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Notice of Independent Review Decision

August 9, 2012

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Left knee scope, loose body removal and synovectomy

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:
☒ Partially Overturned (Agree in part/Disagree in part)

Medical documentation **partially supports** the medical necessity of the health care services in dispute.

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

PATIENT CLINICAL HISTORY [SUMMARY]:
The patient is a male who on xx/xx/xx, was pulling slips off of a pipe while working. He felt something pop in his left knee and had immediate swelling. He stated that he had to jump back to his truck on one leg.

On June 19, 2012, the patient was evaluated by D.O., for left knee pain, locking, instability, decreased range of motion (ROM) and nighttime pain. He was utilizing crutches in a long leg immobilizer. History was positive for open reduction internal fixation (ORIF) of a left femur fracture due to a motor vehicle accident (MVA). Examination revealed mild effusion on the knee, significant loss of motion, inability to manipulate the knee due to pain and medial joint line pain. X-rays of the left knee revealed rod through the middle and distal portion of the femur with two locking screws, degenerative changes in the medial femoral condyle affecting the medial joint space, two large osteochondral loose bodies through the superolateral aspect of the joint which were roughly the size of a quarter and two

large pieces on the anteroposterior and lateral views of the knee. Dr. was worried about an anterior cruciate ligament (ACL) tear in addition to the large loose bodies with the joint. He ordered magnetic resonance imaging (MRI), prescribed small dose of Norco and recommended nonweightbearing in a long leg splint.

On June 21, 2012, MRI of the left knee revealed a complex joint effusion; large osteochondral defects within the medial compartment, at least two of these involving the medial femoral condyle and a third involving the anterior tibial plateau; donor sites visualized on image #14 and 15 of 20, sagittal T2 data set and the orphaned pieces of cartilage/articular surface were identified floating about within the fluid superior to the patella; the larger of these measured about 3.7 cm in maximal long axis by about 6-7 mm A to P; the smaller one measured about 2.7 cm in long axis by about 8 mm. There were smaller loose bodies present superiorly. The medial trochlea was slightly hypoplastic with grade 4 chondromalacia medial trochlea and a prominent trochlear lesion; much of the medial compartment was virtually bone-on-bone. Additional small loose bodies were present posteriorly within the joint, identified on image #13 of 20, series #3 where a loose body measured about 12 mm. There was bursal prolapse or Baker's cyst measuring about 3.7 cm x 2.1 cm. The posterior horn medial meniscus was diminutive and there was horizontal oblique tear thought present within the remainder of posterior horn. There was truncation or foreshortening of the inner one-third to one-half of body medial meniscus possibly on the basis of prior tear versus meniscal lysis. Evaluation of the lateral meniscus revealed subtle horizontal oblique tear within the posterior horn of the lateral meniscus with mild thickening of the proximal medial cruciate ligament (MCL) suggesting low-grade MCL injury. Medial/suprapatellar plica was present with an element of synovial thickening or synovitis. There was scant perifascial fluid about the medial head gastrocnemius likely leakage of fluid.

On July 3, 2012, Dr. noted ongoing pain and problems with knee. The patient had severe osteochondral changes that appeared to be posttraumatic with bone edema. He recommended knee arthroscopy with partial meniscectomy medial and laterally cleaning up the osteochondral debris, possible microfracture of the osteochondral lesion with installation of bone marrow aspirate concentrate. The patient had a positive McMurray's with joint line pain, locking, catching and giving way symptomatically with onset of nighttime pain and failure of conservative care with rest and anti-inflammatories.

Per utilization review dated July 19, 2012, the request for arthroscopy, loose body removal, synovectomy with bone marrow aspirate possible microfracture to the left knee (CPT 29880, 29875, 38230, 38241 and 29879) was denied with the following rationale: *"The claimant is noted to have sustained an injury to the left knee on xxxxx. He has a history of previous ORIF of left femur fracture with retained hardware. The patient complains of locking, instability, decreased range of motion and nighttime pain of left knee. Imaging studies revealed loose bodies in suprapatellar region, with severe grade IV chondromalacia of the knee. There is evidence of horizontal oblique tear in posterior horn of both medial and lateral menisci. Stem cell autologous transplantation is under study. Based on*

the clinical information provided, ODG (Official Disability Guidelines) criteria for microfracture surgery are not met. Also, there is no documentation the patient has had any conservative treatment to date. Given the current clinical data, medical necessity is not established."

Per reconsideration review dated July 25, 2012, the appeal for arthroscopy, loose body removal, synovectomy with bone marrow aspirate possible microfracture to the left knee (CPT 29880, 29875, 38230, 38241 and 29879) was denied with the following rationale: *"The claimant injured his left knee while working on an oil rig. He complains of left knee pain with locking, instability, decreased range of motion and nighttime pain. The MRI showed large loose bodies in suprapatellar region and grade IV chondromalacia. There was a horizontal oblique tear of the medial and lateral meniscus. There is no indication that the claimant has had an appropriate trial of conservative care prior to proceeding with surgical intervention, and no evidence of locked/blocked knee that would obviate the need for conservative treatment. As such, the requested surgical procedure is not medically necessary at this time."*

On August 1, 2012, Dr. noted ongoing pain and problems with the knee. There were severe osteochondral changes which appeared to be posttraumatic with bone edema. Examination showed positive McMurray's with joint line pain, locking, catching and giving way symptomatically with onset of nighttime pain and failure of conservative care with rest and anti-inflammatories. Dr. opined that there were dramatic osteochondral changes on plain film with large osteochondral chunks. There was a good chance that the patient would improve with open capsular removal of multiple large osteochondral pieces. The patient had more than several small what looked to be almost rocks within his joint that were calcified osteochondral debris. He recommended knee arthroscopy with partial meniscectomy medial and laterally cleaning up the osteochondral debris, possible microfracture of the osteochondral lesion with installation of bone marrow aspirate concentrate.

