

INDEPENDENT REVIEWERS OF TEXAS, INC.

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Notice of Independent Review Decision

Date notice sent to all parties:

December 6, 2012

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Reconsideration: 1) for hardware removal 20680, 2) arthroscopic debridement of tenosynovitis 29897, 3) stabilization of anterior talo-fibular ligament 27695

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

Board Certified Orthopedic Surgeon

REVIEW OUTCOME:

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

Overturned (Disagree)

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:

Clinical note dated 07/11/12
Clinical notes dated 08/28/12 – 10/01/12
Radiographs left ankle dated 09/11/12
CT left lower extremity dated 09/11/12
Prior reviews dated 09/18/12 and 10/17/12
Cover sheet and working documents

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who sustained an injury on xx/xx/xx when he rolled his left ankle. The patient was followed for a left ankle fracture and required an open reduction internal fixation of the left ankle on 10/26/10. The patient was initially

seen on 08/28/12 for complaints of weakness and limited range of motion in the left ankle. The patient is reported not to have improved with physical therapy. The patient reported pain with activity such as walking and standing for long periods of time. Physical examination revealed intact strength within the left ankle. Pain to palpation over the lateral malleolus, anterior talofibular ligament, and anterolateral ankle was noted. This pain was aggravated with range of motion. Anterior drawer sign was 2+ and there was a 7 degree left ankle tilt. The patient ambulated with an antalgic limp bearing the left lower extremity. The patient was recommended for updated imaging studies of the left ankle and foot. The patient did continue with physical therapy. Radiographs of the left ankle completed on 09/11/12 revealed lateral plate and transfibular screw fixation of the distal fibula. An accessory ossicle was noted inferior to the malleolus. CT studies of the left lower extremity completed on 09/11/12 revealed a healed distal fibular fracture. There was evidence of a chronic syndesmotic injury with hypertrophic bone noted along fibular attachment of the distal anterior tibiofibular ligament. There were corticated ossifications along the inferior margin of the medial malleolus measuring up to 7mm. There was mild overall osteoarthritis of the left ankle joint; however, there was no evidence of an osteochondral lesion or defect. Thickening of the anterior talofibular ligament was noted with no evidence of severe tearing. The anterior and posterior tendons were intact with slight thickening of the retromalleolar sulcus consistent with tendinosis. Follow-up on 09/12/12 stated that the patient continued to have left ankle pain with no change in symptoms. Physical examination was relatively unchanged from prior evaluations in 08/12. The patient was recommended for removal of hardware with arthroscopic tenosynovectomy and ATF ligament repair as well as Brostrum repair at this visit. Follow-up on 10/01/12 reported no change in the patient's symptoms. Physical examination was also unchanged from the 08/12 physical examination. Radiographs with fluoroscopy performed in clinic were stated to show a healed fracture line at the left fibula.

The request for ankle hardware removal, arthroscopic debridement of tenosynovitis, and stabilization of the anterior talofibular ligament was denied by utilization review on 09/18/12 as there was no evidence of a syndesmotic injury or peroneal tendon tearing. Per the contact information, the requesting physician agreed to perform stress x-rays and fluoroscopy.

The request was again denied by utilization review on 10/17/12 as there was no documentation regarding physical therapy, home exercise, or use of anti-inflammatories.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL

The requested hardware removal with arthroscopic debridement of tenosynovitis and stabilization of the anterior talofibular ligament is supported as medically necessary, based on the clinical documentation provided for review. The patient reported no significant changes in symptoms despite continued physical therapy through 09/12. The patient's physical examination revealed clear evidence of instability in the left ankle as there was a 2+ anterior drawer sign and up to 70

degrees of opening in the left ankle. The patient had no instability changes in the right ankle. CT studies did identify extensive tenosynovitis in the left ankle and given the patient's hardware present in the left ankle, MRI studies would be contraindicated at this point in time due to reasonable expected metal artifacts. Given the patient's objective findings consistent with disruption of the anterior talofibular ligament and extensive tenosynovitis with failure of conservative treatment to date, medical necessity would be supported per guideline recommendations and the prior determinations are overturned.

BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

Hardware implant removal (fracture fixation)

Not recommend the routine removal of hardware implanted for fracture fixation, except in the case of broken hardware or persistent pain, after ruling out other causes of pain such as infection and nonunion. Not recommended solely to protect against allergy, carcinogenesis, or metal detection. Although hardware removal is commonly done, it should not be considered a routine procedure. The decision to remove hardware has significant economic implications, including the costs of the procedure as well as possible work time lost for postoperative recovery, and implant removal may be challenging and lead to complications, such as neurovascular injury, refracture, or recurrence of deformity. Current literature does not support the routine removal of implants to protect against allergy, carcinogenesis, or metal detection. ([Busam, 2006](#)) Despite advances in metallurgy, fatigue failure of hardware is common when a fracture fails to heal. Revision procedures can be difficult, usually requiring removal of intact or broken hardware. ([Hak, 2008](#)) Following fracture healing, improvement in pain relief and function can be expected after removal of hardware in patients with persistent pain in the region of implanted hardware, after ruling out other causes of pain such as infection and nonunion. ([Minkowitz, 2007](#)) The routine removal of orthopaedic fixation devices after fracture healing remains an issue of debate, but implant removal in symptomatic patients is rated to be moderately effective. Many surgeons refuse a routine implant removal policy, and do not believe in clinically significant adverse effects of retained metal implants. Given the frequency of the procedure in orthopaedic departments worldwide, there is an urgent need for a large randomized trial to determine the efficacy and effectiveness of implant removal with regard to patient-centred outcomes. ([Hanson, 2008](#))

ODG Indications for Surgery™ -- Lateral ligament ankle reconstruction:

Criteria for lateral ligament ankle reconstruction for chronic instability or acute sprain/strain inversion injury:

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

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

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

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.

Procedures Not supported: Use of prosthetic ligaments, plastic implants, calcaneus osteotomies.