UnitedHealthcare®

MEDICAL POLICY

MENISCUS IMPLANT AND ALLOGRAFT

Policy Number: 2014T0543E
Effective Date: October 1, 2014

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Related Policies:

- Osteochondral Grafting of the Knee
- Unicondylar Spacer Devices for Treatment of Pain or Disability
- Autologous Chondrocyte Transplantation In The Knee

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage.

COVERAGE RATIONALE

Meniscus allograft transplantation with human cadaver tissue is proven and medically necessary for replacement of major meniscus loss due to trauma or previous meniscectomy when all of the following are present:

- Adult who has achieved mature skeletal growth
- Patient has significant knee pain and limited function
- Patient is missing more than half of the meniscus due to surgery or injury or has a tear that cannot be repaired
- Radiographic criteria established by a standing anteroposterior (AP) view demonstrates all of the following:
  - Normal alignment or correctable varus or valgus deformities
  - No osteophytes or marginal osteophytes
  - No articular cartilage defects
  - No significant joint space narrowing
- Ligamentous stability has been achieved prior to surgery or achieved concurrently with meniscal transplantation (e.g., concomitant anterior cruciate ligament surgery)
- There is minimal to absent degenerative changes in surrounding articular cartilage (Outerbridge Grade II or less)
- There is no evidence of active inflammatory arthritis or systemic arthritis
- Patient who has failed conservative treatment including physical therapy and/or bracing techniques.

Collagen meniscus implants are unproven and not medically necessary for the treatment of meniscus injuries or tears.

There is insufficient evidence that collagen 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 to slow joint degeneration, delay the progression of osteoarthritis, and reduce pain for long durations.

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

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

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

DESCRIPTION OF SERVICES

Allografts are grafts of tissues made available from a live person or a human cadaver. Allografts from cadavers avoid morbidity from harvesting tissue from a different site on the person requiring

meniscus repair. The goal of meniscal allograft transplantation is to restore knee function and prevent further joint degeneration by replacing the damaged or destroyed meniscus with allograft tissue having similar properties as the damaged tissue.

Meniscal allograft transplantation is a surgical procedure that has been proposed as treatment for a subset of patients with irreparable meniscal tears, or who have undergone previous total meniscectomy.

Patient selection criteria for meniscal allograft transplantation are not well-defined and vary across studies. However, candidates are generally young, with minimal degenerative changes, have a stable knee and normal axial alignment, and have failed to respond to conservative care.

A meniscus is a crescent-shaped wedge of cartilage located on the proximal articulating surface of the tibia within the synovial joint of the knee. Small, unstable tears in the periphery of the meniscus may be sutured. The procedure can be performed either arthroscopically or by open technique and involves grafting a donor meniscus into the knee of the patient. Treatment of severe meniscal injury usually involves partial excision of the damaged tissue or complete meniscectomy. The loss of tissue frequently leads to osteoarthritis and irreversible joint damage. Many different materials have been evaluated for prostheses to replace lost or damaged menisci, including artificial materials, autogenous tissue (graft tissue obtained from oneself), and allograft tissue (graft tissue obtained from another person).

The Menaflex collagen meniscus implant is a device made of a biologically derived material, primarily bovine type I collagen, which is designed to guide new tissue growth in the meniscus using the body's own healing process. This new tissue has the potential to restore function, reduce pain, and possibly slow the degenerative process that begins with the loss of meniscus tissue. To prepare the meniscus for the implant, a partial meniscectomy or removal any loose or damaged meniscal tissue is preformed arthroscopically. The Menaflex implant is then trimmed to fit the meniscus defect and is sutured into place. Once imbedded, the implant provides a matrix into which the body's own cells may begin to migrate. New tissue potentially forms as these cells aggregate and multiply, with the Menaflex material subsequently being absorbed by the body (ECRI, 2010). The Menaflex collagen meniscus implant is the only collagen meniscus implant with FDA clearance at this time.

Meniscal allograft transplantation is a surgical procedure that involves grafting a donor meniscus into the knee of a recipient. The rationale for meniscal allograft transplant is to prevent the development of arthritis resulting form the loss of the meniscal function following trauma or meniscectomy. Donor menisci are obtained from genetically unrelated individuals, usually through organ procurement programs, coroners' offices, hospitals, and morgues. The allografts may be implanted fresh from cadaver donor, although this presents problems regarding the timing of the surgery and also increases the risk of disease transmission. Fresh menisci can be maintained in culture for 2 weeks, which allows time for infectious disease testing while preserving cell viability. Cryopreservation, in which the graft is treated with a cryoprotectant and frozen, preserves fibrochondrocytes and does not distort the graft. Fresh freezing is another technique used in the preservation of the allograft; however, this process kills the cells and can damage the collagen net of the graft.

