES

Meniscus Implants

National Institute for Health and Care Excellence (NICE)

The 2012 NICE guidance on the use of biodegradable scaffolds, including implants containing collagen or polyurethane, for partial replacement of the meniscus, stated the following:¹³

“Current evidence on partial replacement of the meniscus of the knee using a biodegradable scaffold raises no major safety concerns. Evidence for any advantage of the procedure over standard surgery, for symptom relief in the short term, or for any reduction in further operations in the long term, is limited in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

NICE encourages further research and data collection on partial replacement of the meniscus of the knee using a biodegradable scaffold.”

CENTERS FOR MEDICARE & MEDICAID

As of 8/12/2021, the following Centers for Medicare & Medicaid (CMS) coverage guidance was identified which addresses collagen meniscus implants for the treatment of meniscal injury/tear:

National Coverage Determination (NCD) for Collagen Meniscus Implant (150.12)¹⁴

This NCD states:

“the Centers for Medicare & Medicaid Services has determined that the evidence is adequate to conclude that the collagen meniscus implant does not improve health outcomes and, therefore, is not reasonable and necessary for the treatment of meniscal injury/tear under section 1862(a)(1)(A) of the Social Security Act. Thus, the collagen meniscus implant is non-covered by Medicare.”

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POLICY SUMMARY

Meniscal Allograft Transplantation (MAT)

The body of evidence regarding meniscal allografting of the knee has limitations. However, overall the evidence indicates that this procedure has demonstrated acceptable mid-term benefit in terms of pain reduction and, improved physical function, and successful incorporation of the graft into the knee. Several long-term studies have demonstrated mid- to long-term transplant survival to 10 years or longer, with a survival rate reported over 85% at mid-term (5-10 years) while 52-56% of transplants survived long term (>10 years). Lastly, the literature has consistently emphasized the importance adequate joint stability and alignment, as well as absence of moderate to severe cartilage damage (Outerbridge Grade 3 or 4).

Meniscal Implants

There is insufficient evidence that collagen or polyurethane meniscus implants improve health outcomes such as reduction of symptoms and restoration of knee function in patients with meniscus injuries or tears. Additional studies with long term follow-up are needed to determine whether implantation of a collagen scaffold is able improve health outcomes such as slowing joint degeneration, delaying the progression of osteoarthritis, and reducing pain for long durations.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

U.S. Food & Drug Administration (FDA)

Meniscal Allografts

The FDA regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research. Tissues such as meniscal cartilage are

included in these regulations. Under these regulations, these tissues are exempt and therefore, do not follow the traditional FDA regulatory pathway.¹⁵

Meniscus Implants

In 2017, the FDA granted 510(k) clearance for the Collagen Meniscus Implant XL (CMI XL) (Ivy Sports Medicine, LLC). Collagen Meniscus Implant XL is “intended for use in surgical procedures for the reinforcement and repair of soft tissue injuries of the medial meniscus. In repairing and reinforcing medial meniscal defects, the patient must have an intact meniscal rim and anterior and posterior horns for attachment of the mesh. In addition, the surgically prepared site for the CMI must extend at least into the red/white zone of the meniscus to provide sufficient vascularization.”¹⁶

No polyurethane meniscus implant (PMI) has FDA approval or is available in the U.S. for marketing; this includes the Actifit® biodegradable meniscus polyurethane scaffold (Saratoga Partners, LLC formerly known as Orteq Sports Medicine Ltd.).

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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