AUTOLOGOUS CHONDROCYTE TRANSPLANTATION IN THE KNEE

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

COVERAGE RATIONALE

Autologous chondrocyte transplantation (ACT) with Carticel® is proven in patients with a single symptomatic full-thickness articular cartilage defect when all of the following are present:

- adult patient younger than age 55,
- defect is greater than 2 squared cm,
- defect is caused by acute or repetitive trauma,
- defect is in the articular cartilage of the femoral condyle (medial, lateral, or trochlea),
- patient has had an inadequate response to a prior arthroscopic or other surgical repair procedure (e.g., debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft), and
- patient has failed to respond to conservative treatment such as physical therapy, braces, and/or nonsteroidal anti-inflammatory drugs (NSAIDs)
Autologous chondrocyte transplantation is unproven for indications other than those listed as proven.

Unproven indications include but are not limited to the following:

- cartilage defects in locations other than the femoral condyle of the knee
- children (growth plates have not closed)
- partial-thickness defects
- multiple defects
- defects of the patella
- osteochondritis dissecans
- previous history of cancer in the bones, cartilage, fat or muscle of the treated limb
- treatment of cartilage damage associated with generalized osteoarthritis
- pre-existing conditions, including meniscus tears, joint instability, or malalignment, unless these conditions are assessed and treated prior to or concurrent with autologous chondrocyte implantation

There is insufficient evidence to conclude that ACT is beneficial for health outcomes in patients with osteochondritis dissecans, osteoarthritis, or for cartilage defects.

Information Pertaining to Medical Necessity Review (When Applicable)
The above indications apply to medical necessity review.

BACKGROUND

Normal articular cartilage is a complex tissue composed of matrix, chondrocytes and water. The chondrocytes are responsible for synthesizing the matrix, which is composed primarily of collagen fibers, hyaluronate, and sulfated proteoglycans. Cartilage has a poor intrinsic ability to heal itself. When a full-thickness cartilage injury occurs, the articular surface does not usually regenerate on its own. Surgical treatment options include autologous chondrocyte transplantation.

Autologous chondrocyte transplantation, also referred to as autologous chondrocyte implantation, is a form of tissue engineering that creates a graft from a patient's own cartilage cells to repair defects in the articular cartilage. The procedure involves the collection and culture of articular cartilage cells (i.e., chondrocytes), which are then implanted into the defect with the goal of generating new hyaline or hyaline-like tissue which will repair the articular surface.

With the patient under general anesthesia, an arthrotomy is performed, the cultured cells are placed into the cartilage defect, and held in place with a periosteal patch. Repair of ligamentous or other soft tissue structures is performed concurrently, as needed. After the initial non-weight-bearing period immediately following surgery, an intensive physical rehabilitation program is initiated, with a gradual increase in weight bearing, and return to full activities.

CLINICAL EVIDENCE

Harris et al. (2010) conducted a systematic review to compare autologous chondrocyte implantation with other cartilage repair or restoration techniques. Thirteen studies (n = 917) were included. Patients underwent autologous chondrocyte implantation (n = 604), microfracture (n = 271), or osteochondral autograft (n = 42). Three of 7 studies showed better clinical outcomes after autologous chondrocyte implantation in comparison with microfracture after 1 to 3 years of follow-up, whereas 1 study showed better outcomes 2 years after microfracture and 3 other studies showed no difference in these treatments after 1 to 5 years. Clinical outcomes after microfracture deteriorated after 18 to 24 months (in 3 of 7 studies). Autologous chondrocyte implantation and osteochondral autograft demonstrated equivalent short-term clinical outcomes, although there was more rapid improvement after osteochondral autograft (2 studies). A defect size of >4 cm(2) was the only factor predictive of better outcomes when autologous chondrocyte transplantation in the Knee: Medical Policy (Effective 10/01/2013)

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implantation was compared with a non-autologous chondrocyte implantation surgical technique. The authors concluded that all of the cartilage repair/restoration techniques provide short-term success.

A systematic review of 9 different trials (n=626) by Vasiliadis et al. (2010) found that ACI is an effective treatment for full thickness chondral defects of the knee, providing an improvement of clinical outcomes. The authors note, however, that there is insufficient data to say whether ACI is superior to other treatment strategies in full thickness articular cartilage defects of the knee. Additional studies are needed before specific clinical recommendations can be made.

Vavken and Samartzis (2010) conducted a systematic review of 9 studies (n=526) to compare ACI to other methods of cartilage repair or placebo. The authors found that there was no clear recommendation concerning the efficacy of ACI compared to other treatment options such as microfracture or osteochondral grafts. There is, however, some evidence for better clinical outcomes for ACI compared with osteochondral grafts and equivalent outcomes compared with microfracture. Additional studies are needed to further assess the benefits of ACI compared to other treatments.

