



Louisiana

Meniscal Allografts and Other Meniscal Implants

Policy # 00083

Original Effective Date: 06/05/2002

Current Effective Date: 11/17/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions is addressed separately in medical policy 00006.

Note: Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions is addressed separately in medical policy 00091.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider meniscal allograft transplantation (MAT) of the knee as a treatment for individuals with significant partial (more than 50%) or complete loss of the meniscus, as documented by previous operative reports, magnetic resonance imaging (MRI), or diagnostic arthroscopy, to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility will be considered for meniscal allograft transplantation (MAT) of the knee as a treatment for individuals with significant partial (more than 50%) or complete loss of the meniscus, as documented by previous operative reports, MRI, or diagnostic arthroscopy, when **ALL** of the following criteria are met:

- Age 55 or younger and skeletally mature; **AND**
- Knee pain refractory to conservative treatment (see Policy Guidelines); **AND**
- Ligamentous stability either prior to surgery or achieved concurrently with meniscal transplantation; **AND**
- Normal alignment without varus or valgus deformities; **AND**
- Mild to moderate articular damage (Outerbridge grade II or less).

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Note: Corrective procedures (e.g., ligament or tendon repair, osteotomy for realignment, osteochondral treatment) may be performed in combination with, or prior to, transplantation.

Note:

Grade Description of Outerbridge Scale:

Grade 0 normal articular cartilage

Grade I softening or blistering of joint cartilage

Grade II cartilage fragmentation or fissuring on the surface <1cm diameter

Grade III cartilage fragmentation or fissuring > 1cm diameter

Grade IV cartilage erosion down to subchondral bone

When Services Are Considered Not Medically Necessary

The use of meniscal allograft transplantation of the knee when patient selection criteria are not met is considered to be **not medically necessary****, including but not limited to the following:

- Treatment for asymptomatic individuals with partial or complete loss of the meniscus;
- Use of other meniscal implants incorporating materials such as collagen and polyurethane.

Policy Guidelines

General Information

The terms in the section provide operational definitions when they are referenced as requirements in the policy.

Documentation supporting medical necessity and a clearly stated plan of care should be submitted at the time of the request and must include the following components:

Operative report of a prior arthroscopic procedure and/or MRI of the knee performed within the past 12 months: The provider shall submit a detailed imaging report that correlates with clinical findings of the requested procedure. In the absence of the detailed report, the provider will be required to submit a report from an independent radiologist. The results of all imaging studies should correlate with the clinical findings in support of the requested procedure.

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Conservative management must include a combination of strategies to reduce inflammation, alleviate pain, and correct underlying dysfunction, including physical therapy **AND at least one** complementary conservative treatment strategy.

- **Physical therapy requirement** includes **ANY** of the following:
 - Physical therapy rendered by a qualified provider of physical therapy services; **OR**
 - Supervised home treatment program which includes flexibility and muscle strengthening exercises that includes **ALL** of the following:
 - Participation in a patient-specific or tailored program; **AND**
 - Initial active instruction by MD/DO/PT with redemonstration of patient ability to perform exercises; **AND**
 - Compliance (documented or by clinician attestation on follow-up evaluation);

OR

- Exception to the physical therapy requirement in unusual circumstances (for instance intractable pain so severe that physical therapy is not possible) when clearly documented in the medical record.
- **Complementary conservative treatment requirement** includes **ANY** of the following:
 - Anti-inflammatory medications and analgesics¹; **OR**
 - Adjunctive medications such as nerve membrane stabilizers or muscle relaxants¹; **OR**
 - Intraarticular corticosteroid injection(s)¹; **OR**
 - Alternative therapies such as activity modification, and/or a trial period of rest (e.g., from the aggravating/contributing factors) where applicable.

¹ In the absence of contraindications

Clinical reevaluation. In most cases, reevaluation should include a physical examination. Direct contact by other methods, such as telephone communication or electronic messaging, may substitute for in-person evaluation when circumstances preclude an office visit. Clinical reevaluation must be done in reasonable proximity to the anticipated date of service such that the patient's condition would be unlikely to change by the date of service.



