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August 13, 2018: **Amended August 16, 2018**

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

XX bone growth stimulator for XX fracture

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

American Board of Orthopaedic 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 XX hand. XXXX was able to XXXX.

On XXXX, the patient was seen by XXXX. XXXX complained of severe XX hand pain. On exam, the XX hand had decreased sensation in the XX XX. XXXX had no movement of the XX digit. There was an open fracture on the XX surface and the XX digit, closed fracture of XX and XX digits. The plan was to admit to Orthopedics.

On XXXX., evaluated the patient. Radiographs showed fractures of the XX/XX/XX finger XX, XX/XX/XX XX. The plan was XX and XX and XX pinning.

From XXXX, the patient was admitted at XXXX. On XXXX, XXXX underwent XX hand XX and XX skin to bone, XX XX finger XX XX, XX XX finger XX XX, open XX, internal XX (XX) and pin XX of XXXX XX metacarpal. XXXX also had a wound vacuum-assisted closure (XX) device placed. Through XXXX hospital stay, XXXX continued to undergo serial XX and XX every other day. On XXXX, XXXX was able to be partially closed with the placement of the synthetic XX inside the wound and the wound XX was placed back on top of the XXXX. XX oxygen therapy was ordered. On XXXX, XXXX was approved for home wound XX and XXXX XX 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 XX XX from the XX XX XX XX site.

On XXXX, a utilization review referral for XX XX was documented.

On XXXX, an orthopedic follow-up note was documented by XXXX. It was noted the patient underwent XX hand XX and XX with XX-XX XX grafting and placement of XX soft XX XX 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 XX.XX cm x XX.XX cm x XX.XX cm in depth demonstrating good XX XX with no exposed XX or XX. XX graft over the medial aspect of the wound appeared to be healing well and tacked down with absorbable suture of XX XX. It was healing well. The donor site appeared to be healing with no signs of infection, XX or drainage. XXXX placed XX over the wound. A XX XX was left in place. Dry dressings were applied over the XX XX wound. XXXX was encouraged to perform ROM exercises.

On 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 XX hand. XXXX had not worked with OT yet. On exam, there was healing and intact XX XX. No notable sutures could be seen. XX of XX wires subdermally could be appreciated. XXXX was able to flex notable XX 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 XX finger XX comminuted XX fracture. There was interval XX pinning of the XX XX finger XX XX healing fracture.

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

On XXXX, performed a utilization review. The request for XX XX Stimulator XX 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 XX millimeters. Given the date of injury, the request was inconsistent with the criteria as the guideline stated a minimum of XX 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 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 XX-XX, numbness/pain at XXXX scar sites. There was an intermittent pain at the XX of the XX finger. On exam, the incisions were well healed. There was flexion contracture of the XX XX 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 XX finger XX XX. XX through though diminished with XX on the XX XX of the XX finger, over the XX and XX. XXXX was able to make a fish with some effort and had limited flexion at the XX XX finger XX. X-rays of the XX hand showed XX of the XX XX XX with less than XX cm fracture gapping. No significant healing was noted as compared with prior x-ray. XX XX was in place with no evidence of failure. XXXX diagnosed XX of the XX XX XX, XX XX of the XX XX finger XX and XX XX at the XX XX finger XX. 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 XX Healing System. XXXX stated that in a follow-up visit of XXXX, the patient's x-rays revealed XX XX and XX XX. 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 XX-XX fracture which would require surgery. XX XX 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 XX Stimulator XX 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 XX Growth Stimulator and reasoning for prescription. As per evidence-based guidelines, XX XX stimulators are recommended in selected long bone fractures. It is supported for fresh or poorly healing XX XX or fractures with poor healing despite XX 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 XX XX 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 XX Stimulator is not certified."

On XXXX, the patient underwent an initial PT evaluation at Momentum Physical Therapy. The diagnosis was XXXX 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 XX growth stimulator (XX XX) may be effective in preventing further surgical intervention on the XX XX (such as revision XX, XX XX). Even if such surgery became necessary after attempting further conservative management with the XX XX, the device would be indicated and necessary postoperatively.

However, three problems remain:

1. The most recent x-ray description is from XXXX, wherein XXXX notes there is not adequate XX 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 XX XX finger (XX) XX 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 XX 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 XX, as XXXX identifies the "XX XX" having been fractured and does not discuss the XX XX 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 thus the XX bone growth stimulator is not medically necessary.

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

☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**