

# P&S Network, Inc.

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## Notice of Independent Review Decision

**DATE OF REVIEW:** December 13, 2007

**IRO CASE #:**

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

**This case was reviewed by a Orthopaedic Surgery, Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.**

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

Implantation of the autologous cultured chondrocytes (Carticel)

### **REVIEW OUTCOME**

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

Overturn (Disagree)

### **INFORMATION PROVIDED TO THE IRO FOR REVIEW**

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o September 19, 2007 operative report by M.D.
- o June 27, 2007 operative report by M.D.
- o December 2003 article from Sports Medicine and Arthroscopy Review volume 11, number four entitled Autologous Chondrocyte Implantation by M.D.
- o 2007 article from Acta Orthopaedica Belgica, Volume 73-2 entitled Repair of symptomatic cartilage lesions of the knee-the place of autologous chondrocyte implantation by multiple authors
- o October 16, 2007 peer review report
- o November 13, 2007 peer review report
- o November 19, 2007 appeal letter
- o October 24, 2007 report from M.D.
- o October 23, 2007 report by M.D.
- o October 24, 2007 letter by D.C.
- o October 10, 2007 letter by D.C Care
- o July 27, 2007. September 28, 2007 chart notes from M.D.

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

According to the medical records, the patient is a male who sustained an industrial injury involving the left knee. According to an October 10, 2007 letter requesting approval for Carticel implantation, the patient has disabling knee pain with inability to perform activities of daily living. His BMI is 32.1 and he has no known allergies to gentamicin or bovine. There is a focal articular cartilage defect on the medial femoral condyle that is unipolar and is contained with near-normal surrounding articular cartilage. The defect size is 9 cm<sup>2</sup> and less than 7 mm in depth. The patient does have a stable knee and meniscus with no active inflammatory or other type of arthritis present. The procedure is not being done for the treatment of degenerative arthritis or osteoarthritis. He has reportedly failed conservative therapy for over the past several months and has undergone previous surgeries with extensive physical therapy. Previous surgeries have included a left knee arthroscopy, chondroplasty of the medial femoral condyle, resection of scar tissue, and articular cartilage biopsy in September 2007. He also underwent left knee arthroscopy, chondroplasty medial femoral condyle, partial medial meniscectomy, and removal of loose body

in the medial joint space in June 2007. Stage I cell harvest was reportedly completed in September 2006.

On October 16, 2007, a non-certification was rendered for the procedure. The reviewing physician stated that the patient has undergone medial meniscectomy and it is unclear if the patient has sufficient meniscal tissue to support a Carticel implant. Furthermore, the report states that it is unclear if the patient has any other tibial or femoral sites of defects. It should be noted that this peer review report quotes the Official Disability Guidelines regarding the osteochondral autograft transplant system (OATS).

An October 24, 2007 letter from the requesting physician states that the patient has a full-thickness chondral defect on the medial femoral condyle, grade 4 on his left knee measuring about 12 cm<sup>2</sup>. He has been complaining of pain from an acute work-related injury occurring on April 23, 2007. He underwent previous surgeries in June and September of 2007. The goal of the requested surgery is to restore a more normal surface and ultimately relieve his symptoms. The letter states that the physician is not willing to let the patient undergo another procedure that he has seen fail in the past. He enclosed literature discussing the procedure.

A November 13, 2007 peer review report also rendered a non-certification. This report notes a lesion size of 4 cm x 3 cm x 7 mm depth. The reviewer stated that the claimant essentially fits all the current guidelines for surgery with the exception of the size of the chondral defect. The reviewer stated that the current guidelines recommend less than 3 cm in diameter and 1 cm in depth. However, it should be noted that this report also referred to the Official Disability Guidelines recommendations regarding osteochondral autograft transplant system (OATS). The requesting physician's office specified that they are not requesting the OATS procedure but are requesting autologous cartilage implantation (ACI).

In reviewing relevant past records, the June 27, 2007 operative report states that the loose body was fragmented and had to be removed. It could not be reimplanted into the defect. This left the patient with about a 2-3 cm defect. It was decided that the area was too large for microfracture and since the space had a corresponding meniscal tear and had some chondral damage to the tibial plateau, he would most likely not be a candidate for autologous chondrocyte implantation. A September 19, 2007 operative report states that the patient has a large femoral condyle defect that measured about 3 x 3 cm in size. Once it was débrided, it was decided that the lesion was a candidate for chondrocyte implantation. A representative with Carticel was present at the operation and agreed.

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

Medical records contain a discrepancy in the form of the size of the osteochondral lesion. Some sources state that it is 12 cm<sup>2</sup> and others state that it is 9 cm<sup>2</sup>. The operative report and indications for the requesting physician point to the 9 cm<sup>2</sup> sized being more likely. However, I disagree with the previous peer review physician that stated that the lesion is too large for the guidelines as the incorrect guidelines (OATS) were cited. The Official Disability Guidelines (ODG) regarding autologous cartilage implantation state that the lesion should measure between 1 to 10 sq cm in area. In addition, this patient is young, has a significant lesion, and is a good candidate for the procedure. He certainly has failed extensive treatment to date. The size of the lesion is always in question because it is an estimate based on the arthroscopic view. Therefore, I recommend to overturn the decisions to non-certify the request for implantation of the autologous cultured chondrocytes (Carticel).

The IRO's decision is consistent with the following guidelines:

**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 KNOWLEDGBASE

\_\_\_\_ 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

\_\_\_\_x\_\_\_\_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

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)