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Notice of Independent Review Decision

DATE OF REVIEW: November 24, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
Knee arthrotomy with autologous cultured chondrocyte implantation (27412)

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION
Board Certified Orthopedic Surgeon

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

☒ Upheld (Agree)

Medical documentation **does not support** the medical necessity of the health care services in dispute.

ODG have been utilized for denials.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a xx-year-old male who injured his left knee on xx/xx/xx. He was stepping out of an elevator that was not at the same height as the floor he was stepping onto. This jammed his left knee a little bit and it got very swollen.

PRE – INJURY RECORDS: In xx/xxxx, the patient struck his left knee on the computer desk impacting the anteromedial aspect of the knee. He came under the care of , M.D. Magnetic resonance imaging (MRI) of the left knee revealed osteochondritis dissecans (OCD) lesion of the medial femoral condyle. On December 17, 2003, Dr. performed diagnostic arthroscopy of the left knee and open reduction internal fixation (ORIF) of OCD fragment of the medial femoral condyle. The patient completed physical therapy (PT) and attained full ROM. On February 27, 2004, Dr. performed a diagnostic left knee arthroscopy with removal of hardware and chondroplasty of the medial femoral condyle. The patient attended PT but remained persistently painful over the medial femoral condyle. MRI of the left knee showed apparent healing of the OCD fragment.

On January 14, 2005, Dr. performed left knee arthroscopic cartilage harvesting for reimplantation at a later date. On April 15, 2005, Dr. performed open exploration of the left knee with autologous chondrocyte implantation filling the unstable OCD defect.

In xxxx, the patient slipped and fell injuring his left knee. MRI of the left knee revealed postsurgical changes related to Carticel procedure in the lateral aspect of the medial femoral condyle, mild reactive bone marrow edema adjacent to this area, moderate-to-large joint effusion, some synovitis, and some nonspecific periarticular soft tissue edema. The patient was continued on ACI protocol.

POST – INJURY RECORDS

2005: In September, the patient was seen by Dr. for stiffness and inability of to fully extend and flex the left knee. On November 4, 2005, Dr. performed left knee diagnostic arthroscopy with debridement of the hypertrophic graft of the medial femoral condyle. The patient was recommended postoperative PT.

2006: , M.D., performed a required medical evaluation (RME) and opined as follows: (1) The patient sustained injury to his left knee on xx/xx/xxxx, and aggravated his pre-existing OCD injury to his left knee. (2) The medical condition caused by this injury on xx/xx/xxxx, had resolved either via time or through the fifth arthroscopic surgery. (3) No medical condition besides the initial condition claimed naturally arose from the xx/xx/xxxx, incident. The patient's ongoing pain, locking, catching, and dysfunction were related to the original injury on xx/xx/xx, and/or the subsequent surgeries he had. None of the patient's current medical problems were causally related to the work incident of xx/xx/xx. (4) The fact that the patient had increased swelling after the alleged injury of xx/xx/xxxx, might represent an aggravation or was just coincidental and presented either a failed Genzyme or a prior injury of xx/xxxx. The treatment and surgeries were reasonable and necessary to treat the injuries. (5) A reasonable future treatment would be occasional use of anti-inflammatory medications and nonnarcotic analgesics. A series of three Synvisc injections might be reasonable. The patient might go on to have significant arthritis of his medial joint space requiring future operative interventions to include a replacement, osteotomy, or future allograft implantation. However these treatments would be directly related to the xx/xxxx injury. (6) The patient could work in full unrestricted activity as a blue collar worker.

Dr. too agreed that the patient's problem was an aggravation of a pre-existing work-related condition and thus should be cared for under the same injury previsions and insurance that took care of the original surgery.

2007: Dr. opined that the patient sustained an aggravation of his prior asymptomatic left knee OCD injury and not an exacerbation.

Dr. noted the patient had persistent pain, swelling, and crepitations in the left knee. The debridement of hypertrophic graft indicated the graft had failed. He recommended another ACI.

2008: On January 25, 2008, Dr. performed a diagnostic arthroscopy with chondroplasty of medial femoral condylar placement.

, M.D., performed a peer review and opined as follows: (1) None of the current complaints could be related to the xxxx incident because there was no objective evidence of any injury or any aggravation of previous pathology that could possibly be attributed to that incident. There was no evidence of any enhancement, acceleration, or worsening of the pre-injury condition beyond a

mere manifestation or flare-up in pain that could be attributed to the compensable event in xxxx. (2) Office visits, PT, and further surgery would not be reasonable and medically necessary and related to the xxxx incident because the effects of that injury had resolved.

In January, Dr. opined that when the patient recovered from his arthroscopy, he would proceed with ACI.

In June, , M.D., a designated doctor, opined: (1) The patient was not at MMI as he still had definite symptoms in his knee and these were related to the injury of xx/xx/xx. (2) The compensable injury of xx/xx/xxxx, extended to the previous surgical area where the OCD was treated and involved the medial femoral condyle with elevation of the periosteal flap over the previously implanted autologous cartilage cells. (3) He could return to work with restrictions.

On September 10, 2008, M.D., denied the request for arthrotomy with autologous cultured chondrocyte implantation with following rationale: *"There is insufficient clinical information provided to support this request. The patient is noted to have undergone multiple surgeries to the left knee including a previous autologous chondrocyte implant in April 2005. Most recently, the patient underwent left knee surgery in January 2008 for chondrocyte harvest. Progress note dated January 31, 2008, indicates that the patient was found at that time of surgery to not have any additional damage to the knee other than the medial femoral condyle. The recommendation was for the patient to proceed with repeat autologous chondrocyte implantation after recovering from his arthroscopy. No subsequent progress notes for the past seven months were provided indicating current status. Without additional clinical data, the proposed surgical procedure cannot be certified as medically necessary at this time".*

On September 29, 2008, the patient returned to Dr. for left knee pain. There was crepitation and activity related swelling. The symptoms were worse when standing, sitting, climbing stairs, moving, and walking. Examination revealed antalgic gait, minimal effusion, tenderness over the medial knee, and patellofemoral crepitus. He recommended left knee autologous chondrocyte implantation (Genzyme).

On October 7, 2008, , M.D., denied the appeal for the arthrotomy with autologous cultured chondrocyte implantation with the following rationale: *"In recent years the surgical implantation of health cartilage cells (autologous cartilage implantation 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. Based on the clinical information submitted to this review and using the evidenced-based, peer-reviewed guidelines referenced above, this request for arthrotomy with autologous cultured chondrocyte implantation is not medically necessary."*

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

The following is made in consideration of the evidence based ODG guides as it pertains to recommendations for autologous chondrocyte implantation.

The surgery would remain investigational based on the evidence based guides. According to the ODG the procedure ACI is still considered investigational. To that extent there is no medical necessity for the ACI procedure in this case.

Of note, however, within the ODG guides there are comments made regarding criteria for individuals for this particular procedure if deemed reasonable. This individual, by reports, would appear to fall within those reasonable criteria based on age, full thickness cartilaginous defect, absence of structural instability of the knee and a reasonable body mass index. This individual has also failed previous conservative care. Thus, although investigational, this individual would appear to meet those reasonable criteria within ODG. Of note, the only concern in this particular case regarding the indication for surgery would be the fact that this individual already underwent an ACI procedure in that compartment. Reportedly the 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. Obviously one could not make that statement with certainty but that may in fact be the more reasonable scenario based on what appeared to be a relatively benign injury in xxxx.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**