



Louisiana

Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

Policy # 00006

Original Effective Date: 08/26/2002

Current Effective Date: 10/20/2024

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: Meniscal Allografts and Other Meniscal Implants is addressed separately in medical policy 00083.

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

Note: Continuous Passive Motion (CPM) is addressed separately in medical policy 00020.

When Services Are 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 autologous chondrocyte implantation (ACI) for the treatment of disabling full-thickness articular cartilage defects of the knee caused by acute or repetitive trauma to be **eligible for coverage**** when all of the following criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered when all of the following criteria are met:

- Adolescent individuals should be skeletally mature with documented closure of growth plates (e.g., 15 years or older). Adult individuals should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., younger than 55 years); and
- Focal, full-thickness (grade III or IV) unipolar lesions of the patella or the weight-bearing surface of the femoral condyles or trochlea at least 1.5 cm² in total area, as documented by MRI or arthroscopy (defects greater than 15 cm² may require more than one membrane); and

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- Documented minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge grade II or less), and normal-appearing hyaline cartilage surrounding the border of the defect; and
- Normal knee biomechanics or alignment and stability achieved concurrently with autologous chondrocyte implantation (ACI).

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 Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers autologous chondrocyte implantation (ACI) for all other joints, including talar, and any indications other than those listed above to be **investigational**.*

The use of autologous chondrocyte implantation (ACI) for the treatment of disabling full-thickness articular cartilage defects of the knee caused by acute or repetitive trauma when patient selection criteria are not met is considered to be **investigational**.*

Policy Guidelines

For smaller lesions (eg, <4 cm²), if debridement is the only prior surgical treatment, then consideration should be given to marrow-stimulating techniques before autologous chondrocyte implantation is performed.

The average defect size reported in the literature is about 5 cm²; many studies treated lesions as large as 15 cm².

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Severe obesity (eg, body mass index $>35 \text{ kg/m}^2$) may affect outcomes due to the increased stress on weight-bearing surfaces of the joint.

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. In addition, meniscal allograft transplantation may be performed in combination, either concurrently or sequentially, with autologous chondrocyte implantation. The charges for the culturing component of the procedure are submitted as part of the hospital bill.

The entire matrix-induced autologous chondrocyte implantation procedure consists of 4 steps: (1) initial arthroscopy and biopsy of normal cartilage, (2) culturing of chondrocytes on an absorbable collagen matrix, (3) a separate arthrotomy to place the implant, and (4) postsurgical rehabilitation. The initial arthroscopy may be scheduled as a diagnostic procedure; as part of this procedure, a cartilage defect may be identified, prompting biopsy of normal cartilage in anticipation of a possible chondrocyte transplant. The biopsied material is then sent for culturing and returned to the hospital when the implantation procedure (i.e., arthrotomy) is scheduled.

Background/Overview

Articular Cartilage Lesions

Damaged articular cartilage typically fails to heal on its own and can be associated with pain, loss of function, and disability, and may lead to debilitating osteoarthritis over time. These manifestations can severely impair a patient's activities of daily living and adversely affect quality of life.

Treatment

Conventional treatment options include debridement, subchondral drilling, microfracture (MF), and abrasion arthroplasty. Debridement involves the removal of synovial membrane, osteophytes, loose articular debris, and diseased cartilage, and it is capable of producing symptomatic relief. Subchondral drilling, MF, and abrasion arthroplasty attempt to restore the articular surface by inducing the growth of fibrocartilage into the chondral defect. Compared with the original hyaline cartilage, fibrocartilage has less capability to withstand shock or shearing force and can degenerate over time, often resulting in the return of clinical symptoms. Osteochondral grafts and autologous chondrocyte implantation attempt to regenerate hyaline-like cartilage and thereby restore durable function.

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With autologous chondrocyte implantation, a region of healthy articular cartilage is identified and biopsied through arthroscopy. The tissue is sent to a facility licensed by the U.S. Food and Drug Administration (FDA) where it is minced and enzymatically digested, and the chondrocytes are separated by filtration. The isolated chondrocytes are cultured for 11 to 21 days to expand the cell population, tested, and then shipped back for implantation. With the patient under general anesthesia, an arthrotomy is performed, and the chondral lesion is excised up to the normal surrounding cartilage. Methods to improve the first-generation autologous chondrocyte implantation procedure have been developed, including the use of a scaffold or matrix-induced autologous chondrocyte implantation (MACI) composed of biocompatible carbohydrates, protein polymers, or synthetics. The only FDA approved MACI product to date is supplied in a sheet, which is cut to size and fixed with fibrin glue. This procedure is considered technically easier and less time-consuming than the first-generation technique, which required suturing of a periosteal or collagen patch and injection of chondrocytes under the patch.

