MEDICAL CONTESTED CASE HEARING NO. 09020

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.

ISSUES

A contested case hearing was held on September 25, 2008, to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the IRO that the autochondrocyte implant (ACI) knee with a tibial tubercle osteotomy is not reasonably necessary heath care for the compensable injury of _____?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by SR.
Respondent/Carrier appeared and was represented by TW, attorney.

BACKGROUND INFORMATION

Claimant and his treating doctor, Dr. JB, M.D., testified at the September 25, 2008, CCH. Claimant is 38 years-old and an eleven-year veteran senior corporal with the (Employer). On _____, Claimant was attempting to arrest a suspect when he twisted his knee, it popped, and the suspect fell onto his right knee. A February 6, 2008, MRI right knee revealed patellar dislocation-relocation osteochondral impaction pattern with complete disruption of the medial patellofemoral ligament. On March 21, 2008, Claimant underwent patellar chondroplasty of the right knee for his diagnoses of patellar dislocation of right knee; patellar chondromalacia of the right knee; and patellar malalignment of right knee. In the operative report, Dr. JB noted that the recent traumatic dislocation had created new traumatic chondromalacia changes, and that there were several small fragments of articular cartilage found within the joint. Dr. JB also noted that because of the significant injury to the patella, the Claimant underwent articular cartilage biopsy, which meant that several fragments of the articular cartilage were harvested.

On August 26, 2008, Dr. MVH, M.D., examined Claimant, and his impression was of chondral change of significance down to basically grade IV in areas of the patella. Dr. MVH discussed the options Claimant had. Dr.MVH noted that at age 38, there were no joint replacement procedures that were worthy of consideration for Claimant. He opined that the issue really boiled down to whether or not to proceed with the cartilage transfer implantation technique. According to Dr. MVH, the patella joint is one of the most difficult areas to get this to work although the new advances have suggested that the patella cartilage is now more amenable to implantation. He then opined that although there is no long-term follow-up data available for review from multiple sources, there are some early studies that suggest this is a worthwhile procedure. Dr. MVH's report then stated that whether Claimant was going to be able to return to the arduous task of being a police officer on patrol was dubious, but that he would agree that a

trial of the cartilage implantation transfer was the next reasonable intervention rather than just watching and hoping.

Dr. JB recommended Claimant undergo an autologous chondrocyte implantation of right knee, and an anterior tibial tubercleplasty. The procedure was denied, and the request for reconsideration was also denied. An IRO was requested and on July 21, 2008, the IRO upheld the previous adverse determination. In the IRO determination, it was noted that the case was reviewed by a Board Certified orthopedic surgeon. In the "Analysis and Explanation" section of the IRO determination, the IRO reviewer explained:

> As noted in the references, the Official Disability Guidelines do not recommend autologous cartilage implantation. The guidelines repeat this recommendation against the procedure, however, provide criteria that must be met if the procedure is to be done despite the negative recommendation. The guidelines then list exclusion criteria and specifically state that ACI is definitely not recommended for a lesion that involves any portion of the patellofemoral articular cartilage, bone, or is due to osteochondritis dissecans. The lesion to be addressed in this case involves the patellofemoral articular cartilage. Based on the Official Disability Guidelines, there is no medical justification for proceeding with this procedure. Therefore, my determination is to uphold the previous non-certification.

According to the Official Disability Guidelines (2008) Knee Chapter:

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 that ACI is more effective than other conventional 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 harm 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: 1. 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).

Dr. JB, the recommending physician, testified at the CCH. Dr. JB explained that he has suggested Claimant undergo what is called an autologous chondrocyte implantation which is an implantation of cultured chondrocytes. Claimant has already had a biopsy, meaning that he had a piece of articular cartilage harvested from his knee. This was sent to a special laboratory in Boston where more cartilage cells were grown/cultured, and in a second operative procedure he is to have these implanted into the defect in his kneecap. Dr. JB also testified that along with that operation he is also to have a tibial tubercle osteotomy which is to elevate and transfer the tibial tubercle which means it realigns the tibial tubercle up and to the inside; the reason for that part of the operation is that the original operations done on the patella, which were done 10 and 15 years ago, had a relatively poor success rate of about 62%, and since the need for the tibial tubercle osteomy has been recognized, those success rates have gone up to now to 87 to 89%.

Dr. JB was asked why he had recommended this particular treatment for the Claimant. Dr. JB testified as follows:

> The defect in his kneecap is a traumatic injury to the kneecap. The defect measured at arthroscopy is approximately 2.5 cm x 3.0 cm. It is larger than could be addressed by any of the options available.

Dr. JB testified that it was his understanding that the ODG do not recognize the procedure in the kneecap, and he said that he thought that was significantly misleading because of several things: 1) the Guidelines state that debridement and lavage alone do not constitute a traditional surgical intervention for ACI. He opined that is outdated because the FDA has now approved a study called the "Star Study," which is a study for treatment of articular cartilage. That study was accepted by the FDA in January of this year. It specifically states that debridement is a first-stage treatment for cartilage injuries. The Star study is published by Genzyme Corporation and should come out formally in the literature probably in the fourth quarter of this year. He did not have a copy of the literature submitted for publication, but he had a synopsis of the study.

