MEDICAL CONTESTED CASE HEARING NO 09147
M6-09-16882-01

DECISION AND ORDER

This case is decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and Rules of the Division of Workers' Compensation adopted thereunder.

ISSUE

A contested case hearing was held on April 16, 2009, to decide the following disputed issues:

1. Is the preponderance of the evidence contrary to the decision of the Independent Review Organization that Claimant is not entitled to a knee arthrotomy with autologous cultured chondrocyte implantation for the compensable injury of _____?

PARTIES PRESENT

Petitioner/Claimant appeared, and was represented by MS, attorney. Respondent/Carrier appeared, and was represented by RG, attorney.

BACKGROUND INFORMATION

Claimant, on _____, injured his left knee when he stepped out of an elevator that was not at the same height as the floor he was stepping onto. He has been treated by Dr. BM for pre and post-injury problems. Pre-injury, on January 14, 2005 Dr. BM performed left knee arthroscopic cartilage harvesting for re-implantation at a later date. On April 15, 2005, Dr. BM performed an open exploration of the left knee with autologous chondrocyte implantation (ACI) filling the unstable OCD defect. Then the incident with the elevator occurred. Post-injury, on November 4, 2005, Dr. BM performed left knee diagnostic arthroscopy with debridement since the autologous chondrocyte implant had delaminated and separated from the underlying bone. On January 25, 2008 Dr. BM performed another diagnostic arthroscopy with chondroplasty of medial femoral condylar placement. In February 2008 the second ACI surgery was approved but had an expiration date of April 4, 2008. Claimant was not able to have the surgery as scheduled due to a dispute of his claim. Based upon a Benefit Dispute Agreement dated August 8, 2008 the parties agreed that the compensable injury extended to include the clinical findings of a large bulbous lesion/flap of fibrous tissue from graft hypertrophy per the June 11, 2008 report of the designated doctor, Dr. JC. Dr. BM then requested an extension for the prior surgery authorization.

On September 10, 2008 Dr. RS denied the requested surgery stating that there was insufficient clinical information to support the request. On September 28, 2008 Claimant returned to Dr. BM with increased crepitation and swelling in the left knee. Dr. BM again recommended left knee ACI. On October 7, 2008 Dr. GG denied the reconsideration for the requested surgery stating that ACI only has been seen as an alternative option.

On November 24, 2008 an Independent Review Organization (IRO) denied the requested procedure. In its denial, the IRO Reviewer, a board certified orthopedic physician, reported that the surgery remains investigational based on the evidence based ODG. But the IRO Reviewer added that although investigational, Claimant did fall within the criteria for the surgery if deemed reasonable. Claimant met the criteria on age, full thickness cartilaginous defect, absence of structural instability of the knee, a reasonable body mass index, and failed previous conservative care. But the IRO Reviewer went on to state that: "the only concern in this particular case regarding the indication for surgery would be the fact that this injury aggravated and/or substantially changed the course of that particular procedure. The alternative scenario, however, is the fact that the previous procedure failed and thus the findings to second look arthroscopy were not traumatic in nature but rather a result of the failure of the previous ACI." The IRO Reviewer used the Official Disability Guidelines (ODG) as the basis of the screening criteria.

DISCUSSION

Section 408.021 of the Texas Labor Code provides that an employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed. Section 401.011(22-a) defines health care reasonably required as "health care that is clinically appropriate and considered effective for the injured employee's injury and provided in accordance with best practices consistent with: (A) evidence based medicine; or (B) if that evidence is not available, generally accepted standards of medical practice recognized in the medical community." "Evidence based medicine" is further defined, by Section 401.011(18-a) as the use of the current best quality scientific and medical evidence formulated from credible scientific studies, including peer-reviewed medical literature and other current scientifically based texts, and treatment and practice guidelines in making decisions about the care of individual patients.

In accordance with the above statutory guidance, the Division of Workers' Compensation has adopted treatment guidelines by Division Rule 137.100. This rule directs health care providers to provide treatment in accordance with the current edition of the Official Disability Guidelines (ODG), and such treatment is presumed to be health care reasonably required as defined in the Texas Labor Code. Thus, the focus of any health care dispute starts with the health care set out in the ODG.