Desired features of articular cartilage repair procedures are the ability (1) to be implanted easily, (2) to reduce surgical morbidity, (3) not to require harvesting of other tissues, (4) to enhance cell proliferation and maturation, (5) to maintain the phenotype, and (6) to integrate with the surrounding articular tissue. In addition to the potential to improve the formation and distribution of hyaline cartilage, use of a scaffold with MACI eliminates the need for harvesting and suture of a periosteal or collagen patch. A scaffold without cells may also support chondrocyte growth.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

The culturing of chondrocytes is considered by the FDA to fall into the category of manipulated autologous structural cells, which are subject to a biologic licensing requirement. In 1997, Carticel^{®‡} (Genzyme; now Vericel) received FDA approval for the repair of clinically significant, “...symptomatic cartilaginous defects of the femoral condyle (medial-lateral or trochlear) caused by acute or repetitive trauma...”

In December 2016, MACI^{®‡} (Vericel) received FDA approval for “the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults.” MACI consists of autologous chondrocytes that are cultured onto a bioresorbable porcine-

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derived collagen membrane. In 2017, production of Carticel was phased out, and MACI is the only autologous chondrocyte implantation product available in the United States.

A number of other second-generation methods for implanting autologous chondrocytes in a biodegradable matrix are currently in development or testing or are available outside of the United States. They include Atelocollagen (Koken), a collagen gel; Bioseed[®] C (BioTissue Technologies), a polymer scaffold; CaReS (Ars Arthro), collagen gel; Cartilix (Biomet), a polymer hydrogel; Chondron (Sewon Cellontech), a fibrin gel; Hyalograft C (Fidia Advanced Polymers), a hyaluronic acid-based scaffold; NeoCart (Histogenics), an autologous chondrocyte implantation with a 3-dimensional chondromatrix in a phase 3 trial; and Novocart[®] 3D (Aesculap Biologics), a collagen-chondroitin sulfate scaffold in a phase 3 trial. ChondroCelect[®] (TiGenix), characterized as a chondrocyte implantation with a completed phase 3 trial, uses a gene marker profile to determine in vivo cartilage-forming potential and thereby optimizes the phenotype (eg, hyaline cartilage vs. fibrocartilage) of the tissue produced with each autologous chondrocyte implantation cell batch. Each batch of chondrocytes is graded based on the quantitative gene expression of a selection of positive and negative markers for hyaline cartilage formation. Both Hyalograft C and ChondroCelect have been withdrawn from the market in Europe. In 2020, the FDA granted breakthrough status to Agili-CTM (CartiHeal, Ltd.), a proprietary cell-free biocompatible and biodegradable tapered-shape implant for the treatment of cartilage lesions in arthritic and non-arthritic joints that, when implanted into a pre-prepared osteochondral hole, acts as a 3-dimensional scaffold that potentially supports and promotes the regeneration of the articular cartilage and its underlying subchondral bone. Agili-C was FDA-approved in 2021 for the treatment of knee-joint surface lesions with a treatable area of 1 to 7 cm² without severe osteoarthritis.

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.

A variety of procedures are being developed to resurface articular cartilage defects. Autologous chondrocyte implantation involves harvesting chondrocytes from healthy tissue, expanding the cells

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in vitro, and implanting the expanded cells into the chondral defect. Second- and third-generation techniques include combinations of autologous chondrocytes, scaffolds, and growth factors.

Summary of Evidence

For individuals who have focal articular cartilage lesion(s) of the weight-bearing surface of the femoral condyles, trochlea, or patella who receive autologous chondrocyte implantation, the evidence includes systematic reviews, randomized controlled trials (RCTs), and observational studies. Relevant outcomes are symptoms, change in disease status, morbid events, functional outcomes, and quality of life. There is a large body of evidence on autologous chondrocyte implantation for the treatment of focal articular cartilage lesions of the knee. For large lesions, autologous chondrocyte implantation results in better outcomes than microfracture, particularly in the long term. In addition, there is a limit to the size of lesions that can be treated with osteochondral autograft transfer, due to a limit on the number of osteochondral cores that can be safely harvested. As a result, autologous chondrocyte implantation has become the established treatment for large articular cartilage lesions in the knee. In 2017, first-generation autologous chondrocyte implantation with a collagen cover was phased out and replaced with an autologous chondrocyte implantation preparation that seeds the chondrocytes onto a bioresorbable collagen sponge. Although the implantation procedure for this second-generation autologous chondrocyte implantation is less technically demanding, studies to date have not shown improved outcomes compared with first-generation autologous chondrocyte implantation. Some evidence has suggested an increase in hypertrophy (overgrowth) of the new implant that may exceed that of the collagen membrane-covered implant. Long-term studies with a larger number of patients will be needed to determine whether this hypertrophy impacts graft survival. Based on mid-term outcomes that approximate those of first-generation autologous chondrocyte implantation and the lack of alternatives, second-generation autologous chondrocyte implantation may be considered an option for large disabling full-thickness cartilage lesions of the knee. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have focal articular cartilage lesions of joints other than the knee who receive autologous chondrocyte implantation, the evidence includes case series, systematic reviews of case series, and a network meta-analysis of prospective (none of which evaluated autologous chondrocyte implantation) and retrospective studies. Relevant outcomes are symptoms, change in disease status, morbid events, functional outcomes, and quality of life. The greatest amount of literature is on autologous chondrocyte implantation of the talus. Comparative trials are needed to determine

