Introduction

The meniscus is a disc of cartilage that cushions the knee. Each knee has two, one at the outer edge of the knee and another at the inner edge. These two discs act as shock absorbers. Replacing the meniscus can be done using donor material. This type of transplant is called an allograft. Meniscus transplants are usually done in patients who are too young for a total knee replacement or other reconstructive surgery. There are several factors that need to be taken into account prior to a meniscus transplant. Three of these factors are age, the amount of meniscus in the knee, and whether pain has responded to other treatment. This policy discusses when meniscal allograft transplants may be considered medically necessary. Meniscal implants using collagen or man-made material are unproven (investigational). There is not enough medical evidence to show whether these types of meniscal implants are effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
We will review for medical necessity these elective surgical procedures.

**The surgical procedure subject to medical necessity review for site of service addressed in this policy is limited to:**

- **Knee arthroscopy, with meniscus repair**

Site of service is defined as the location where the surgical procedure is performed, such as an off campus-outpatient hospital or medical center, an on campus-outpatient hospital or medical center, an ambulatory surgical center, or an inpatient hospital or medical center.

<table>
<thead>
<tr>
<th>Site of Service for Elective Surgical Procedures</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medically necessary sites of service:</td>
<td>Certain elective surgical procedures will be covered in the most appropriate, safe, and cost effective site. These are the preferred medically necessary sites of service for certain elective surgical procedures.</td>
</tr>
<tr>
<td>• Off campus-outpatient hospital/medical center</td>
<td></td>
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<tr>
<td>• On campus-outpatient hospital/medical center</td>
<td></td>
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<tr>
<td>• Ambulatory Surgical Center</td>
<td></td>
</tr>
<tr>
<td>Inpatient hospital/medical center</td>
<td>Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. This site is considered medically necessary only when the patient has a clinical condition which puts him or her at increased risk for complications including any of the following (this list may not be all inclusive):</td>
</tr>
<tr>
<td></td>
<td>- Anesthesia Risk</td>
</tr>
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<td></td>
<td>- ASA classification III or higher (see definition)</td>
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<td></td>
<td>- Personal history of complication of anesthesia</td>
</tr>
<tr>
<td></td>
<td>- Documentation of alcohol dependence or history of cocaine use</td>
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<tr>
<td></td>
<td>- Prolonged surgery (&gt;3 hours)</td>
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<tr>
<td></td>
<td>- Cardiovascular Risk</td>
</tr>
<tr>
<td></td>
<td>- Uncompensated chronic heart failure (NYHA class III or IV)</td>
</tr>
<tr>
<td>Site of Service for Elective Surgical Procedures</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td></td>
<td>o Recent history of myocardial infarction (MI) (&lt;3 months)</td>
</tr>
<tr>
<td></td>
<td>o Poorly controlled, resistant hypertension*</td>
</tr>
<tr>
<td></td>
<td>o Recent history of cerebrovascular accident (&lt; 3 months)</td>
</tr>
<tr>
<td></td>
<td>o Increased risk for cardiac ischemia (drug eluting stent placed &lt; 1 year or angioplasty &lt;90 days)</td>
</tr>
<tr>
<td></td>
<td>o Symptomatic cardiac arrhythmia despite medication</td>
</tr>
<tr>
<td></td>
<td>o Significant valvular heart disease</td>
</tr>
<tr>
<td>• Liver Risk</td>
<td>o Advance liver disease (MELD Score &gt; 8)**</td>
</tr>
<tr>
<td>• Pulmonary Risk</td>
<td>o Chronic obstructive pulmonary disease (COPD) (FEV1 &lt;50%)</td>
</tr>
<tr>
<td></td>
<td>o Poorly controlled asthma (FEV1 &lt;80% despite treatment)</td>
</tr>
<tr>
<td></td>
<td>o Moderate to severe obstructive sleep apnea (OSA)***</td>
</tr>
<tr>
<td>• Renal Risk</td>
<td>o End stage renal disease (on dialysis)</td>
</tr>
<tr>
<td>• Other</td>
<td>o Morbid obesity (BMI ≥ 50)</td>
</tr>
<tr>
<td></td>
<td>o Pregnancy</td>
</tr>
<tr>
<td></td>
<td>o Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criteria])</td>
</tr>
<tr>
<td></td>
<td>o Anticipated need for transfusion(s)</td>
</tr>
</tbody>
</table>

