

<b>Case Number:</b>	CM15-0123189		
<b>Date Assigned:</b>	07/07/2015	<b>Date of Injury:</b>	04/15/2003
<b>Decision Date:</b>	08/18/2015	<b>UR Denial Date:</b>	06/11/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/25/2015

### 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Family Practice

### 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 (IW) is a 59 year old male who sustained an industrial injury on 04/15/2003. He reported slipping and hyperextending his right knee which later began locking on him. A MRI on 05/05/20013 showed medial and lateral meniscal tears with areas of high grade cartilage loss. Treatment to date has included right knee arthroscopic surgery (2004), steroid injections (02/14/2012), and on 04/08/2014, a right knee arthroplasty. Currently, the injured worker complains of knee pain with a feeling of fullness and tightness. The pain is located to the lateral aspect of the patella and wakes him at up at night, disrupting his sleep pattern. On exam, the knee has good range of motion. The pain is isolated to the anterolateral corner when in full extension. He walks at least 60 minutes daily at the gym. A CT of the right knee on 01/082015 shows no evidence of loosening of the femoral tibial components. His current diagnoses are: right knee atrophy, and right knee arthritis, status post TKA. Medications include Ambien, and Zorvolex. He is retired. The treatment plan is for a right knee arthroscopy. Medications are ordered for inflammation and pain. A request for authorization is made for the following: 1. One (1) prescription for Terocin patches 4% #30, 2. One (1) prescription for Exoten C lotion, 3. One (1) prescription of Norco 10/325mg #90, and 4. One (1) prescription of Zorvolex 35mg #60 with 4 refills.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**One (1) prescription for Terocin patches 4% #30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of topical analgesics, including the components of the requested medication. Topical analgesics are considered as largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Terocin is a topical analgesic that contains the following ingredients: capsaicin, lidocaine, menthol and methyl salicylate. Regarding the use of lidocaine as a topical analgesic, the MTUS guidelines state the following: Lidocaine Indication: Neuropathic pain. Lidocaine is recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tricyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). In this case, the records do not indicate that the patient has a neuropathy that is being treated with this compounded topical analgesic. Given the absence of neuropathic pain, lidocaine is not indicated. Since lidocaine is not medically necessary, the entire compounded topical analgesic is not medically necessary. In summary, Terocin patches are not medically necessary as the component lidocaine is not supported by these MTUS guidelines.

**One (1) prescription for Exoten C lotion: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of topical analgesics, including the components of the requested medication. Topical analgesics are considered as largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Exoten C Lotion is a topical analgesic that contains the following ingredients: capsaicin, menthol and methyl salicylate. Regarding the use of capsaicin as a topical analgesic, the MTUS guidelines state the following: Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. Regarding the use of menthol as a component of a topical analgesic, there is no evidence in support of its efficacy. Given the lack of support for two of the ingredients of this topical analgesic, the requested compounded medication (Exoten C Lotion) is not medically necessary.

**One (1) prescription of Norco 10/325mg #90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Hydrocodone/Acetaminophen; Opioids.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-78, 80.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the long-term use of opioids, including Norco. These guidelines have established criteria of the use of opioids for the ongoing management of pain. Actions should include: prescriptions from a single practitioner and from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. There should be an ongoing review and documentation of pain relief, functional status, appropriate medication use and side effects. Pain assessment should include: current pain, the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; 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. There should be evidence of documentation of the "4 As for Ongoing Monitoring." These four domains include: pain relief, side effects, physical and psychological functioning, and the occurrence of any potentially aberrant drug-related behaviors. Further, there should be consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain that does not improve on opioids in 3 months. There should be consideration of an addiction medicine consult if there is evidence of substance misuse (Pages 76-78). Finally, the guidelines indicate that for chronic pain, the long-term efficacy of opioids is unclear. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy (Page 80). Based on the review of the medical records, there is insufficient documentation in support of these stated MTUS/Chronic Pain Medical Treatment Guidelines for the ongoing use of opioids. There is insufficient documentation of the "4 As for Ongoing Monitoring." The treatment course of opioids in this patient has extended well beyond the timeframe required for a reassessment of therapy. In summary, there is insufficient documentation to support the chronic use of an opioid in this patient. Treatment with Norco is not considered as medically necessary.

**One (1) prescription of Zorvolex 35mg #60 with 4 refills: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs GI symptoms and cardiovascular risks.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of NSAIDs, including Zorvolex (diclofenac), as a treatment modality. The indications for an NSAID are as follows: Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. In this case, the records indicate that Zorvolex is being used as a treatment for the patient's osteoarthritis of the knee. The MTUS guidelines support its use; however, the issue in this case is demonstration of long-term effectiveness. In the Utilization Review process, the request for Zorvolex with 4 refills was modified to 1 refill. This action will allow for appropriate monitoring of relevant outcomes, reduction in pain and improved function, before it can be determined that long-term use is warranted. For this reason, Zorvolex 35 mg #60 with 4 refills is not medically necessary.