

<b>Case Number:</b>	CM14-0150485		
<b>Date Assigned:</b>	09/19/2014	<b>Date of Injury:</b>	06/13/2003
<b>Decision Date:</b>	10/24/2014	<b>UR Denial Date:</b>	08/31/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/16/2014

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Physical Medicine and Rehabilitation 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 expert 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:

The injured worker is a 71-year-old male who reported an injury on 06/13/2003. The mechanism of injury was not provided. The injured worker's diagnoses included knee pain, pain in the lower leg joint and chronic pain syndrome. The injured worker's past treatments included a home exercise program and medications. The injured worker's diagnostic testing included a urine toxicology screening. There were no relevant surgeries documented. On 04/02/2014, the injured worker complained of right knee pain. He reported that his quality of sleep is poor, averaging 4 hours per night. He reported that since the last visit, and his quality of life had remained unchanged. He reported his social activity level had decreased, and reported no change in activities of daily living. Upon physical examination, the injured worker was noted to have a slow gait; his right knee range of motion was restricted with flexion, extension, internal and external rotation. There was 1+ effusion in the right knee joint. The motor testing was limited by pain. His current medications included Lidoderm 5% patch, Naproxen 250 mg, Norco 10/325 mg, Celebrex 200 mg and blood pressure medications. The request was for Terocin patch 4-4%, Norco 10/325 mg, Theramine, and Celebrex 200 mg. The rationale for the request was not provided. The Request for Authorization was signed and submitted on 08/25/2014.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Terocin patch 4-4% # 30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Capsaicin, topical, Lidocaine Indications, Sal.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics; Lidocaine Page(s): 111;112.

**Decision rationale:** The California MTUS Guidelines states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, however, there is little to no research to support the use of many of these agents. Any compounded product that contains at least 1 drug or drug class that is not recommended, therefore, is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Terocin patches include Lidocaine and menthol. Lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first line therapy. Topical Lidocaine, in the formulation of a dermal patch, Lidoderm, has been designated for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulations of Lidocaine are indicated for neuropathic pain. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than postherpetic neuralgia. In 02/2007, the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical Lidocaine. Those at particular risk were individuals that apply large amounts of the substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Only FDA approved products are currently recommended. The use of Lidocaine may be recommended in the formulation of dermal patch, Lidoderm, for orphan status by the FDA for neuropathic pain. The injured worker complained of pain to his right knee, however, the documentation did not provide a thorough pain assessment to include a quantified current pain, the least reported pain over the period since last assessment, intensity of pain after taking the medications, and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. In the absence of documentation with evidence of significant objective functional improvement and a complete and thorough pain evaluation, the request is not supported at this time. Additionally, as the request is written there is no frequency provided. Therefore, the request is not medically necessary.

**Norco 10/325mg # 60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, specific drug list, Opioids for chronic pain, Opioids, cr.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78-80.

**Decision rationale:** The California MTUS Guidelines may recommend continue opioid therapy for patients with ongoing review and documentation of pain relief, functional status, appropriate medication use and side effects. The pain assessment should include current pain, the least

reported pain over the period since last assessment, intensity of pain after taking the medication, and how long pain relief last. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function or improved quality of life. 4 domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug related behaviors. The injured worker reported that his quality of life had remained unchanged; his social activity level had decreased, and reported no change in activities of daily living. The documentation does indicate that the patient was being monitored for the occurrence of potentially aberrant drug related behaviors by urine toxicology screening. The guidelines state to continue opioids if the patient has returned to work, or if the patient has improved functioning and pain. The documentation included a urine toxicology screening from 10/2011; the injured worker was noted to have been taking Norco since at least 10/2013. Opioids for chronic pain appear to be efficacious when limited for short term pain relief, and long term efficacy is unclear. The injured worker reported that he is not working, and he reported no change in activities of daily living. In the absence of documentation with evidence of increased functional status, decreased pain, and improved quality of life, the request is not supported. Additionally, as the request is written there was no frequency provided. Therefore, the request is not medically necessary.

**Theramine #90: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Theramine

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Theramine

**Decision rationale:** The Official Disability Guidelines state that Theramine is not recommended for the treatment of chronic pain. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. The injured worker was noted to have chronic pain syndrome, however, there was not a complete and thorough pain evaluation documented to include a quantified current pain, the least reported pain over the period since last assessment, intensity of pain after taking the medications, and how long pain relief lasts. Additionally, the guidelines do not recommend Theramine. Furthermore, as the request is written there is no frequency provided. Therefore, the request is not medically necessary.

**Celebrex 200mg #30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, specific d.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs; Celebrex Page(s): 67-68; 30.

**Decision rationale:** The California MTUS guidelines state that NSAIDs may be recommended at the lowest dose for the shortest period in patients with moderate to severe pain. It is recommended as an option for short term symptomatic relief. The documentation provided indicated that the patient has been using Celebrex at least since 10/21/2013; the guidelines do not recommend NSAIDs for long term use. In the absence of documentation for the evidence of increased functional status, and decreased pain the request is not supported at this time. Additionally, as the request is written there is no frequency provided. Therefore, the request is not medically necessary.