

<b>Case Number:</b>	CM14-0168625		
<b>Date Assigned:</b>	10/16/2014	<b>Date of Injury:</b>	09/15/2002
<b>Decision Date:</b>	12/24/2014	<b>UR Denial Date:</b>	09/15/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/13/2014

### 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 Emergency Medicine and is licensed to practice in New York. 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 sustained a work related injury on September 15, 2002. The exact mechanism of the work related injury was not provided in the documentation supplied. On August 27, 2014, the Primary Treating Physician noted the injured worker had complaints of pain, medical tenderness, and limping ambulation of the bilateral knees, as well as progressive pain to the lumbar spine. The Physician noted the request for the injured worker to see a spine specialist with return to modified work on August 28, 2014. The Physician requested authorization for Orphenadrine/Caffeine, Gabapentin/Pyridoxine, Omeprazole/Flurbiprofen, Keratek Analgesic gel, Flurbiprofen/Cyclobenzaprine/Menthol Cream, Diclofenac/lidocaine, and Hydrocodone/APAP/Ondansetron on September 4, 2014. On November 19, 2014, an orthopedic consultation was noted to show the injured worker doing poorly, with progressive shoulder, left elbow, bilateral knee, and low back pain. Physical examination was noted to show the injured worker in marked distress with global tenderness about the shoulder, left elbow, bilateral knees, and lower back. X-rays of the cervical spine show severe loss of cervical lordosis, and x-rays of the thoracic and lumbar spine showing a severe loss of lumbar lordosis with degenerative disc disease at the L5-S1 level. X-rays of the left elbow, right and, left knees showed advanced degenerative changes. The injured worker underwent an ultrasound guided injection to the left elbow. The Physician noted the plan for the injured worker to undergo pain management for the narcotic medication management. On September 12, 2014, Utilization Review evaluated the request for Hydrocodone/APAP/Ondansetron 10/300/2 mg #40, Diclofenac/Lidocaine 3%/5% #120 gm, Orphenadrine 50 mg/Caffeine 10 mg #60, Gabapentin/Pyridoxine 250 mg/10 mg #120, Omeprazole 10 mg/Flurbiprofen 100 mg #60, Keratek Gel # 4 oz, and Flurbiprofen/Cyclobenzaprine/Menthol Cream 20%/10%/4% #180 gm. Citations utilized for the Utilization Review included MTUS Chronic pain Medical Treatment Guidelines, ODG-TWC

Pain Procedure Summary last updated August 4, 2014, and Mosby's Drug Consult. The UR Physician noted no documentation of evidence of objective functional benefit with medication use, and no documentation of the indication for the medication being compounded in the requested manner. The UR Physician recommended non-certification decisions for all of the requested items. The decisions were subsequently appealed to Independent Medical Review.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Hydrocodone/APAP/Ondansetron 10/300/2 mg #40:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Treatment in Workers Compensation (TWC), Pain Procedure Summary, updated 08/04/2014

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 74-92. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Antiemetic's (for opioid nausea)

**Decision rationale:** This medication is a compounded opioid analgesic and antiemetic, containing the opioid hydrocodone, acetaminophen, and Ondansetron. Chronic Pain Medical Treatment Guidelines state that opioids are not recommended as a first line therapy. Opioid should be part of a treatment plan specific for the patient and should follow criteria for use. Criteria for use include establishment of a treatment plan, determination if pain is nociceptive or neuropathic, failure of pain relief with non-opioid analgesics, setting of specific functional goals, and opioid contract with agreement for random drug testing. If analgesia is not obtained, opioids should be discontinued. The patient should be screened for likelihood that he or she could be weaned from the opioids if there is no improvement in pain of function. It is recommended for short term use if first-line options, such as acetaminophen or NSAIDS have failed. Opioids may be a safer choice for patients with cardiac and renal disease than antidepressants or anticonvulsants. In this case the patient had been using opioid medication since at least August 2014 and had not obtained analgesia. In addition there is no documentation that the patient has signed an opioid contract or is participating in urine drug testing. Criteria for long-term opioid use have not been met. Hydrocodone is not recommended. Acetaminophen is recommended for treatment of chronic pain & acute exacerbations of chronic pain. Acetaminophen overdose is a well-known cause of acute liver failure. Hepatotoxicity from therapeutic doses is unusual. Renal insufficiency occurs in 1 to 2% of patients with overdose. The recommended dose for mild to moderate pain is 650 to 1000 mg orally every 4 hours with a maximum of 4 g/day. Ondansetron, a serotonin 5-HT<sub>3</sub> receptor antagonist, is an antiemetic. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. Antiemetic's are not recommended for nausea and vomiting secondary to chronic opioid use. Nausea and vomiting is common with use of opioids. These side effects tend to diminish over days to weeks of continued exposure. Studies of opioid adverse effects including nausea and vomiting are limited to short-term duration (less than four weeks) and have limited application to long-term use. If nausea and vomiting remains prolonged, other etiologies of these symptoms should be evaluated for. The

