Icon Medical Solutions, Inc.

P.O. BOX 169
Troup, TX 75789
P 903.749.4272
F 888.663.6614

DATE: 3/31/18
IRO CASE #: XXXXXX

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Spinal Cord Stimulator Implantation

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
The reviewer is certified by The American Board of Anesthesia with over 11 years of experience.

REVIEW OUTCOME:
Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:
☒ Upheld (Agree)

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]:
Claimant is a XX with a date of injury of XXXX when XX.
XXXX: Office Visit with XX. Pt c/o bilateral foot pain. The pain is the same on both sides. States XX walks with a limp. ROM is normal. Treatment has included PT, which help and NSAIDs, which relieves the pain. Rt foot; pain is located plantar. Pain is dull, aching, and burning. Symptoms are increased with activity; standing from a sitting position, and the first steps in the morning are the worst. Left foot; pain is located dorsal. Pain is dull, aching, and burning. Symptoms are increased with activity; standing from a sitting position, and the first steps in the morning are the worst. Right peroneal tendon repair on XXXX. Pt has pain at the rt and lt hindfoot in the plantar fascia insertion. Peroneal tendonitis; left and right leg, sprain of calcaneofibular ligament of left ankle, plantar fascial fibromatosis.

XXXX: Office Visit with XX. Pt underwent ultrasound guided plantar fasciitis release and indicated procedures on XXXX. XX is not having any pain in XX left foot. XX pain level is 5/10 in XX right foot, unless XX is walking and standing. There is still numbness and tingling on XX left foot. Swelling in both feet. Norco 7.5-325 1-ii po q4-6h prn. Pain in right lateral hindfoot. MRI to rt heel due to lateral heel pain.
XXXX: Office Visit with XX. Active ROM-Right Ankle Exam- Degrees of inversion:30, eversion:15, dorsiflexion:20, plantarflexion:30. MRI rt heel reviewed: peroneus brevis tendinopathy with flattening vs split tear, and chronic thickening and inflammation of the central plantar fascia bundle. Symptoms are impacting their quality of life and ability to undertake necessary and desired activity despite appropriate conservative care. We have discussed further non-operative treatment options at length. We will plan for open plantar fascia release and peroneus brevis debridement with tendon transfer.

XXXX: Operative Report. Right peroneus longus tendon tenolysis. Right peroneus brevis tendon transfer. Right open plantar fascia release. Peroneal tear was initially treated with debridement of the tendon and tear involved less than 50% of the tendon. XX failed to fully recover and resolve XX pain on this side. XX also had minimally invasive partial plantar fascia release, which also failed to alleviate XX pain on this side. Repeat MRI continued to show plantar fasciitis as well as evidence of a peroneus brevis tendon tear with signal changes prior to excision. Due to findings and the patients continued pain, I recommended excision of the peroneus tendon and transfer to

the peroneus longus tendon and do a tenodesis proximally and distally. I also recommended an open plantar fascia release due to failure to resolve XX pain with prior conservative treatment measures as well as minimally invasive plantar fascia release.

XXXX- XXXX: Psychological Evaluation. Results of this testing suggested an absence of depression, anxiety, or psychopathology, and indicated that XX is not suffering from any current psychological condition which would prevent XX from making an educated, competent decision or from having a positive post-surgical recovery.

XXXX: Chronic Pain Program Sheets (handwritten). XX. Group therapy session of Interpersonal skills. Pain management education class on Assertiveness Training. Much relief with MFR. Chief Complaint is maintaining motivation through the pain. Taking Cymbalta, Gabapentin. Not taking any opioids.

XXXX: Chronic Pain Program Sheets. Group therapy- XX. Pain Management education Class-XX. Good lifting technique, making great progress towards goals.

XXXX: Chronic Pain Program Sheets. Group therapy session- XX/ Group Progress. Pain Management Class-XX. Tried TENS unit last night, felt good for a while but then later, the pain was really high. Decreased tol with activities today.

XXXX: Chronic Pain Program Sheets. XX. GTS- XX. PMC- XX. Doing better today, not so much burning in XX foot.

