Medical Policy
Meniscal Allografts and Other Meniscal Implants

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Policy Number: 110
BCBSA Reference Number: 7.01.15
NCD/LCD: National Coverage Determination (NCD) for Collagen Meniscus Implant (150.12)

Related Policies
- Osteochondral Allograft Transplantation and Osteochondral Autograft Transplantation, #111
- Autologous Chondrocyte Implantation, #374

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Meniscal allograft transplantation may be 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 (e.g., younger than 55 years), AND
- Disabling knee pain with activity that is refractory to conservative treatment (i.e., physical therapy and analgesic medications), AND
- Absence or near absence (more than 50%) of the meniscus, established by imaging or prior surgery, AND
- Documented minimal to absent degenerative changes in the surrounding articular cartilage (e.g., Outerbridge grade II or less, < 50% joint space narrowing), AND
- Normal knee biomechanics, or alignment and stability achieved concurrently with meniscal transplantation.

Meniscal allograft transplantation may be 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
- Osteochondral allografting or
- Osteochondral autografting.
Use of other meniscal implants incorporating materials such as collagen and polyurethane are INVESTIGATIONAL.

Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

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.

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

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required. Yes indicates that prior authorization is required. No indicates that prior authorization is not required. N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Provider Type</th>
<th>Outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>No</td>
</tr>
<tr>
<td>Medicare HMO Blue℠</td>
<td>This is not a covered service.</td>
</tr>
<tr>
<td>Medicare PPO Blue℠</td>
<td>This is not a covered service.</td>
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</table>

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Code Description</th>
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</thead>
<tbody>
<tr>
<td>29868</td>
<td>Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral</td>
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<table>
<thead>
<tr>
<th>ICD-9 Procedure Codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>81.47</td>
<td>Other repair of knee</td>
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</table>
ICD-10-PCS Procedure Codes

<table>
<thead>
<tr>
<th>ICD-10-PCS procedure codes</th>
<th>Code Description</th>
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</thead>
<tbody>
<tr>
<td>0SQC0ZZ</td>
<td>Repair Right Knee Joint, Open Approach</td>
</tr>
<tr>
<td>0SQC4ZZ</td>
<td>Repair Right Knee Joint, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0SQD0ZZ</td>
<td>Repair Left Knee Joint, Open Approach</td>
</tr>
<tr>
<td>0SQD4ZZ</td>
<td>Repair Left Knee Joint, Percutaneous Endoscopic Approach</td>
</tr>
</tbody>
</table>

The following HCPCS code is considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>G0428</td>
<td>Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)</td>
</tr>
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</table>

Description
The meniscus plays a crucial role in the well-being of the knee, including load bearing, shock absorption, joint stability, lubrication, and nutrition. Meniscal injuries or total loss of menisci (i.e., from meniscectomy) can lead to joint instability, functional impairment and early destructive changes resulting in degenerative osteoarthritis and irreversible joint damage. Preservation of the meniscus has been shown to have a significant impact on the prevention of degenerative changes in the knee. The current standard of care for patients with meniscal tears is open or arthroscopic meniscal repair.

Meniscal allograft transplantation is a surgical procedure that replaces the meniscus with cadaver allograft tissue. The transplant may be performed in patients with irreparable meniscal tears, or in patients who have undergone previous meniscectomy. The procedure is performed either arthroscopically or by open technique and involves grafting a donor meniscus into the knee of the patient. The goals of meniscal allograft transplantation are to restore knee function and to prevent further joint degeneration by replacing the damaged or destroyed meniscus with allograft tissue having similar properties.

Summary
Meniscal allograft transplantation, performed in combination with other surgical interventions, appears to improve symptoms in some patients with a prior meniscectomy who are considered too young to undergo total knee replacement. Evidence consisting primarily of retrospective case series indicates that this procedure may produce short- to intermediate-term pain relief in selected patients. Although short- to intermediate-term results are promising, the literature does not permit conclusions concerning the effect of meniscal transplantation on the long-term progression of degenerative changes and joint space narrowing.

Meniscal allograft transplantation is associated with a high number of complications, including tears of the transplanted meniscus, displacement, or arthrofibrosis. Careful selection of patients and surgical technique appear to be critical for success of this procedure. (4, 11) These major interventions are considered salvage procedures and are not recommended to be performed casually or by surgeons without extensive experience and expertise in complex knee reconstruction. Therefore, meniscal allograft transplant may be considered medically necessary for patients with prior meniscectomy who have disabling knee pain, and who are too young to be considered for total knee arthroscopy.

Similar types of evidence are available for meniscal allograft transplantation in combination with treatment of focal articular lesions, with case series reporting short- to intermediate-term improvement in pain and functioning. Based on the available evidence and clinical input, meniscal allograft transplantation may be considered medically necessary when performed in combination with treatment of focal articular cartilage.
lesions in patients younger than 55 years with disabling knee pain that has not shown an adequate response to physical therapy and analgesic medications.

The collagen meniscus implant, for which the FDA decided to rescind the clearance for marketing in 2010, is considered investigational. Current RCTs do not report improvements in outcomes for the majority of pain and functional status measures. In addition to FDA approval, mid-to long-term follow-up from controlled studies with a larger number of subjects is needed to determine whether implantation of a collagen scaffold is able to slow joint degeneration, reduce pain, or otherwise improve the net health outcome.

There are no randomized controlled trials for the polyurethane meniscal scaffold, and this product is not approved for marketing in the U.S. at this time. Therefore, synthetic meniscal implants are considered investigational.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>5/2017</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>9/2015</td>
<td>Clarified coding language.</td>
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<tr>
<td>5/2015</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>6/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
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<tr>
<td>9/2013</td>
<td>BCBSA National medical policy review.</td>
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<tr>
<td></td>
<td>Title and investigational statement changed from “collagen&quot; to other.&quot;</td>
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<tr>
<td>7/2010</td>
<td>Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine, and Rheumatology. No changes to policy statements.</td>
</tr>
<tr>
<td>7/2009</td>
<td>Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine, and Rheumatology. No changes to policy statements.</td>
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<tr>
<td>7/1/2009</td>
<td>BCBSA National medical policy review. Changes to policy statements.</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines
References


