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MEDICAL POLICY – 7.01.15

Meniscal Allografts and Other Meniscal Implants

BCBSA Ref. Policy:	7.01.15
Effective Date:	July 1, 2024
Last Revised:	Oct. 16, 2024
Replaces:	7.01.517

RELATED MEDICAL POLICIES:

1.03.501	Custom-made Knee Orthoses (Braces), Ankle foot Orthoses and Knee-Ankle-Foot-Orthoses
7.01.48	Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions
7.01.78	Osteochondral Autografts in the Treatment of Articular Cartilage Lesions
8.01.52	Orthopedic Applications of Stem-Cell Therapy
11.01.524	Site of Service: Select Surgical Procedures

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

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 individuals 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

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.

Site of Service for Elective Surgical Procedures	Medical Necessity
Medically necessary sites of service: • **Off campus-outpatient hospital/medical center** • **On campus-outpatient hospital/medical center** • **Ambulatory Surgical Center**	**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.**

Inpatient hospital/medical center	**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 individual 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):**
	• Anesthesia Risk
	  ○ ASA classification III or higher (see **definition**)
	  ○ Personal history of complication of anesthesia
	  ○ Documentation of alcohol dependence or history of cocaine use
	  ○ Prolonged surgery (>3 hours)

Site of Service for Elective Surgical Procedures	Medical Necessity

	• Cardiovascular Risk
	  ○ Uncompensated chronic heart failure (**NYHA class** III or IV)
	  ○ Recent history of myocardial infarction (MI) (<3 months)
	  ○ Poorly controlled, resistant hypertension*
	  ○ Recent history of cerebrovascular accident (< 3 months)
	  ○ Increased risk for cardiac ischemia (drug eluting stent placed < 1 year or angioplasty <90 days)
	  ○ Symptomatic cardiac arrhythmia despite medication
	  ○ Significant valvular heart disease
	• Liver Risk
	  ○ Advance liver disease (MELD Score > 8)**
	• Pulmonary Risk
	  ○ Chronic obstructive pulmonary disease (COPD) (FEV1 <50%)
	  ○ Poorly controlled asthma (FEV1 <80% despite treatment)
	  ○ Moderate to severe obstructive sleep apnea (OSA)***
	• Renal Risk
	  ○ End stage renal disease (on dialysis)
	• Other
	  ○ Morbid obesity (BMI ≥ 50)
	  ○ Pregnancy
	  ○ Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criteria])
	  ○ Anticipated need for transfusion(s)
	
	Note: * 3 or more drugs to control blood pressure
	** **https://reference.medscape.com/calculator/meld-score-end-stage-liver-disease**
	*** 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.**

Treatment	Medical Necessity
Meniscal allograft transplantation	**Meniscal allograft transplantation may be considered medically necessary in individuals who have had a prior meniscectomy and have symptoms related to the affected side, when ALL of the following criteria are met:** • Individuals should be 15 years or older or younger than 55 years of age (too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery) **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:** Individuals 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

Treatment	Medical Necessity
	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. Severe obesity (e.g., 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 individuals who are too young for total knee arthroplasty.

Treatment	Investigational
Other meniscal implants	**Use of other meniscal implants incorporating materials such as collagen are considered investigational.**

Documentation Requirements
The individual'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

Code	Description
CPT	
29882	Arthroscopy, knee, surgical; with meniscus repair (medial OR lateral)
29868	Arthroscopy, knee, surgical meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral
HCPCS	
G0428	Collagen meniscus implant procedure for filling meniscal defects (e.g., 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 range listed in this policy, 15 to 55 years of age, takes into consideration skeletal maturity and the age at which total knee replacements are considered. Skeletal maturity is reached around the age of 15, and adults younger than 55 are generally considered unsuitable candidates for total knee replacement.

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, e.g., 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, e.g., 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

Description

Meniscal allografts and other meniscal implants (e.g., collagen) are intended to improve symptoms and reduce joint degeneration in individuals 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 individuals with disabling knee pain following meniscectomy who are considered too young to undergo total knee arthroplasty or in individuals 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 individuals, Cvetanovich et al (2015) estimated an annual incidence of MAT in the United States of 0.24 per 100,000.[1] 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 three general groups of individuals who have been treated with MAT:

- Young individuals with a history of meniscectomy who have symptoms of pain and discomfort associated with early OA that is localized to the meniscus-deficient compartment
- Individuals 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 appropriate surgical techniques. 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; these 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.[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. Individuals 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 (CMI) (by Stryker, formerly the ReGen Collagen Scaffold by ReGen Biologics), is a resorbable 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 individual'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 (i.e., 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 MAT, the evidence includes systematic reviews of mostly case series and a randomized controlled trial (RCT). The 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 MAT can delay or prevent the development of knee OA. A limitation of the evidence is its reliance primarily on case series. Because of the results of the single RCT, which enrolled a very small number of individuals, 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 an 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 MAT, the evidence includes one systematic review of case series as well as case series published after the systematic review. The 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 individuals with more severe cartilage damage experienced favorable outcomes similar to individuals 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 an improvement in the net health outcome.