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

This young individual has documentation of large osteochondral loose bodies within the joint. The MRI confirmed an effusion and seemed to confirm large osteochondral defects which would produce these loose bodies, also confirming the loose bodies themselves. Synovitis was also appreciated.

This young individual has large loose bodies which in and of themselves can be damaging. Arthroscopy with debridement to include correction of any meniscal damage, debridement of the sites where the osteochondral fragments arose, and removal of the large fragments themselves should definitely be considered medically necessary.

To specifically answer your question: Left knee arthroscopy, loose body removal,

and synovectomy should definitely be considered medically necessary. However, I would add that the request also seems to include stem cell instillation, which would be experimental. As long as the stem cell instillation is not still planned, the request as raised in your question satisfies evidence-based guidelines.

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

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

☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**

Official Disability Guidelines Treatment in Worker's Comp, 17th edition, 2012, Knee and Leg Chapter – Diagnostic Arthroscopy, Meniscectomy, Microfracture Surgery, Stem Cell Stem cell autologous transplantation

ODG Indications for Surgery -- Diagnostic arthroscopy:
Criteria for diagnostic arthroscopy:
1. Conservative Care: Medications. OR Physical therapy. PLUS
2. Subjective Clinical Findings: Pain and functional limitations continue despite conservative care. PLUS
3. Imaging Clinical Findings: Imaging is inconclusive.

ODG Indications for Surgery -- Meniscectomy:
Criteria for meniscectomy or meniscus repair (Suggest 2 symptoms and 2 signs to avoid scopes with lower yield, e.g. pain without other symptoms, posterior joint line tenderness that could just signify arthritis, MRI with degenerative tear that is often false positive):
1. Conservative Care: (Not required for locked/blocked knee.) Physical therapy. OR Medication. OR Activity modification. PLUS
2. Subjective Clinical Findings (at least two): Joint pain. OR Swelling. OR Feeling of give way. OR Locking, clicking, or popping. PLUS

3. Objective Clinical Findings (at least two): Positive McMurray's sign. OR Joint line tenderness. OR Effusion. OR Limited range of motion. OR Locking, clicking, or popping. OR Crepitus. PLUS
4. Imaging Clinical Findings: (Not required for locked/blocked knee.) Meniscal tear on MRI.

ODG Indications for Surgery -- Microfracture surgery
Procedure: Subchondral drilling or microfracture. Requires all 4 below:
1. Conservative Care: Medication OR Physical therapy (minimum of 2 months). PLUS
2. Subjective Clinical Findings: Joint pain AND Swelling. PLUS
3. Objective Clinical Findings: Small full thickness chondral defect on the weight bearing portion of the medial or lateral femoral condyle AND Knee is stable with intact, fully functional menisci and ligaments AND Normal knee alignment AND Normal joint space AND Ideal age 45 or younger. PLUS
4. Imaging Clinical Findings: Chondral defect on the weight-bearing portion of the medial or lateral femoral condyle on: MRI OR Arthroscopy

Stem Cell Stem cell autologous transplantation
Under study for severe arthritis, including knee arthritis (adult stem cells, not embryonic stem cells). Stem cell therapy is used for osteoarthritis, rheumatoid arthritis, spinal injury, degenerative joint disease, autoimmune diseases, systemic lupus erythematosus, cerebral palsy, critical limb ischemia, diabetes type 2, heart failure, multiple sclerosis, and other conditions. Adult stem cells are harvested from many areas of the body, including the bone marrow, fat and peripheral blood, and they are purified and reintroduced back in the patient. According to the theory, stem cells isolated from a patient (i.e. from the bone marrow or fat) have the ability to become different cell types (i.e. nerve cells, liver cells, heart cells and cartilage cells), and they are capable of "homing in" on and repairing damaged tissue. Autologous hematopoietic stem cell transplantation can induce sustained remissions for more than 5 years in patients with severe autoimmune diseases refractory to conventional therapy. (Farge, 2010) Stem cell transplantation has potential for cartilage repair and cell-based therapies for osteoarthritis. (Mobasheri, 2009) Stem cells hold great promise to harness the body's ability to heal itself, and to cure diseases and alleviate suffering without the use of drugs or invasive surgery, but there may be risks. In this study no complications were detected from stem cells re-injected into peripheral joints (n=213) or into intervertebral discs (n=13). (Centeno, 2010) In an animal study reported in the *Lancet*, tissue formed by stem cells from the host was implanted and re-grew their own joints, complete with cartilage. Researchers hypothesized that such a joint should last longer and work more naturally than a metal joint, and the technique could benefit patients with advanced arthritis. While metal joints only last 10-15 years but this type should last longer, but not all patients may have this regenerative capacity, especially the elderly. (Lee, 2010) Note: This treatment is not FDA approved in the U.S