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Notice of Independent Review Decision

DATE OF REVIEW: 01/15/2010

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 arthroplasty with 23 hours of observation

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 09-24-99 Operative report from Dr.
- o 06-16-05 Right ankle x-rays read by Dr.
- o 10-27-06 Evaluation report from Orthopedics
- o 10-19-07 Follow-up visit report from Dr.
- o 01-08-08 Follow-up visit report from Dr.
- o 04-08-08 Follow-up visit report from Dr.
- o 08-18-08 Follow-up visit report from Dr.
- o 02-27-09 Follow-up visit report from Dr.
- o 06-02-09 Follow-up visit report from Dr.
- o 10-13-09 Follow-up visit report from Dr.
- o 10-20-09 Follow-up visit report from Dr.
- o 11-03-09 Pre-cert request fax sheet from Dr.
- o 11-04-09 Surgery Reservation fax from Dr.
- o 11-05-09 History and Physical Report #1 from Dr.
- o 11-05-09 Consultation report from Dr.
- o 11-24-09 Follow-up visit report from Dr.
- o 11-30-09 Adverse Determination letter
- o 12-15-09 Adverse Determination Letter - reconsideration -
- o 01-05-10 Request for IRO from the provider
- o 01-05-10 Confirmation of Receipt of IRO from RDI
- o 01-06-10 Notice of Case Assignment of IRO from TDI

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records and prior reviews the patient is a employee who sustained an industrial injury to the right ankle on xx/xx/xx associated with a fall and twisting injury while crossing railroad tracks. X-rays revealed a displaced medial malleolar fracture, widening of the mortise diastasis of the syndesmosis and fibular shaft comminuted fracture. He developed methamoglobinemia. The patient underwent surgery on September 24, 1999 of ORIF right ankle trimalleolar

fracture with fixation of the medial malleolus, syndesmosis screw and plate fixation of the fibular shaft.

The patient has been followed orthopedically since October 27, 2006. The initial examination noted removal of hardware in 2001 with persisting ankle pain since. He has also been diagnosed with posttraumatic arthritis. He is working at a job where he can mostly sit down. He can walk fairly comfortable and is using orthotics. Imaging shows lateral tilting of the talus with rotation of the lateral tibiotalar joint and some medial malleolar degenerative changes. No hardware is seen and there is a healed proximal fibular fracture. Impression is posttraumatic arthritis. He will be sent for orthotics to realign the hindfoot.

The medical report of April 8, 2009 notes the patient is having a fair amount of pain with some swelling and ecchymosis. He wears a high top boot for support. Ankle motion is limited with dorsiflexion of 70 or 90 degrees and plantar flexion of 30 degrees. There is mild crepitus. An injection was provided. The injection provided good relief and on August 18, 2009 the patient reports walking on a treadmill and doing exercises. Dorsiflexion is 5 degrees and plantar flexion 30 degrees.

On October 20, 2008 increasing pain was noted over the lateral side of his joint. An AFO brace was considered if his symptoms worsen. On November 24, 2008 it was noted that the last injection provided 3 months of relief. He does not desire a surgery. A repeat injection was provided. An AFO brace was ordered.

The patient returned on February 27, 2009. He was denied an AFO brace. He is wearing high top boots. His pain has returned since the last injection. There is tenderness and crepitus at the ankle. AN injection was provided. When the patient returned in June 2, 2009 the relief provided by the injection had worn off. He reported some increased pain and swelling. He is interested in an ankle arthroplasty but not at the present time. If we get to that point other specialist will be consulted as this is outside this provider's expertise.

At reevaluation of October 13, 2009 the patient reported gradually worsening symptoms. He would like to proceed with an arthroplasty. Dorsiflexion is to 5 degrees and plantar flexion to about 25 degrees. There is limited subtalar motion and moderate effusion. Mild to moderate crepitus is noted. Surgical options are arthrodesis versus arthroplasty. He desires an arthroplasty and he will be referred to a specialist.

The patient was provided an orthopedic consultation on November 5, 2009. The patient had an open Weber C. bimalleolar ankle fracture which was fixed well with standard means. He has his fibula fixed, his medial malleolus fixed and his syndesmosis fixed. This fracture pattern almost always ends up with avascular necrosis of the lateral tibial plafond and that was his problem. This leads to rapidly progressive arthrosis. As seen on x-rays, he does have lateral joint collapse via avascular necrosis of the lateral tibial plafond. He has been maintained conservatively with cortisone injections. He is in moderately severe pain and has a limp, and is very inactive. He does sedentary work most of the time. He has no significant contraindications to a surgery. He is a non-smoker and does not have diabetes. X-rays reveal, end-stage arthrosis of the ankle, high nonunion of the fibula that was asymptomatic on the physical examination, bone-on-bone arthrosis of the ankle and arthritic spur formation posterior part of the posterior facet with thinning of the joint cartilage in that area. His two options are ankle fusion or an ankle replacement. If he had no subtalar arthrosis, an ankle fusion would be a reasonable choice. But in the face of subtalar arthrosis, an ankle fusion is just going to rapidly progress to subtalar arthrosis by taking all of the forces of the ankle and transferring them into the subtalar joint. He would be pretty miserable with pain then from his subtalar joint and not from his ankle joint. In these cases, it is better to go with an ankle replacement, which will preserve motion rather than forcing untoward loads onto the subtalar joint. His function should be quite good. He has a reasonable preoperative motion in his ankle joint which can be maintained or improved. Surgery, however is not recommended at the present time as we will try to continue with conservative treatments as long as possible. Once a decision is made regarding a surgery, he will return for pre-op.