* 3 or more drugs to control blood pressure
*** Moderate-AHI≥15 and ≤ 30, Severe-AHI ≥30
****DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin)

**Inpatient hospital/medical center**

This site of service is considered NOT medically necessary for certain elective surgical procedures when the site of service criteria listed above are not met.
Meniscal allograft transplantation may be considered 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

AND

- Absence or near absence (more than 50%) of the existing meniscus, established by imaging or prior surgery

AND

- Documented minimal to absent diffuse degenerative changes in the surrounding articular cartilage (e.g., Outerbridge grade II or less, and the original joint space has decreased by less than 50%)

AND

- Normal knee biomechanics, or alignment and stability achieved concurrently with meniscal transplantation

Meniscal allograft transplantation may be considered 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

Notes: Patients should exhibit symptoms of persistent disabling knee pain that has not adequately responded to physical therapy and analgesic medications. Uncorrected misalignment and instability of the joint are contraindications. Therefore, additional procedures, such as repair of ligaments or tendons or creation of an osteotomy for realignment of the
Treatment | Medical Necessity
--- | ---
 | joint, may be performed at the same time.
 | Severe obesity (eg, body mass index greater than 35 kg/m\(^2\)) may affect outcomes due to the increased stress on weight-bearing surfaces of the joint. Meniscal allograft transplantation is typically recommended for young active patients who are too young for total knee arthroplasty.

Treatment | Investigational
--- | ---
Other meniscal implants | Use of other meniscal implants incorporating materials such as collagen and polyurethane are considered investigational.

Documentation Requirements

The patient’s medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:
- Diagnosis/condition
- History and physical examination documenting the severity of the condition
- Conservative care attempted, with length of time attempted
- Pertinent imaging reports
- If procedure is planned as inpatient, indications supporting need for inpatient procedure

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT</strong></td>
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</tr>
<tr>
<td>29882</td>
<td>Arthroscopy, knee, surgical; with meniscus repair (medial OR lateral)</td>
</tr>
<tr>
<td>29868</td>
<td>Arthroscopy, knee, surgical meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral (eg, ReGen Collagen Scaffold)</td>
</tr>
<tr>
<td><strong>HCPCS</strong></td>
<td></td>
</tr>
<tr>
<td>G0428</td>
<td>Collagen meniscus implant procedure for filling meniscal defects (eg, CMI, collagen scaffold, Menaflex)</td>
</tr>
</tbody>
</table>

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).
Related Information

Consideration of Age

The age stated in this policy for which meniscal allograft transplantation may be considered medically necessary is 55 and younger because these patients are considered too young for total knee arthroplasty or other reconstructive knee surgery. The age is recommended by the American Academy of Orthopaedic Surgeons.

Definition of Terms

American Society of Anesthesiologists (ASA) Score:

ASA 1 A normal healthy patient.
ASA 2 A patient with mild systemic disease.
ASA 3 A patient with severe systemic disease.
ASA 4 A patient with severe systemic disease that is a constant threat to life.
ASA 5 A moribund patient who is not expected to survive

New York Heart Association (NYHA) Classification:

Class I No symptoms and no limitation in ordinary physical activity, eg, shortness of breath when walking, climbing stairs etc.
Class II Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
Class III Marked limitation in activity due to symptoms, even during less-than-ordinary activity, eg, walking short distances (20–100 m). Comfortable only at rest.
Class IV Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients
Description

Meniscal allografts and other meniscal implants (e.g., collagen) are intended to improve symptoms and reduce joint degeneration in patients who have had a total or partial meniscus resection.