For individuals who are undergoing partial meniscectomy who receive collagen meniscal implants (CMIs), the evidence includes two systematic reviews primarily of case series. The relevant outcomes are symptoms, functional outcomes, and quality of life. The reviews reported overall positive results with the CMI, but the quality of the included studies (RCTs, observational studies) was low. Radiologic evaluations have shown reduction in the size of the implant in a large portion of individuals. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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
Ongoing			
NCT02483988	The SUN Clinical Trial (Safety Utilizing NUsurface Meniscus Implant). A Multi-Center, Single-arm, Prospective, Open-label, Non-randomized, Observational Clinical Study	115	Dec 2023
Unpublished			
NCT02108496[a]	The VENUS Clinical Study (Verifying the Effectiveness of the NUSurface System): A Multi-centered, Prospective, Randomized, Interventional Superiority Clinical Study	127	May 2022 (completed)
NCT01712191[a]	Treatment of the Medial Meniscus with the NUSurface Meniscus Implant	150	March 2016 (completed)

NCT: national clinical trial

[a] Denotes industry-sponsored or cosponsored trial

Clinical Input 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 one physician specialty society (three reviewers) and three academic medical centers while this policy was under review in 2011. Input considered combined 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 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 three 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 MAT to be beneficial in selected patients, with evidence of short to intermediate pain relief when performed in younger patients who had a prior meniscectomy and disabling knee pain. Contraindications noted were uncorrected instability, uncorrected malalignment, and the presence of significant articular disease.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

International Meniscus Reconstruction Experts Forum

In 2015, the International Meniscus Reconstruction Experts Forum published consensus statements on the practice of MAT (see **Table 2**).[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

Statements
Indications for MAT: • Unicomparental 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: Western Ontario Meniscal Evaluation Tool • Region-specific: Knee injury and Osteoarthritis Outcome Score • Activity: Marx Activity Rating Scale • QOL/utility: EuroQoL 5 dimensions questionnaire

MAT: meniscal allograft transplantation; OA: osteoarthritis

National Institute for Health and Care Excellence

In 2012, the guidance from the National Institute for Health and 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 (2009) updated its 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

The Centers for Medicare & Medicaid Services (2010) issued a national non-coverage determination for the CMI.[29] A number of concerns regarding the efficacy and safety were raised by the Centers for Medicare & Medicaid Services analysis, which compared data reported to the US Food and Drug Administration (FDA) and published data. Concerns included an increased number of reoperations and a higher serious adverse event rate than the control group. Centers for Medicare & Medicaid Services concluded that the CMI does not improve health outcomes in the Medicare population and determined that the CMI 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 US Food and Drug Administration (FDA) through the 510(k) process. The 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 CMI with FDA clearance at that time. Amid controversy about the 510(K) clearance, the 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, was manufactured by Ivy Sports Medicine (now Stryker). 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.
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.

Date	Comments
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 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.
05/01/19	Minor update, clarified Site of Service requirements.
10/01/19	Annual Review, approved September 5, 2019. Policy updated with literature review through May 2019; no references added. Policy statement clarified patients should be 15 years or older or younger than 55 years of age. .
04/01/20	Interim Review, approved March 10, 2020. Updates to this policy are effective for dates of service on or after July 2, 2020, following provider notification. The site of service

Date	Comments
	criteria and reference to policy 11.01.524 – Site of Service: Select Surgery Procedures, have been removed. Site of service will be included within the review for the primary procedure (knee arthroscopy) using InterQual criteria and determine the appropriate site for this procedure, if medically necessary.
06/10/20	Interim Review, approved June 9, 2020, effective June 10, 2020. The site of service criteria and reference to policy 11.01.524 – Site of Service: Select Surgery Procedures, have been added back to the policy. Site of service will not be determined using InterQual criteria.
10/01/20	Annual Review, approved September 1, 2020. Policy updated with literature review through May 2020; no references added. Policy statements unchanged.
11/01/20	Added Related Policy 1.03.501 Knee Orthoses (Braces), Ankle foot Orthoses and Knee-Ankle-Foot-Orthoses, effective Feb. 5, 2021.
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through February 17, 2021; no references added. Policy statements unchanged.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through February 20, 2022; no references added. Policy statements unchanged.
10/03/22	Update Related Policies. 1.03.501 – title changed from "Knee Orthoses (Braces), Ankle-Foot-Orthoses, and Knee-Ankle-Foot-Orthoses" to "Custom-made Knee Orthoses (Braces), Ankle-Foot-Orthoses, and Knee-Ankle-Foot-Orthoses"
07/01/23	Annual Review, approved June 12, 2023. Policy updated with literature review through February 17, 2023; no references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
11/01/23	Minor correction. Removed ReGen Collagen Scaffold from CPT 29868 as it was inadvertently added in the code description.
07/01/24	Annual Review, approved June 10, 2024. Policy updated with literature review through February 20, 2024; no references added. Policy statements unchanged.
10/16/24	Minor spelling edit.

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.