

# Icon Medical Solutions, Inc.

11815 CR 452  
Lindale, TX 75771  
P 903.749.4272  
F 888.663.6614

## Notice of Independent Review Decision

**DATE:** August 14, 2012

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Postoperative CPM Rental for the Left Knee and Cryotherapy Unit

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

This physician is Board Certified by the American Board of Orthopaedic Surgery with over 40 years of experience.

**REVIEW OUTCOME:**

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

Upheld (Agree)

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:**

09/07/11: Office Visit  
09/12/11: Initial Therapy Evaluation, PT  
09/13/11: Progress Note  
09/14/11, 09/16/11, 09/21/11, 09/27/11, 09/30/11, 02/15/12, 02/17/12, 02/22/12, 02/24/12: Physical Therapy Notes  
10/06/11: MRI of the Left Knee  
10/11/11: Progress Note  
11/30/11: Operative Report  
12/06/11: Postoperative Visit  
01/19/12, 03/01/12, 04/10/12: Followup Visit  
03/01/12: Followup Visit

04/15/12, 04/24/12, 05/01/12: Euflexxa Injection  
06/05/12: Followup Visit  
06/27/12: UR  
07/02/12: UR

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The claimant is a male who injured his left knee while working. He is status post viscosupplementation injections, steroid injections, and physical therapy status post surgical interventions.

09/07/11: The claimant was evaluated who noted that he had been taking medications as well as attended physical therapy and was feeling better. On physical exam, the left knee joint was stable with no deformity. There was negative drawer sign and no ecchymosis, knee effusion, or erythema. There was no giving way or locking. There was no popliteal fossa swelling. He had full range of motion in the left knee. Foot sensation was intact. He had normal dorsalis pedis pulse. He had normal gait without pain. ASSESSMENT: Sprain/strain knee/leg unspecified site. Enthesopathy of the knee.

09/12/11: The claimant was evaluated who noted that he stated he fell off a ladder and landed straight on flat concrete when he injured his left knee. He complained of medial and posterior knee popping, clicking, and giving way. He rated his knee pain as 7-8/10 when on the knee constantly. Knee tests and measures were within normal limits. Flexion ROM of the left knee was 107, extension lacking 3. Muscle testing was 4/5 in flexion and 5-/5 in extension. He had pain with forced knee hyperextension and pain with max knee flexion. ASSESSMENT: The patient examination is consistent with the medical diagnosis of left knee strain. IMPAIRMENT LIST: AROM, PROM, Pain, Muscle Performance, Joint Mobility. PLAN: 3-9 visits prn.

09/13/11: The claimant was reevaluated for a recheck of his left knee injury. He stated that the pattern of symptoms was improving. He had been working within the duty restrictions. On physical exam, there were no changes from exam performed on 09/07/11. He was to continue with therapy.

The claimant underwent 21 sessions of physical therapy. He reported the same pain worse with prolonged walking, and he rated his pain as 8/10. KNEE AROM: Ext -7, flexion 103. KNEE MMT: Quads 5/5 pain, hams 5-/5. IMPAIRMENT LIST: AROM, Pain, Muscle Performance, Joint Mobility. Overall Progress: Not progressing. ASSESSMENT: He has improved pain with use of patella taping and tracking brace but no significant carryover in improvement between visits. He has continued ROM limitations and weight bearing sensitivity to prolonged activity. He is unable to tolerate prolonged sitting and sleep is limited due to pain. Pain limits ability to perform stairs or ladders - a necessary job requirement. At this point, he has plateaued with significant improvement. He was instructed in HEP and referred back to medical provider for further advisement.

10/06/11: MRI of the Left Knee IMPRESSION: Subtle tear posterior horn medial meniscus and midbody medial meniscus. Subtly enlarged lateral meniscus indicating a minimal discoid meniscus. No meniscal tear. Tricompartmental osteoarthritis. Intact cruciate ligaments and collateral ligaments.

10/11/11: The claimant was evaluated for a recheck of his left knee injury. He stated that walking had improved with therapy but he still had pain to the knee with popping. He noted numbness to the distal patella. On physical exam, he had no effusion or edema of the left knee. There was tenderness to the medial joint line. There was popping with flexion. He had positive McMurray with valgus stress. He had a mildly antalgic gait. There was no patellar apprehension. PLAN: Ortho referral. Hold PT, continue HEP. RTC 10 days, sooner if problem.

Operative Report. Postoperative Diagnosis: Internal derangement, left knee. Posterior horn medial meniscus tear. Focal traumatic chondral defect, lateral femoral condyle with intra-articular loose body. Diffuse degenerative chondromalacia, medial femoral condyle with loose marginal flaps, grade 3. Synovitis, anteromedial/anterolateral compartments. PROCEDURES PERFORMED: Examination under anesthesia. Diagnostic left knee arthroscopy. Partial medial meniscectomy. Medial femoral condyle chondroplasty. Lateral femoral condyle chondroplasty (separate compartment). Intra-articular loose body removal (lengthened incision). Synovectomy, anteromedial/anterolateral compartments. Anesthetic injection. Simple closure.