Background

**Meniscal Cartilage Damage**

Meniscal cartilage is an integral structural component of the human knee, functioning to absorb shocks as well as providing load sharing, joint stability, congruity, proprioception, and lubrication and nutrition of the cartilage surfaces. Total and partial meniscectomy frequently result in degenerative osteoarthritis (OA). The integrity of the menisci is particularly important in knees in which the anterior cruciate ligament (ACL) has been damaged. In these situations, the menisci act as secondary stabilizers of anteroposterior and varus-valgus translation.

Treatment

Meniscal allograft transplantation (MAT) is considered a salvage procedure, reserved for patients with disabling knee pain following meniscectomy who are considered too young to undergo total knee arthroplasty or in patients who require a total or near total meniscectomy for irreparable tears. As a result, the population intended to receive these transplants is relatively limited. Using a large database of privately insured non-Medicare patients, Cvetanovich et al (2015) estimated an annual incidence of MAT in the United States of 0.24 per 100,000. It is not expected that clinical trials will be conducted to compare meniscal allografts with other orthopedic procedures, although trials comparing allograft transplant with medical therapy are possible.

There are 3 general groups of patients who have been treated with MAT:

- Young patients with a history of meniscectomy who have symptoms of pain and discomfort associated with early OA that is localized to the meniscus-deficient compartment
- Patients undergoing ACL reconstruction in whom a concomitant meniscal transplant is intended to provide increased stability
• Young athletes with few symptoms in whom the allograft transplantation is intended to
deter the development of OA. Due to the risks associated with this surgical procedure,
prophylactic treatment for this purpose is not frequently recommended

Issues under study include techniques for processing and storing the grafts, proper sizing of the
grafts, and the most appropriate surgical. The four primary ways of processing and storing
allografts are fresh viable, fresh frozen, cryopreserved, and lyophilized. Fresh viable implants,
harvested under sterile conditions, are less frequently used because the grafts must be used
within a couple of days to maintain viability. Alternatively, the harvested meniscus can be fresh
frozen for storage until needed. Cryopreservation freezes the graft in glycerol, which aids in
preserving the cell membrane integrity and donor fibrochondrocyte viability. CryoLife is a
commercial supplier of such grafts. Donor tissues may also be dehydrated (freeze-dried, or
lyophilized), permitting storage at room temperature. Lyophilized grafts are prone to reduced
tensile strength, shrinkage, poor rehydration, post-transplantation joint effusion, and synovitis;
they are no longer used in the clinical setting. Several secondary sterilization techniques may be
used, with gamma irradiation the most common. The dose of radiation considered effective has
been shown to change the mechanical structure of the allograft; therefore, non-irradiated grafts
from screened donors are most frequently used. In a survey conducted by the International
Meniscus Reconstruction Experts Forum, when surgeons were asked about allograft preference,
68% s preferred fresh frozen nonirradiated allografts, with 14% responding fresh viable
allografts.²

There are several techniques for MAT; most are arthroscopically assisted or all-arthroscopic.
Broadly, the techniques are either all-suture fixation or bone fixation. Within the bone fixation
category, the surgeon may use either bone plugs or a bone bridge. Types of bone bridges
include keyhole, trough, dove-tail, and bridge-in-slot. The technique used depends on laterality
and the need for concomitant procedures. Patients with malalignment, focal chondral defects,
and/or ligamentous insufficiency may need concomitant procedures (osteotomy, cartilage
restoration, and/or ligament reconstruction, respectively).³

Tissue engineering that grows new replacement host tissue for individual patients is also being
investigated. For example, the Collagen Meniscus Implant (Ivy Sports Medicine, formerly the
ReGen Collagen Scaffold by ReGen Biologics), is a re-absorbable collagen matrix composed
primarily of type I collagen from bovine Achilles tendons. The implant is provided in a semi-
lunar shape and trimmed to size for suturing to the remaining meniscal rim. The implant
provides an absorbable collagen scaffold that is replaced by the patient’s soft tissue; it is not
intended to replace normal body structure. Because it requires a meniscal rim for attachment, it
is intended to fill meniscus defects after a partial meniscectomy. Other scaffold materials and
cell-seeding techniques are being investigated. Non-absorbable and non-porous synthetic
implants for total meniscus replacement are in development. One total meniscus replacement that is in early phase clinical testing is NUsurface® (Active Implants); it is composed of a polyethylene reinforced polycarbonate urethane.