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Failure of conservative management requires **ALL** of the following:

- Patient has completed a full course of conservative management (as defined above) or the current episode of care; **AND**
- Worsening of or no significant improvement in signs and/or symptoms upon clinical reevaluation; **AND**
- More invasive forms of therapy are being considered.

Documentation of compliance with a plan of therapy that includes elements from these areas is required where conservative management is appropriate.

Reporting symptom severity: Severity of pain and its associated impact on activities of daily living (ADLs) and instrumental ADLs (IADLs) are key factors in determining the need for intervention. For purposes of this guideline, significant pain and functional impairment refer to pain that is at least 3 out of 10 in intensity and is associated with inability to perform ADLs and/or IADLs.

Background/Overview

Meniscal Cartilage Damage

Meniscal cartilage is an integral structural component of the human knee, functioning to absorb shocks and providing load sharing, joint stability, congruity, proprioception, and lubrication and nutrition of the cartilage surfaces. Total and partial meniscectomy frequently result in degenerative osteoarthritis. The integrity of the menisci is particularly important in knees in which the anterior cruciate ligament 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 U.S. 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.

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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 osteoarthritis that is localized to the meniscus-deficient compartment.
- patients undergoing anterior cruciate ligament 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 osteoarthritis. 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 4 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, posttransplantation 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, nonirradiated 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.

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).

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Tissue engineering that grows new replacement host tissue 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 semilunar 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. Nonabsorbable and nonporous 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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. The FDA determined that this device was substantially equivalent to existing absorbable surgical mesh devices. The ReGen Collagen Scaffold (also known as MenaFlex^{TM‡} CMI) was the only collagen meniscus implant with FDA clearance at that time. Amid controversy about this 510(k) clearance, the FDA reviewed its decision. In October 2010, the FDA rescinded the approval, stating that MenaFlex^{TM‡} is intended for different purposes and is technologically dissimilar from the predicate devices identified in the approval process. The manufacturer appealed the rescission 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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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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.

Summary of Evidence

For individuals who are undergoing partial meniscectomy who receive meniscal allograft transplantation (MAT), the evidence includes systematic reviews of mostly case series and a randomized controlled trial (RCT). 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 a 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 osteoarthritis. A limitation of the evidence is its reliance primarily on case series. Because the results of the single RCT, which enrolled a very small number of patients, 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 a 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 published subsequently reported an overall 9.7-year survival of the implant. A limitation of the evidence is its reliance primarily on case series. The

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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 2 systematic reviews primarily of case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The reviews reported overall positive results with the CMI, but the quality of the selected studies (RCTs, observational studies) was low. Radiologic evaluations have shown reductions in the size of the implant in a large portion of patients. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may 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 for patients younger than 55 years of age who have failed conservative treatment. Reviewers agreed that the collagen meniscus implant is investigational, although some considered it to be both investigational and medically necessary for some patients.

2008 Input

In response to requests, input was received from 1 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 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.

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Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ 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 (Table 1). The Forum's statements included guidance on indications, graft procurement and preparation, surgical technique, and rehabilitation.

Table 1. Select Consensus Statements on the Practice of Meniscal Allograft Transplantation

Statements
Indications for MAT: <ul style="list-style-type: none">• Unicompartmental pain post-meniscectomy• In combination with anterior cruciate ligament reconstruction when meniscus deficient• In combination with articular cartilage repair 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, the superiority of 1 surgical technique over another (all-suture vs bone) is not established.
Outcome scores should include: <ul style="list-style-type: none">• Disease-specific: Western Ontario Meniscal Evaluation Tool• Region-specific: Knee injury and Osteoarthritis Outcome Score• Activity: Marx Activity Rating Scale

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- Quality of life/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 raises no major safety concerns," but evidence for any advantage of the procedure over standard surgery was limited.

