

## MEDICAL POLICY – 7.01.15

## Meniscal Allografts and Other Meniscal Implants

BCBSA Ref. Policy: 7.01.15

Effective Date: July 1, 2018

Last Revised: April 1, 2019

Replaces: 7.01.517

## RELATED MEDICAL POLICIES:

1.03.501 Knee Orthoses (Braces), Ankle-Foot-Orthoses, and Knee-Ankle-Foot-Orthoses

7.01.549 Knee Arthroscopy in Adults


7.01.550 Knee Arthroplasty

8.01.52 Orthopedic Applications of Stem-Cell Therapy

11.01.524 Site of Service: Select Surgical Procedures

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## 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.

## Policy Coverage Criteria

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.

**Surgical procedures subject to review for site of service addressed in this policy are limited to:**

- Knee arthroscopy, with meniscus repair

Site of Service for Elective Surgical Procedures	Medical Necessity
<p><b>Medically necessary sites of service:</b></p> <ul style="list-style-type: none"> <li>• Off campus-outpatient hospital/medical center</li> <li>• On campus-outpatient hospital/medical center</li> <li>• Ambulatory Surgical Center</li> </ul>	<p><b>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.</b></p>
<p><b>Inpatient hospital/medical center</b></p>	<p><b>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):</b></p> <ul style="list-style-type: none"> <li>• Anesthesia Risk <ul style="list-style-type: none"> <li>○ ASA classification III or higher (see <a href="#">definition</a>)</li> <li>○ Personal history of complication of anesthesia</li> <li>○ Documentation of alcohol dependence or history of cocaine use</li> <li>○ Prolonged surgery (&gt;3 hours)</li> </ul> </li> <li>• Cardiovascular Risk <ul style="list-style-type: none"> <li>○ Uncompensated chronic heart failure (<a href="#">NYHA class III</a> or IV)</li> <li>○ Recent history of myocardial infarction (MI) (&lt;3 months)</li> <li>○ Poorly controlled, resistant hypertension*</li> <li>○ Recent history of cerebrovascular accident (&lt; 3 months)</li> </ul> </li> </ul>



Site of Service for Elective Surgical Procedures	Medical Necessity
	<ul style="list-style-type: none"> <li>○ Increased risk for cardiac ischemia (drug eluting stent placed &lt; 1 year or angioplasty &lt;90 days)</li> <li>○ Symptomatic cardiac arrhythmia despite medication</li> <li>○ Significant valvular heart disease</li> <li>● Liver Risk <ul style="list-style-type: none"> <li>○ Advance liver disease (MELD Score &gt; 8)**</li> </ul> </li> <li>● Pulmonary Risk <ul style="list-style-type: none"> <li>○ Chronic obstructive pulmonary disease (COPD) (FEV1 &lt;50%)</li> <li>○ Poorly controlled asthma (FEV1 &lt;80% despite treatment)</li> <li>○ Moderate to severe obstructive sleep apnea (OSA)***</li> </ul> </li> <li>● Renal Risk <ul style="list-style-type: none"> <li>○ End stage renal disease (on dialysis)</li> </ul> </li> <li>● Other <ul style="list-style-type: none"> <li>○ Morbid obesity (BMI ≥ 50)</li> <li>○ Pregnancy</li> <li>○ Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criteria])</li> <li>○ Anticipated need for transfusion(s)</li> </ul> </li> </ul> <p>* 3 or more drugs to control blood pressure  ** <a href="https://reference.medscape.com/calculator/meld-score-end-stage-liver-disease">https://reference.medscape.com/calculator/meld-score-end-stage-liver-disease</a>  *** Moderate-AHI ≥15 and ≤ 30, Severe-AHI ≥30  ****DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin)</p>
<b>Inpatient hospital/medical center</b>	<b>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.</b>

Treatment	Medical Necessity
<b>Meniscal allograft transplantation</b>	<b>Meniscal allograft transplantation may be considered medically necessary in patients who have had a prior meniscectomy and have symptoms related to the affected side,</b>