**Outcome Measures**

The outcomes of this treatment (ie, pain, functional status) are subjective, patient-reported outcomes that are prone to placebo effects. On the other hand, the natural history of a severely damaged meniscus is predictable, with progressive joint damage, pain, and loss of function.

**Summary of Evidence**

For individuals who are undergoing partial meniscectomy who receive meniscal allograft transplantation, the evidence includes systematic reviews of mostly case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic reviews concluded that most studies have shown statistically significant improvements in pain and function following the procedure. The benefits have also been shown to have long-term effect (>10 years). Reviews have also reported acceptable complication and failure rates. There remains no evidence that meniscal allograft transplantation can delay or prevent the development of knee osteoarthritis. A limitation of the evidence is its reliance primarily on case series. Because the single RCT, which enrolled a very small number of patients and pooled data from randomized and nonrandomized groups, results cannot be interpreted in a meaningful way. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are undergoing partial meniscectomy and concomitant repair of malalignment, focal chondral defects, and/or ligamentous insufficiency who receive meniscal allograft transplantation, the evidence includes one systematic review of case series as well as case series published after the systematic review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review concluded that pain and function improved following the procedure. One of the series published after the review showed that patients with more severe cartilage damage experienced favorable outcomes similar to patients with less cartilage damage. Another series subsequently published reported an overall 9.7-year survival of the implant. A limitation of the evidence is its reliance primarily on case series. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.
For individuals who are undergoing partial meniscectomy who receive collagen meniscal implants, the evidence includes two systematic reviews primarily of case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The reviews reported overall positive results with the collagen meniscus implant, but the quality of the included studies (randomized controlled trials, observational studies) was low. Radiologic evaluations have shown reduced size of the implant in a large portion of patients. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Currently ongoing and unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>NCT01712191</td>
<td>Treatment of the Medial Meniscus with the Treatment of the Medial Meniscus</td>
<td>150</td>
<td>Jun 2017 (ongoing)</td>
</tr>
<tr>
<td></td>
<td>with the NUSurface® Meniscus Implant</td>
<td></td>
<td></td>
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<tr>
<td>NCT01059409</td>
<td>The Clinical and Medico-economical Evaluation of Meniscal Allografts in</td>
<td>120</td>
<td>Sep 2017 (ongoing)</td>
</tr>
<tr>
<td></td>
<td>the Sequelae of Total or Sub-total Meniscectomy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02136901</td>
<td>The VENUS Clinical Study (Verifying the Effectiveness of the NUSurface®</td>
<td>37</td>
<td>Feb 2019</td>
</tr>
<tr>
<td></td>
<td>System): A Multi-center, Prospective, Randomized, Interventional Superiority</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NCT: national clinical trial

\(^a\) Denotes industry-sponsored or cosponsored trial

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.
2011 Input
In response to requests, input was received from 1 physician specialty society (3 reviewers) and 3 academic medical centers while this policy was under review in 2011. Input considered combined meniscal allograft transplantation (MAT) and focal cartilage repair procedures to be medically necessary in patients younger than 55 years of age who have failed conservative treatment. The reviewers agreed that the collagen meniscus implant (CMI) is investigational, although some considered the implant to be both investigational and medically necessary for some patients.

2008 Input
In response to requests, input was received from one physician specialty society and 3 academic medical centers while this policy was under review in 2008. Although long-term effects on joint space narrowing were unknown, all of the reviewers considered meniscal allograft (MAT) to be beneficial in selected patients, with evidence of short to intermediate pain relief when performed in younger patients with disabling knee pain who had a prior meniscectomy. Contraindications were noted as uncorrected instability, uncorrected malalignment, and the presence of significant articular disease.

Practice Guidelines and Position Statements
International Meniscus Reconstruction Experts Forum
In 2015, the International Meniscus Reconstruction Experts Forum published consensus statements on the practice of meniscal allograft transplantation (MAT) (see Table 2). The Forum’s statements included guidance on indications, graft procurement and preparation, surgical technique, and rehabilitation.

