MEDICAL POLICY

POLICY TITLE	**AUTOLOGOUS CHONDROCYTE IMPLANTATION FOR FOCAL ARTICULAR CARTILAGE LESIONS**
POLICY NUMBER	**MP-1.022**

Original Issue Date (Created):	**7/1/2002**
Most Recent Review Date (Revised):	**7/1/2018**
Effective Date:	**9/1/2018** **RETIRED**

I. POLICY

Autologous chondrocyte implantation may be considered **medically necessary** for the treatment of disabling full-thickness articular cartilage defects of the knee caused by acute or repetitive trauma, when **all** of the following criteria are met:

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

Autologous chondrocyte implantation for all other joints, including talar, and any indications other than those listed in the policy criteria above is considered **investigational.**

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

Policy Guidelines

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

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

Severe obesity, e.g., body mass index greater than 35 kg/m2 , 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 ACI. The charges for the culturing component of the procedure are submitted as part of the hospital bill.

The entire ACI procedure consists of 4 steps: (1) initial arthroscopy and biopsy of normal cartilage, (2) culturing of chondrocytes, (3) a separate arthrotomy to create a periosteal flap and implant the chondrocytes, 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.

Cross-references:

MP-9.003 Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions
MP-1.010 Meniscal Allografts and Other Meniscal Implants
MP-2.080 Orthopedic Applications of Stem Cell Therapy (Including Allograft and Bone Substitute Products Used with Autologous Bone Marrow)

II. PRODUCT VARIATIONS TOP

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO - Refer to FEP Medical Policy Manual MP-7.01.48, Autologous Chondrocyte Implantation and Other Cell Based Treatments of Focal Articular Cartilage Lesions. The FEP Medical Policy Manual can be found at: www.fepblue.org

III. DESCRIPTION/BACKGROUND TOP

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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, and abrasion arthroplasty. Debridement involves the removal of synovial membrane, osteophytes, loose articular debris, and diseased cartilage and is capable of producing symptomatic relief. Subchondral drilling, microfracture, 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 (ACI) attempt to regenerate hyaline-like cartilage and thereby restore durable function. Osteochondral grafts for the treatment of articular cartilage defects are discussed in MP-9.003

With ACI, 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 ACI 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.

REGULATORY STATUS

The culturing of chondrocytes is considered by 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) FDA approved 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 which are cultured onto a bioresorbable porcine-derived collagen membrane. In 2017, production of Carticel® was phased out, and MACI® is the only ACI 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 ACI 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), a characterized 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 (e.g., hyaline cartilage vs fibrocartilage) of the tissue produced with each ACI 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.

IV. RATIONALE

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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 ACI, the evidence includes systematic reviews, randomized controlled trials, and prospective 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 ACI for the treatment of focal articular cartilage lesions of the knee. For large lesions, ACI 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, ACI has become the established treatment for large articular cartilage lesions in the knee. In 2017, first-generation ACI with a collagen cover was phased out and replaced with an ACI preparation that seeds the chondrocytes onto a bioresorbable collagen sponge. Although the implantation procedure for this second-generation ACI is less technically demanding, studies to date have not shown improved outcomes compared with first-generation ACI. 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 ACI and the lack of alternatives, second-generation ACI 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 a meaningful improvement in the net health outcome.

V. DEFINITIONS

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ARTHROSCOPY is direct joint visualization by means of an arthroscope, usually to remove tissue such as cartilage fragments or torn ligaments.

ARTHROTOMY refers to cutting into a joint.

CHONDROCYTE is a cartilage cell.

OSTEOARTHRITIS is a type of arthritis marked by progressive cartilage deterioration in the synovial joints and vertebrae.

PERIOSTEAL refers to the fibrous membrane that forms the covering of bones except at their articular surfaces.