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 of age, with the goal of replacing the meniscus cushion before the articular cartilage is damaged. The website also notes that "synthetic (artificial) meniscal tissue has been tried, but there is conflicting information at this time."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services (2010) issued a national noncoverage determination for the collagen meniscus implant. 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 U.S. Food and Drug Administration and published data. Concerns included an increased number of reoperations and a higher serious adverse event rate than in the control group. Centers for Medicare & Medicaid Services concluded that the collagen meniscus implant does not improve health outcomes in the Medicare population and that collagen meniscus implant is not reasonable and necessary for the treatment of meniscal injury or tear.

Ongoing and Unpublished Clinical Trials

Currently ongoing and unpublished trials that might influence this review are listed in Table 2.

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Table 2. Summary of Ongoing Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
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
<i>Unpublished</i>			
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	Mar 2016 (completed)

NCT: national clinical trial. ^a Denotes industry-sponsored or cosponsored trial.

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Policy History

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- 05/16/2002 Medical Policy Committee review
06/05/2002 Managed Care Advisory Council approval
06/24/2002 Format revision. No substance change to policy
06/01/2004 Medical Director review
06/15/2004 Medical Policy Committee review
06/28/2004 Managed Care Advisory Council approval
07/12/2006 Medical Director review
07/19/2006 Medical Policy Committee review. Format changes and FDA information added.
07/02/2008 Medical Director review
07/16/2008 Medical Policy Committee review. Coverage eligibility unchanged.
07/02/2009 Medical Director review
07/22/2009 Medical Policy Committee review. Coverage changed from investigational to eligible with criteria.
07/01/2010 Medical Policy Committee approval
07/21/2010 Medical Policy Implementation Committee approval. Policy statement added; collagen implant considered investigational; collagen meniscus implant added to policy title.
07/07/2011 Medical Policy Committee review.
07/20/2011 Medical Policy Implementation Committee approval. Meniscal allograft transplantation when performed in combination, either concurrently or sequentially, with autologous chondrocyte implantation, osteochondral allografting

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or osteochondral autografting for focal articular cartilage lesions is now considered eligible for coverage instead of investigational.

06/28/2012	Medical Policy Committee review.
07/27/2012	Medical Policy Implementation Committee approval. No change to coverage.
06/27/2013	Medical Policy Committee review
07/17/2013	Medical Policy Implementation Committee approval. Title and investigational statement changed from "collagen" to "other" and included polyurethane as an example of other meniscal implants in the investigational statement.
07/10/2014	Medical Policy Committee review
07/16/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/25/2015	Medical Policy Committee review
07/15/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Updated rationale and references.
08/04/2016	Medical Policy Committee review
08/17/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
08/03/2017	Medical Policy Committee review
08/23/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/03/2018	Medical Policy Committee review
05/16/2018	Medical Policy Implementation Committee approval. Coverage section revised.
05/02/2019	Medical Policy Committee review
05/15/2019	Medical Policy Implementation Committee approval. Policy coverage and Policy Guidelines sections revised.
04/02/2020	Medical Policy Committee review
04/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/01/2021	Medical Policy Committee review
04/14/2021	Medical Policy Implementation Committee approval. Revised Policy Guidelines. Coverage eligibility unchanged.
04/07/2022	Medical Policy Committee review

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04/13/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/02/2022	Medical Policy Committee review
06/08/2022	Medical Policy Implementation Committee approval. Revised Policy Guidelines Coverage eligibility unchanged.
06/01/2023	Medical Policy Committee review
06/14/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/02/2024	Medical Policy Committee review
07/10/2024	Medical Policy Implementation Committee approval. Minor revisions made for clarity. Coverage eligibility unchanged.
09/05/2024	Medical Policy Committee review
09/11/2024	Medical Policy Implementation Committee approval. Added a <i>Note</i> after the Patient Selection Criteria with examples of corrective procedures that may be performed in combination with, or prior to, transplantation. Removed the number requirement of inability to perform at least two ADLs and IADLs from the Policy Guidelines section under the Reporting symptom severity paragraph. Coverage eligibility unchanged.

Next Scheduled Review Date: 09/2025

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	29868
HCPCS	G0428
ICD-10 Diagnosis	All related Diagnoses

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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