CLINICAL EVIDENCE

Collagen Meniscus Implants

Rodkey et al. (2008) conducted a randomized controlled trial that included 311 patients with an irreparable injury of the medial meniscus or a previous partial medial meniscectomy. There were two study arms, one consisting of 157 patients who had had no prior surgery on the involved meniscus (the acute arm of the study) and one consisting of 154 patients who had had one, two, or three prior meniscal surgical procedures (the chronic arm). Patients were randomized either to

receive the collagen meniscus implant (CMI) or to serve as a control subject treated with a partial meniscectomy only. Patients underwent frequent clinical follow-up examinations over two years and completed validated outcomes questionnaires over seven years. Patients who received the collagen meniscus implant followed a different post-op protocol, receiving a specific rehabilitation protocol and the requirement of a second-look arthroscopy with biopsy one year after implant placement. In the acute group, seventy-five patients received a collagen meniscus implant and eighty-two were controls. In the chronic group, eighty-five patients received the implant and sixty-nine were controls. The mean duration of follow-up was fifty-nine months. The 141 repeat arthroscopies done at one year showed that the collagen meniscus implants had resulted in significantly increased meniscal tissue compared with that seen after the original index partial meniscectomy. The implant supported meniscus-like matrix production and integration as it was assimilated and resorbed. In the chronic group, the patients who had received an implant regained significantly more of their lost activity than did the controls and they underwent significantly fewer non-protocol re-operations. No differences were detected between the two treatment groups in the acute arm of the study. The investigators concluded that new biomechanically competent meniscus-like tissue forms after placement of a collagen meniscus implant, and use of the implant appears safe. The collagen meniscus implant supports new tissue ingrowth that appears to be adequate to enhance meniscal function as evidenced by improved clinical outcomes in patients with a chronic meniscal injury. According to the investigators, the implant was not found to have any benefit for patients with an acute injury.

An assessment by the California Technology Assessment Forum (CTAF), (Tice, 2010) concluded that the collagen meniscus implant does not meet CTAF criteria. The CTAF assessment found that the pivotal randomized clinical trial (citing Rodkey et al, 2008) failed to demonstrate any improvement in pain or symptoms in either arm of the trial and the trial has substantial risk for selection bias, confounding, and reporting bias because of the large number of patients lost to follow-up after randomization and the lack of blinding for subjective outcomes. In addition, no data on osteoarthritis were presented. The CTAF assessment concluded that the trial "presents evidence that the collagen meniscus implant offers no important clinical benefits, requires longer and more intensive post-operative rehabilitation, and some uncertainty remains about the potential for long-term harm from the device."

The data from the Rodkey study was used by the U.S. Food and Drug Administration (FDA) in the 510(k) application process for the Menaflex collagen meniscus implant. An FDA executive summary of the Rodkey data indicated that patients who received the collagen meniscus implant followed a different post-op protocol than the control group and control patients were not required to undergo a planned second-look arthroscopy since it was assumed that there was no tissue regrowth in these patients. The FDA also indicated that more meniscal tissue was removed from the collagen meniscus implant patients than in the control patients. The FDA noted that the re-look arthroscopy results for collagen meniscus implant group showed that 16% of evaluated devices were not firmly attached to the host rim and 18% of knee compartments were determined to be worse than during the operative procedure at the time of the re-look arthroscopic procedure. According to the FDA summary, the Tegner Index is meant to complement other functional scores (Lysholm knee score) for patients with ligamentous injuries, however, the investigators reported the Tegner Index in isolation and there was no pre-specified hypothesis for its use in the study design, thus, it is unclear how this endpoint should be interpreted given that there is no defined clinical significance for the Tegner Score when used in isolation. In addition, the FDA executive summary stated that at the 3 to 7 year annual follow-up time points, there is approximately 50% of the data available. It is not clear how the missing data has impacted the presentation of the safety and effectiveness endpoints at time-points later than 24 months. The primary endpoint was a 24-month endpoint. See the following Web site for more information: (http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4400b1-01FDA%20Summary%20and%20Questions%20.pdf. Accessed June 27, 2014.