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whether autologous chondrocyte implantation improves outcomes for lesions in joints other than the knee. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

2015 Input

In response to requests, input was received from 2 physician specialty societies (6 reviewers) and 4 academic medical centers while this policy was under review in 2015. Input was generally supportive of the use of autologous chondrocyte implantation for large patellar lesions, although the degree of support varied. Reviewers indicated that outcomes were improved when realignment procedures were performed concurrently with autologous chondrocyte implantation of the patella, and that success rates were lower when using autologous chondrocyte implantation after a prior microfracture. Most reviewers recommended that a prior surgical procedure not be required for lesions greater than 4 cm².

2011 Input

In response to requests, input was received from 2 physician specialty societies and 3 academic medical centers while this policy was under review in 2011. Input was generally in agreement with the stated criteria for autologous chondrocyte implantation, except the following: input was mixed on the requirement for an inadequate response to a prior surgical procedure and the requirement for an absence of meniscal pathology. Input was also mixed on the investigational status of autologous chondrocyte implantation in patellar and talar joints.

Supplemental Information

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

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.

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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.

American Academy of Orthopaedic Surgeons

In its 2023 guidelines on the diagnosis and treatment of osteochondritis dissecans, the American Academy of Orthopaedic Surgeons did not recommend for or against a specific cartilage repair technique in symptomatic skeletally mature patients with an unsalvageable osteochondritis dissecans lesion, or symptomatic skeletally immature patients with unsalvageable fragment. The finding of insufficient evidence for symptomatic skeletally mature patients with an unsalvageable osteochondritis dissecans lesion was based on a systematic review that found 4 level IV studies addressing cartilage repair techniques for an unsalvageable osteochondritis dissecans lesion. Because each level IV article used different techniques, different outcome measures, and differing

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lengths of follow-up, the Academy deemed the evidence for any specific technique inconclusive. The finding of insufficient evidence for symptomatic skeletally immature patients with unsalvageable fragments was based on a Level II study; this study did not address many outcomes and techniques and had inconclusive results.

National Institute for Health and Care Excellence

In 2018, NICE updated its 2005 guidance on the use of autologous chondrocyte implantation. The NICE recommendations are stated below:

"...as an option for treating symptomatic articular cartilage defects of the femoral condyle and patella of the knee (International Cartilage Repair Society grade III or IV) in adults, only if:

- the person has not had previous surgery to repair articular cartilage defects;
- there is minimal osteoarthritic damage to the knee (as assessed by clinicians experienced in investigating knee cartilage damage using a validated measure for knee osteoarthritis); and
- the defect is over 2 cm²."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing 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
<i>Ongoing</i>			
NCT04785092	All Autologous Cartilage Regeneration in the Treatment of the Knee Cartilage Defects	20	March 2024

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NCT03219307	Safety and Efficacy of NOVOCART 3D in the Treatment of Articular Cartilage Defects Following Failure on Microfracture	30	Dec 2023
NCT01656902 ^a	A Prospective Randomized Controlled Multicenter Phase-III Clinical Study to Evaluate the Safety and Effectiveness of NOVOCART [®] 3D Plus Compared to the Standard Procedure Microfracture in the Treatment of Articular Cartilage Defects of the Knee	263	June 2023
NCT04744402	A Multi-Center, Active-Controlled, Open-Label, Phase 2 Trial to Compare the Efficacy and Safety of CartiLife [®] , and Microfracture for Patients With Articular Cartilage Defects in the Knee	50	Dec 2023
NCT01957722 ^a	A Phase 3, Prospective, Randomized, Partially Blinded Multi-Center Study to Measure the Safety and Efficacy of NOVOCART 3D Compared to Microfracture in the Treatment of Articular Cartilage Defects	233	Dec 2024
NCT05651997	Randomized Study Comparing Two Methods for the Treatment of Large Chondral and Osteochondral Defects of the Knee: Augmented Microfracture Technique vs 3rd Generation of ACI	80	June 2028
NCT05402072 ^a	Autologous Matrix-Induced Chondrogenesis Compared With Microfracture for Focal Articular Cartilage Damage of the Hip (REPAIR): A Pilot Randomized Controlled Trial	30	Jan 2026
NCT05328674	Clinical and Comparative Evaluation of the Treatment Results of Arthroscopic Reconstruction of Cartilage Defects in the Knee Joint With the Use	60	June 2022