A systematic review conducted by authors at Vanderbilt University attempted to define the comparative effectiveness of, and indications for, ACI and osteochondral autograft transfer system (OATS) to treat full-thickness (Outerbridge stage 3 or 4) defects (Magnussen et al., 2008). The review included four trials (Bentley et al., 2003; Horas et al., 2003; Knutsen et al., 2004; Visna et al., 2004), a comparison of ACI using collagen membrane cover (ACI-C) with matrix-guided ACI (MACI), and a comparison of autologous osteochondral grafting with microfracture. The authors were not able to demonstrate a clear superiority of one procedure over the other.

A Cochrane Review by Wasiak et al. (2006) concluded that evidence was insufficient to determine whether ACI was superior to other treatment options for full-thickness cartilage lesions of the knee.

Another Cochrane Review by Vasiliadis and Wasiak (2010) concluded that there was insufficient evidence to draw conclusions on the use of ACI for treating full thickness articular cartilage defects in the knee.

Basad et al. (2010) compared the clinical outcomes of patients with symptomatic cartilage defects treated with matrix-induced autologous chondrocyte implantation (MACI) or microfracture (MF). The 60 patients included were 18 to 50 years of age with symptomatic, post-traumatic, single, isolated chondral defects (4-10 cm2) and were randomized to receive MACI (40) or MF (20). Patients were followed up 8-12, 22-26 and 50-54 weeks post-operatively for efficacy and safety evaluation. The difference between baseline and 24 months post-operatively for both treatment groups was significant for the Lysholm, Tegner, patient ICRS and surgeon ICRS scores. However, MACI was significantly more effective over time (24 months versus baseline) than MF according to the Lysholm, Tegner, ICRS patient and ICRS surgeon scores. According to the authors, MACI is superior to MF in the treatment of articular defects over 2 years.

Zeifang et al. (2010) evaluated whether matrix-associated autologous chondrocyte implantation or the original periosteal flap technique provides superior outcomes in terms of clinical efficacy and safety. Twenty-one adult patients (mean age, 29.3 +/- 9.1 years) with symptomatic isolated full-thickness cartilage defects (mean 4.1 +/- 0.9 cm2) at the femoral condyle were randomized to matrix-associated autologous chondrocyte implantation or the original periosteal flap technique. The primary outcome parameter showed improvement of patients 1 year after autologous chondrocyte implantation, but there was no difference between the periosteal flap technique and matrix-associated ACI; 2 years after ACI, a similar result was found. The authors concluded that there was no difference in the efficacy between the original and the advanced ACI technique 12 and 24 months after surgery regarding International Knee Documentation Committee, Tegner
Activity Score, and Short Form-36; however, with respect to the Lysholm and Gillquist score, better efficacy was observed in the periosteal flap technique group.

Comparative results varied according to the comparison surgery. Fu et al. (2005) observed that at 3 years, Cincinnati Knee Rating System (CKRS) scores were 2 to 3 points higher (on 10-point scales) in the ACI group than in the debridement alone group, both for overall condition and for individual symptoms. The difference in overall scores was significant. However, this was a retrospective study and CKRS data were missing for 28% to 60% of debridement patients, depending on the individual measure. Furthermore, the study did not differentiate between first- and second-line use of ACI, and several other aspects of the study design introduced bias.

In the comparisons with marrow stimulation, improvements in pain and various functional measures were either comparable between the two types of procedures or slightly better following abrasion or microfracture than following ACI (Knutsen et al., 2004; Visna et al., 2004; Knutsen et al., 2007; Saris et al., 2008). This was true of both 5-year and more short-term outcomes. These studies represented moderately strong evidence, but baseline differences in the study by Saris and colleagues created a small bias in favor of microfracture.

Saris et al. (2009) evaluated clinical outcome at 36 months after characterized chondrocyte implantation (CCI) versus microfracture (MF). Based on the results of the trial, the authors concluded that characterized chondrocyte implantation for the treatment of articular cartilage defects of the femoral condyles of the knee results in significantly better clinical outcome at 36 months in a randomized trial compared with MF. Time to treatment and chondrocyte quality were shown to affect outcome.

