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DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
XX bone growth stimulator for nonunion fracture

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
American Board of Orthopedic Surgery

REVIEW OUTCOME:
Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:
X Upheld (Agree)
Medical documentation **does not support** the medical necessity of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:
The patient presented as a XXXX who sustained a work-related injury on XXXX. XXXX was trying to use a XXXX and sustained a crush injury to XXXX hand. XXXX was able to extract XXXX.
On XXXX, the patient was seen by XXXX for urgent care. XXXX complained of severe XXX-hand pain. On exam, the XX hand had decreased sensation in the ulnar distribution. XXXX had no movement of the third digit. There was an open fracture on the palmar surface and the third digit, closed fracture of second and fourth digits. The plan was to admit to Orthopedics.
On XXXX evaluated the patient. Radiographs showed fractures of the index/long/ring finger P1, second/third/fourth metacarpals. The plan was irrigation and debridement and percutaneous pinning.
From XXXX, the patient was admitted at XXXX. On XXXX, XXXX underwent XX hand irrigation and debridement skin to bone, XX index finger ray amputation, XX long finger ray amputation, open reduction, internal fixation (ORIF) and pin fixation of XXXX fourth metacarpal. XXXX also had a wound vacuum-assisted closure (VAC) device placed. Through XXXX hospital stay, XXXX continued to undergo serial irrigation and debridement every other day. On XXXX, XXXX was able to be partially closed with the placement of the synthetic skin inside the wound and the wound VAC was placed back on top of the Integra. Hyperbaric oxygen therapy was ordered. On XXXX, XXXX was approved for home wound VAC and XXXX hyperbaric oxygen therapy were set up as an outpatient.
On XXXX, the patient was seen at the XXXX. XXXX planned outpatient surgery on XXXX. The procedure was XX hand split-thickness skin graft from the XX lower extremity donor site.
On XXXX, a utilization review referral for skin graft was documented.
On XXXX, an orthopedic follow-up note was documented by XXXX. It was noted the patient underwent XX hand irrigation and debridement with split-thickness skin grafting and placement

of artificial soft tissue substitute on XXXX. XXXX had been overall doing quite well. Two sutures were still in place. This was healing well. There was a small wound approximately 0.3 cm x 0.2 cm x 0.1 cm in depth demonstrating good granulation tissue with no exposed tendon or bone. Skin graft over the medial aspect of the wound appeared to be healing well and tacked down with absorbable suture of Chromic gut. It was healing well. The donor site appeared to be healing with no signs of infection, erythema or drainage. XXXX placed ACell over the wound. A skin graft was left in place. Dry dressings were applied over the central palmar wound. XXXX was encouraged to perform ROM exercises.

On XXXX, XXXX performed a follow-up evaluation. It was noted postoperatively the patient had been overall doing well. XXXX had been complaining that some of the pins had been causing XXXX pain in XXXX hand. XXXX was able to feel the pins with XXXX contralateral hand. XXXX had not worked with OT yet. On exam, there was healing and intact skin grafting. No notable sutures could be seen. Abutment of K wires sub dermally could be appreciated. XXXX was able to flex notable free digits; however, XXXX was unable to extend them. The plan was to proceed with bone stimulator.

On XXXX, x-rays of the XX hand showed stable status post percutaneous pinning of the XX middle finger metacarpal comminuted diaphyseal fracture. There was interval percutaneous pinning of the XX ring finger metacarpal diaphyseal healing fracture.

On XXXX, a Utilization Review Referral for XX Bone Stimulator E0760 was documented.

On XXXX, performed a utilization review. The request for XX Bone Stimulator E0760 was denied based on the following rationale: "*Per evidence-based guidelines, bone stimulators are routinely used for delayed unions and nonunions, but not indicated for the treatment of acute fractures or stress fractures. However, it was recommended in selected long bone fractures. Also, there was no objective evidence that the two portions of the bone involved in the non-union are separated by less than 5 millimeters. Given the date of injury, the request was inconsistent with the criteria as the guideline stated a minimum of 90 days has elapsed from the time of the original fracture. Moreover, conservative care was not addressed in the medicals prior to considering this request.*"

On XXXX, XXXX ordered hand therapy.