The claimant was evaluated for postoperative status. It was noted that his left knee was fairly sore. On physical exam, he had no mechanical symptoms. There was no distal swelling. There was negative Homan's. NVID. Portals were are well healed. No evidence of infection. PLAN: We will get him some physical therapy per ODG criteria. We will see him back in 3-4 weeks. Hopefully, he will be able to return to work at that time. PROCEDURE: After obtaining informed consent, under sterile prep, I performed arthrocentesis of the left knee removing a small amount of normal-appearing joint fluid. I then injected 40 mg of Kenalog and 1 ml of plain lidocaine into the medial compartment without complications. Tolerated well. Standard instructions.

The claimant was reevaluated MD who noted on that he had persistent lateral and anterolateral knee pain and was given an injection of 40 mg of Kenalog on that day. On the left knee exam showed good extension but flexion past about 120 degrees caused anterior knee pain. The patellar tracking was not good-complete loss of normal J curve, seems very tight along the lateral retinaculum and LPFL. Very difficult to mobilize the patella. ASSESMENT: Postoperative synovitis. Postoperative patellar lateral maltracking. He was given an injection of Depo-Medrol. On he was noted to have failed steroid and that he was "not doing well." He still had a lot of aching pain in the joint. Dr recommended a trial of series of Euflexxa injections.

04/15/12, 04/24/12, 05/01/12: The claimant underwent a series of three Euflexxa injections. ASSESSMENT: Focal traumatic chondral defect, femoral condyle, status post direct contact injury. Status post partial meniscectomy-mechanical symptoms resolved. Dr plan was: I will inject the Euflexxa #3 today and see him back in six weeks. If he is remaining substantially symptomatic, he may be a candidate for an Arthrosurface procedure. That being said, I remain quite concerned over his very high BMI and potential complication of such procedure. Also, I am concerned that he is not going to be able to return to his workplace activities, no matter what his outcome at this point, as a relatively high demand.

06/05/12: The claimant was reevaluated who noted that he was "miserable." He stated that his left knee was "killing me." He noted that he could only make it through 30 minutes of standing at work before he started having progressively achy pain laterally that started radiating down the lateral shin. He stated that the Euflexxa injections had basically failed. On physical exam, the left knee showed well-healed arthroscopy portal scars, boggy and very minimal synovitic effusion at most. He had distinct pain over the lateral femoral condyle. The medial compartment was completely nontender. The patellofemoral compartment was completely nontender with full range of motion. Deep knee flexion did not increase his anterior or medial compartment pain. There were no mechanical symptoms and negative McMurray's. There was no distal swelling. Negative Homan's. NVID. Antalgic gait. ASSESSMENT: Symptomatic, traumatic lateral femoral condyle osteochondritis dissecans. PLAN: We had a long and thorough discussion today in the clinic. I discussed thoroughly the indications and benefits, as well as the possible risks, complications, and alternatives of operative and nonoperative management for the traumatic LFC lesion. We went through all the options. At this point, conservative management has failed. Yet, he young for TKA. The only reason I would even consider a TKA is because he does have some medial compartment arthrosis. However, clinically it is very asymptomatic. All his pain is directly laterally and in particularly directly over the traumatic OCD of the LFC. Therefore, I would recommend a left knee hemiarthroplasty using the Arthrosurface implant system. This is essentially a resurfacing system that is bone and cartilage sparing. Because of his body habitus, I do not think a Carticel procedure or an OATS procedure is going to have any success. Ultimately, if the Arthrosurface components fail, it would be relatively easy to convert to a TKA, which is certainly not the case with more traditional unicompartmental arthroplasties. He elects to proceed.

06/27/12: UR performed. Questions for Review: Is a left knee hemiarthroplasty with arthrosurface implant with a 3 day inpatient stay medically necessary? If the surgery is medically necessary, please advise if a CMP rental and cryotherapy unit rental is medically necessary and for how many days. RATIONALE: The patient is of age. There are no notes with examination, deficits, or recent conservative care, Synvisc or cortisone injections, or recent imaging from the treating doctor. There are PT notes and notes from the PA. The request for surgery and the request for CPM and Cryotherapy are not medically necessary per evidence based guidelines based on the records available for review. There

is no plain x-ray showing arthritis. There has been no documentation of failure of viscosupplementation or cortisone injections. Therefore, the request is not medically necessary.

