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**DATE OF REVIEW:** SEPTEMBER 20, 2007

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

Left knee arthroscopy, micro-fracture, possible carticeal biopsy

**A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION**

Board certified in Orthopaedic Surgery, licensed in the State of Texas.

**REVIEW OUTCOME**

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

Health Care Service(s) in Dispute	CPT Codes	Date of Service(s)	Outcome of Independent Review
Left knee arthroscopy, micro-fracture, possible carticeal biopsy	29881	Upon approval	Adverse determination upheld

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

Record Date
03/30/07
06/01/07
06/07/07
06/15/07
06/28/07
07/19/07
07/25/07
07/28/07
08/08/07

#### **PATIENT CLINICAL HISTORY [SUMMARY]:**

The patient is 5'7" weighing 265 pounds with an antalgic gait and bilateral subluxating patellae per standing x-rays. She had an arthroscopic lateral release which also documented a 20x20mm lateral femoral defect (this defect may be greater) and grade III patellofemoral changes and a normal meniscus. Follow up MRI revealed the patient also has a torn lateral meniscus. Additionally, the treating doctor is concerned that the symptoms are localized to one particular area. Physical therapy has improved the knee problem 50%.

#### **ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.**

This patient has a body mass index of greater than 35. She also has grade III patellofemoral degenerative changes and bilateral patellae subluxation due to knee malalignment aggravated by her obesity. She has not had traditional arthroscopic treatment (drilling, microfracture or abrasion) and there may be a "kissing lesion" on the opposite tibial surface per follow up MRI. Additionally, once she has a lateral menisectomy, she will not have an intact meniscus. All of these findings do not support a carticeal biopsy for anticipated autologous cartilage implantation. Therefore based upon the above rationale, the decision to deny this procedure is upheld.

#### **A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:**

ODG, 4<sup>th</sup> ed. Pg. 657 2006

Not recommended. In recent years the surgical implantation of healthy cartilage cells (autologous cartilage implantation [ACI]) into damaged areas has been seen as an alternative option and is currently under investigation as a potential improvement over the current strategies for the management and treatment of articular cartilage defects. A Cochrane review concluded that there is not enough evidence to make a determination that would influence current practice and determined that ACI must currently be considered as a technology under investigation with an effectiveness that is yet to be determined. ([Wasiak-Cochrane, 2002](#)) ([Bentley, 2003](#)) ([Horas, 2003](#)) ([Blue Cross Blue Shield, 2003](#)) The use of ACI and other chondral resurfacing techniques is becoming increasingly widespread. However, there is at present no evidence of significant difference between ACI and other interventions. ([Wasiak-Cochrane, 2006](#)) Available data afford no evidence that ACI is more effective than other conventional techniques in treating chondral lesions of the knee. ([Ruano-Ravina, 2005](#)) ([Ruano-Ravina, 2006](#)) There is insufficient evidence at present to say that ACI is cost-effective. ([Clar, 2005](#)) Autologous chondrocyte implantation (ACI) is being used to treat patients with cartilaginous defects of the femoral condyle. The ACI process involves obtaining healthy chondrocyte cells from a patient's knee, culturing the cells through a process termed Carticel (Genzyme), and implanting the cultured chondrocytes back into the patient via a surgical procedure. The revised FDA labeling suggests a more restricted use of autologous chondrocytes, i.e., as a second-line therapy after failure of initial arthroscopic or surgical repair. The main deficiency of the existing evidence is that there are no controlled studies that actually compare the outcomes of ACT with any standard treatment or even with the natural progression of the disease. When no improvement has been achieved using all available alternative treatments that can be performed arthroscopically, only alternatives requiring open arthrotomy and major knee surgery are available. It is possible in this case that ACT might be a reasonable consideration, particularly in cases when osteochondral allograft is not technically feasible or available to the patients and when total knee replacement is not a clinically acceptable alternative. However, empirical evidence supporting this position is limited. A temporary improvement in symptoms might delay the need for joint replacement or provide symptomatic improvement while awaiting the availability of an osteochondral allograft. However, no

conclusions on benefits and harms can be drawn from the available evidence. ([Regence BlueCross BlueShield, 2004](#))

**ODG Indications for Surgery™ -- Autologous cartilage implantation (ACI):**

*Not recommended until further studies are completed, but if used anyway, Criteria for autologous chondrocyte implantation (ACI):*

**1. Conservative Care:** Physical therapy for a minimum of 2 months. PLUS

**2. Subjective Clinical Findings:** Injured worker (IW) is capable and willing to follow the rehabilitation protocol. PLUS

**3. Objective Clinical Findings:** Failure of traditional surgical interventions (i.e., microfracture, drilling, abrasion, osteochondral graft). Debridement alone does not constitute a traditional surgical intervention for ACI. AND Single, clinically significant, lesion that measures between 1 to 10 sq cm in area that affects a weight-bearing surface of the medial femoral condyle or the lateral femoral condyle. AND Full-thickness lesion [\*Modified Outerbridge Grade III-IV] that involves only cartilage. AND Knee is stable with intact, fully functional menisci and ligaments. AND Normal knee alignment. AND Normal joint space. AND Patient is less than 60 years old. AND Body Mass Index of less than 35. [\* Modified Outerbridge Classification: I. Articular cartilage softening , II. Chondral fissures or fibrillation <1.25 cm in diameter, III. Chondral fibrillation >1.25 cm in diameter ("crabmeat changes"), IV. Exposed subchondral bone.] PLUS

**4. Imaging Clinical Findings:** Chondral defect on the weight-bearing surface of the medial or lateral femoral condyle on: MRI. OR Arthroscopy.

**ACI Exclusion Criteria:** ACI is definitely not recommended in the following circumstances: Lesion that involves any portion of the patellofemoral articular cartilage, bone, or is due to osteochondritis dissecans; A "kissing lesion" or Modified Outerbridge Grade II, III, or IV exists on the opposite tibial surface; Mild to severe localized or diffuse arthritic condition that appears on standing x-ray as joint space narrowing, osteophytes, or changes in the underlying bone; Unhealthy cartilage border; the synovial membrane in the joint may be used as a substitute border for up to 1/4 of the total circumference; Prior total meniscectomy of either compartment in the affected knee (Must have at least 1/3 of the posterior meniscal rim.); History of anaphylaxis to gentamycin or sensitivity to materials of bovine origin; Chondrocalcinosis is diagnosed during the cell culture process.

([Washington, 2003](#)) ([Bentley, 2003](#)) ([Wasiak, 2002](#))