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	of Autogenous Cartilage Graft with PRP GF (Platelet-rich Plasma With Growth Factors)		
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NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Louisiana

Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

Policy # 00006

Original Effective Date: 08/26/2002

Current Effective Date: 10/20/2024

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Louisiana

Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

Policy # 00006

Original Effective Date: 08/26/2002

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Louisiana

Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

Policy # 00006

Original Effective Date: 08/26/2002

Current Effective Date: 10/20/2024

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Policy History

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Current Effective Date: 10/20/2024

- 07/01/2001 Medical Director review
- 07/18/2002 Medical Policy Committee review
- 08/26/2002 Managed Care Advisory Council approval
- 06/24/2002 Format revision. No substance change to policy
- 08/10/2004 Medical Director review
- 08/31/2004 Medical Director review
- 09/21/2004 Medical Policy Committee review. Format revision. No Substance change to policy
- 09/27/2004 Managed Care Advisory Council approval
- 09/07/2005 Medical Director review
- 09/20/2005 Medical Policy Committee review. Format revision. Coverage eligibility unchanged.
- 09/22/2005 Quality Care Advisory Council approval
- 07/12/2006 Medical Director review
- 07/19/2006 Medical Policy Committee approval. Format changes. FDA information added. Coverage eligibility unchanged.
- 05/02/2007 Medical Director review
- 05/23/2007 Medical Policy Committee approval. Added when patient selection criteria are not met is considered to be investigational.
- 05/07/2008 Medical Director review
- 05/21/2008 Medical Policy Committee approval. Rationale updated.

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Louisiana

Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

Policy # 00006

Original Effective Date: 08/26/2002

Current Effective Date: 10/20/2024

05/07/2009 Medical Director review
05/20/2009 Medical Policy Committee approval. No change to coverage eligibility.
06/03/2010 Medical Director review
06/16/2010 Medical Policy Implementation Committee approval. No change to coverage eligibility.
05/05/2011 Medical Director review
05/18/2011 Medical Policy Implementation Committee approval. No change to coverage eligibility
05/03/2012 Medical Director review
05/16/2012 Medical Policy Implementation Committee approval. No change to coverage eligibility
08/01/2013 Medical Director review
08/21/2013 Medical Policy Implementation Committee approval. Sections and statements on minced cartilage moved to policy (Osteochondral Autografts and Allografts) and “Other Cell-based Treatments” removed from title.
08/07/2014 Medical Director review
08/20/2014 Medical Policy Implementation Committee approval. No change to coverage.
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
12/03/2015 Medical Director review
12/16/2015 Medical Policy Implementation Committee approval. Removed need for a prior surgical procedure from eligibility statement. Patella added to the eligibility statement.
12/01/2016 Medical Policy Committee review
12/21/2016 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. Investigational statement on matrix-induced autologous chondrocyte implantation removed.
04/05/2018 Medical Policy Committee review
04/18/2018 Medical Policy Implementation Committee approval. No change to coverage.
05/02/2019 Medical Policy Committee review
05/15/2019 Medical Policy Implementation Committee approval. No change to coverage.

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Louisiana

Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

Policy # 00006

Original Effective Date: 08/26/2002

Current Effective Date: 10/20/2024

05/07/2020 Medical Policy Committee review
 05/13/2020 Medical Policy Implementation Committee approval. No change to coverage.
 07/02/2020 Medical Policy Committee review
 07/08/2020 Medical Policy Implementation Committee approval. No change to coverage.
 09/10/2020 Coding update
 08/05/2021 Medical Policy Committee review
 08/11/2021 Medical Policy Implementation Committee approval. No change to coverage.
 06/02/2022 Medical Policy Committee review
 06/08/2022 Medical Policy Implementation Committee approval. No change to coverage.
 07/06/2023 Medical Policy Committee review
 07/12/2023 Medical Policy Implementation Committee approval. No change to coverage.
 07/02/2024 Medical Policy Committee review
 07/10/2024 Medical Policy Implementation Committee approval. Added “total area, as documented by MRI or arthroscopy (defects greater than 15 cm² may require more than one membrane)” to the second bullet under patient selection criteria.

Next Scheduled Review Date: 07/2025

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Louisiana

Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

Policy # 00006

Original Effective Date: 08/26/2002

Current Effective Date: 10/20/2024

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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	27412, 29866
HCPCS	J7330, S2112
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment,

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Louisiana

Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

Policy # 00006

Original Effective Date: 08/26/2002

Current Effective Date: 10/20/2024

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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