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Autologous chondrocyte implantation for ALL joints (including talar), other than the knee is investigational; therefore not covered:

CPT Codes®								
28899	29999							

Covered when medically necessary:

CPT Codes®								
27412	29870							

HCPCS Codes	Description
J7330	Autologous cultured chondrocytes, implant
S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)

ICD-10-CM Diagnosis Codes	Description
M12.561	Traumatic arthropathy, right knee
M12.562	Traumatic arthropathy, left knee
M12.569	Traumatic arthropathy, unspecified knee
M22.00	Recurrent dislocation of patella, unspecified knee
M22.01	Recurrent dislocation of patella, right knee
M22.02	Recurrent dislocation of patella, left knee
M22.10	Recurrent subluxation of patella, unspecified knee
M22.11	Recurrent subluxation of patella, right knee
M22.12	Recurrent subluxation of patella, left knee
M22.40	Chondromalacia patellae, unspecified knee
M22.41	Chondromalacia patellae, right knee
M22.42	Chondromalacia patellae, left knee
M22.8X1	Other disorders of patella, right knee
M22.8X2	Other disorders of patella, left knee

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ICD-10-CM Diagnosis Codes	Description
M22.8X9	Other disorders of patella, unspecified knee
M23.200	Derangement of unspecified lateral meniscus due to old tear or injury, right knee
M23.201	Derangement of unspecified lateral meniscus due to old tear or injury, left knee
M23.202	Derangement of unspecified lateral meniscus due to old tear or injury, unspecified knee
M23.203	Derangement of unspecified medial meniscus due to old tear or injury, right knee
M23.204	Derangement of unspecified medial meniscus due to old tear or injury, left knee
M23.205	Derangement of unspecified medial meniscus due to old tear or injury, unspecified knee
M23.206	Derangement of unspecified meniscus due to old tear or injury, right knee
M23.207	Derangement of unspecified meniscus due to old tear or injury, left knee
M23.209	Derangement of unspecified meniscus due to old tear or injury, unspecified knee
M23.211	Derangement of anterior horn of medial meniscus due to old tear or injury, right knee
M23.212	Derangement of anterior horn of medial meniscus due to old tear or injury, left knee
M23.219	Derangement of anterior horn of medial meniscus due to old tear or injury, unspecified knee
M23.221	Derangement of posterior horn of medial meniscus due to old tear or injury, right knee
M23.222	Derangement of posterior horn of medial meniscus due to old tear or injury, left knee
M23.229	Derangement of posterior horn of medial meniscus due to old tear or injury, unspecified knee
M23.231	Derangement of other medial meniscus due to old tear or injury, right knee
M23.232	Derangement of other medial meniscus due to old tear or injury, left knee
M23.239	Derangement of other medial meniscus due to old tear or injury, unspecified knee
M23.241	Derangement of anterior horn of lateral meniscus due to old tear or injury, right knee
M23.242	Derangement of anterior horn of lateral meniscus due to old tear or injury, left knee
M23.249	Derangement of anterior horn of lateral meniscus due to old tear or injury, unspecified knee
M23.251	Derangement of posterior horn of lateral meniscus due to old tear or injury, right knee
M23.252	Derangement of posterior horn of lateral meniscus due to old tear or injury, left knee
M23.259	Derangement of posterior horn of lateral meniscus due to old tear or injury, unspecified knee
M23.261	Derangement of other lateral meniscus due to old tear or injury, right knee
M23.262	Derangement of other lateral meniscus due to old tear or injury, left knee
M23.269	Derangement of other lateral meniscus due to old tear or injury, unspecified knee
M23.300	Other meniscus derangements, unspecified lateral meniscus, right knee
M23.301	Other meniscus derangements, unspecified lateral meniscus, left knee
M23.302	Other meniscus derangements, unspecified lateral meniscus, unspecified knee
M23.303	Other meniscus derangements, unspecified medial meniscus, right knee
M23.304	Other meniscus derangements, unspecified medial meniscus, left knee
M23.305	Other meniscus derangements, unspecified medial meniscus, unspecified knee
M23.306	Other meniscus derangements, unspecified meniscus, right knee