With regard to autologous cartilage implantation (ACI), the ODG sets forth the following:

> "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 ACI 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 ACI 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)"

The initial inquiry in any dispute regarding medical necessity is whether the proposed care is consistent with the ODG. As noted, the ODG lists exclusion criteria and specifically states that ACI is definitely not recommended for a lesion that involves any portion of the patellofemoral articular cartilage, bone, or is due to osteochondritits dissecans. The lesion to be addressed in the instant cases involves not only cartilage but also bone that has been affected by previous surgeries. On September 10, 2008, based upon a review of the records, Dr. RS diagnosed Claimant with chondromalacia of the patella, unspecified internal derangement, and osteochondritis dissecans. Claimant presented medical studies, supported by the testimony of Dr. BM, to show that patients who have had the ACI procedure have done well. But these studies do not specifically address Claimant's situation wherein the original ACI failed, due to an aggravating incident. The IRO report is supported by Dr. G who testified that he had talked with a representative at the (name), the qualified trainer of the ACI procedure, and was told that when a first ACI procedure was unsuccessful, a second ACI procedure would not be recommended. Since Claimant's medical records do not demonstrate the criteria as set forth by the ODG, and Claimant has been unable to show through evidence-based medicine that the requested procedure justifies a departure from the ODG, a decision in Carrier's favor is appropriate with respect to the medical necessity issue presented for resolution herein.

Even though all the evidence presented was not discussed, it was considered. The Findings of Fact and Conclusions of Law are based on all of the evidence presented.

FINDINGS OF FACT

1. The parties stipulated to the following facts:

   A. Venue is proper in the (City) Field Office of the Texas Department of Insurance, Division of Workers' Compensation.

   B. On _____, Claimant was employed by (Employer).

   C. On _____ Claimant sustained a compensable injury.

   D. The Independent Review Organization (IRO) determined that the requested service of a knee arthrotomy with autologous cultured chondrocyte implantation was not reasonable and necessary health care for Claimant's compensable injury of _____.

2. Carrier delivered to Claimant and Provider a single document stating the true corporate name of Carrier, and the name and street address of Carrier's registered agent, which document was admitted into evidence as Hearing Officer's Exhibit Number 2.

3. Dr. BM recommended that Claimant undergo a second left knee arthrotomy with autologous cultured chondrocyte implantation.

4. The ODG does not recommend the requested procedure for a lesion that involves any portion of the patellofemoral articular cartilage, bone, or is due to osteochondritis dissecans.

5. Claimant's injury involves the cartilage and bone, with a diagnosis of osteochondritis dissecans.

6. The evidence based medical literature in evidence does not address the medical necessity nor effectiveness of a repeat ACI procedure if the first ACI procedure was unsuccessful.

7. A knee arthrotomy with autologous cultured chondrocyte implantation is not health care reasonably required for Claimant's compensable injury of _____.

CONCLUSIONS OF LAW

1. The Texas Department of Insurance, Division of Workers' Compensation, has jurisdiction to hear this case.

2. Venue is proper in the (City)Field Office.

3. The preponderance of the evidence is not contrary to the decision of the Independent Review Organization that a knee arthrotomy with autologous cultured chondrocyte implantation is not health care reasonably required for the compensable injury of _____.

DECISION

Claimant is not entitled to a knee arthrotomy with autologous cultured chondrocyte implantation for the compensable injury of _____.

ORDER

Carrier is not liable for the benefits at issue in this hearing. Claimant remains entitled to medical benefits for the compensable injury in accordance with §408.021.

The true corporate name of the insurance carrier is **AMERICAN CASUALTY COMPANY OF READING, PENNSYLVANIA** and the name and address of its registered agent for service of process is

CT CORPORATION SYSTEM
350 NORTH ST. PAUL STREET
DALLAS, TEXAS 75201

Signed this 22nd day of April, 2009.

Judy L. Ney
Hearing Officer