Date notice sent to all parties: 4/27/2018
IRO CASE #: XXXX

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
The item in dispute is the prospective medical necessity of an exogen bone stimulator.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
The reviewer is a Medical Doctor who is board certified in orthopedic surgery.

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

☒ Upheld (Agree)

☐ Overturned (Disagree)

☐ Partially Overturned (Agree in part/Disagree in part)

The reviewer agrees with the previous adverse determination regarding the prospective medical necessity of an exogen bone stimulator.

PATIENT CLINICAL HISTORY [SUMMARY]:
This patient is a XX who sustained an XX injury on XXXX when XX was XX. XX reported that XX and dorsiflexed XX ankle. The XX treating physician report documented radiology results showing left talus (anterior) possible fracture, and negative fracture or dislocation of the left metatarsals and deltoid. The XXXX left ankle MRI impression documented contusion of the calcaneus and adjacent cuboid, no displaced fracture, and strain injuries of the peroneus tendons and tibialis posterior tendon. The XXXX orthopedic report indicated that the patient was still having left ankle pain and weakness. XX had undergone XX of physical therapy which made it worse. Previous MRI overall impression was contusion of the calcaneus and adjacent cuboid, no fractures with strain injury of the peroneus tendons and tibialis posterior tendon. Left ankle exam documented slight swelling laterally. XX was very tender anywhere XX was palpated laterally, tender along the deltoid ligament medially, and tender over the anterior aspect of the ankle. XX had restricted ankle range of motion. The orthopedist was not quite sure why XX had such hypersensitivity and pain with any movement or palpation to the left ankle. A new MRI of the left ankle was ordered. XX was to continue with the boot and light duty work. The XXXX left ankle/foot MRI impression documented anterior calcaneal process acute non-displaced articular fracture, hallux tibial

sesamoid fracture, and hallux fibular sesamoid AVN changes with predominant sclerosis and minimal edema. The XXXX podiatry report cited complaints of persistent moderate left ankle pain with walking and daily activities. Associated symptoms included weakness, numbness, tingling, swelling, catching/locking, and popping/clicking. Aggravating factors included standing, walking, twisting, bending/squatting, pushing, pulling, and range of motion, bearing weight, getting out of bed, and going up or down stairs. Physical therapy did not help. XX was working modified duty. XX still had significant discomfort with ambulation and walking. Physical exam documented antalgic gait and left lower extremity limp. Left ankle/foot exam documented swelling deformity, hind foot valgus, midfoot planus, and forefoot pronated. There was tenderness of the medial ankle, lateral ankle, gutter ankle, dome and head of the talus, and inferior tibiofibular joint. There was tenderness over the tibialis posterior, tibialis anterior, Achilles tendon, peroneus longus and brevis, sinus tarsi, lateral anterior talofibular ligament, anterior talofibular ligament, calcaneofibular ligament, posterior talofibular ligament, peroneal retinaculum, and deltoid ligament. Active range of motion was decreased and painful. There was a positive anterior drawer sign, 4/5 peroneus longus and brevis weakness, and guarding secondary to pain. There was talar tilt pain and instability, ankle eversion test, abnormal deltoid ligament complex, and clunk test. The diagnosis was left ankle calcaneal anterior process fracture with avascular necrosis (AVN) of the fibular sesamoids. It was noted that the patient had a very difficult problem. MRI scan results were reviewed. An Exogen bone stimulator was recommended. The treatment plan recommended consideration of surgery in the future. The XXXX utilization review non-certified the request for a bone growth stimulator. The rationale stated that guidelines criteria had not been met as there was no clear documentation that the fracture remaining adequately immobilized. The XXXX podiatry report cited persistent grade 6/10 left ankle pain with associated symptoms including weakness, numbness, tingling, swelling, catching/locking, and popping/clicking. The patient had worsening symptoms. Physical exam findings were unchanged. The diagnosis was left ankle calcaneal anterior process fracture with avascular necrosis of the fibular sesamoids. It was noted that the patient fit the Exogen criteria given non-union/malunion of fracture over XX. A bone growth stimulator was recommended as an alternative to surgery. The XXXX utilization review non-certified the request for a bone growth stimulator. The rationale state that there was inadequate documentation to demonstrate that all of the guideline criteria had been met. There was no documentation provided to confirm that no progressive signs of healing had occurred, and no documentation to demonstrated adequate immobilization efforts. The XXXX podiatry report indicated that the patient continued to be symptomatic with left foot/ankle pain. XX had pain along the lateral and medial aspect of the foot with weight bearing. XX reported the pain was getting worse. XX had swelling and redness mainly at the end of the day. XX was unable to do therapy, continued to have difficulty with activities of daily living, and had continued pain in the boot and standing. XX continued to wear the boot. XX had acute tenderness along the plantar sesamoid complex with noted pain along the lateral ankle and sinus tarsi. Dorsiflexion and plantar flexion were

limited and painful. There was lateral ankle and lateral foot swelling, painful midfoot range of motion with noted dorsal and lateral swelling, and discoloration of the dorsal and lateral foot. A cast mold was obtained and a custom AFO brace was ordered. XX had continued pain and inability to weight bear. A bone growth stimulator was recommended as a great alternative for calcaneal fracture and AVN of the sesamoid. It was noted that if bone growth stimulator was denied, surgery was the only other alternative.

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

The Official Disability Guidelines, Ankle and Foot Chapter, recommend bone growth stimulators as an option for delayed or non-union of fracture, especially with significant associated risk factors. Low-intensity pulsed ultrasound (LIPUS) is no longer recommended for fresh fractures. Guidelines state that low-intensity pulsed ultrasound may be considered medically necessary in patients with delayed or nonunion of bones, when all of the following criteria are met: (1) At least three months have elapsed since the date of fracture and the initiation of conventional fracture treatments; (2) Serial x-rays have confirmed that no progressive signs of healing have occurred; (3) The fracture gap is one centimeter or less; & (4) fracture is adequately immobilized.

This patient sustained a left ankle/foot injury on XXXX. Initial radiographs and imaging were reported negative for fracture or dislocation. XX experienced on-going pain and functional limitations in ambulation. XX was worsened with initial physical therapy and remained in a cast boot. Repeat MRI on XXXX demonstrated anterior calcaneal process acute non-displaced articular fracture, hallux tibial sesamoid fracture, and hallux fibular sesamoid AVN changes with predominant sclerosis and minimal edema. XX has been recommended for a bone growth stimulator since XXXX. Guideline criteria have not been met. There is no evidence that XX of conventional fracture treatments had elapsed at the time of the initial request. There is no evidence of adequate immobilization. There is no documentation of serial radiographs confirming that no progressive signs of healing have occurred. Therefore, the request for a bone stimulator is not medically necessary at this time.

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)**