Treatment	Medical Necessity
	<p><b>when ALL of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (eg, younger than 55 years)</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Disabling knee pain with activity that is refractory to conservative treatment</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Absence or near absence (more than 50%) of the existing meniscus, established by imaging or prior surgery</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Documented minimal to absent diffuse degenerative changes in the surrounding articular cartilage (eg, Outerbridge grade II or less, and the original joint space has decreased by less than 50%)</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Normal knee biomechanics, or alignment and stability achieved concurrently with meniscal transplantation</li> </ul> <p><b>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:</b></p> <ul style="list-style-type: none"> <li>• Autologous chondrocyte implantation</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Osteochondral allografting</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Osteochondral autografting</li> </ul> <p><b>Notes:</b> 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 joint, may be performed at the same time.</p> <p>Severe obesity (eg, body mass index greater than 35 kg/m<sup>2</sup>) may affect outcomes due to the increased stress on weight-bearing surfaces of the joint. Meniscal allograft transplantation is typically recommended for</p>



Treatment	Medical Necessity
	young active patients who are too young for total knee arthroplasty.

Treatment	Investigational
<b>Other meniscal implants</b>	<b>Use of other meniscal implants incorporating materials such as collagen and polyurethane are considered investigational.</b>

Documentation Requirements
<p><b>The patient’s medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:</b></p> <ul style="list-style-type: none"> <li>• Diagnosis/condition</li> <li>• History and physical examination documenting the severity of the condition</li> <li>• Conservative care attempted, with length of time attempted</li> <li>• Pertinent imaging reports</li> <li>• If procedure is planned as inpatient, indications supporting need for inpatient procedure</li> </ul>

## Coding

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

**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

## Evidence Review

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### Description

Meniscal allografts and other meniscal implants (eg, 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.<sup>1</sup> 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% preferred fresh frozen nonirradiated allografts, with 14% responding fresh viable allografts.<sup>2</sup>

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).<sup>3</sup>

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**

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

NCT: national clinical trial

<sup>a</sup> 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](#)).<sup>2</sup> 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**

<b>Statements</b>
Indications for MAT: <ul style="list-style-type: none"><li>• Unicompartmental pain post-meniscectomy</li></ul>



Statements
<ul style="list-style-type: none"> <li>• In combination with ACL reconstruction when meniscus deficient</li> <li>• In combination with ACR if meniscus deficient</li> </ul>
MAT not recommended for asymptomatic meniscus deficient patient
Potentially poorer outcomes expected in patients with moderate to severe OA (Kellgren-Lawrence grade $\geq 3$ )
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: <ul style="list-style-type: none"> <li>• Disease-specific: WOMAT</li> <li>• Region-specific: KOOS</li> <li>• Activity: Marx Activity Rating Scale</li> <li>• QOL/utility: EQ-5D</li> </ul>

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.<sup>27</sup>

### ***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.<sup>28</sup> 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.<sup>29</sup> 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.

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## History

Date	Comments
01/97	Add to Surgery Section - New Policy
04/14/98	Replace Policy - Reviewed with changes; description, rationale clarified
06/25/98	Replace Policy - Revision of title from Meniscal Allograft
10/09/01	Replace Policy - Reviewed; policy statement unchanged.
03/11/03	Replace Policy - Policy replaces CP.MP.BC.7.01.15. Meniscal allograft transplantation may be considered medically necessary.
08/12/03	Replace Policy - Policy statement unchanged; rationale section and references updated.
05/11/04	Replace Policy - Policy reviewed; no change to policy statement; references updated.
09/01/04	Replace Policy - Policy renumbered from PR.7.01.117. No changes to dates.
05/10/05	Replace Policy - Policy reviewed; no change to policy statement.
04/11/06	Replace Policy - Policy reviewed; no change to policy statement.
06/06/09	Disclaimer and Scope update - No other changes.
04/10/07	Replace Policy - Policy updated with literature review; reference added. No change in policy statement.



Date	Comments
05/13/08	Replace Policy - Policy updated with literature search; no change to the policy statement. Policy Guidelines updated; obesity deleted (3PrdP bullet), and "who have >early grade III arthritis" deleted as this is a duplicate of the 1PstP bullet.
03/10/09	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.
01/12/10	Replace Policy - Policy updated with literature search. Policy statement added "collagen implant considered investigational". Collagen Meniscus implant added to the title. References added.
06/13/11	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.
05/08/12	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.
08/15/12	Remove Related Policies: 7.01.48, it was archived.
09/27/12	Remove Related Policies: 7.01.506; ICD-10 codes are now effective 10/01/2014.
05/13/13	Replace policy. Policy updated with literature review through January 30, 2013; references 21-24 added; title and investigational statement changed from "collagen" to "other".
06/14/13	Update Related Policies. Add 8.01.52.
07/16/13	Update Related Policies. Add 7.01.549
10/17/13	Update Related Policies. Add 1.03.501.
11/21/13	Update Related Policies. Add 7.01.550.
05/12/14	Annual Review. Policy updated with literature review through February 21, 2014. Reference 23 added; others renumbered/removed. Policy statements unchanged.
07/24/14	Update Related Policies. Change title to 7.0.549.
09/17/14	Update Related Policies. Change title to 7.01.550.
03/24/15	Update Related Policies. Change title to 7.01.549.
05/12/15	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.
08/01/16	Annual Review, approved July 12, 2016. Policy updated with literature review through