According to an FDA data review of the Rodkey et al. 2008 trial, of the 87 CMI patients in the chronic group, 8 (9.2%) had serious device-related adverse events. Additionally, the percentage of all serious adverse events per patient was higher for the CMI group than the control group (43% vs 33%), although it is not reported if this difference is statistically significant. See the following Web site for more information: 13. http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm183745.htm Accessed June 27, 2014.

Harston et al (2012) examined collagen meniscus implant (CMI) effectiveness for improving patient function, symptoms, and activity level. Study methodologies, rehabilitation, and return to sports guidelines were also reviewed. A total of 11 studies with 520 subjects met inclusion criteria. The authors concluded that knee function, symptoms, and activity level generally improved following CMI use, but poor research report quality was common. They stated that additional well-designed long-term prospective studies are needed to better determine knee osteoarthrosis prevention efficacy and appropriate patient selection.

Zaffagnini et al. (2011) conducted a cohort study that included 33 nonconsecutive patients (men; mean age, 40 years) with meniscal injuries. Study participants received medial collagen meniscus implant (MCMI) or served as a control patient treated with partial medial meniscectomy (PMM). The choice of treatment was decided by the patient. All patients were clinically evaluated at time 0 and at 5 years and a minimum of 10 years after surgery by Lysholm, visual analog scale (VAS) for pain, objective International Knee Documentation Committee (IKDC) knee form, and Tegner activity level scores. The MCMI group, compared with the PMM one, showed significantly lower VAS for pain and higher objective IKDC, Teger index, and SF-36 for Physical Health Index scores. Radiographic evaluation showed significantly less medial joint space narrowing in the MCMI group than in the PMM group. The MRI evaluation of the MCMI patients revealed 11 cases of myxoid degeneration signal: 4 had a normal signal with reduced size, and 2 had no recognizable implant. The investigators concluded that pain, activity level, and radiological outcomes are significantly improved with use of the MCMI at a minimum 10-year follow-up compared with PMM alone. According to the investigators, randomized controlled trials on a larger population are necessary to confirm MCMI benefits at long term.

Sixty patients (19 to 68 years) with subtotal loss of the medial meniscus and varus morphotype were treated as part of a prospective, randomized, arthroscopically controlled study. The sample consisted of 30 patients with high tibial valgus osteotomy combined with implantation of a CMI, and 30 patients with correction osteotomy only. The CMI had to be removed from one patient because of a dislocation. Evaluation on the Lysholm Score, IKDC (International Knee Documentation Committee), and subjective pain data revealed only slight, nonsignificant differences for 39 patients after 24 months. According to the investigators, the chondroprotective effect of the CMI in the long term remains to be seen. This study is limited by small sample size and short-term follow-up (Linke et al. 2006).

Bulgheroni et al. (2010) investigated the clinical outcomes and any progression of knee osteoarthritis in 34 patients who underwent arthroscopic placement of a collagen meniscus implant. Lysholm and Tegner activity scores at 2 and 5 years after surgery improved significantly compared to the preoperative score. These patients showed good to excellent clinical results after 5 years from a CMI placement. In most of cases, the CMI-new tissue complex had a slight reduction in size, compared to a normal medial meniscus, but the new tissue had no apparent negative effects. According to the investigators, 5 years after the implant, the regenerated tissue still was not completely similar to a normal meniscus. This study is limited by a small sample size and lack of a control group.

Zaffagnini et al. (2007) prospectively assessed the results of bioreadsorbable collagen matrix (CMI) implantation in 8 patients (mean age 25) who were evaluated at a final observation point from 6 to 8 years after implantation. There were no complications related to the device. All patients were able to return to day activities without limitations 3 months after surgery. Both

subjective Cincinnati Knee Rating Scale (CKRS) score and objective IKDC score showed improvement in all cases except one patient with an ACL re-injury. In two cases, scores were slightly worse from 2 years after surgery to the final observation point. The other five cases obtained maximum score at final follow-up. The investigators concluded that the implant may have helped reduce the deterioration of the knee joint at final observation time. The value of this study is limited by the small sample size and a lack of a comparison group.