Table 2. Select Consensus Statements on the Practice of MAT

<table>
<thead>
<tr>
<th>Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for MAT:</td>
</tr>
</tbody>
</table>
Statements

- Unicompartmental pain post-meniscectomy
- In combination with ACL reconstruction when meniscus deficient
- In combination with ACR if meniscus deficient

MAT not recommended for asymptomatic meniscus deficient patient

Potentially poorer outcomes expected in patients with moderate to severe OA (Kellgren-Lawrence grade ≥ 3)

Non-irradiated fresh frozen or fresh viable grafts are recommended

Mechanical axis alignment should be performed prior to MAT; if mechanical axis deviation present, consider realignment osteotomy

Based on current evidence, superiority of 1 surgical technique over another (all-suture vs bone) is not established

Outcome scores should include:
- Disease-specific: WOMAT
- Region-specific: KOOS
- Activity: Marx Activity Rating Scale
- QOL/utility: EQ-5D

MAT: meniscal allograft transplantation; OA: osteoarthritis

**National Institute for Health and Care Excellence**

The 2012 guidance from the United Kingdom's National Institute for Health Care Excellence stated that the evidence on partial replacement of the meniscus of the knee using a biodegradable scaffold raised no major safety concerns but evidence for any advantage of the procedure over standard surgery was limited.27

**American Academy of Orthopaedic Surgeons**

The American Academy of Orthopaedic Surgeons stated in 2009 position in 2014, still recommending MAT for active people younger than 55 years old, with the goal of replacing the meniscus cushion before the articular cartilage is damaged.28 The website also notes that “synthetic (artificial) meniscal tissue has been tried, but there is conflicting information at this time.”
Medicare National Coverage

In May 2010, the Centers for Medicare and Medicaid Services (CMS) issued a national non-coverage determination for the collagen meniscus implant. A number of concerns regarding efficacy and safety were raised by the CMS analysis, which compared data reported to the FDA and published data. Concerns included an increased number of reoperations and a higher serious adverse event rate than the control group. CMS concluded that the collagen meniscus implant does not improve health outcomes in the Medicare population and determined that the collagen meniscus implant is not reasonable and necessary for the treatment of meniscal injury or tear.

Regulatory Status

Collagen Meniscus Implants

In 2008, the ReGen Collagen Scaffold was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA determined that this device was substantially equivalent to existing absorbable surgical mesh devices. The ReGen Collagen Scaffold (also known as Menaflex™ CMI) was the only collagen meniscus implant (CMI) with FDA clearance at that time. Amid controversy about the 510(K) clearance decision, FDA reviewed its decision. In October 2010, FDA rescinded the approval, stating that Menaflex™ is intended for different purposes and is technologically dissimilar from the predicate devices identified in the approval process. The manufacturer appealed the decision, and won its appeal in 2014. The product, now called CMI®, is manufactured by Ivy Sports Medicine. CMI® is the only FDA-approved collagen meniscus product currently on the market.

FDA product code: OLC.