Date	Comments
	June 23, 2016. Reference added. Policy statements unchanged.
12/01/16	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.
07/01/17	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.
06/19/18	Added Site of Service information to the policy.
07/01/18	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.
04/01/19	Minor update, added Documentation Requirements section.

**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 425-918-5592, 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 <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services  
200 Independence Avenue SW, Room 509F, HHH Building  
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)  
Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

**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 by certain deadlines to keep your health coverage or help with 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).

**አማርኛ (Amharic):**

ይህ ማስታወቂያ አስፈላጊ መረጃ ይዟል። ይህ ማስታወቂያ ስለ ማመልከቻዎ ወይም የ Premera Blue Cross ሽፋን አስፈላጊ መረጃ ሊኖረው ይችላል። በዚህ ማስታወቂያ ውስጥ ቁልፍ ቀናት ሊኖሩ ይችላሉ። የጤና ሽፋንዎን ለመጠበቅና በአስፈላጊ እርዳታ ለማግኘት በተውሰኑ የጊዜ ገደቦች እርምጃ መውሰድ ይገባዎት ይሆናል። ይህን መረጃ እንዲያገኙ እና የለምንም ክፍያ በቋንቋዎ እርዳታ እንዲያገኙ መሰብሰብ አለዎት። በስልክ ቁጥር 800-722-1471 (TTY: 800-842-5357) ይደውሉ።

**العربية (Arabic):**

يحتوي هذا الإشعار على معلومات هامة. قد يحوي هذا الإشعار معلومات مهمة بخصوص طلبك أو التخطيط التي تزيد الحصول عليها من خلال Premera Blue Cross. قد تكون هناك تواريخ مهمة في هذا الإشعار. وقد تحتاج لاتخاذ إجراء في تاريخ معينة للحفاظ على تغطيتك الصحية أو للمساعدة في دفع التكاليف. يحق لك الحصول على هذه المعلومات والمساعدة بلغتك دون تكبد أية تكلفة. اتصل بـ 800-722-1471 (TTY: 800-842-5357)

**中文 (Chinese):**

**本通知有重要的訊息。**本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或者費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)。

**Oromoo (Cushite):**

**Beeksisni kun odeeffannoo barbaachisaa qaba.** Beeksisni kun sagantaa yookan karaa Premera Blue Cross tiin tajaajila keessan ilaalchisee odeeffannoo barbaachisaa qabaachuu danda'a. Guyyaawwan murteessaa ta'an beeksisa kana keessatti ilaalaa. Tarii kaffaltiidhaan deeggaramuuf yookan tajaajila fayyaa keessaniif guyyaa dhumaa irratti wanti raawwattan jiraachuu danda'a. Kaffaltii irraa bilisa haala ta'een afaan keessaniin odeeffannoo argachuu fi deeggarsa argachuuf mirga ni qabaattu. Lakkoofsa bilbilaa 800-722-1471 (TTY: 800-842-5357) tii bilbilaa.

**Français (French):**

**Cet avis a d'importantes informations.** Cet avis peut avoir d'importantes informations sur votre demande ou la couverture par l'intermédiaire de Premera Blue Cross. Le présent avis peut contenir des dates clés. Vous devez peut-être prendre des mesures par certains délais pour maintenir votre couverture de santé ou d'aide avec les coûts. Vous avez le droit d'obtenir cette information et de l'aide dans votre langue à aucun coût. Appelez le 800-722-1471 (TTY: 800-842-5357).

**Kreyòl ayisyen (Creole):**

**Avi sila a gen Enfòmasyon Enpòtan ladann.** Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w lan oswa konsènan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kèk aksyon avan sèten dat limit pou ka kenbe kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewva enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rele nan 800-722-1471 (TTY: 800-842-5357).