Steadman and Rodkey (2005) reported on the five to six year follow-up of the 8 patients (reported in Rodkey and Steadman, 1999) who underwent arthroscopic placement of a collagen meniscus implant to reconstruct and restore the irreparably damaged medial meniscus. All patients returned for clinical, radiographic, magnetic resonance imaging, and arthroscopic examinations an average of 5.8 years after collagen meniscus implant placement. Lysholm scores and average Tegner activity scores improved significantly. Pain scores improved from 23 to 11 (0 = no pain, 100 = worst pain). Imaging studies confirmed that the chondral surfaces of the medial compartment had not degenerated further since the placement of the implant 5.8 years earlier. Relook arthroscopy with direct measurement of the newly generated tissue revealed 69% defect filling. The investigators concluded that the meniscus-like tissue that developed after collagen meniscus implant placement has maintained its structure and functioned without negative effects for more than 5 years. The hypothesis was affirmed that these patients were improved significantly compared with their preoperative status and unchanged compared with 2-year evaluations. This study is limited by small sample size and lack of a control group.

A technology assessment conducted by Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). (2010) concluded that the collagen meniscal implant for irreparable medical meniscus injury did not meet technology assessment criteria. The published evidence did not support improvement in health outcomes or that clinical improvement was attainable outside of the investigational setting. Although promising, long-term data supporting safety, efficacy and improved clinical outcomes, including prevention of osteoarthritis, are not yet available to support widespread use of this bioactive scaffold for meniscal regeneration

Meniscus Allograft Transplantation

Elattar et al. (2011) conducted a meta-analysis of published trials reporting outcomes of meniscal allograft transplantation to establish its safety and reproducibility. The outcomes of 678 medial and 458 lateral grafts in 613 male, 265 female and 190 non-defined patients with a mean age of 34.8 years were included in the meta-analysis. According to the authors, all studies reported a continuously satisfactory outcome with restoration of working capacity in these active patients. The authors stated that meniscal allograft transplantation can be considered as safe and reliable for the treatment of refractory post-meniscectomy symptoms in selected patients.

Hergan et al. (2011) performed a systematic review evaluating meniscal allograft transplantation (MAT). Included in the review were 14 studies with at least 2 years' follow-up, studies with validated outcome measures, and studies in which the allograft meniscal horns were secured with bony fixation. Thirteen of the articles provided Level IV evidence, and one article (Stollsteimer et al. 2000) provided Level III evidence. The authors concluded that good early and midterm results of cryopreserved or fresh-frozen, nonirradiated MAT can be achieved in a relatively young patient with only mild chondromalacia (lower than Outerbridge grade 3) who is not overweight and has a stable, mechanically aligned lower extremity, if the allograft is sized radiographically by use of anteroposterior and lateral films and the allograft meniscal horns have bony attachments and are fixed by bony techniques. Similar results can be expected if the transplant is performed alone or with a concomitant cartilage repair procedure; however, significant cartilage defects (Outerbridge grade 2 or greater) on both the femoral and tibial sides in the same compartment requiring autologous cartilage implantation result in a high failure rate. Good outcomes of MAT can be expected when performing a concomitant ligament reconstruction or malalignment procedure on the knee, unless greater than 3 concomitant procedures are performed. There is no significant difference in outcome between medial and lateral MAT. According to the authors, despite a

growing body of knowledge on the topic, there remains a lack of consensus regarding optimal allograft sizing technique, allograft fixation techniques, tissue processing, indications, and long-term efficacy. The authors stated that a prospective, randomized trial comparing MAT in a meniscectomized knee with a control group is needed to determine the best technique and patient selection criteria.

Crook et al. (2009) reviewed the current literature to consolidate the evidence surrounding the use of human meniscal allograft transplantation. No Level I or II studies were identified. Many studies had small study groups with limited follow-up and patient selection and description of patient factors varied greatly. This made comparing data difficult. Four types of graft are used--fresh, fresh-frozen, cryopreserved and freeze-dried (lyophilised) graft. Cryopreserved and fresh-frozen allografts are deemed most suitable. Most authors advocate the use of non-irradiated grafts from screened donors to reduce transmission of infection. Patients have an improved outcome if they have less severe degenerative changes within the knee prior to transplantation. The authors concluded that no statistically significant studies looking at isolated meniscal transplantations have been found. The evidence suggests that meniscal allograft transplantation provides improvement of pain and function in the short and intermediate term. The effect on future joint degeneration is still unknown. The authors stated that the ideal patient group includes patients less than 40 years of age with knee pain, proven meniscal injury and a normally aligned, stable joint without severe degenerative changes.

