



Kaiser Foundation Health Plan of Washington

Clinical Review Criteria Collagen Meniscus Implant

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Collagen Meniscus Implant (150.12) <i>This service is not covered per Medicare criteria.</i>
Local Coverage Determinations (LCD)	None
Local Coverage Article	Collagen Meniscus Implant CAG-00414N

For Non-Medicare Members

Kaiser Permanente has elected to use the Collagen Meniscus Implant (A-0643) MCG* for medical necessity determinations. Per MCG guidelines this is a non-covered service. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above

If requesting this service, please send the following documentation to support medical necessity:

- Last 3 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The knee meniscus is a fibrocartilaginous crescent-shaped structure that plays an important part in the biomechanics of the joint. It functions as load bearing, shock absorption, lubrication, and stabilization of the joint. The avascular nature of the articular cartilage and its hypocellular composition make it incapable of self-repair after injury. In the past, total or subtotal meniscectomy was routinely performed for patients with meniscal tears. This was based on the assumption that removal of the meniscus did not lead to adverse effects. More recently however, repair of the meniscus has become the standard treatment for tears, after studies have shown that total or even partial removal of the meniscus is associated with increased joint pressure, mechanical changes, and ultimately hyaline cartilage degradation and irreversible joint damage. If the meniscus is irreparable, arthroscopic partial meniscectomy of only the torn segments is recommended. In cases of substantial damage, subtotal or total meniscectomy may be inevitable. Researchers have evaluated different materials to substitute for the removed meniscus in order to avoid the joint deterioration that may occur after its removal (Rodkey 1999, Yoldas 2003).

The first meniscal transplantation was performed in the early 1990s. Over the years, different graft types were used including autogenous tissue, allograft tissue, and artificial material. More recently, a group of scientists used

tissue engineering techniques to develop a collagen meniscus implant which serves as a scaffold to support the production of a new meniscus-like tissue rather than artificially replacing it. Collagen meniscus implants (collagen scaffold) are fabricated from type I collagen derived from bovine Achilles tendons. The bovine collagen fibers undergo several chemical treatments and techniques to purify them, after which they are swelled in hyaluronic acid and chondroitin sulphate, homogenized, precipitated, dehydrated and manually oriented in a mold which undergoes other processes and sterilization before they are ready for use. Collagen meniscus implants are provided as a semi-lunar shaped device with a triangular cross-section. The surgeon assesses the defect and trims the implant to the size necessary for repair of the damaged or weakened soft tissue (Rodkey 1999, Steadman 2005, Rodkey 2008).

Collagen meniscal implant is not intended to replace the entire meniscus as it requires a meniscal rim for attachment. In a routine arthroscopic surgical procedure, partial meniscectomy is performed to remove only damaged or pathological tissue, leaving the native meniscus intact. A specially designed arthroscopic measuring device is then used to determine the dimensions of the total meniscus and the defect. On the surgical field the collagen implant is trimmed to fit the lesion then delivered into the joint through a cannula, manipulated into the prepared lesion and fixed to the host meniscus rim with nonabsorbable sutures (Rodkey 1999, Steadman 2005, Rodkey 2008).

ReGen Collagen Scaffold (CS), now called Menaflex, was cleared by the FDA in December 2008 to be used in surgical procedures for the reinforcement and repair of soft tissue injuries of the medial meniscus. 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. The CS reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue. CS is not a prosthetic device and is not intended to replace normal body structure. It is contraindicated in patients allergic to bovine or other animal derived products, with an overly sensitized immune system, systemic or local infection, evidence of osteonecrosis in the targeted area, medical history of severe degenerative osteoarthritis, or without an intact meniscal rim and anterior and posterior horns.

Medical Technology Assessment Committee (MTAC)

Collagen Meniscus Implant

04/06/2009: MTAC REVIEW

Evidence Conclusion: The published literature to date, does not provide sufficient evidence to determine the short-term or long-term safety and efficacy of collagen meniscus implants in reducing pain, restoring the knee function, and preventing degenerative osteoarthritis in patients with irreparable damage to the medial meniscus. The only published randomized controlled trial on collagen meniscal implants had several threats to its validity which make it hard to draw any conclusion on the benefits and harms associated with the implant. In addition to the relatively small size, short follow-up duration, and industry funding, the trial had potential selection and observational biases including; the inappropriate randomization process, unblinding of the patients and surgeons, vast differences in the postoperative rehabilitation programs received by the two treatment groups, performing follow-up arthroscopy only among the meniscal transplant group, and assessing improvement in activity level based on historical data subject to recall bias. Overall, the results of the trial show insignificant differences between patients receiving the collagen meniscus implant and the controls in reducing their pain and improving and/or restoring function.

Articles: To determine whether using collagen meniscus implants in patients with medial meniscus defects would lead to better clinical outcomes than total meniscectomy or implanting an allograft. To determine if using collagen meniscus implants is safe for the patient and whether it leads to long-term joint damage. The search yielded 14 articles. There was one RCT that compared collagen meniscus implant with partial meniscectomy and 4 very small case series with less than 15 patients each. All studies were conducted by the same group of investigators who developed the implant, except for a small case series with 8 patients. The RCT was selected for critical appraisal: Rodkey WG, DeHaven KE, Montgomery WH, et al. Comparison of the collagen meniscus implant with partial meniscectomy. *J Bone Joint Surg Am* 2008; 90:1413-1426. See [Evidence Table](#).

The use of Collagen Meniscus Implants for the reinforcement and repair of soft tissue injuries of the medial meniscus does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
G0428	Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Date Created	Date Reviewed	Date Last Revised
05/15/2009	07/06/2010 ^{MDCRPC} , 05/03/2011 ^{MDCRPC} , 03/06/2012 ^{MDCRPC} , 01/08/2013 ^{MDCRPC} , 11/05/2013 ^{MPC} , 09/02/2014 ^{MPC} , 07/07/2015 ^{MPC} , 05/03/2016 ^{MPC} , 03/07/2017 ^{MPC} , 01/09/2018 ^{MPC} , 11/06/2018 ^{MPC} , 11/05/2019 ^{MPC} , 11/03/2020 ^{MPC} , 11/02/2021 ^{MPC} , 11/01/2022 ^{MPC}	11/22/2017

^{MDCRPC} Medical Director Clinical Review and Policy Committee

^{MPC} Medical Policy Committee

Revision History	Description
11/22/2017	Added MLN article