medication is not recommended. Furthermore, the guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." This medication contains drugs that are not recommended. Therefore the medication cannot be recommended. The request is not medically necessary.

**Diclofenac/Lidocaine 3%/5% #120 gm:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 111-112. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Lidoderm (lidocaine patch)

**Decision rationale:** This is a compounded topical medication containing Diclofenac and Lidocaine. Topical analgesics are recommended for neuropathic pain when anticonvulsants and antidepressants have failed. Compounded topical analgesics are commonly prescribed and there is little to no research to support the use of these compounds. Furthermore, the guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Diclofenac is non-steroidal anti-inflammatory drug (NSAID) that can be used topically. Topical NSAIDs have been shown to be superior to placebo in the treatment of osteoarthritis, but only in the short term and not for extended treatment. The effect appears to diminish over time. Absorption of the medication can occur and may have systemic side effects comparable to oral form. It is indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Lidocaine is recommended for localized peripheral pain after the evidence of a trial for first-line therapy, such as an antidepressant or antiepileptic drug. It is only FDA approved for the treatment of post-herpetic neuralgia. The guidelines state that further research is needed to recommend this treatment for chronic neuropathic pain. The diagnosis of neuropathic pain is not supported by the documentation. Lidocaine is not recommended. This medication contains drugs that are not recommended. In addition there is no documentation that the patient has failed treatment with antidepressants or anticonvulsants. Therefore the medication cannot be recommended. The request is not medically necessary.

**Orphenadrine 50 mg/Caffeine 10 mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Treatment in Workers Compensation (TWC), Pain Procedure Summary, updated 08/04/2014

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 63, 65. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Drugs for Pain Treatment Guidelines from The Medical Letter; April 1, 2013 (Issue 128) page 31

**Decision rationale:** This medication is a compounded medication containing the muscle relaxant Orphenadrine and caffeine. Orphenadrine is similar to diphenhydramine, but has greater anticholinergic effects. Effects are thought to be secondary to analgesic and anticholinergic properties. Side effects are primarily anticholinergic and include drowsiness, urinary retention, and dry mouth. Side effects may limit use in the elderly. This medication has been reported in case studies to be abused for euphoria and to have mood elevating effects. Non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment (less than two weeks) of acute exacerbations in patients with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. The duration of treatment surpasses the recommended short-term duration of two weeks. The medication is not recommended. Caffeine in doses of 65-200 mg may enhance the analgesic effect of acetaminophen, aspirin or ibuprofen. It does not enhance the effect of Orphenadrine. Caffeine is not recommended. Furthermore, the guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." This medication contains drugs that are not recommended. Therefore the medication cannot be recommended. The request is not medically necessary.

**Gabapentin/Pyridoxine 250 mg/10 mg capsule #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs). Decision based on Non-MTUS Citation Mosby's Drug Consult

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) carpal tunnel syndrome, Vitamin B6 (pyridoxine); Pain Vitamin B

**Decision rationale:** This medication is a compounded medication containing Gabapentin and Pyroxidine. Gabapentin 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 and has FDA approval for treatment of post-herpetic neuralgia. Gabapentin appears to be effective in reducing abnormal hypersensitivity, to have anti-anxiety effects, and may be beneficial as a sleep aid. Gabapentin has a favorable side-effect profile, few clinically significant drug-drug interactions and is generally well tolerated; however, common side effects include dizziness, somnolence, confusion, ataxia, peripheral edema, dry mouth, and weight gain. It has been recommended for the treatment of pain from spinal cord injury, fibromyalgia, lumbar spinal stenosis, and chronic regional pain syndrome. Recommended trial period is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. If inadequate control of pain is found, a switch to another first-line drug is recommended. In this case the patient had been taking gabapentin since at least August 2014 and had not obtained analgesia. Gabapentin is not recommended. Pyroxidine is Vitamin B6. It is not recommended for the treatment of chronic

pain. Furthermore, the guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." This medication contains drugs that are not recommended. Therefore the medication cannot be recommended. The request is not medically necessary.