Results were less consistent for comparisons with autologous osteochondral grafting. Differences between ACI procedures and a mix of single and multiple osteochondral grafting procedures slightly favored osteochondral grafting (Horas et al., 2003). This study also represented a mix of firstline and second-line applications; results were not reported separately. Mean defect size was 3.75 cm². Bentley et al. (2003) reported results that favored ACI: 88% of ACI recipients and only 69% of mosaicplasty recipients had a good or excellent overall modified CKRS score at 19 months. However, mean defect size in this study was relatively large (4.66 cm²), and one critic suggested that some patients may not have been appropriate candidates for mosaicplasty (Kish and Hangody, 2004). In the study by Dozin et al. (2005), outcomes were considerably better in the mosaicplasty group: 68% patients had a Lysholm score of 90 or more, compared with 46% of ACI patients. Significance testing was not reported, follow-up was less than 1 year, and the study had several other significant weaknesses. This study differed from the other two osteochondral grafting comparisons in that it involved first-line rather than second-line application and mean lesion size was smaller. Mean defect size was approximately 2 cm², consistent with guidelines for mosaicplasty reported in review articles (Clar et al., 2005; Vanlauwe et al., 2007).

A case series by Peterson et al. (2010) evaluated the clinical outcomes of autologous chondrocyte implantation in 224 patients 10 to 20 years after implantation (mean = 12.8 years). The authors found that autologous chondrocyte implantation is an effective and durable solution for the treatment of large full-thickness cartilage and osteochondral lesions of the knee joint and clinical and functional outcomes remain high even 10 to 20 years after the implantation.

Best Candidates for ACI
Scientific literature reflects the following consensus regarding the best selection criteria for ACI (Clar et al., 2005; Lewis et al., 2006; Vanlauwe et al., 2007; Brittberg, 2008):

- Adults younger than 55 years who will return to a relatively high activity level.
- Symptomatic lesion.
- Single, contained (healthy articular cartilage at lesion border), unipolar (no lesion on opposing surface), full thickness defect > 2 cm². (Some authors recommend ACI as an alternative to marrow stimulation if the lesion is uncontained.)
- No significant bone loss.
• Full range-of-motion, intact ligaments and physiologically correct lower limb axis (corrective procedures may be performed in combination with or prior to ACI).
• No osteoarthritis of the knee, autoimmune connective tissue disease, active rheumatoid arthritis, or malignancy.
• Patient motivated and willing to comply with rigorous rehabilitation program.

Bony defects greater than 8 mm should be corrected with bone grafts before chondrocyte implantation.

**Adverse Events and Complications**

Studies involving 75 or more autologous chondrocyte implantation (ACI) procedures (total n=540 patients) reported failure rates of 4% to 13%, depending on how failure is defined and depending on where procedures are performed (Peterson et al., 2000; Minas, 2001; Browne et al., 2005). Adverse events were generally reported in terms of the need for arthroscopic evaluation of symptoms or for subsequent surgery. Such a need occurred in 25% to 65% of patients (nonuniform follow-up intervals). Symptomatic complications related to the periosteal flap were by far the most common adverse effects, prompting arthroscopic investigation in 20% to 26% of study participants (Peterson et al., 2000; Minas, 2001) and accounting for 10% of subsequent surgeries among ACI successes (Browne et al., 2005) or 51% of all subsequent surgeries (Henderson et al., 2006). Flap-related complications included both periosteal hypertrophy and implant extrusion.

Another review by Wood et al. (2006) found that the most common adverse events following Carticel implantation included graft failure, delamination, and tissue hypertrophy.

**ACI in Adolescents**

Some experts believe the use of ACI in children is not reasonable, since regenerative capacities are so much greater than in adults and due to potential interference epiphysis closure (Vanlauwe et al., 2007). However, other authors have seen the potential for faster healing to be a good reason to try ACI in athletes. A review of 37 adolescent (age 11-17) ACI procedures listed in the Cartilage Repair Registry showed an 88% rate of good/excellent outcomes (Micheli et al., 2006).

**ACI for Trochlear and Patellar Defects**

Published trials comparing ACI with other surgical repair procedures for defects in the knee included relatively few patients with trochlear or patellar defects. A review of 40 Cartilage Repair Registry patients who underwent ACI for trochlear cartilage defects reported positive outcomes (Mandelbaum et al., 2007). In most cases, ACI followed previous attempts at surgical repair, often marrow stimulation. Defects were generally large (mean 4.5 cm2). A longitudinal study separately analyzed results for 45 patients who underwent ACI for defects on the patella, trochlea, patella plus trochlea, weight bearing condyle plus patella, weight bearing condyle plus trochlea, or weight bearing condyle plus patella plus trochlea (Minas and Bryant, 2005). Affected patellar surface averaged 4.86 cm2, and affected trochlear surface averaged 5.22 cm2. Most (71%) patients reported a good or excellent overall outcome. However, the rate of graft failure was rather high (18%).

