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DATE OF REVIEW: 06/16/09

IRO CASE #:

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

This case was reviewed by a Orthopaedic Surgery, Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Right total ankle replacement/hardware removal

REVIEW OUTCOME

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

Overturn (Disagree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o 12-27-05 Medical report from Dr
- o 12-27-05 Right foot and ankle x-ray reports read by Dr.
- o 12-27-05 Medical report from Dr.
- o 02-13-09 Right foot and ankle x-rays reports read by Dr.
- o 02-13-09 Medical report from Dr.
- o 03-19-09 Preliminary medical report and Consultation report from Dr.
- o 04-10-09 Physical Medicine and Rehabilitation report (RME report) from Dr.
- o 05-08-09 Pre-authorization request from Dr.
- o 05-14-09 Notification of Determination
- o 05-20-09 Fax request for pre-authorization from Dr.
- o 05-28-09 Notification of non-certification for reconsideration ankle surgery

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records and prior reviews the patient is a worker who sustained an injury to the back and bilateral lower extremities on xx-xx-xx associated with a fall of about 20 feet. He

apparently landed feet first. The patient's treatment history has been summarized as: Closed reduction and splinting right calcaneus fracture, 1999. Open reduction internal fixation left talus fracture, 1999. Arthrodesis of right subtalar joint using bone graft from the proximal right tibia and plate and screws across the anterior calcaneus and cuboid bones, April 2000. Multiple Sclerosis, 2001. Arthrodesis left ankle, subtalar and tibiocalcaneal joints, distal fubulotomy to use for autologous bone graft and removal of deep hardware, April 2002. Right ankle pain, progression of ankle post traumatic arthritis with development of grade 2 osteochondritis of talar dome. L5-S1 posterior discectomy and fusion with interbody cage and autologous bone, pedicle screws and rods, June 2001. Removal of painful hardware with exploration of lumbar fusion, February 2003. Viscosupplementation injection to the right ankle of November 2008 provided temporary improvement for several months.

When examined on December 27, 2005 his left foot ankle pain had resolved but pain continued in the right ankle. It hurts

intermittently when he walks and he thinks it is unstable. He has had a right subtalar fusion. The subtalar joint is stable and there is good range of motion. An x-ray shows good fusion and no osteoarthritis and the joint is stable. He appears to have some mild laxity in the ankle collateral ligaments. He is recommended to see a foot and ankle surgeon.

Updated right foot x-rays were taken on February 13, 2009 and show evidence of a surgical subtalar fusion. There are mild degenerative changes in the first three metatarsal joints. The subtalar fusion is solidly united. Right ankle views shows the two screws between the talus and the os calcis with a fused subtalar joint. Alignment is good and there is no evidence of osteoarthritis of the ankle.

The patient was examined for right foot pain on February 13, 2009. He fractured his left foot and ankle in 1999 which was treated with a fusion. A fracture of his right talus was treated with a subtalar fusion. He also had an injury to his low back and he has had three back operations. He is using 5-6 hydrocodone tablets daily. His right ankle has become more painful over the past few months. A Synvisc injection was not helpful. He uses a brace on his foot tends to go over. He is unemployed and on permanent disability. There is good motion at the right ankle. There is no subtalar motion. The right foot has full sensation. X-rays show good fusion. The ankle joint appears unremarkable. He is referred to a foot specialist.

The patient returned on March 19, 2009 reporting significant pain that precludes ability to perform any desired activities. He strongly desires definitive care. The exam is essentially unchanged, although there is now noted significantly reduced articular height on x-rays. Assessment is right ankle posttraumatic arthritis with inpatient left ankle fusion and right subtalar arthrodesis. He is an excellent candidate for a total ankle replacement. An arthrodesis is not desirable due his contralateral fusion.

Per a three-phase bone scan of April 10, 2009 there is no evidence of loosening or failure of ankle fusions.

An RME was performed on April 10, 2009 (updated April 20, 2009). The patient has found an ankle specialist who is advising that the only procedure which can help his right ankle is fusion. This is very unattractive, since it would cause him to have severely inflexible ankles bilaterally, which would make gait unstable and difficult. He is now wearing a hinged AFO on the right to control medial-lateral instability and to prevent extremely painful plantarflexion of the ankle. He can walk about 1 block with a straight cane. He has been told to limit time on his feet due to the breakdown of his right ankle fusion. He has difficulty filling medications due carrier delays. There is painful popping and crunching at end range of motions of the right foot. In the left foot there is painful crepitation with ankle eversion-inversion.

