MEDICAL REVIEW OF TEXAS

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Notice of Independent Review Decision

DATE OF REVIEW: SEPTEMBER 14, 2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
Right knee ConforMIS implant

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION
MD, Board Certified in Orthopedic Surgery

REVIEW OUTCOME

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

X Upheld (Agree)

☐ Overturned (Disagree)

☐ Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

* MRIoA reviews [8/6/07, 8/15/07]; MD correspondence
* Preliminary report regarding experience with the ConforMIS knee device apparently presented at the Society 52nd annual meeting in March 2006
* MD notes [4/06 – 8/07]; ConforMIS correspondence [8/2/07, 7/23/07]; Hospital [7/25/07]; Hospital [8/31/06]; Nydic correspondence [9/7/06]; Consultants in Radiology [11/18/04]
* denial letter [8/7/07, 8/16/07]

PATIENT CLINICAL HISTORY [SUMMARY]:

This individual apparently sustained a work-related injury to the right knee. Initial arthroscopic surgery was done on 2/24/05 by Dr. This demonstrated grade 3 chondromalacia of the medial femoral condyle and a full thickness cartilaginous loss of the patella, which were treated with arthroscopic debridement and abrasion arthroplasty on the patella. A second operation was done on 8/31/06 for decompression of the common peroneal nerve due to nerve entrapment. Clinical records from Dr. indicate that he saw the patient on multiple occasions between 4/7/06 and August 2007. She was treated with multiple modalities including anti-inflammatory medications, unloader bracing, viscosupplementation, and intra-articular steroid injections and had persistent complaints of medial knee pain. Dr. corresponded regarding the proposed surgery indicating that the claimant's symptoms were on the medial side of the joint and the fact that she did not have any patellofemoral symptoms substantiated his opinion that the interpositional device was a reasonable surgical alternative as it was minimally invasive and his opinion based on his experience would help relieve her medial knee pain.

Previous reviews by Dr. and Dr. indicated that in their opinion the device was not indicated due to the fact that it was experimental and investigational and that the claimant also had patellofemoral arthritic changes.

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

INFORMATION FROM CONFORMIS INCLUDED IN THE INDEPENDENT RADIOLOGICAL REVIEW REPORT INDICATES THAT THE SURGICAL INDICATIONS FOR THE CONFORMIS IFORMA IMPLANT INCLUDE TREATMENT OF OSTEOARTHRITIS IN THE KNEE OF A MODERATE DEGENERATIVE NATURE OF THE MEDIAL OR LATERAL COMPARTMENT WITH GRADE 2 THROUGH GRADE 4 CHONDROMALACIA AND MINIMAL DEGENERATION GRADE 1 THROUGH GRADE 2 CHONDROMALACIA OF THE PATELLOFEMORAL JOINT SPACE. REVIEW OF RECORDS FROM THIS CASE INDICATES THAT AT THE TIME OF INITIAL ARTHROSCOPY, THE PATIENT HAD A FULL THICKNESS CARTILAGINOUS LOSS OF THE PATELLA, WHICH WOULD QUALIFY AS AT LEAST A GRADE 3 LESION. THEREFORE, BASED UPON THE RECOMMENDATIONS OF THE MANUFACTURER, THE SURGERY WOULD NOT MEET THE STANDARD INDICATIONS DUE TO THE PATELLO-FEMORAL CHANGES NOTED AT THE FIRST ARTHROSCOPY.

ADDITIONALLY, THERE IS INSUFFICIENT EVIDENCE REGARDING THE LONG-TERM EFFICACY OF THE IMPLANT. THERE WERE NO LONG-TERM STUDIES WITH LONG-TERM FOLLOW-UP TO REFERENCE, WHICH WERE EVIDENCE-BASED, SUGGESTING THAT THE IMPLANT IS SAFE AND EFFECTIVE. THE ONE REPORT FROM THE MEDICAL LITERATURE CITED ABOVE DEMONSTRATED ONLY VERY SHORT-TERM FOLLOW-UP OF 8

PATIENTS. THIS REPORT WAS A PRELIMINARY REPORT AND DUE TO THE SMALL NUMBER OF PATIENTS AND LIMITED FOLLOW-UP TIME, IT WOULD NOT MEET THE CRITERIA OF CONFIRMING THE LONG-TERM EFFICACY OF THE IMPLANT. ADDITIONALLY, IT IS NOTED THAT DR. SLIGAR'S PREVIOUS EXPERIENCE WITH THE UNISAVER IMPLANT HAVE BEEN DISAPPOINTING. THIS IS A SIMILAR CONCEPT WITH THE INTERPOSITION OF WEIGHT BEARING MATERIAL BETWEEN THE FEMORAL CONDYLE AND THE TIBIAL PLATEAU. HOWEVER, THIS DEVICE HAS NOT BEEN SHOWN TO BE EFFECTIVE AND PREVIOUS STUDIES HAVE BEEN DISAPPOINTING AS NOTED BY DR. SLIGAR IN THE ARTICLE, *THE BONE AND JOINT SURGERY*, AUGUST 1, 2005, VOLUME 87.

THEREFORE, BASED UPON CURRENT MEDICAL KNOWLEDGE REGARDING THE EFFECTIVENESS OF THIS IMPLANT, THE PROPOSED SURGERY DOES NOT HAVE EVIDENCE-BASED SUPPORT. FURTHERMORE, THE PATELLOFEMORAL JOINT CHANGES ARE A CONTRAINDICATION TO THE IMPLANT AS NOTED IN THE MANUFACTURER'S INFORMATION REGARDING INDICATION FOR SURGERY.

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**
- X **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**

X **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE**

* *THE BONE AND JOINT SURGERY*, AUGUST 1, 2005, VOLUME 87

X **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**

* **CONFORMIS PRODUCT INFORMATION WEB SITE**