

# IRO Express Inc.

An Independent Review Organization

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## IRO REVIEWER REPORT TEMPLATE -WC

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**DATE OF REVIEW:** OCTOBER 12, 2007

**IRO CASE #:**

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

First stage Carticel implantation

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

Board Certified Orthopedic Surgeon

**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)

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

Left knee MRI, 08/17/06 and 01/24/07

Office note, Dr., 08/15/07

Denial Letters from the URA, 8/30/07 and 09/14/07

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The claimant is a male construction worker who slipped and fell at which time he suffered a direct impact injury to his left knee. He underwent arthroscopic surgery on 08/24/06 and 02/15/07, at which time he was found to have a large chondral defect on the medial femoral condyle. First stage Carticel implantation is currently requested.

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

After a careful review of all medical records, the Reviewer's medical assessment is that the first stage Carticel implantation is not recommended as being medically necessary. This claimant, reportedly 5 feet 6 inches tall and 248 pounds and has a body mass index of 40. The Official Disability Guidelines do not recommend the requested procedure on patients with a body mass index greater than 35. No operative report defining the size and location of the lesion as well as other circumstances which might exclude the claimant from consideration of the requested procedure was provided. The X-rays noted in Dr. 08/15/07 office note date from fifteen months ago. Updated imaging studies showing to confirm that there is no generalized degenerative process in the knee would be required before consideration of the requested surgery. In general, the procedure is not recommended as it has not been proven to be an effective long term solution even though it can provide temporary improvement in symptoms and might possibly delay the need for joint replacement. As such, the requested first stage Carticel implantation is not recommended as being medically necessary for this claimant.

Official Disability Guidelines Treatment in Workers' Comp 2007 Updates: Knee – Autologous cartilage implantation (ACI)

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.

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

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)