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ICD-10-CM Diagnosis Codes	Description
M23.307	Other meniscus derangements, unspecified meniscus, left knee
M23.309	Other meniscus derangements, unspecified meniscus, unspecified knee
M23.311	Other meniscus derangements, anterior horn of medial meniscus, right knee
M23.312	Other meniscus derangements, anterior horn of medial meniscus, left knee
M23.319	Other meniscus derangements, anterior horn of medial meniscus, unspecified knee
M23.321	Other meniscus derangements, posterior horn of medial meniscus, right knee
M23.322	Other meniscus derangements, posterior horn of medial meniscus, left knee
M23.329	Other meniscus derangements, other medial meniscus, right knee
M23.331	Other meniscus derangements, other medial meniscus, right knee
M23.332	Other meniscus derangements, other medial meniscus, left knee
M23.339	Other meniscus derangements, other medial meniscus, unspecified knee
M23.341	Other meniscus derangements, anterior horn of lateral meniscus, right knee
M23.342	Other meniscus derangements, anterior horn of lateral meniscus, left knee
M23.349	Other meniscus derangements, anterior horn of lateral meniscus, unspecified knee
M23.351	Other meniscus derangements, posterior horn of lateral meniscus, right knee
M23.352	Other meniscus derangements, posterior horn of lateral meniscus, left knee
M23.359	Other meniscus derangements, posterior horn of lateral meniscus, unspecified knee
M23.361	Other meniscus derangements, other lateral meniscus, right knee
M23.362	Other meniscus derangements, other lateral meniscus, left knee
M23.369	Other meniscus derangements, other lateral meniscus, unspecified knee
M23.40	Loose body in knee, unspecified knee
M23.41	Loose body in knee, right knee
M23.42	Loose body in knee, left knee
M23.50	Chronic instability of knee, unspecified knee
M23.51	Chronic instability of knee, right knee
M23.52	Chronic instability of knee, left knee
M23.8X1	Other internal derangements of right knee
M23.8X2	Other internal derangements of left knee
M23.8X9	Other internal derangements of unspecified knee
M23.90	Unspecified internal derangement of unspecified knee
M23.91	Unspecified internal derangement of right knee
M23.92	Unspecified internal derangement of left knee
M25.861	Other specified joint disorders, right knee
M25.862	Other specified joint disorders, left knee
M25.869	Other specified joint disorders, unspecified knee
M94.261	Chondromalacia, right knee

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ICD-10-CM Diagnosis Codes	Description
M94.262	Chondromalacia, left knee
S83.211D	Bucket-handle tear of medial meniscus, current injury, right knee, subsequent
S83.211S	Bucket-handle tear of medial meniscus, current injury, right knee, sequela
S83.212D	Bucket-handle tear of medial meniscus, current injury, left knee, subsequent
S83.212S	Bucket-handle tear of medial meniscus, current injury, left knee, sequela
S83.221D	Peripheral tear of medial meniscus, current injury, right knee, subsequent
S83.221S	Peripheral tear of medial meniscus, current injury, right knee, sequela
S83.222D	Peripheral tear of medial meniscus, current injury, left knee, subsequent
S83.222S	Peripheral tear of medial meniscus, current injury, left knee, sequela
S83.231A	Complex tear of medial meniscus, current injury, right knee, initial encounter
S83.231D	Complex tear of medial meniscus, current injury, right knee, subsequent
S83.231S	Complex tear of medial meniscus, current injury, right knee, sequela
S83.232D	Complex tear of medial meniscus, current injury, left knee, subsequent
S83.232S	Complex tear of medial meniscus, current injury, left knee, sequela
S83.241A	Other tear of medial meniscus, current injury, right knee, initial encounter
S83.241D	Other tear of medial meniscus, current injury, right knee, subsequent
S83.241S	Other tear of medial meniscus, current injury, right knee, sequela
S83.242D	Other tear of medial meniscus, current injury, left knee, subsequent
S83.242S	Other tear of medial meniscus, current injury, left knee, sequela
S83.251D	Bucket-handle tear of lateral meniscus, current injury, right knee, subsequent encounter
S83.251S	Bucket-handle tear of lateral meniscus, current injury, right knee, sequela
S83.252D	Bucket-handle tear of lateral meniscus, current injury, left knee, subsequent encounter
S83.252S	Bucket-handle tear of lateral meniscus, current injury, left knee, sequela
S83.261D	Peripheral tear of lateral meniscus, current injury, right knee, subsequent encounter
S83.261S	Peripheral tear of lateral meniscus, current injury, right knee, sequela
S83.262D	Peripheral tear of lateral meniscus, current injury, left knee, subsequent encounter
S83.262S	Peripheral tear of lateral meniscus, current injury, left knee, sequela
S83.271D	Complex tear of lateral meniscus, current injury, right knee, subsequent encounter
S83.271S	Complex tear of lateral meniscus, current injury, right knee, sequela
S83.272D	Complex tear of lateral meniscus, current injury, left knee, subsequent encounter
S83.272S	Complex tear of lateral meniscus, current injury, left knee, sequela
S83.281D	Other tear of lateral meniscus, current injury, right knee, subsequent encounter
S83.281S	Other tear of lateral meniscus, current injury, right knee, sequela
S83.282D	Other tear of lateral meniscus, current injury, left knee, subsequent encounter
S83.282S	Other tear of lateral meniscus, current injury, left knee, sequela
S83.31XA	Tear of articular cartilage of right knee, current, initial encounter