**Deutsche (German):**

**Diese Benachrichtigung enthält wichtige Informationen.** Diese Benachrichtigung enthält unter Umständen wichtige Informationen bezüglich Ihres Antrags auf Krankenversicherungsschutz durch Premera Blue Cross. Suchen Sie nach eventuellen wichtigen Terminen in dieser Benachrichtigung. Sie könnten bis zu bestimmten Stichtagen handeln müssen, um Ihren Krankenversicherungsschutz oder Hilfe mit den Kosten zu behalten. Sie haben das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Rufen Sie an unter 800-722-1471 (TTY: 800-842-5357).

**Hmoob (Hmong):**

**Tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb.** Tej zaum tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb txog koj daim ntawv thov kev pab los yog koj qhov kev pab cuam hnu ntawm Premera Blue Cross. Tej zaum muaj cov hnuv tseem ceeb uas sau rau hauv daim ntawv no. Tej zaum koj kuj yuav tau ua qee yam uas peb kom koj ua tsis pub dhau cov caij nyoog uas teev tseg rau hauv daim ntawv no mas koj thiaj yuav tau txais kev pab cuam kho mob los yog kev pab them tej nqi kho mob ntawd. Koj muaj cai kom lawv muab cov ntshiab lus no uas tau muab sau ua koj hom lus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

**Iloko (Ilocano):**

**Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion.** Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyonyo wenno coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a petsa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a naituding nga aldaw tapno mapagtalinaedyo ti coverage ti salun-atyto wenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagsasao nga awan ti bayadanyo. Tumawag iti numero nga 800-722-1471 (TTY: 800-842-5357).

**Italiano (Italian):**

**Questo avviso contiene informazioni importanti.** Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero esserci date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente. Chiama 800-722-1471 (TTY: 800-842-5357).

**日本語 (Japanese):**

この通知には重要な情報が含まれています。この通知には、Premera Blue Cross の申請または補償範囲に関する重要な情報が含まれている場合があります。この通知に記載されている可能性がある重要な日付をご確認ください。健康保険や有料サポートを維持するには、特定の期日までに行動を取らなければならない場合があります。ご希望の言語による情報とサポートが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

**한국어 (Korean):**

본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하의 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 도움을 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357) 로 전화하십시오.

**ລາວ (Lao):**

ແຈ້ງການນີ້ມີຂໍ້ມູນສໍາຄັນ. ແຈ້ງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄໍາຮ້ອງສະໝັກ ຫຼື ຄວາມຄົມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີ່ສໍາຄັນໃນແຈ້ງການນີ້. ທ່ານອາດຈະຈໍາເປັນຕ້ອງດໍາເນີນການຕາມກຳນົດ ເວລາສະເພາະເພື່ອຮັກສາຄວາມຄົມຄອງປະກັນສະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເວັ້ນເວີ້ ຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄດ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໃບທາ 800-722-1471 (TTY: 800-842-5357).

**ភាសាខ្មែរ (Khmer):**

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកកាមរយ: Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កិច្ចសន្យាជាមួយនាគា ដើម្បីនឹងរក្សាទុកការធានារ៉ាប់រងសុខភាពរបស់អ្នក ឬប្រាក់ដុល្លារចេញថ្លៃ។ អ្នកមានសិទ្ធិទទួលព័ត៌មាននេះ និងដុល្លារនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

**ਪੰਜਾਬੀ (Punjabi):**

ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਟਿਸ ਨਵ ਖਾਸ ਤਾਰੀਖਾਂ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀਂ ਜਸਰਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾਂ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਛੁੱਕ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਢੁੱਝ ਖਾਸ ਕਰਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫਤ ਵਿੱਚ ਤੋਂ ਅਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

**فارسی (Farsi):**

این اعلامیه حاوی اطلاعات مهم میباشد. این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید. شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید. شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کلیر بران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

**Polskie (Polish):**

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

**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 datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou 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).

**Română (Romanian):**

Prezenta notificare conține informații importante privind cererea sau acoperirea asigurării dumneavoastră de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența provizorie la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

**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).

**Fa'asamoa (Samoan):**

Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'matalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

**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 clave 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):**

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganiitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

**ไทย (Thai):**

ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับกาการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือนี้ในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

**Український (Ukrainian):**

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

**Tiếng Việt (Vietnamese):**

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).