**Omeprazole 10 mg/Flurbiprofen 100 mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk and NSAIDs (non-steroi.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 67-68.

**Decision rationale:** This is a compound medication containing Omeprazole and Flurbiprofen. Omeprazole is a proton pump inhibitor (PPI). PPI's are used in the treatment of peptic ulcer disease and may be prescribed in patients who are using non-steroidal anti-inflammatory drugs and are at high risk for gastrointestinal events. Risk factors for high-risk events are age greater than 65, history of peptic ulcer, GI bleeding or perforation, concurrent use of ASA, corticosteroids, and/or an anticoagulant, or high dose/multiple NSAID (e.g., NSAID + low-dose ASA). The patient in this case was using NSAID medication, but did not have any of the risk factors for a gastrointestinal event. The medication is not recommended. Flurbiprofen is a non-steroidal anti-inflammatory drug (NSAID). Flurbiprofen is recommended as an oral agent for the treatment of osteoarthritis and the treatment of mild to moderate pain. Chronic Medical Treatment Guidelines state that "anti-inflammatory drugs are the traditional first line of treatment, but long term use may not be warranted". For osteoarthritis it was recommended that the lowest dose for the shortest length of time be used. It was not shown to be more effective than acetaminophen, and had more adverse side effects. Adverse effects for GI toxicity and renal function have been reported. Medications for chronic pain usually provide temporary relief. Medications should be prescribed only one at a time and should show effect within 1-3 days. Record of pain and function with the medication should be documented. In this case the patient had been receiving the medication since at least August 2014 and had not obtained analgesia. The duration of treatment increases the risk of adverse effects with little benefit. Flurbiprofen is not recommended. The guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." This medication contains drugs that are not recommended. Therefore the medication cannot be recommended. The request is not medically necessary.

**Keratek Gel #4 oz: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 111-112. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: UpToDate: Camphor and menthol: Drug

information; Treatment Guidelines from the Medical Letter, April 1, 2013, Issue 128: Drugs for pain

**Decision rationale:** Keratek is a compound medication containing methyl salicylate and menthol. Topical analgesics are recommended for neuropathic pain when anticonvulsants and antidepressants have failed. Compounded topical analgesics are commonly prescribed and there is little to no research to support the use of these compounds. Furthermore, the guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Methyl salicylate is a topical salicylate and is recommended, being significantly better than placebo in chronic pain. Camphor and menthol are topical skin products that available over the counter and used for the relief of dry itchy skin. Topical analgesics containing menthol, methyl salicylate or capsaicin are generally well-tolerated, but there have been rare reports of severe skin burns requiring treatment or hospitalization. Menthol is not recommended. This medication contains a drug that is not recommended. Therefore the medication cannot be recommended. The request is not medically necessary.

**Flurbiprofen/Cyclobenzaprine/Menthol cream 20%/10%/4% #180 gm: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 111-112. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: UpToDate: Camphor and menthol: Drug information; Treatment Guidelines from the Medical Letter, April 1, 2013, Issue 128: Drugs for pain

**Decision rationale:** This medication is a topical analgesic containing Flurbiprofen, Cyclobenzaprine, and Menthol. Topical analgesics are recommended for neuropathic pain when anticonvulsants and antidepressants have failed. Compounded topical analgesics are commonly prescribed and there is little to no research to support the use of these compounds. Furthermore, the guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Flurbiprofen is a non-steroidal anti-inflammatory drug (NSAID). Flurbiprofen is recommended as an oral agent for the treatment of osteoarthritis and the treatment of mild to moderate pain. It is not recommended as a topical preparation. Cyclobenzaprine is a muscle relaxant. There is no evidence for use of Cyclobenzaprine as a topical product. It is not recommended. Camphor and menthol are topical skin products that available over the counter and used for the relief of dry itchy skin. This medication contains drugs that are not recommended. Therefore the medication cannot be recommended. The request should not be authorized. Topical analgesics containing menthol, methyl salicylate or capsaicin are generally well-tolerated, but there have been rare reports of severe skin burns requiring treatment or hospitalization. The request is not medically necessary.