07/02/12: UR performed. RATIONALE: The clinical documentation submitted for review indicates that the patient continues with complaints of pain to his left knee. The patient has undergone viscosupplementation injections, steroid injections, and physical therapy status post surgical interventions on 11/30/11. However, the patient has not met criteria for hemiarthroplasty. The clinical documentation submitted for review did not include any diagnostic imaging studies of the patient's pathology to the left knee. Furthermore, the clinical notes indicate that the patient is of age. Based on the clinical note dated 09/07/11, the patient has a BMI of 41.8. This exceeds Official Disability Guidelines criteria for less than 35. In addition, the BMI is approximately 10 months old. This request previously received an adverse determination due to the lack of documentation of conservative measures, the patient's age, and no diagnostic studies submitted for review. As such, the request for a left knee hemiarthroplasty with arthroscopic implant with a 3-day inpatient stay is not medically necessary.

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

The previous adverse decisions are upheld. After reviewing his records, I would not recommend left knee hemiarthroplasty. He has chondral changes of a grade 3 nature in the medial side. He also has symptoms of a patellofemoral joint tracking problem as well as the osteochondral defect on the lateral side. Hemiarthroplasty is not indicated for more than one compartment arthritic change. Also, indications for denial of the procedure are a BMI over 41 and an age under , both of which measurements are out of range for in this case for recommendation of a total knee arthroplasty, and particularly hemiarthroplasty as requested. Therefore, the request for Postoperative CPM Rental for the Left Knee and Cryotherapy Unit is not medically necessary and is non-certified as the left knee hemiarthroplasty with arthroscopic implant with a 3-day inpatient stay is not medically necessary and is non-certified.

ODG:

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| Continuous passive motion (CPM) | Recommended as indicated below, for in-hospital use, or for home use in patients at risk of a stiff knee, based on demonstrated compliance and measured improvements, but the beneficial effects over regular PT may be small. Routine home use of CPM has minimal benefit. Although research suggests that CPM should be implemented in the first rehabilitation phase after surgery, there is substantial debate about the duration of each session and the total period of CPM application. A Cochrane review on this topic concluded that short-term use of CPM leads to greater short-term range of motion. But in a recent RCT results indicated that routine use of prolonged CPM should be reconsidered, since neither long-term effects nor better functional performance was detected. The experimental group received CPM + PT in the home situation for 17 consecutive days after surgery, whereas the usual care group received the same treatment during the in-hospital phase (i.e. about four |
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|  | <p>days), followed by PT alone (usual care) in the first two weeks after hospital discharge. (<a href="#">Lenssen, 2008</a>) Continuous passive motion (CPM) combined with PT, may offer beneficial results compared to PT alone in the short-term rehabilitation following total knee arthroplasty. Results favoring CPM were found for the main comparison of CPM combined with physical therapy (PT) versus PT alone at end of treatment. For the primary outcomes of interest, CPM combined with PT was found to statistically significantly increase active knee flexion and decrease length of stay. CPM was also found to decrease the need for post-operative manipulation. CPM did not significantly improve passive knee flexion and passive or active knee extension. (<a href="#">Milne-Cochrane, 2003</a>) (<a href="#">Kirschner, 2004</a>) (<a href="#">Brosseau, 2004</a>) (<a href="#">Bennett, 2005</a>) (<a href="#">Lenssen, 2006</a>) Continuous passive motion can stimulate chondrocyte production of proteoglycan 4 (PRG4), a molecule found in synovial fluid with putative lubricating and chondroprotective properties. (<a href="#">Nugent-Derfus, 2006</a>) A recent Cochrane review concluded that there is high-quality evidence that continuous passive motion increases passive knee flexion range of motion (mean difference 2 degrees) and active knee flexion range of motion (mean difference 3 degrees), but that these effects are too small to be clinically worthwhile, and there is low-quality evidence that continuous passive motion has no effect on length of hospital stay but reduces the need for manipulation under anaesthesia. (<a href="#">Harvey, 2010</a>) The adjunctive home use of CPM may be an effective treatment option for patients at risk of knee flexion contractures, regardless of whether the patient is being treated as part of a worker's compensation claim or not. Recent literature suggests that routine home use of CPM has minimal benefit when combined with standard physical therapy, but studies conducted in a controlled hospital setting suggest that CPM can improve rehabilitation. (<a href="#">Dempsey, 2010</a>)</p> <p><b>Criteria for the use of continuous passive motion devices:</b></p> <p><i>In the acute hospital setting</i>, postoperative use may be considered medically necessary, for 4-10 consecutive days (no more than 21), for the following surgical procedures:</p> <ol style="list-style-type: none"> <li>(1) Total knee arthroplasty (revision and primary)</li> <li>(2) Anterior cruciate ligament reconstruction (if inpatient care)</li> <li>(3) Open reduction and internal fixation of tibial plateau or distal femur fractures involving the knee joint (<a href="#">BlueCross BlueShield, 2005</a>)</li> </ol> <p><i>For home use</i>, up to 17 days after surgery while patients at risk of a stiff knee are immobile or unable to bear weight:</p> <ol style="list-style-type: none"> <li>(1) Under conditions of low postoperative mobility or inability to comply with rehabilitation exercises following a total knee arthroplasty or revision; this may include patients with: <ol style="list-style-type: none"> <li>(a) complex regional pain syndrome;</li> <li>(b) extensive arthrofibrosis or tendon fibrosis; or</li> <li>(c) physical, mental, or behavioral inability to participate in active physical therapy.</li> </ol> </li> <li>(2) Revision total knee arthroplasty (TKA) would be a better indication than primary TKA, but either OK if #1 applies.</li> </ol> |
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| <p>Continuous-flow cryotherapy</p> | <p>Recommended as an option after surgery, but not for nonsurgical treatment. Postoperative use generally may be up to 7 days, including home use. In the postoperative setting, continuous-flow cryotherapy units have been proven to decrease pain, inflammation, swelling, and narcotic usage; however, the effect on more frequently treated acute injuries (eg, muscle strains and contusions) has not been fully evaluated. Continuous-flow cryotherapy units provide regulated temperatures through use of power to circulate ice water in the cooling packs. (<a href="#">Hubbard, 2004</a>) (<a href="#">Morsi, 2002</a>) (<a href="#">Barber, 2000</a>) The available scientific literature is insufficient to document that the use of continuous-flow cooling systems (versus ice packs) is associated with a benefit beyond convenience and patient compliance (but these may be worthwhile benefits) in the outpatient setting. (<a href="#">BlueCross BlueShield, 2005</a>) This meta-analysis showed that cryotherapy has a statistically significant benefit in postoperative pain control, while no improvement in postoperative range</p> |
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|  | <p>of motion or drainage was found. As the cryotherapy apparatus is fairly inexpensive, easy to use, has a high level of patient satisfaction, and is rarely associated with adverse events, we believe that cryotherapy is justified in the postoperative management of knee surgery. (<a href="#">Raynor, 2005</a>) There is limited information to support active vs passive cryo units. Aetna considers passive hot and cold therapy medically necessary. Mechanical circulating units with pumps have not been proven to be more effective than passive hot and cold therapy. (<a href="#">Aetna, 2006</a>) This study concluded that continuous cold therapy devices, compared to simple icing, resulted in much better nighttime pain control and improved quality of life in the early period following routine knee arthroscopy. (<a href="#">Woolf, 2008</a>) Two additional RCTs provide support for use after total knee arthroplasty (TKA). Cold compression reduced blood loss by 32% and pain medication intake by 24%. (<a href="#">Levy, 1993</a>) It improved ROM and reduced hospital stay by 21%. (<a href="#">Kullenberg, 2006</a>) See also <a href="#">Cold/heat packs</a>.</p> <p><i>Recent research:</i> This systematic review concluded that solely an analgesic effect was demonstrated by the use of continuous cooling. (<a href="#">Cina-Tschumi, 2007</a>) Another systematic review concluded that, despite some early gains, cryotherapy after TKA yields no apparent lasting benefits, and the current evidence does not support the routine use of cryotherapy after TKA. (<a href="#">Adie, 2010</a>) Although the use of cryotherapy may not be a statistically effective modality, according to this systematic review, it may provide patient benefits. (<a href="#">Markert, 2011</a>)</p> |
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| <p>Knee joint replacement</p> | <p><b><u>ODG Indications for Surgery™ -- Knee arthroplasty:</u></b><br/> <b>Criteria</b> for knee joint replacement (If only 1 compartment is affected, a unicompartmental or partial replacement may be considered. If 2 of the 3 compartments are affected, a total joint replacement is indicated.):</p> <p><b>1. Conservative Care:</b> Medications. AND (Visco supplementation injections OR Steroid injection). PLUS</p> <p><b>2. Subjective Clinical Findings:</b> Limited range of motion. AND Nighttime joint pain. AND No pain relief with conservative care AND Documentation of current functional limitations demonstrating necessity of intervention. PLUS</p> <p><b>3. Objective Clinical Findings:</b> Over 50 years of age AND Body Mass Index of less than 35, where increased BMI poses elevated risks for post-op complications. PLUS</p> <p><b>4. Imaging Clinical Findings:</b> Osteoarthritis on: Standing x-ray. OR Arthroscopy. (<a href="#">Washington, 2003</a>) (<a href="#">Sheng, 2004</a>) (<a href="#">Saleh, 2002</a>) (<a href="#">Callahan, 1995</a>)</p> <p>For average hospital LOS if criteria are met, see <a href="#">Hospital length of stay</a> (LOS). See also <a href="#">Skilled nursing facility LOS</a> (SNF)</p> |
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**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**
- 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 FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**