Request was made for ankle surgery on November 13, 2009.

Request for reconsideration, right ankle total arthroplasty was considered in review on November 30, 2009 with recommendation for non-certification. His history of treatment is noted. At this time cortisone shots do not provide relief. He complains of pain and swelling, which is supported on clinical exam along with crepitus. Dorsiflexion is to 5 degrees and plantar flexion to 25 degrees. There is a valgus angle. He also has an antalgic gait. Radiographs reveal what is reported as avascular necrosis (AVN) of the lateral tibial plafond and arthritis with decreased joint space and spurring. There is no MRI report supporting the AVN. The official reading of the radiographs also does not mention the AVN as present. A peer discussion was attempted but not realized.

Request for reconsideration, right ankle total arthroplasty was considered in review on December 15, 2009 with recommendation for non-certification. The current medications are not reported. A radiologist report was not submitted with the radiographs which were undated. A peer discussion was attempted but not realized. The complete physical examination of the ankle regarding gait analysis and inability to bear weight was not presented for review. He underwent conservative therapy but the physical therapy progress notes and the official report of the injection was not presented in the clinical notes. Additional information is needed to substantiate the need of the request. Additional relevant information from a peer-to-peer is needed to substantiate the medical necessity of the request.

Request was made for an IRO.

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

ODG states, ankle replacement is not recommended for total ankle using cemented devices approved via the FDA 510(k)

process. Four ankle prostheses are currently 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.

Following repair of an open bimalleolar ankle fracture, the patient developed rapidly progressive arthrosis which has been maintained until recently with injections. The patient complains of pain and swelling at the right ankle and has difficulty with walking. Injections are no longer helpful and a surgery is being considered with options of a fusion or joint replacement. He has had a consultation with a specialist who notes dorsiflexion to 5 degrees, plantar flexion to 25 degrees, a valgus angle and antalgic gait. X-rays are interpreted as revealing, end-stage arthrosis of the ankle, high nonunion of the fibula that was asymptomatic on the physical examination, bone-on-bone arthrosis of the ankle and arthritic spur formation posterior part of the posterior facet with thinning of the joint cartilage in that area. Per the specialist, he does have lateral joint collapse via avascular necrosis of the lateral tibial plafond per the x-rays. Recommendation is made for a joint replacement due the amount of subtalar arthrosis with rationale that an ankle fusion is just going to rapidly progress to subtalar arthrosis by taking all of the forces of the ankle and transferring them into the subtalar joint.

While AVN may not be verified, the examination and rationale for a joint replacement surgery has been well presented and has merit. This patient meets all the criteria for ankle replacement arthroplasty, has failed conservative treatments and has substantial arthritis which is the main reason for the surgery, not the AVN.

Therefore, my recommendation is to disagree with the previous non-certification for right total ankle arthroplasty with 23 hours of observation.

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 Chapter (12-18-2009), Arthroplasty - Total Ankle replacement:

Not recommended for total ankle using cemented devices approved via the FDA 510(k) process. [The FDA 510(k) process does not require data demonstrating improved outcomes.] Under study for first metatarsophalangeal joint implant arthroplasty.

Recommended as an option in selected patients for non-constrained uncemented devices with FDA PMA approval. See Scandinavian total ankle replacement system (STAR). 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.

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.

Post-traumatic osteonecrosis of the lateral tibial plafond - Foot and Ankle Surgery, Volume 13, Issue 1, Pages 24-29, M. Assal, B. Sangeorzan, S. Hansen:

We report a series of patients who presented with post-traumatic osteonecrosis of the lateral tibial plafond. Nine patients were identified with evidence of osteonecrosis limited to the lateral tibial plafond. All of them were seriously impaired with a mean valgus collapse of the ankle joint of 15.3°. Seven patients had a Weber C open medial fracture-dislocation, and two had a closed Weber C fracture-dislocation. This series confirms that post-traumatic osteonecrosis of the lateral tibial plafond is associated with Weber C fracture-dislocation. It evolves into a valgus deformity of the ankle due to collapse of the lateral tibial plafond. The prognosis is poor and required further reconstructive surgery in all cases.

[<http://linkinghub.elsevier.com/retrieve/pii/S126877310600066X>]