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Notice of Independent Review Decision

DATE OF REVIEW: July 21, 2008

IRO CASE #:

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

This case was reviewed by an Orthopedic Surgeon, 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

Autochondrocyte implant knee with a tibial tubercle osteotomy

REVIEW OUTCOME

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

Upheld (Agree)

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 February 5, 2008 through June 23, 2008 utilization review reports from IMO and e-mail correspondence between and
- o April 3, 2008 and April 9, 2008 physical therapy notes from
- o February 6, 2008 MRI report by , M.D.
- o March 21, 2008 operative report from
- o February 6, 2008 through May 1, 2008 records from
- o February 4, 2008 through February 20, 2008 records from
- o June 3, 2008 appeal information from
- o March 31, 2008 approval request from
- o June 11, 2008 appeal letter from M.D.
- o Undated text excerpt from and and Related Research entitled Improves Patellofemoral Cartilage Treatment Outcomes by , M.D.
- o May 7, 2008 appeal letter from , M.D.
- o Undated article from Acta Orthopaedica Belgica, Vol 73-2-2007 entitled Repair of symptomatic cartilage lesions of the knee The place of autologous chondrocyte implantation
- o May 8, 2008 appeal letter and information from

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records, the patient is a xx year-old male who sustained an industrial injury on xx/xx/xx involving the knee. According to a June 6, 2008 adverse determination letter, the patient injured the right knee for which he underwent right knee arthroscopy in March 2008 and was found to have a patellar defect and underwent articular cartilage biopsy. Specifically, the patient was found to have articular cartilage damage of the patella through the medial and lateral facets. The patient had articular cartilage damage down to a very thin layer of cartilage in some areas. In the medial facet, the patient was down to subchondral bone. Following debridement of both the medial and lateral facets, the patient had a defect of the patella measuring 2.5 x 3.0 cm. There were several small fragments of articular cartilage found within the joint. They were not large, but were indicative of the traumatic patellar chondromalacia and the injury to the articular surface of the patella.

A March 31, 2008 letter requesting the above-captioned procedure states that the patient presents with symptoms of disabling knee pain related to a full-thickness defect as stated in the clinical notes. The letter states that the patient's BMI is 29.4. He has no known allergies to gentamycin or bovine. There is presence of disabling knee pain, popping, swelling, and disability. There is a focal articular cartilage defect on the patella that is unipolar and is contained with near-normal surrounding articular cartilage. The defect size is 7.5 square cm and it is less than 7 mm in depth. The patient has a stable knee and meniscus. There are no active inflammatory or other arthritic conditions present. The procedure is not being done for the treatment of degenerative arthritis or osteoarthritis. The patient has failed conservative therapy over the previous two months. He has undergone a previous surgery and has had extensive physical therapy along with conservative daily living activities. The patient is informed and willing to comply with the postoperative weight bearing and activity restrictions and postoperative rehabilitation.

The MRI scan of the knee, dated February 6, 2008, revealed a patellar dislocation-relocation osteochondral impaction with grade 1 medial collateral ligament sprain and moderate knee effusion. The claimant is noted to have had extensive conservative care, including physical therapy and continues with knee pain and disability. The request has been made for performance of the procedure to correct the chondral defect. The request was non-certified on June 6, 2008 as it was deemed investigational with the effectiveness yet to be determined.

The request was again non-certified on June 10, 2008 by another reviewer as no additional clinical information was provided. Again, the reviewer stated that the procedure is considered investigational per the current guidelines.

A June 11, 2008 appeal letter states that despite numerous and persistent efforts, the patient's condition deteriorated significantly and more aggressive intervention was mandated. The letter states that the patient has been an active, healthy worker his entire life. He has had extensive physical therapy with no resolution of knee pain. He has early onset of osteoarthritis, which can lead to early total knee replacement.

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

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-certifications.

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 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

__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

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 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)