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/97</td>
<td>Add to Surgery Section - New Policy</td>
</tr>
<tr>
<td>04/14/98</td>
<td>Replace Policy - Reviewed with changes; description, rationale clarified</td>
</tr>
<tr>
<td>06/25/98</td>
<td>Replace Policy - Revision of title from Meniscal Allograft</td>
</tr>
<tr>
<td>10/09/01</td>
<td>Replace Policy - Reviewed; policy statement unchanged.</td>
</tr>
<tr>
<td>03/11/03</td>
<td>Replace Policy - Policy replaces CP.MP.BC.7.01.15. Meniscal allograft transplantation may be considered medically necessary.</td>
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<tr>
<td>08/12/03</td>
<td>Replace Policy - Policy statement unchanged; rationale section and references updated.</td>
</tr>
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<td>05/11/04</td>
<td>Replace Policy - Policy reviewed; no change to policy statement; references updated.</td>
</tr>
<tr>
<td>09/01/04</td>
<td>Replace Policy - Policy renumbered from PR.7.01.117. No changes to dates.</td>
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<tr>
<td>05/10/05</td>
<td>Replace Policy - Policy reviewed; no change to policy statement.</td>
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<tr>
<td>04/11/06</td>
<td>Replace Policy - Policy reviewed; no change to policy statement.</td>
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<tr>
<td>06/06/09</td>
<td>Disclaimer and Scope update - No other changes.</td>
</tr>
<tr>
<td>04/10/07</td>
<td>Replace Policy - Policy updated with literature review; reference added. No change in policy statement.</td>
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<td>05/13/08</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement. Policy Guidelines updated; obesity deleted (3PrdP bullet), and &quot;who have &gt; early grade III arthritis&quot; deleted as this is a duplicate of the 1PstP bullet.</td>
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<tr>
<td>03/10/09</td>
<td>New BC Policy - Policy statement in alignment with the PR version, therefore decision was made to convert back to the BC version. Policy replaces PR.7.01.517.</td>
</tr>
<tr>
<td>01/12/10</td>
<td>Replace Policy - Policy updated with literature search. Policy statement added &quot;collagen implant considered investigational&quot;. Collagen Meniscus implant added to the title. References added.</td>
</tr>
<tr>
<td>06/13/11</td>
<td>Replace Policy - Policy updated with literature review through February 2011; references added and reordered; clinical input reviewed; allograft considered medically necessary in patients under 55 years; combined procedures may be medically necessary; “lasting at least 6 months” removed from Policy Guidelines. ICD-10 codes added to policy.</td>
</tr>
<tr>
<td>05/08/12</td>
<td>Replace policy. Policy updated with literature review through December 2011; Rationale section revised; reference 17 added and references reordered; some references removed. Policy statement for meniscal allograft transplantation changed from investigational to medically necessary when combination procedures performed.</td>
</tr>
<tr>
<td>08/15/12</td>
<td>Remove Related Policies: 7.01.48, it was archived.</td>
</tr>
<tr>
<td>09/27/12</td>
<td>Remove Related Policies: 7.01.506; ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<td>05/13/13</td>
<td>Replace policy. Policy updated with literature review through January 30, 2013; references 21-24 added; title and investigational statement changed from “collagen” to “other”.</td>
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<tr>
<td>06/14/13</td>
<td>Update Related Policies. Add 8.01.52.</td>
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<tr>
<td>07/16/13</td>
<td>Update Related Policies. Add 7.01.549</td>
</tr>
<tr>
<td>10/17/13</td>
<td>Update Related Policies. Add 1.03.501.</td>
</tr>
<tr>
<td>05/12/14</td>
<td>Annual Review. Policy updated with literature review through February 21, 2014.Reference 23 added; others renumbered/removed. Policy statements unchanged.</td>
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<tr>
<td>07/24/14</td>
<td>Update Related Policies. Change title to 7.0.549.</td>
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<tr>
<td>09/17/14</td>
<td>Update Related Policies. Change title to 7.01.550.</td>
</tr>
<tr>
<td>03/24/15</td>
<td>Update Related Policies. Change title to 7.01.549.</td>
</tr>
<tr>
<td>05/12/15</td>
<td>Annual Review. Policy updated with literature review through January 28, 2015; Rationale extensively revised; references 10, 17, and 21 added; policy statements unchanged. ICD-9 and ICD-10 diagnosis and procedure codes removed; these are not utilized in policy adjudication.</td>
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| 08/01/16   | Annual Review, approved July 12, 2016. Policy updated with literature review through
<table>
<thead>
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<th>Date</th>
<th>Comments</th>
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<tr>
<td>12/01/16</td>
<td>Minor update, approved November 8, 2016. Language added to the rationale section to indicate that the scope of this policy applies to those age 55 or younger based on the recommendation of the American Academy of Orthopaedic Surgeons.</td>
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<tr>
<td>07/01/17</td>
<td>Annual Review, approved June 6, 2017. Policy moved into the new format. Policy updated with literature review through February 23, 2017; references 1, 6, 16-17, 19, 27, and 30 added. Removed CPT code 27403. Policy statements unchanged.</td>
</tr>
<tr>
<td>06/19/18</td>
<td>Added Site of Service information to the policy.</td>
</tr>
<tr>
<td>07/01/18</td>
<td>Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; references 7 and 22 added; reference 28 updated. Multiple references were deleted. “Polyurethane” removed from the policy; statements otherwise unchanged.</td>
</tr>
<tr>
<td>04/01/19</td>
<td>Minor update, added Documentation Requirements section.</td>
</tr>
<tr>
<td>05/01/19</td>
<td>Minor update, clarified Site of Service requirements.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2019 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5992, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action before a certain date to keep your health insurance or help with your costs. You have the right to get this information and help in your language at no cost.
Call 800-722-1471 (TTY: 800-842-5357).

