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DATE: June 25, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Left Ankle Arthrotomy, Left Medial Malleolus Osteotomy, Left Brostrom, Left Talar Dome Autologous Tissue Transfer, Left Knee Scope with Autologous Cartilage Harvest

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

The reviewer is certified by the American Board of Orthopaedic Surgery with over 13 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.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a female who injured her left lower extremity when she stood from her chair and twisted her left ankle while working on xx/xx/xx.

02/11/15: The claimant was evaluated. She stated that her ankle was "killing" her, and she was ready to have something done with the left ankle. She stated that it "rolled over again" on her the day prior. She complained of hurting, burning, and aching down to the joint. She stated that it was really giving her some pain and difficulties. On exam, dorsalis pedis and posterior tibial pulses were 2/4 bilaterally. Capillary refill time was less than 3 seconds in all digits bilaterally. Digital hair was present bilaterally. Skin was normal to texture, turgor, and temperature bilaterally with no wounds or break in integument. Ankles were in rectus alignment with 5/5 muscle strength of all tendons crossing the ankle bilaterally. Intact achilles and patellar reflexes bilaterally. 5/5 strength of all flexors and extensors to the digits. Extreme pain on palpation over the anterior aspect of the left ankle ATF ligament. There was an anterior shift. Small amount of pain on forced dorsiflexion and plantar flexion into the medial aspect of the talus and ankle mortis. Gross epicritic sensations were intact bilaterally to the

digits and the balls of the feet to the semms Weinstein 5.0 monofilament tester. Sharp/dull discrimination intact to the plantar feet bilaterally. Assessment was traumatic arthritis of the ankle, ankle instability, and lateral ankle instability. CT scan done on 09/29/14 was reviewed and showed a 9 x 8 mm chronic osteochondral regular medial talar dome and large amounts of edema. PLAN: "We spent a long time diagramming out doing an ankle arthrotomy with medial osteotomy with screw fixation. Need for brostrum ligament repair for sure to repair this area with talar dome autologous tissue transfer where will take a scope and get a harvest for us for the knee." "Still need for an ankle fusion on this in the future." It was noted that "new x-rays were taken today where you can visualize the talar dome lesions and the on the tibia."

04/14/15: The claimant was evaluated. It was noted that she was to have ankle surgery and that she would be at moderate risk due to her severe CMP; warfarin can be stopped 5 days before and she will need to be covered with Lovenox in postop period until INR at target 2.5 to 3.5.

05/11/15: The claimant was evaluated for surgery consult for left knee scope. It was noted that she had never had any injury to her knees that she recalled. She related no pain with being seated for long periods of time, no pain with ascending or descending stairs, and no episodes of instability. She was noted to take no medications for her knees. Her past medical history included diabetes, arthritis, osteoporosis, anemia, and coronary artery disease. Past surgical history included left foot surgery in 2008, open heart surgery x 3, tonsillectomy, pacemaker placement, defibrillator placement, and C-section. She did not drink alcohol and was never a smoker. She has never had a stroke. On exam, the left knee demonstrated full range of motion from 0-105 degrees; anterior/posterior drawer was negative. She had no joint line tenderness and no patellofemoral crepitus. She had normal patellofemoral tracking with range of motion. She ambulated with an antalgic gait, which she stated was from her ankle pain. 0/10 knee pain. Assessment was osteochondral defect of the talus. Risks of arthroscopic autograft harvest from the knee were discussed with her. It was discussed that it was planned to obtain this from a non-weight bearing portion and non-articulating portion of the lateral trochlea. It was discussed that should she have chondromalacia of this area, harvest would not be performed. Also discussed was former diagnostic arthroscopy and the remainder of the knee; should she have a meniscus tear or any other pathology that would be treated at the same time. She was to have physical therapy following the surgery. She acknowledged understanding that she would be non-weight bearing for her ankle for 12 weeks after surgery. Bilateral knee 4V, weight bearing, x-rays were obtained, which showed some early degenerative changes to the medial compartment of the knee with swollen osteophyte but maintenance of joint space. No lateral osteophyte formation, no subchondral sclerosis, and no loose bodies. No osteophytes noted on the lateral views of the knee to the patella. Sunrise views bilaterally demonstrated normal patellar tracking, normal overall patellar alignment, and no loss of patellofemoral joint space.