Dr. JB was asked to address evidence-based medicine with regard to the proposed treatment. He opined that evidence-based medicine is difficult because evidence-based medicine presumes that you have a study on the right hand and a control on the left. In his opinion, it would be difficult and perhaps unethical to create a controlled study with cartilage cells. The reason for that is – a controlled study would be sort of a placebo study – it would be almost unethical to make an incision in a patient's knee go in and do nothing and then see if that works as opposed to making an incision in a patient's knee doing something such as implanting cartilage cells and seeing if that works. So the evidence-based study would be a very difficult almost impossible study to do for that reason. Therefore all the evidence for the efficiency of the operative procedure is a retrospective study on patients who have already had the procedure and how well they have done.

When asked if he had reviewed the IRO decision, Dr. JB testified that he had not read it, but that his understanding of the denial is that they are denying it on the basis of it is the patellofemoral joint. He opined that Claimant has an isolated injury to the patella not the patellar femoral so this is not a kissing lesion (it is not the top and bottom of that joint); it is just the kneecap. This is a traumatic injury, meaning he has a well-defined history of injury; his kneecap was knocked out of place and when it went back into place he knocked off a piece. It is a well-defined injury it is therefore by definition traumatic and not degenerative; he is young man with a high level of activity; the injury is too large to be adaptable to any of the other various options available to orthopedic surgeons in today's medicine; and the recent literature as recently as 2002 where you do have published articles on the patellofemoral joint show that the patella with appropriate realignment procedures is a very successful operation upwards of the high 80's in percentile. So for those reasons this patient should have the operation. Then he opined that if the Claimant did not have the operation the lesion because it is so large will progress to an arthritic problem, will deteriorate and cause the other side of the joint, the notch of the joint, the trochlea to be further injured.

When asked if he had performed the procedure, Dr. JB testified that he has been trained in the procedure, had performed the procedure often, and the latest statistics show him to be the 8th number surgeon in volume in the U.S., he lectures and teaches the procedure, and he is on the lecture board for the Genzyme Corporation.

Dr. JB also testified that the Star Study was done on failed knees, and had a 76% success rate. The study was authorized by the FDA and the Genzyme Corporation coordinated the study. He is on the speaking bureau for the corporation. He testified that the Star Study in January changed all the rules. He also testified that the study had not yet been published in the literature. Claimant's lesion is on the kneecap, the patella; and he testified that the ODG did not recommend ACI because it is outdated.

The initial inquiry in any dispute regarding medical necessity is whether the proposed care is consistent with the ODG. All of the credible evidence submitted and considered in the instant case leads to the conclusion that the requested procedure is not consistent with the ODG. Dr. JB testified at length about how he disagreed with the ODG and the IRO determination and referenced an unpublished study called the "Star Study" – see Hearing Officer Exhibit 3. The "Star Study" is actually entitled "Star: A Comprehensive Study" – and is subtitled "The Study of the Treatment of Articular Repair (STAR), and it was designed to determine the safety and effectiveness of CARTICEL in patients who had an inadequate response to a prior repair procedure." According to the Star Study, "CARTICEL" (autologous cultured chondrocytes) is a registered trademark of Genzyme Corporation and is for autologous use and is indicated for the repair of symptomatic cartilage defects of the femoral condyle (medial, lateral or trochlea), caused by acute or repetitive trauma where there has been 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.

As noted in the IRO determination, the ODG list exclusion criteria and specifically state that ACI is definitely not recommended for a lesion that involves any portion of the patellofemoral articular cartilage, bone, or is due to osteochondritis dissecans, and the lesion to be addressed in the instant case involves the patellofemoral articular cartilage. Although Dr. JB testified that the lesion is on the kneecap, the patellofemoral ligament is noted on the MRI as being completely disrupted. In his operative report of March 21, 2008, Dr. JB noted that Claimant had a traumatic injury to the articular surface of the patella through the medial and lateral facets. The Claimant had articular cartilage damage down to a very thin layer of cartilage in some areas, and the medial facet was down to subchondral bone. The patella appeared to have been riding up and onto the lateral femoral condylar area, with some relative misshapening of the patella. There were several small fragments of articular cartilage found within the joint. The patellofemoral joint was first evaluated through the anterior lateral portal, and the patella was noted to ride through the lateral side and was subluxed. Debridement of the lesion was made down to a stable layer of articular cartilage.
Claimant has been unable to show through evidence-based medicine that the requested procedure is health care reasonably required by the nature of the compensable injury. The IRO determination against the procedure is upheld.

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 the employee of (Employer), and sustained a compensable injury.

2. Carrier delivered to Claimant 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. JB has recommended an autochondrocyte implant knee (ACI) with a tibial tubercle osteomy for Claimant's injured right knee, which includes a lesion that involves a portion of the patellofemoral articular cartilage.

4. The ODG does not recommend the requested procedure, and specifically state the procedure is definitely not recommended for a lesion that involves any portion of the patellofemoral articular cartilage.

5. The IRO upheld the Carrier's denial of the requested procedure.

6. Claimant's treating doctor relied on an unpublished "Star Study" for support of the procedure.

7. The autochondrocyte implant knee (ACI) with a tibial tubercle osteomy is not health care reasonably required for the 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 IRO that the autochondrocyte implant knee (ACI) with a tibial tubercle osteomy is not health care reasonably required for the compensable injury of _____

DECISION

Claimant is not entitled to the autochondrocyte implant knee (ACI) with a tibial tubercle osteomy 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 **(EMPLOYER)** and the name and address of its registered agent for service of process is:

SHIRLEY ACY, CITY SECRETARY
1500 MARILLA 5D SOUTH
DALLAS, TEXAS 75201

Signed this 9th day of October, 2008

Cheryl Dean
Hearing Officer