XXXX: Office Visit XX. Pt has participated in XX of a Functional Restoration and Chronic Pain Program. XX reports XX pain is no longer constant, intermittent sharp stabbing pain approximately every 30 minutes lasting 1-2 minutes. XX continues to have a hard time driving longer than 15 minutes. XX is lifting 35 pounds. Pain levels have improved, presently XX level of pain is 1/10. XX continues taking Gabapentin 30mg tid and Cymbalta 60mg q daily. Pt reports noticing having difficulty with cognitive issues, focusing for the last XX. Minimal allodynia right dorsum of foot. DTRs 2+ and symmetrical. No long tract signs, plantar reflexes down going. Gait: right antalgic. Triple phase bone scan suggesting RLE ankle foot CRPS, Type 1 consistent with clinical presentation and exam. Pt will continue with present medication management. Continue participation in Functional Restoration and Chronic Pain Program. Pt plans to progress lifting 40 lbs by the XX as tolerated.

XXXX: Chronic Program Sheet. XX. Slight increased edema bilateral ankles. TENS unit helps. Gabapentin 400mg 3 daily.

XXXX: Chronic Program Sheet. XX. Increased sense of security with MF tape to right ankle.

XXXX: Chronic Program Sheet. XX. MF tape to rt ankle, lateral aspect with wrap around heel. Feels extra support with MF tape.

XXXX: Chronic Program Sheet. XX. Dolphin- foot pain protocol; (scar or scan) protocol (all handwritten). Tolerated well.

XXXX: Office Visit with XX. Pt has been c/o right foot ventral aspect: allodynia, hyperalgesia, coldness to touch and intolerance, swelling, red/purplish color, dec ROM, weakness, nail growth is lower. Pt has been taking Cymbalta and gabapentin which helps but caused AMS. Lyrica caused swelling. Pt has done LSB multiple times, which helped drastically but prolonged time at first. However, currently they help for only a week now,; done by XX. Pain is constant stabbing, burning. States pain is >8, not progressing, sharp, dull, achy and burning. Pain is constant. Symptoms are increased with activity; standing, getting up from a chair, bending forwards or backwards, walking, twisting and climbing stairs. Other symptoms include: swelling, weakness, falls, spasms/cramps and discoloration. Medications: Cymbalta 60mg, Gabapentin 600mg. Trulicity 1.5mg/0.5ml. Pravastatin, Prempro and Metformin. Problems: 1. Complex Regional Pain Syndrome of Right Lower Limb. 2. Stiffness of Right Ankle. Discussed with pt the etiology of XX pain. Informed XX that XX would likely benefit from a SCS trial. Continue Cymbalta and Gabapentin. Continue HEP.

XXXX: Office Visit with XX. Pt underwent SCS trial on XXXX. The effectivetion is a 75% out of 100%.C/O joint swelling and cramps. On physical exam: color, swelling and ROM. CRPS.. Pt would likely benefit from a SCS implant.

XXXX: UR by XX. Rationale- Peer to peer was not established. Guidelines state that permanent placement requires evidence of 50% pain relief and medication reduction or functional improvement after the temporary trial. It was noted that the patient underwent a SCS trial on XX and reported 75% effectiveness with the stimulator. However, there was a lack of documentation regarding medication reduction and functional improvement with the trial. Furthermore, on the clinical note dated on XXXX, there was also a lack of examination findings of complex regional pain syndrome. As such, the request is non-certified.

