

<b>Case Number:</b>	CM13-0022178		
<b>Date Assigned:</b>	11/13/2013	<b>Date of Injury:</b>	09/01/2004
<b>Decision Date:</b>	01/23/2014	<b>UR Denial Date:</b>	09/04/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/09/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Pain Management, has a subspecialty in Disability Evaluation and is licensed to practice in California. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The physician reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

Summary of medical records indicated that the claimant is a 54-year-old former sales clerk, employed by [REDACTED]. She indicates she began that employment in June 2004 and last worked for that employer in February 2005. She indicates that on September 1, 2004, she fell down four to five stairs, landing on her left side. She describes injury to her left foot and ankle. She indicates that she was able to continue working post injury. She indicates that later that day, she was seen at an emergency room facility where she underwent x-rays. She was diagnosed as having a left ankle sprain with a possible cuboid bone fracture. She indicates that she was splinted, and was then referred to [REDACTED], an orthopaedic surgeon. X-rays of the left ankle performed September 1, 2004, noted a questionable cortical avulsion of the cuboid or distal calcaneus. There was no significant soft tissue swelling. She was seen by [REDACTED] on September 7, 2004, and at that time was diagnosed as having a severe left ankle sprain with possible avulsion fracture of the distal calcaneus versus proximal cuboid. She also states that she was initially casted by [REDACTED], and subsequently referred for a course of physical therapy. Repeat x-rays of the left foot and ankle dated October 21, 2004, noted either an avulsion fracture or accessory ossicle. An MRI scan of the ankle and foot was recommended. On January 25, 2005, she underwent an MRI scan of the left ankle and foot. That study showed no acute process or evidence of fracture. The ligaments were intact. The claimant states she was able to return to her normal work activities. She indicates that she continued to have swelling in the foot. She was subsequently terminated by her employer in February 2005. She indicates that she was referred by [REDACTED] to [REDACTED], a neurologist. [REDACTED] diagnosed her as having reflex sympathetic dystrophy and placed her on medications (Neurontin). She also underwent a Qualified

## IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

**Clonidine 0.2mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Catapres (Clonidine).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Clonidine, Page(s): 34-35, 55.

**Decision rationale:** CA-MTUS (Effective July 18, 2009) page 34, 35 and 55 of 127 indicated that Clonidine also known as Catapres is FDA approved for intrathecal delivery, is thought to provide analgesic effect via a non-opioid mechanism. The medication is FDA approved with an orphan drug intrathecal indication for cancer pain only. It has been found to offer only short-term relief when used as a single agent. (Deer, 2007). It is considered a second line treatment in patients with Reflex Sympathetic Dystrophy or Chronic relapsing pain syndrome. One intermediate quality randomized controlled trial found that intrathecal clonidine alone worked no better than placebo. It also found that clonidine with morphine worked better than placebo or morphine or clonidine alone. (Ackermann, 2003) (Hassenbusch, 2002) (Martin, 2001) (Raphael, 2002) (Roberts, 2001) (Siddall, 2000) (Taricco, 2006) Recommended only after a short-term trial indicates pain relief in patients refractory to opioid monotherapy or opioids with local anesthetic. There is little evidence that this medication provides long-term pain relief (when used in combination with opioids approximately 80% of patients had < 24 months of pain relief) and no studies have investigated the neuromuscular, vascular or cardiovascular physiologic changes that can occur over a long period of administration:- Side effects include hypotension, and the medication should not be stopped abruptly due to the risk of rebound hypertension. Oral clonidine is not FDA approved for treatment of chronic pain. Therefore the request for clonidine 0.2mg #60 is not medically necessary.

**Gabapentin 600mg #180:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin (Neurontin).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 18-19. Decision based on Non-MTUS Citation Arch Phys Med Rehabil. 1997 Jan;78(1):98-105. Reflex sympathetic dystrophy treated with gabapentin. Mellick GA, Mellick LB.

**Decision rationale:** Gabapentin is an anti-epilepsy drug (AEDs - also referred to as anti-convulsants), which has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. (Backonja, 2002) (ICSI, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Attal, 2006) This RCT concluded that gabapentin monotherapy appears to be efficacious for the treatment of pain and sleep interference associated with diabetic peripheral neuropathy and exhibits positive effects on

mood and quality of life. (Backonja, 1998) It has been given FDA approval for treatment of post-herpetic neuralgia. The number needed to treat (NNT) for overall neuropathic pain is 4. It has a more favorable side-effect profile than Carbamazepine, with a number needed to harm of 2.5. (Wiffen2-Cochrane, 2005) (Zaremba, 2006) Gabapentin in combination with morphine has been studied for treatment of diabetic neuropathy and postherpetic neuralgia. When used in combination the maximum tolerated dosage of both drugs was lower than when each was used as a single agent and better analgesia occurred at lower doses of each. (Gilron-NEJM, 2005) Recommendations involving combination therapy require further study According to CA-MTUS, Gabapentin should not be abruptly discontinued, although this recommendation is made based on seizure therapy. Weaning and/or switching to another drug in this class should be done over the minimum of a week. (Neurontin package insert). An abstract published in Archives of Physical Medicine and Rehab in January 1997 stated "The use of the recently released anticonvulsant, gabapentin (Neurontin), in the treatment of severe and refractory reflex sympathetic dystrophy (RSD) pain in six patients ranging in age from 42 to 68 years is reported. Satisfactory pain relief obtained in all six patients suggests that this medication is an effective treatment for RSD pain. In addition to pain control, early evidence of disease reversal in these patients is suggested. Patient 6 is the first documented case of successful treatment and cure of the RSD pain syndrome using gabapentin alone. Specifically, reduced hyperpathia, allodynia, hyperalgesia, and early reversal of skin and soft tissue manifestations were noted. Gabapentin was chosen because it has properties similar to other anticonvulsant drugs and because previous studies have shown that it is well tolerated and appears to have a benign efficacy-to-toxicity ratio. It was considered an acceptable and compassionate therapeutic choice because previous medical and surgical approaches had been ineffective for these patients, who represent the first case series documenting the use of gabapentin for pain management. Presently, the mechanism of pain relief in these patients is unknown. In this article, the pathophysiology of RSD is discussed, and a mechanism by which gabapentin provides pain relief is proposed. In view of encouraging results in these and other RSD

**Norco #240:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Norco (hydrocodone)..

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Norco (hydrocodone), Page(s): 52, 76-77, 93.

**Decision rationale:** CA-MTUS (July 18, 2009) Chronic Pain Medical Treatment Guidelines Norco (hydrocodone (is a semi-synthetic opioid which is considered the most potent oral opioid) and Acetamenophen) is Indicated for moderate to moderately severe pain however, page 76 through 77 MTUS stipulated specific criteria to follow before a trial of opioids for chronic pain management..Opioid drugs are available in various dosage forms and strengths. They are considered the most powerful class of analgesics that may be used to manage chronic pain. These medications are generally classified according to potency and duration of dosage duration. Evidence-based guidelines recommend the use of opioid pain medications for the short-term treatment of moderate to severe pain. Ongoing use of opiate medication may be recommended with documented pain relief, an increase in functional improvement, a return to work and

evidence of proper use of the medications. Supplemental doses of break-through medication may be required for incidental pain, end-of dose pain, and pain that occurs with predictable situations. When discontinuing opiate pain medication a slow taper is recommended to wean the patient. Besides results of studies of opioids for musculoskeletal conditions (as opposed to cancer pain) generally recommend short use of opioids for severe cases, not to exceed 2 weeks, and do not support chronic use (MTUS page 82). Therefore the request for Norco #240 is not medically necessary.