Per RME opinions, diagnosis in regard to the feet is: Chronic left foot and ankle pain with post-traumatic arthropathy, status post arthrodesis of the ankle, subtalar and calcaneotibial joints for comminuted subtalar fracture with subsequent avascular necrosis of the talar dome. There appears to be some loss of fixation of the fusion with new movement present at the subtalar joint compared to the last examination in November 2006 and new onset of painful crepitation with passive inversion-eversion. Right ankle pain, status post subtalar arthrodesis related to calcaneus fracture and malunion, with subsequent progression of the ankle post-traumatic arthritis with development of grade 2 osteochondritis of the talar dome. Triple arthrodesis is proposed, but it would be so functionally disabling to him that other conservative measures such as bracing, hyaluronic injections and TES are being tried, with limited success. Right ankle total replacement would be a reasonable approach to prevent the need for fusion - fusion would close the door to all future technological advances in joint replacements and lead to further breakdown of the subtalar joints in the left foot. Right total ankle replacement may give him another 10 years of reasonable function in the right ankle.

Request for right total ankle replacement and hardware removal was not certified in review on May 14, 2009 with rationale that this procedure is not supported by the guidelines. The procedure would be considered experimental. A rationale for the request was not provided and attempts to speak with the provider did not result in a peer discussion.

Request for reconsideration for right total ankle replacement and hardware removal was not certified in review on May 28, 2009 following a peer-to-peer discussion with the provider. The intervention is not supported by guidelines and the provider was unable to provide additional clinical information to warrant the request.

ODG state, total ankle replacement is not recommended. This procedure is under study for the first metatarsophalangeal joint implant arthroplasty. Total ankle replacement has been investigated since the 1970s with initially promising results, but the procedure was essentially abandoned in the 1980s due to a high long-term failure rate, both in terms of pain control and improved function

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

The patient has been recommended fusion for his symptomatic right ankle. Total ankle replacement is now approved by the FDA, as noted by ODG with the note that, at the present time there are inadequate data on available total ankle replacements to permit conclusions regarding their safety and effectiveness. Per ODG, the FDA has approved the Scandinavian Total Ankle Replacement System (STAR) made by Small Bone Innovations in Morrisville, Pennsylvania, to offer patients more mobility to move the foot up and down than fusion surgery and other FDA-approved fixed-ankle replacement systems. To adhere to FDA approval requirements, the company will conduct further studies during the next 8 years to test the safety and effectiveness of the device. The U.S. Food and Drug Administration has recently approved a total ankle replacement system for arthritic or deformed ankles that may preserve some range of motion. Ankle Arthroplasty is probably the only viable option for this patient. Bilateral fusions are a very poor option. The ODG is not clinically up to date on this issue and a Total Ankle Arthroplasty is appropriate.

Therefore, my recommendation is to overturn the prior decision for non-certification right total ankle replacement/hardware removal.

The IRO's decision is consistent with the following guidelines:

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

The Official Disability Guidelines, Ankle and Foot (6-3-2009) Total Ankle Replacement:

Not recommended for total ankle. Under study for first metatarsophalangeal joint implant arthroplasty. Total ankle replacement has been investigated since the 1970s with initially promising results, but the procedure was essentially abandoned in the 1980s due to a high long-term failure rate, both in terms of pain control and improved function. Currently, four ankle prostheses are commercially available or under investigation in the U.S. The main alternative to total ankle replacement is arthrodesis. While both procedures are designed to reduce pain, the total ankle replacement is additionally intended to improve function. At the present time there are inadequate data on available total ankle replacements to permit conclusions regarding their safety and effectiveness. (BlueCross BlueShield, 2004) (SooHoo, 2004) (Stengel, 2005) (Valderrabano, 2007) (Vickerstaff, 2007) Nearly 86% of patients who undergo implant arthroplasty for end-stage degenerative disease of the first metatarsophalangeal joint (MPJ) are satisfied with the outcome, findings from a meta-analysis suggest. The satisfaction rate was even higher when lower quality studies were excluded from the analysis. A number of studies have evaluated these implants over the years, however, they have generally focused on a particular device brand or model, and this is the first meta-analysis that focuses on first MPJ replacement. In terms of implant materials, the findings suggest that metallic hemi, silicone total, metallic total, and ceramic total yield higher patient satisfaction than does silicone hemi. (Cook, 2009) The FDA has approved the Scandinavian Total Ankle Replacement System (STAR) made by Small Bone Innovations in Morrisville, Pennsylvania, to offer patients more mobility to move the foot up and down than fusion surgery and other FDA-approved fixed-ankle replacement systems. To adhere to FDA approval requirements, the company will conduct further studies during the next 8 years to test the safety and effectiveness of the device.