 дискриминация является противозаконной

Пререра Блу Кросс придерживается федеральных законов, запрещающих дискриминацию на основе расы, цвета кожи, национальной принадлежности, возраста, инвалидности или пола. Пререра не исключает людей или не обращается с ними по-разному из-за расы, цвета кожи, национальной принадлежности, возраста, инвалидности или пола.

Пререра:
- Предоставляет бесплатные средства и услуги для людей с инвалидностью, чтобы они могли эффективно общаться с нами, включая:
  - Квалифицированных переводчиков по рукоодническому языку
  - Внедренную информацию в другие форматы (крупным шрифтом, аудио, доступные электронные формы и другие форматы)
- Предоставляет бесплатные языковые услуги для людей, у которых родным языком не является английский, включая:
  - Квалифицированных переводчиков
  - Информацию, написанную на другие языки

Если вам нужны эти услуги, свяжитесь с координатором по вопросам гражданских прав.

Если вы полагаете, что Пререра не предоставила эти услуги или дискриминировала вас по какой-либо иной причине на основе расы, цвета кожи, национальной принадлежности, возраста, инвалидности или пола, вы можете подать жалобу на:
Координатор по вопросам гражданских прав - жалобы и обращения
Почтовый ящик 91102, Сиэтл, WA 98111
Звонок по бесплатному 855-332-4535, Факс 425-918-5992, ТTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

Вы также можете подать жалобу на гражданские права в Управление по гражданским правам Министерства здравоохранения и социального обеспечения США, доступное по электронной связи через Портал по вопросам гражданских прав, доступный по адресу

Помощь в других языках

Эта запись содержит важную информацию. Это заметка может содержать важную информацию о вашем обращении или страховании через Пререра Блу Кросс. Возможно, в этой заметке есть определенные даты, которые вы должны учесть. У вас есть право получить эту информацию и помощь в вашем языке бесплатно.
Позвоните по номеру 800-722-1471 (TTY: 800-842-5357).
Este aviso poderá conter informações importantes privadas, e qualquer pessoa poderá ser notificada sobre a mesma. Por favor, leia as termos e condições de privacidade disponíveis em: [link].

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir data importantes para que você saiba quando cumprir as obrigações de seguros e contribuições. Verifique o conteúdo e a importância da cobertura e de sua saúde e ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e em seu idioma de origem. Ligue para 800-722-1471 (TTY: 800-842-5357) para obter ajuda.

Español (Spanish):
Este aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas relevantes en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):

Romanian (Romanian):

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):
ประกาศนี้มีข้อความสำคัญ ประกาศนี้มีข้อความสำคัญ นับจากข้อความสำคัญในประกาศของ Premera Blue Cross และข้อความสำคัญในการยื่นเอกสารของคุณควรจะดูข้อความในประกาศนี้และประกาศของ Premera Blue Cross เพื่อให้ทราบเนื้อหาที่มีความสำคัญ เช่น การขอรับการคืนเงินหรือการรักษาที่มีความสำคัญ ติดต่อเราที่ 800-722-1471 (TTY: 800-842-5357) เพื่อขอความช่วยเหลือ.

Polskie (Polish):

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir data importantes para que você saiba quando cumprir as obrigações de seguros e contribuições. Verifique o conteúdo e a importância da cobertura e de sua saúde e ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357) para obter ajuda.