In the only study that provided results according to defect type (Bentley et al., 2003), between-group differences for defects on the patella and trochlea were similar to those for femoral defects. The number of patients in those categories was very small. No results specific to osteochondritis dissecans (OCD) were presented by any study.

**Additional Applications**

Current evidence regarding ACI largely examines cartilage restoration of the knee joint. However, two small studies and one case report were identified in the literature that evaluated the use of ACT in other joints. Investigators assessed the use of autologous chondrocytes in osteochondral lesions of the ankle joint and osteochondrosis dissecans of the ankle joint (n=8; n=8). In the first study, at 2 years of follow-up, both subjective and objective clinical improvement was observed in
Arthroscopy and histological analysis revealed cartilaginous tissue covering the lesion area, although cell numbers were increased compared with normal cartilage. Koulassi et al. (2002) reported good to excellent results in the postoperative evaluation scores, with no complications. Arthroscopic examinations in 3 patients revealed the existence of cartilage-like tissue with complete coverage of the chondral effect. Romeo et al. (2002) reported on the use of ACT in the repair of an articular defect in the humeral head of a young patient. After 12 weeks, the patient demonstrated full range of painless motion with no complaints of rest pain or weather-related pain. Despite these early clinical results, the available scientific evidence does not allow definitive conclusions regarding the safety and efficacy of ACT in treating focal defects of joints other than the knee, such as ankle, hip, wrist, or shoulder.

According to Hayes, there is insufficient evidence to evaluate the clinical effectiveness of autologous chondrocyte implantation compared with nonsurgical treatment. However, seven comparison trials of varying quality suggested that ACI provides short-term outcomes comparable to those provided by other surgical options for second-line treatment of full-thickness defects in the articular cartilage of the knee. Four moderately large noncomparison studies suggested that autologous chondrocyte implantation poses no serious safety issues. However, in its original form, autologous chondrocyte implantation often requires follow-up arthroscopic correction of hypertrophy and even high-volume centers have reported that implants can fail completely. There was no evidence from either randomized trials or observational studies regarding the long-term effectiveness of autologous chondrocyte implantation. This does not rule out the possibility of a long-term effect since most of the studies were limited by follow-up intervals of less than 2 years. Very limited and nonsystematic biopsy data suggest that most first-time autologous chondrocyte implantation procedures produce some new hyaline or hyaline-like cartilage. These data corroborate the rationale for autologous chondrocyte implantation but do not prove that long-term outcomes are enhanced compared with other surgical options. Given the typical characteristics of lesions included in the studies, the evidence more strongly supports use of ACI for lesions of the femoral condyle than for lesions in other locations. Although the FDA-approved indication for ACI is restricted to traumatic lesions, not all studies observed this restriction and results were not reported separately by etiology. Only studies with long-term follow-up, in the range of 20 years or more, will provide final answers to questions about the presumed superior ability of ACI to produce hyaline or hyaline-like cartilage and to prevent premature osteoarthritis. Such data can then also be used to clarify which patients and what types of lesions are most likely to benefit from ACI as opposed to another surgical technique (Hayes, 2008).

In a prospective cohort study, Kon et al. (2009) compared the clinical outcome of patients treated with second-generation Hyalograft C autologous chondrocyte implantation implants (n=40) with those treated with the microfracture repair (n=40). All patients had grade III to IV cartilage lesions of the femoral condyles or trochlea. Both groups demonstrated statistically significant improvement of all clinical scores from preoperative interval to 5-year follow-up. When comparing the groups, better improvement of the International Knee Documentation Committee objective (P < .001) and subjective (P = .003) scores was observed in the Hyalograft C group at 5-year follow-up. The return to sports at 2 years was similar in both groups and remained stable after 5 years in the Hyalograft C group; it worsened in the microfracture group. The investigators concluded that better clinical results and sport activity resumption were demonstrated in the group treated with second-generation autologous chondrocyte transplantation.

