Clinical Review Criteria
Collagen Meniscus Implant

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consult the patient’s Medical Coverage Agreement or call Kaiser Permanente Customer Service to determine coverage for a specific
medical service.

Criteria
For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
</tr>
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<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
</tr>
<tr>
<td>National Coverage Determinations (NCD)</td>
<td>Collagen Meniscus Implant (150.12)</td>
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<tr>
<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
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<tr>
<td>Local Coverage Article</td>
<td>None</td>
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</tbody>
</table>

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.

*MCG manuals 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.

The following information was used in the development of this document and is provided as background only. It 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

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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 (http://www.fda.gov/cdrh/pdf8/K082079).

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.
Codes

CPT: G0428