05/20/15: UR. RATIONALE: ODG do not support osteochondral autografting in the ankle. The guidelines state that further sufficiently powered, randomized clinical trials with uniform methodology and validated outcome measures should be initiated to compare the outcome of OATS. Osteochondral autograft transplant is recommended by the ODG in the knee when there is failure of previous subchondral drilling or microfracture, a full-thickness chondral defect, functional ligaments, normal alignment, normal joint space, and body mass index level at 35. The ODG provide specific indications for lateral ligament ankle reconstruction surgery for chronic instability or ankle sprain/strain. The criteria include physical therapy (immobilization with support case or brace and rehabilitation program). Subjective and objective clinical findings showing evidence of instability and posterior anterior drawer are required. Imaging findings are required, including positive stress x-rays identifying motion at the ankle or subtalar joint. The guideline criteria have not been met. The patient presents with significant left ankle pain and instability. There is no documentation of positive anterior drawer sign or positive stress x-rays. There is no imaging evidence relative to ligamentous integrity and joint disease. Detailed evidence of a recent, reasonable and/or comprehensive non-operative treatment protocol trial and failure has not been submitted. There is no guideline support for the use of autologous tissue transfer in the ankle. Therefore, this request is not medically necessary.

05/28/15: UR. RATIONALE: No imaging studies were provided to document significant pathology to the left ankle to warrant this procedure. No imaging studies were provided of the left knee. The records indicate there is evidence of a positive shift to the left ankle on exam indicative of some instability. However, records do not discuss conservative measures such as physical therapy and/or bracing and a 04/14/15 progress note indicates the claimant is active with walking at work indicative of no significant functional deficits.

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

The previous adverse decisions are upheld. The Official Disability Guidelines (ODG) do not recommend osteochondral autologous transfer system (OATS) in the ankle. There may be a role for this procedure in the ankle following failed microfracture surgery. However, the literature does not support OATS in the ankle as a primary procedure.

The ODG recommends lateral ligament reconstruction for ankle instability in patients who have failed conservative care and have subjective, objective, and radiographic clinical findings. Radiographs must demonstrate at least 15 degrees of lateral opening at the ankle joint or abnormal subtalar movement, in the absence of arthritis. These radiographic findings have not been documented in this case. There has also been no documentation of failure of conservative care.

Furthermore, it is not clear why the treating surgeon would recommend such an extensive procedure if he felt that the patient would require an ankle fusion in the future. Therefore, the request for Left Ankle Arthrotomy, Left Medial Malleolus Osteotomy, Left Brostrom, Left Talar Dome Autologous Tissue Transfer, Left

Knee Scope with Autologous Cartilage Harvest is not medically necessary based on the records reviewed.

ODG:

Arthroscopy	<p>Recommended. An arthroscope is a tool like a camera that allows the physician to see the inside of a joint, and the surgeon is sometimes able to perform surgery through an arthroscope, which makes recovery faster and easier. Having started as a mainly diagnostic tool, ankle arthroscopy has become a reliable procedure for the treatment of various ankle problems. (Stufkens, 2009) Ankle arthroscopy provides the surgeon with a minimally invasive treatment option for a wide variety of indications, such as impingement, osteochondral defects, loose bodies, ossicles, synovitis, adhesions, and instability. Posterior ankle pathology can be treated using endoscopic hindfoot portals. It compares favorably to open surgery with regard to less morbidity and a quicker recovery. (de Leeuw, 2009) There exists fair evidence-based literature to support a recommendation for the use of ankle arthroscopy for the treatment of ankle impingement and osteochondral lesions and for ankle arthrodesis. Ankle arthroscopy for ankle instability, septic arthritis, arthrofibrosis, and removal of loose bodies is supported with only poor-quality evidence. Except for arthrodesis, treatment of ankle arthritis, excluding isolated bony impingement, is not effective and therefore this indication is not recommended. Finally, there is insufficient evidence-based literature to support or refute the benefit of arthroscopy for the treatment of synovitis and fractures. (Glazebrook, 2009) See also Diagnostic arthroscopy, or the Surgery listings for detailed information on specific treatments that may be done arthroscopically.</p>
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Surgery for ankle sprains	<p>ODG Indications for Surgery™ -- Lateral ligament ankle reconstruction:</p> <p>Criteria for lateral ligament ankle reconstruction for chronic instability or acute sprain/strain inversion injury:</p> <p>1. Conservative Care: Physical Therapy (Immobilization with support cast or ankle brace & Rehab program). For either of the above, time frame will be variable with severity of trauma. PLUS</p> <p>2. Subjective Clinical Findings: For chronic: Instability of the ankle. Supportive findings: Complaint of swelling. For acute: Description of an inversion. AND/OR Hyperextension injury, ecchymosis, swelling. PLUS</p> <p>3. Objective Clinical Findings: For chronic: Positive anterior drawer. For acute: Grade-3 injury (lateral injury). [Ankle sprains can range from stretching (Grade I) to partial rupture (Grade II) to complete rupture of the ligament (Grade III).¹ (Litt, 1992)] AND/OR Osteochondral fragment. AND/OR Medial incompetence. AND Positive anterior drawer. PLUS</p> <p>4. Imaging Clinical Findings: Positive stress x-rays identifying motion at ankle or subtalar joint. At least 15 degree lateral opening at the ankle joint. OR Demonstrable subtalar movement. AND Negative to minimal arthritic joint changes on x-ray.</p> <p>Procedures Not supported: Use of prosthetic ligaments, plastic implants, calcaneous osteotomies.</p> <p>(Washington, 2002) (Schmidt, 2004) (Hintermann, 2003)</p> <p>For average hospital LOS if criteria are met, see Hospital length of stay (LOS).</p>
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Lateral ligament ankle reconstruction (surgery)	<p>ODG Indications for Surgery™ -- Lateral ligament ankle reconstruction:</p> <p>Criteria for lateral ligament ankle reconstruction for chronic instability or acute sprain/strain inversion injury:</p> <p>1. Conservative Care: Physical Therapy (Immobilization with support cast or ankle brace & Rehab program). For either of the above, time frame will be variable with severity of trauma. PLUS</p> <p>2. Subjective Clinical Findings: For chronic: Instability of the ankle. Supportive findings: Complaint of swelling. For acute: Description of an inversion. AND/OR Hyperextension injury, ecchymosis, swelling. PLUS</p> <p>3. Objective Clinical Findings: For chronic: Positive anterior drawer. For acute: Grade-3 injury (lateral injury). [Ankle sprains can range from stretching (Grade I) to partial rupture (Grade II) to complete rupture of the ligament (Grade III).¹ (Litt, 1992)] AND/OR Osteochondral fragment. AND/OR Medial incompetence. AND Positive anterior drawer. PLUS</p> <p>4. Imaging Clinical Findings: Positive stress x-rays (performed by a physician) identifying motion at ankle or subtalar joint. At least 15 degree lateral opening at the ankle joint. OR Demonstrable subtalar movement. AND Negative to minimal arthritic joint changes on x-ray.</p> <p>Procedures Not supported: Use of prosthetic ligaments, plastic implants, calcaneous osteotomies.</p> <p>(Washington, 2002) (Schmidt, 2004) (Hintermann, 2003)</p> <p>For average hospital LOS if criteria are met, see Hospital length of stay (LOS).</p>
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Osteochondral	Not recommended in the ankle. While osteochondral autografting has been
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autologous transfer system (OATS)	principally performed on the knee, the OATS technique may have promise in the ankle. Although the OATS procedure is generally reserved for salvage of failed debridement and drilling in the ankle, it may have applications in primary surgical management, but long-term outcome of the OATS procedure is not yet available. (Easley, 2003) Further sufficiently powered, randomized clinical trials with uniform methodology and validated outcome measures should be initiated to compare the outcome of osteochondral transplantation (OATS). (Zengerink, 2010) See the Knee Chapter , where Osteochondral autograft transplant system (OATS) is recommended.
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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)**