The results of the reviewed studies indicate that meniscal allografts can be successfully implanted and may produce short to intermediate relief in selected patients. Many patients reported good or satisfactory results with respect to function and pain for both normal daily living and moderate sports activities (Stollsteimer et al., 2000; Rue et al., 2008; Verdonk et al., 2006; Sekiya et al., 2006; Cole et al., 2006; Noyes et al., 2005; Vundelinckx et al., 2010; LaPrade et al., 2010). Short-term functional results from clinical analysis and patient self-assessment appear to be encouraging. However, none of the studies provide strong evidence that meniscal transplantation can slow or stop the degenerative process seen in meniscectomized knees, and none provided a comparison with other treatment options. Some of the studies also reported shrinking or extrusion of the allograft with time. Results of the few long-term studies indicated deterioration of the transplants over a long-term period when compared with short-term analysis (Verdonk et al., 2005; van der Wal et al., 2009). Moreover, differences in patient selection, concomitant procedures, allograft selection and treatment, surgical technique, graft fixation, rehabilitation protocol, and length of follow-up make results difficult to interpret and compare. Issues that remain to be addressed include patient selection criteria, optimal treatment for the allografts (irradiated or non-irradiated), and long-term outcomes (Hayes 2010).

There is insufficient evidence to establish definitive patient selection criteria for meniscal allograft transplantation (Hayes, Updated 2011). Meniscal allograft transplantation is not recommended for patient's age > 50 years, since procedures such as arthroplasty or osteotomy offer a more predictable outcome for these patients. Meniscal allograft transplantation is contraindicated in patients with large areas of significant articular degeneration (Outerbridge grade 3 or 4) or bony architectural changes, including osteophytes. The condition of the meniscus should be firmly established by previous operative reports, magnetic resonance imaging (MRI), or diagnostic arthroscopy (Hayes Updated 2011). Other contraindications include systemic inflammatory disease, obesity (body mass index > 30), immunodeficiency, previous infection of the knee, and skeletal immaturity (Crook et al., 2009; Monllau et al., 2010).

Meniscal allograft transplantation may be indicated in patients who are considered too young or active for arthroplasty if they have all of the following (Friel and Cole, 2010; Monllau et al., 2010):

- Disabling knee pain refractory to conservative treatment
- Ligamentous stability prior to surgery or achieved concurrently with meniscal transplantation
- Documented mild to moderate articular damage (Outerbridge grade I-II)

- Normal alignment without varus or valgus deformities

Society Information

The American Academy of Orthopedic Surgeons published an advisory statement regarding the use of musculoskeletal tissue allografts (AAOS, 2011). The AAOS supports the following:

- The use of musculoskeletal allograft as a therapeutic alternative to autograft use for appropriate patients. Allograft tissues should be acquired from facilities that demonstrate compliance, use well-accepted banking methodology and good tissue practices. The AAOS urges all tissue banks to follow rigorous national guidelines and standards.
- The AAOS strongly favors on-site inspection and accreditation of tissue banks that demonstrate compliance with appropriate standards.
- The AAOS supports informed consent, for both the donor family and the recipient of human tissue, in accordance with local, state and federal laws and regulations.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Collagen meniscus implants, also known as collagen scaffold, or Menaflex, are bioresorbable, primarily bovine type 1 collagen. This product was designed as a tissue-engineered scaffold to support the generation of new meniscus - like tissue.

Menaflex collagen meniscus implant received U. S. Food and Drug Administration (FDA) 510(k) marketing clearance on December 18, 2008 as the ReGen Collagen Scaffold (CS). According to the 510(k) summary, CS 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 CS must extend at least into the red/white zone of the meniscus to provide sufficient vascularization. See the following Web site for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf8/K082079.pdf Accessed June 27, 2014.

Amid controversy about the 510(K) clearance for the ReGen Collagen Scaffold, the FDA initiated a review of the clearance process for this device. In September 2009, the FDA issued a preliminary report on the Review of the ReGen Menaflex®: Departure from Processes, Procedures, and Practices Leave the Basis for a Review Decision in Question. This preliminary report documents findings and recommendations concerning FDA's review and clearance of Menaflex. The FDA has undertaken a reconsideration of the decision to clear ReGen's CS device. The report states that "These findings indicate that a focused scientific reevaluation of the decision to clear the CS device is warranted, and we conclude with general recommendations for better protecting FDA's internal processes against external pressures." See the following Web site for more information: http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm183745.htm. Accessed June 27, 2014.

