

CASEREVIEW

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Notice of Independent Review Decision

[Date notice sent to all parties]: January 26, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Hardware removal, right lower extremity

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

This physician is a Board Certified Orthopedic Surgeon with over 40 years of experience.

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.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male. He is s/p ROH and bone graft of right tibial fracture on 8/19/14.

On October 8, 2014, the claimant presented stating he was doing well and reported decreased discomfort in his right ankle. He reported slightly diminished swelling, however, continued to have limitation with his ankle ROM. He had been attending therapy and reported continued tightness in the right ankle that was limiting his ambulation and ROM. He was now able to bear weight on his right lower extremity. He reported numbness and tingling in the right ankle and foot, and the only point in his right foot and ankle that has sensation is his medial right foot. He is continuing on his daily bone stimulator and use of Vitamin E on his surgical scars. Current medications included: Lyrica, Oxycodone, Tramadol Hydrochloride and Vitamin D2. On physical examination of the right ankle and foot, circulation was intact with normal pulses and no edema. Surgical wounds

looked great with no signs of infection. Incisions were all healed. ROM was moderately limited of the ankle. Sensation had progressed under the heel. He still had decreased sensation on the superior and inferior right foot. 3 Views of the right ankle were taken in the office. Findings: Fractures are consolidating. Good callus formation noted on the medial tibia. IM nail and plates all intact. No signs of complication. Plan: Continue therapy.

On November 12, 2014, the claimant presented with complaints of continued pain and stiffness. He reported he had a pinhole in his great toe that he noticed about 3 weeks prior. He stated when he flexes his toe it begin to bleed. He reported he had been unable to bend his great and second toe. No changes on examination. 3 Views of the right ankle were taken in the office. Findings: Hardware is intact. Ample callus formation noted. Mortise is well maintained. No signs of complication. Plan: f/u early next year to discuss hardware removal.

On December 15, 2014, UR. Rationale for Denial: Per ODG regarding hardware removal of the ankle and foot, "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 medical records provided did not document sufficient complaints referable to the hardware that would support the need for the requested hardware removal within ODG recommendation. Hardware removal is not recommended per ODG except in the case of broken hardware or persistent pain, after ruling out other causes of pain such as infection and nonunion. This has not been documented. Therefore, the request for hardware removal is not medically necessary and as such, non-certified.

On December 31, 2014, UR. Rationale for Denial: The Official Disability Guidelines do not recommend the routine removal of hardware implanted for fracture fixation, except in cases of broken hardware or persistent pain after ruling out other causes of pain, such as infection or nonunion. It is not recommended solely to protect against allergy, carcinogens, or metal detection. This is an appeal. The request was denied previously due to the medical records provided did not document significant complaints referable to the hardware that would support the need for the requested hardware removal within ODG recommendation. Hardware removal is not recommended, per ODG, except in the case of broken hardware or persistent pain after ruling out other cause of pain, such as infection and nonunion. This has not been documented. Therefore, the request for hardware removal is not medically necessary and as such, non-certified.

On December 31, 2014, the claimant presented with continued complaints of pain over his proximal interlocking screw. He felt that his pain was preventing him from progressing with therapy. He had discontinued therapy until the screw can be removed. No other associated signs and symptoms. On examination of the knee and lower leg there was tenderness at the proximal medial plateau and mild-

moderate tenderness over the interlocking screw. Motors were intact and light touch sensation was normal. On examination of the ankle and foot, circulation was intact with normal pulses and no edema. Wounds looked great with no signs of infection. Incisions were all healed. There was good ROM of the knee and mildly limited ankle motion. 2 Views of the right ankle were taken in the office. Findings: Proximal interlocking screw is protruding into the surrounding medial soft tissues. IM nail is intact with no other signs of complication. Fracture is healed. Plan: Proceed with surgery to remove the proximal interlocking screw.

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

The previous adverse determinations are overturned. Although the ODG does not recommend the routine removal of hardware implanted for fracture fixation, for this claimant, it would be recommended to remove the protruding interlocking screw. On the November 12, 2014 evaluation, the claimant reported he had a pinhole in his great toe that he noticed about 3 weeks prior and stated that when he flexes his toe it begins to bleed. On December 31, 2014, the claimant presented with continued complaints of pain over his proximal interlocking screw. There was no sign of infection. The pain was such that it prevented him from progressing with therapy. X-rays that day showed that the proximal interlocking screw was protruding into the surrounding medial soft tissues. ODG does recommend routine removal of hardware in cases of persistent pain, therefore, removal of the interlocking screw is recommended and the request for hardware removal, right lower extremity is found to be medically necessary.

PER ODG:

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
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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](#))

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)