

Case Number:	CM14-0203374		
Date Assigned:	12/16/2014	Date of Injury:	05/19/2014
Decision Date:	12/23/2014	UR Denial Date:	11/05/2014
Priority:	Expedited	Application Received:	12/05/2014

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Orthopedic Surgery and is licensed to practice in California. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This 62-year-old male sustained an industrial injury on 5/19/14. Injury occurred when he twisted his right ankle walking on gravel. He reported an immediate onset of pain and swelling. Past medical history was positive for heart disease. Past surgical history was positive for remote right ankle open reduction and internal fixation. The 7/14/14 right ankle CT scan impression documented a healed trimalleolar fracture, no hardware complications, deformity with mild widening of the distal syndesmosis, and deformity with mild incongruity at the mortise, particularly at the medial malleoli fracture. There was severe secondary tibiotalar arthrosis and a 7x4 mm osteochondral body at the anterior/lateral ankle joint. Findings documented a non-traumatic prominent lateral peroneal tubercle resulting in narrowing of the sub-fibular space. The 10/28/14 treating physician report cited right ankle pain that had significantly worsened over the past month. Symptoms included frequent moderate pain with swelling, stiffness, and instability. Pain was worse with walking or prolonged standing. Right ankle exam documented exquisite, tenderness to palpation over the entire ankle region, anterior and lateral ankle, and over the deltoid ligament. Range of motion was significantly limited. Ankle and general foot strength was within normal limits. Right foot exam documented a midfoot mild pes planus deformity with tenderness to palpation over the sinus tarsi area. There was limited subtalar joint range of motion and midfoot rotation. The patient had an antalgic gait. Right ankle x-rays showed severe end-stage degenerative joint narrowing (bone-on-bone), worse on the lateral side, with subchondral sclerosis and cysts present. Subtalar joint x-rays showed moderate arthritic joint space narrowing. Implants were present and in excellent alignment. Right foot x-rays demonstrated moderate first ray elevatus. The diagnosis was right ankle pain, ankle arthritis, painful orthopedic hardware, degenerative foot arthritis, subtalar joint degenerative joint disease, acquired pes planovalgus, and ankle sprain. The patient had tried custom bracing, activity modification,

corticosteroid injection, and shoe gear modification without success. The treatment plan recommended right total ankle arthroplasty with Wright Medical Infinity total ankle protocol, cotton medial cuneiform osteotomy, and possible gastrocnemius recession with hardware removal and CT scan for surgical planning. The 11/5/14 utilization review denied the right total ankle arthroplasty and associated requests as the use of the Infinity total ankle replacement system was not listed as an FDA approved device consistent with evidence based medical guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

CT Scan Right Ankle: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not cite any medical evidence for its decision.

Decision rationale: Since the primary procedure is not medically necessary, none of the associated services are medically necessary.

Hardware Removal Right Ankle: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not cite any medical evidence for its decision.

Decision rationale: As the surgical request is not supported, this request is not medically necessary.

Right Total Ankle Arthroplasty with Implant, Cotton Medial Cuneiform Osteotomy and possible Gastrocnemius Recession: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Ankle and Foot Chapter, http://www.aetna.com/cpb/medical/data/600_699/0645.html

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Ankle and Foot, Arthroplasty (Total Ankle Replacement).

Decision rationale: The California MTUS guidelines do not provide recommendations for ankle arthroplasty. The Official Disability Guidelines, updated 12/22/14, state that total ankle replacement is not recommended for total ankle arthroplasty using cemented devices approved via the FDA 510(k) process. The FDA 510(k) process does not require data demonstrating

improved outcomes. The main alternative to total ankle replacement is arthrodesis. While fusion and arthroplasty procedures generally 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. Guideline criteria have not been met. The Wright Medical Infinity Total Ankle System received FDA 510(k) approval on 4/1/13 (# 123954) for use as an ankle joint metal/polymer semi-constrained cemented prosthesis. However, the requested implant device for this surgery does not meet guideline criteria as it is a cemented device and there is inadequate data to permit conclusions regarding safety and effectiveness over arthrodesis. Therefore, this request for Right Total Ankle Arthroplasty with Implant, Cotton Medial Cuneiform Osteotomy and possible Gastrocnemius Recession is not medically necessary.