On XXXX, performed a follow-up evaluation. The patient denied redness/swelling or drainage from the XX hand. XXXX had not been wearing a padded dressing over the hand due to the cost of buying supplies. XXXX had some tenderness over the skin overlying the K-wires, numbness/pain at XXXX scar sites. There was an intermittent pain at the tip of the ring finger. On exam, the incisions were well healed. There was flexion contracture of the XX ring finger PIP joint with intact extensor mechanism but a mechanical block prior to full extension. XXXX had intact flexion/extension (though not full) of the XX ring finger DIP joint. SILT through though diminished with paresthesias on the radial aspect of the ring finger, over the graft and scars. XXXX was able to make a fish with some effort and had limited flexion at the XX ring finger MCP. X-rays of the XX hand showed <u>nonunion of the XX third metacarpal</u> with less than 1 cm fracture gapping. <u>No significant healing was noted as compared with prior x-ray</u>. K wire was in place with no evidence of failure. XXXX diagnosed nonunion of the XX third metacarpal, flexion contracture of the XX ring finger PIP and limited flexion at theXX ring finger MCP. The plan was to start hand therapy, begin bone stimulation and stay out of work until next follow-up visit.

On XXXX, a Reconsideration/Appeal was documented.

On an unknown date, XXXX appealed the authorization of XX Bone Healing System. XXXX

stated that in a follow-up visit of XXXX, the patient's x-rays revealed minimal healing and persistent nonunion. The request for XX device was made to assist with healing. XXXX felt that this fracture had a high likelihood of not healing ever and was presently consistent with a non-union fracture which would require surgery. XX Bone Healing System was requested as a conservative treatment to prevent future surgical intervention. XXXX stated that based on the clinical information, the patient's condition and anticipated outcomes, the use of the XX was medically necessary and warranted coverage and reimbursement.

On XXXX, a Notification of Reconsideration Adverse Determination was documented by XXXX. The denial for XX Bone Stimulator E0760 was upheld with the following rationale: *"The previous noncertification on* XXXX, *was due to lack of medical necessity. The previous noncertification is supported. Additional records included an appeal on* XXXX, *which documented information regarding guidelines on the XX Bone Growth Stimulator and reasoning for prescription. As per evidence-based guidelines, bone growth stimulators are recommended in selected long bone fractures. It is supported for fresh or poorly healing scaphoid fractures or fractures with poor healing despite three months of appropriate conservative care. It is routinely used for delayed unions and nonunions, but not indicated for the treatment of acute fractures or stress fractures. The records do not reflect clearly the fracture has been adequately immobilized. The claimant has K wire placement with no evidence of failure. The x-ray in* XXXX *was unofficial. The remainder of the hand immobilization was not noted. The request for an appeal of an XX Bone Stimulator is not certified."*

On XXXX, the patient underwent an initial PT evaluation at XX. The diagnosis was crushing injury of XX hand. The plan was therapy two times a week for six weeks.

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

XXXX states in XXXX appeal letter, "I am requesting this as a conservative treatment to prevent future surgical intervention." I agree that the XX bone growth stimulator (XX BGS) may be effective in preventing further surgical intervention on the 3rd metacarpal (such as revision ORIF, bone grafting). Even if such surgery became necessary after attempting further conservative management with the XX BGS, the device would be indicated and necessary postoperatively.

However, three problems remain:

1. The most recent x-ray description is from XXXX on XXXX, wherein XXXX notes there is not adequate callus formation at the fracture site, but fails to describe the "site," the alignment, the displacement, the fixation, or any other commonly discussed parameter. The radiologist, XXXX, similarly fails to identify a nonunion or characterize the appearance, noting the left middle finger (3rd) metacarpal comminuted fracture was "stable." The lack of description of this and previous x-rays was noted by the two preauthorization reviewers and used by them as a major criterion for non-authorization due to lack of objective evidence of medical necessity. I concur.

2. The documentation herewith does not include any record or description of a XX-hand x-ray since the XXXX study. Interval healing may have occurred since this study taken nearly three months ago. At this time, more contemporaneous x-ray documentation is necessary before authorization can be considered (and with regard to #1 above, more descriptive and concise interpretation).
3. XXXX authored an appeal letter that is undated. XXXX introduces confusion into the request for the XX BGS, as XXXX identifies the "4th metacarpal" having been fractured and does not

discuss the 3rd metacarpal at all.
Until the additional, more concise and descriptive documentation is produced and the site of the fracture nonunion clarified, the non-authorization determination by the previous reviewers appears to have been appropriately derived.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:
☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**