According to a ReGen 24-hour summary report from the FDA, the Orthopaedic and Rehabilitation Devices Panel met on March 23, 2010 to discuss and make recommendations on scientific issues relevant to FDA's reevaluation of the ReGen Collagen Scaffold (CS) device (marketed as the Menaflex®). The panel gave scientific and clinical input on the data that was submitted in the 510(k). The Panel deliberated on the safety and effectiveness of this product as evidenced from data provided from the submitted studies. The Panel formed a consensus that due to the low number of device failures, the device can be viewed as reasonably safe, but the device's effectiveness would need to be analyzed further. In order to determine effectiveness, the panel stated that follow-ups on participants, further imaging studies and predetermined endpoints would need to be analyzed. See the following Web site for more information: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDe

vicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/ucm205996.htm. Accessed June 30, 2014.

On October 14, 2010, the FDA announced that Menaflex Collagen Scaffold should not have been cleared for marketing in the United States. “To correct this error,” the FDA said it will begin the process to rescind clearance of the device. As part of that process, the agency has requested a meeting with ReGen Biologics Inc., the manufacturer of the device, to discuss alternative marketing pathways for the device and the additional data needed for the agency to properly evaluate the safety and effectiveness of the device. According to the FDA, it has now concluded that the Menaflex device is intended to be used for different purposes and is technologically dissimilar from devices already on the market, called predicate devices. These differences can affect the safety and effectiveness of the Menaflex device. For example, instead of simply repairing or reinforcing damaged tissue like predicate devices, Menaflex is intended to stimulate the growth of new tissue to replace tissue that was surgically removed. The FDA said that because of these differences, the Menaflex device should not have been cleared by the agency. The device will remain on the market until the agency rescinds its clearance. See the following Web site for more information: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm229384.htm. Accessed June 27, 2014.

The FDA has indicated that no recall is necessary. Explanting the implant is not an option because the material is resorbed and replaced with new tissue. However, the agency advised patients who received Menaflex to talk with their surgeons or other healthcare professionals about what, if any, steps should be taken. See the following web site for more information: http://healthland.time.com/2010/10/14/fda-admits-it-was-wrong-to-approve-a-knee-treatment/ Accessed June 27, 2014.

Transplantation of meniscal allografts is a surgical procedure and, as such, is not subject to regulation by the FDA. However, the FDA does regulate certain aspects of tissue banking, and tissues are subject to FDA registration and requirements for good tissue practices and infectious disease screening and testing, as well as to the good manufacturing practice requirements applicable to drugs and devices. According to current rules, FDA premarket review or marketing approval is not required for minimally processed tissues transplanted from one person to another for their normal structural functions; these criteria apply to meniscal allografts. See the following Web site for more information: http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm. Accessed June 30, 2014.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does cover meniscus allograft transplantation when criteria are met. A National Coverage Determination (NCD) does not exist. However, Local Coverage Determinations (LCDs) are available. Refer to the LCDs for Major Joint Replacement (Hip and Knee), Surgery: Major Joint Replacement (Hip and Knee) and Total Joint Arthroplasty.

Medicare does not cover collagen meniscus implant, as it is considered to be not reasonable and necessary for the treatment of meniscal injury/tear under section 1862(a) (1) (A) of the Social Security Act. Refer to the National Coverage Determination (NCD) for NCD for Collagen Meniscus Implant (150.12). Local Coverage Determinations (LCDs) do exist. See to the LCDs for Non-Covered Services and Non-Covered Services. (Accessed July 1, 2014)

REFERENCES

American Academy of Orthopaedic Surgeons (AAOS). Use of Musculoskeletal Tissue Allografts. 1991. Revised 2011 Position and advisory statements. Available at: http://www.aaos.org/about/papers/advistmt/1011.asp Accessed June 27, 2014.

Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Meniscal Allograft Transplantation. TEC Assessments 1997; Volume 12, Tab 14

Bulgheroni P, Murena L, Ratti C, et al. Follow-up of Collagen Meniscus Implant patients: clinical, radiological, and Magnetic Resonance imaging results at 5 years. Knee. 2010 Jun;17(3):224-9.