Zaslav et al. (2009) assessed the effectiveness of autologous chondrocyte implantation in a prospective clinical study of patients who failed prior treatments for articular cartilage defects of the knee. Follow-up was 48 months. One hundred twenty-six patients (82%) completed the study protocol. Seventy-six percent of patients were treatment successes at the end of the study and 24% were identified as treatment failures. Mean improvements were observed from baseline to all time points (P < .001) for all outcome measures. Preoperative to 48-month values, respectively, were as follows: On the Knee injury and Osteoarthritis Outcome Score subscales of pain: 48.7 to 72.2; other symptoms: 51.8 to 70.8; sports/recreation: 25.8 to 55.8; knee quality of life: 20.9 to 52.2; and activities of daily living: 58.6 to 81.0; on the Modified Cincinnati Overall Knee score: 3.3
to 6.3; on the visual analog scale: 28.8 to 69.9; and on the SF-36 Overall Physical Health: 33.0 to 44.4. Results did not differ between patients whose primary surgery had been a marrow-stimulating procedure and those whose primary procedure had been a debridement alone. The median difference in duration of benefit between autologous chondrocyte implantation and the failed non-autologous chondrocyte implantation prior procedure was at least 31 months (P < .001). Seventy-six patients (49%) had subsequent surgical procedure(s), predominantly arthroscopic. The investigators concluded that patients with moderate to large chondral lesions with failed prior cartilage treatments can expect sustained and clinically meaningful improvement in pain and function after autologous chondrocyte implantation. The subsequent surgical procedure rate observed in this study (49% overall; 40% related to autologous chondrocyte implantation) appears higher than generally reported after autologous chondrocyte implantation.

Niemeyer et al. (2008) reported the clinical results obtained in 70 patients treated with ACI for full-thickness defects of the patella. At a mean follow-up of 38.4 months, patients' subjective functional knee scores (IKDC, Lysholm) were analyzed, as were the results of objective examination (according to International Cartilage Research Society [ICRS]). The mean Lysholm score at the time of follow-up was 73.0 (+/-22.4) and the subjective IKDC score was 61.6 (+/-21.5); normal and nearly normal clinical results according to ICRS were achieved in 67.1% of the patients, while abnormal results were achieved in 20.0% of the patients and severely abnormal results, in 12.9% of the patients.

National Institute for Health and Clinical Excellence (NICE): Current NICE Guidance recommends against ACI for the treatment of articular cartilage defects of the knee joint, except in the context of ongoing or new clinical studies that are designed to generate robust and relevant outcome data, including the measurement of health-related quality of life and long-term follow-up (NICE, 2008).

Center for Orthopaedics and Sports Medicine (COSM): According to the COSM, ACI is generally applied to patients aged 15-55 years, although it is ultimately the treating surgeon's assessment of the physiologic condition of the affected joint that will determine appropriateness for treatment (COSM, 2003).

Additional Search Terms
Cartilage cell service, fibrocartilage, OCD, spongialization

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Carticel: The culturing of chondrocytes is considered by the FDA to fall into the category of manipulated autologous structural cells (MAS), which are subject to a biologic licensing requirement. At the present time, only Carticel™ (Genzyme) has received FDA approval for the culturing of chondrocytes through a biologics license.

On August 22, 1997, the FDA granted a Biologics License for Carticel®, approving it for provision of autologous chondrocytes for the repair of clinically significant, symptomatic cartilaginous defects of the femoral condyle caused by acute or repetitive trauma. The FDA granted a supplement to the Biologics License for Carticel® on March 2, 2000. In response to a request made by Genzyme, the FDA narrowed the indication for use of autologous cultured chondrocytes to second-line therapy for patients who have failed other therapies.

The current FDA-approved indications for Carticel state that Carticel is indicated for the repair of symptomatic cartilage defects of the femoral condyle (medial, lateral or trochlea), caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure (e.g., debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft).
Carticel should only be used in conjunction with debridement, placement of a periosteal flap and rehabilitation.

Carticel is not indicated for:
- treatment of cartilage damage associated with generalized osteoarthritis.
- patients with total meniscectomy unless surgically reconstructed prior to or concurrent with Carticel implantation.

Prescribing information for Carticel specifies administration only by physicians who have completed Genzyme Biosurgery's Surgeon Training Program.

Pre-existing conditions, including meniscal tears, joint instability, or malalignment should be assessed and treated prior to or concurrent with Carticel implantation. Carticel should not be used in patients who have previously had cancer in the bones, cartilage, fat or muscle of the treated limb. Use in children or patients over age 65 has not been assessed.

Additional information is available at:

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for autologous chondrocyte transplantation in the knee. Local Coverage Determinations (LCDs) specific to autologous chondrocyte transplantation in the knee do not exist at this time. However, LCDs do exist for autologous chondrocyte implantation of the knee. Refer to the LCDs for NonCovered Services. (Accessed August 21, 2013)

APPLICABLE CODES

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

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<td>S2112</td>
<td>Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)</td>
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REFERENCES


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**POLICY HISTORY/REVISION INFORMATION**

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| 10/01/2013 | • Updated description of services to reflect most current clinical evidence, CMS information and references; no change to coverage rationale or lists of applicable codes  
• Archived previous policy version 2012T0030J |