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ICD-10-CM Diagnosis Codes	Description
S83.31XD	Tear of articular cartilage of right knee, current, subsequent encounter
S83.31XS	Tear of articular cartilage of right knee, current, sequela
S83.32XA	Tear of articular cartilage of left knee, current, initial encounter
S83.32XD	Tear of articular cartilage of left knee, current, subsequent encounter
S83.32XS	Tear of articular cartilage of left knee, current, sequela

IX. REFERENCES TOP

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Other Sources:

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X. POLICY HISTORY

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MP 1.022	**CAC 9/30/03**
	CAC 5/31/05
	CAC 7/26/05
	CAC 1/31/06
	CAC 1/30/07
	CAC 11/27/07
	CAC 9/29/09 Consensus Review Policy retitled "Autologous Chondrocyte Implantation"
	CAC 11/30/2010 Medically necessary criteria for autologous chondrocyte implantation (ACI) revised to be consistent with BCBSA. Investigational statements added for matrix-induced ACI and treatment with autologous or allogeneic minced cartilage or cartilage cells.
	CAC 11/22/11 Adopt BCBSA- Absence of meniscal pathology removed from medical necessity statement.
	CAC 1/29/13 Consensus. No change to policy statements. References updated. Changed FEP variation to reference the policy manual.
	CAC 1/28/14 Consensus. Sections and statements on minced cartilage moved to MP-9.003 Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions. Changed title, "Other Cell-based Treatments" removed. Policy coded.
	CAC 1/27/15 Consensus review. Reference and rationale update. No changes to the policy statements. Coding reviewed
	CAC 1/26/16 Minor revision. Removed the need for a prior surgical

	procedure in the first policy statement. Also added a statement that autologous chondrocyte implantation of the patella is considered medically necessary. Rationale and reference update**.** Coding reviewed/updated.
	Admin Update 11/10/16:Variation Reformatting
	CAC 1/31/17 Consensus. No change to policy statement. Added policy guidelines. Rationale and references reviewed. Coding reviewed.
	CAC 7/25/17 Minor review with the following changes. • Investigational statement on matrix-induced autologous chondrocyte implantation removed. • The criteria were revised in the medically necessary policy statement for autologous chondrocyte implantation (ACI) of the knee, removing ACI of the patella. Background, Rationale and References updated. Coding Reviewed**.**
	4/9/18 Minor review. Added matrix-induced autologous chondrocyte implantation of the patella as medically necessary. Background and references updated. Rationale condensed to include summary of evidence only. Coding Reviewed.
	7/16/18 Retirement. Policy to be managed by Turning Point.

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