XXXX: UR by XX. Rationale- In this case, the claimant does have a history of CRPS diagnosis; however, documentation dated XXXX does not diagnose the claimant with CRPS, and documentation from XXXX states that there is no evidence of CRPS on examination. On XXXX it's noted that sensation is normal overall though there is hypersensitivity to light touch on the right leg. In contrast, documentation dated XXXX specialty evaluation notes; right foot ventral aspect: allodynia, hyperalgesia, coldness to touch and intolerance, swelling, red/purplish color, dec ROM, weakness, nail growth is lower. This abrupt change in symptoms is not characteristic of the onset of CRPS. Provider notes improvement with SCS trial of XX duration. He notes 75% improvement in records, and on call the records do not identify functional gains. Though, in case discussion, the provider asserts increased function in all aspects of daily life, most notably in standing and walking. There was no change in medication, which would not be anticipated for an antidepressant (Cymbalta) and anticonvulsant (Gabapentin); as these are not as needed medications and require a downward titration. While the case discussion notes that the claimant does have a clear diagnosis of CRPS and had a positive response to the spinal cord stimulator trial, the medical necessity of implantation are not met as all criteria per ODG is not supported by clinical documentation. The criteria include evidence of 50% pain relief and medication reduction or functional improvement. Absent clinical evidence of functional improvement during the trial, medical necessity is not established.

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

The previous adverse decisions are upheld. Based on the records submitted and peer reviewed guidelines, this request is non-certified. In this case, changing physical examination and symptomatology make a confirmed diagnosis of CRPS impossible. Provider notes improvement of pain relief of 75% with SCS trial of XX duration. However, there is no documentation of reduction in medication usage or functional improvement. Therefore, this request is considered not medically necessary.

PER ODG:

Spinal cord stimulators (SCS)	Recommended only for selected patients for specific conditions and in cases when less invasive procedures have failed or are contraindicated (see blue criteria to be met when considering use of a spinal cord stimulator). Spinal cord stimulators (SCS) are indicated for selected patients with Complex Regional Pain Syndrome (CRPS) Type I. For use in failed back surgery syndrome (FBSS), see the Low Back Chapter. See also Psychological evaluations (SCS) in the Mental Illness & Stress Chapter. **Indications for stimulator implantation:** • Complex Regional Pain Syndrome (CRPS) when all of the following are present: (1) There has been limited response to non-interventional care; (2) Psychological clearance indicates realistic expectations and clearance for the procedure; (3) There is no current evidence of substance abuse issues; (4) There are no contraindications to a trial; (5) Permanent placement requires evidence of 50% pain relief and medication reduction or functional improvement after temporary trial.

	• For use in failed back surgery syndrome (FBSS), see the Low Back Chapter. • For average hospital LOS if criteria are met, see Hospital length of stay (LOS). More trials are needed to confirm whether SCS is an effective treatment for certain types of chronic pain. (Mailis-Gagnon-Cochrane, 2004) (BlueCross BlueShield, 2004). This supporting evidence is significantly supplemented and enhanced when combined with the individually based observational evidence gained through an individual trial prior to implant. This individually based observational evidence should be used to demonstrate effectiveness and to determine appropriate subsequent treatment. (Sundaraj, 2005) Further, the introduction of the percutaneous electrode implantation has enabled trial stimulation, which is now commonly recognized as an indispensable step in assessing whether the treatment is appropriate for individual patients. (Furlan-Cochrane, 2004) CRPS patients implanted with SCS reported pain relief of at least 50% over a median follow-up period of 33 months. (Taylor, 2006) SCS appears to be an effective therapy in the management of patients with CRPS. (Kemler, 2004) (Kemler, 2000) Recently published 5-year data from this study showed that change in pain intensity was not significantly different between the SCS plus PT group and the PT alone group, but in the subgroup analysis of implanted SCS patients, the change in pain intensity between the two groups approached statistical significance in favor of SCS, and 95% of patients with an implant would repeat the treatment for the same result. A thorough understanding of these results including the merits of intention-to-treat and as-treated forms of analysis as they relate to this therapy (where trial stimulation may result in a large drop-out rate) should be undertaken prior to definitive conclusions being made. (Kemler, 2008) Permanent pain relief in CRPS-I can be attained under long-term SCS therapy combined with physical therapy. (Harke, 2005) As batteries for both rechargeable and nonrechargeable systems are nearing end of life, there are both early replacement indicators and end of service notifications. Typical life may be 8-9 years for rechargeable batteries, but this depends on the unit. In addition, the physician programmer can be used to interrogate the implanted device and determine the estimated remaining battery life. (Restore, 2011)

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)**