Cole, BJ, Dennis, MG, Lee, SJ, et al. Prospective evaluation of allograft meniscus transplantation: a minimum 2-year follow-up. *Am J Sports Med*. 2006;34(6):919-927.

Crook TB, Ardolino A, Williams LA, Barlow IW. Meniscal allograft transplantation: a review of the current literature. *Ann R Coll Surg Engl*. 2009;91(5):361-365.

ECRI Institute. Hotline Response. Meniscal Allograft Transplantation for Damaged or Removed Meniscus. December Updated 2011.

ECRI Institute. Hotline Response. Menaflex Collagen Meniscus Implant for Reinforcement and Repair of Medical Meniscus Injuries. June 2009.

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 Feb;19(2):147-57.

Friel NA, Cole BJ. Meniscal allograft transplantation. Curr Orthop Pract. 2010;21(1):22-26.

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

Hayes Directory. Meniscal Allograft Transplantation. Updated December 2011.

Hergan D, Thut D, Sherman O, Day MS. Meniscal allograft transplantation. Arthroscopy. 2011 Jan;27(1):101-12.

Hommen JP, Applegate GR, Del Pizzo W. Meniscus allograft transplantation: ten-year results of cryopreserved allografts. Arthroscopy. 2007 Apr;23(4):388-93.

LaPrade RF, Wills NJ, Spiridonov SI, et al. A prospective outcomes study of meniscal allograft transplantation. Am J Sports Med. 2010 Sep;38(9):1804-12.

Linke RD, Ulmer M, Imhoff AB. Replacement of the meniscus with a collagen implant (CMI). Oper Orthop Traumatol. 2006 Dec;18(5-6):453-62..

Monllau JC, González-Lucena G, Gelber PE, Pelfort X. Allograft meniscus transplantation: a current review. *Tech Knee Surg*. 2010;9(2):107-113.

Noyes, FR, Barber-Westin, SD, Rankin, M. Meniscal transplantation in symptomatic patients less than fifty years old. *J Bone Joint Surg Am*. 2004;86-A(7):1392-1404.

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 Jul;90(7):1413-26.

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.

Sekiya, JK, West, RV, Groff, YJ, et al. Clinical outcomes following isolated lateral meniscal allograft transplantation. *Arthroscopy*. 2006;22(7):771-780.

Steadman JR, Rodkey WG. Tissue-engineered collagen meniscus implants: 5- to 6-year feasibility study results. Arthroscopy. 2005 May;21(5):515-25.

Stollsteimer GT, Shelton WR, Dukes A, et al. Meniscal allograft transplantation: a 1- to 5-year follow-up of 22 patients. Arthroscopy. 2000 May-Jun;16(4):343-7.

Tice J. Collagen meniscus implant for repair of medial meniscus injury of the knee. California Technology Assessment Forum. June 2, 2010. Accessed: April 19, 2013. Available at URL address: http://www.ctaf.org/assessments?field_condition_tid=15&field_specialty_tid=38&field_met_ctaf_criteria__tid=All&items_per_page=10&=Apply

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.

Verdonk, PC, Demurie, A, Almqvist, KF, Veys, EM, Verbruggen, G, and Verdonk, R. Transplantation of viable meniscal allograft. Surgical technique. *J Bone Joint Surg Am*. 2006;88(Suppl 1 Pt 1):109-118.

Verdonk PC, Demurie A, Almqvist KF, Veys EM, Verbruggen G, Verdonk R. Transplantation of viable meniscal allograft. Survivorship analysis and clinical outcome of one hundred cases. *J Bone Joint Surg Am*. 2005;87(4):715-724.

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 Nov;38(11):2240-7.

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 May;39(5):977-85.

Zaffagnini S, Giordano G, Vascellari A, et al. Arthroscopic collagen meniscus implant results at 6 to 8 years follow up. Knee Surg Sports Traumatol Arthrosc. 2007 Feb;15(2):175-83.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
10/01/2014	• Reorganized policy content • Added benefit considerations language for *Essential Health Benefits for Individual and Small Group* plans to indicate: o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs") o Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-

	Grandfathered plans o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage • Updated coverage rationale: o Reformatted and relocated information pertaining to medical necessity review; added language to indicate if service is "medically necessary" or "not medically necessary" to applicable proven/unproven statement o Removed reference to specific product name ("Menaflex™") for collagen meniscus implants • Updated supporting information to reflect the most current clinical evidence, CMS information and references • Archived previous policy version 2013T0543D