

<b>Case Number:</b>	CM14-0207855		
<b>Date Assigned:</b>	12/19/2014	<b>Date of Injury:</b>	07/08/2011
<b>Decision Date:</b>	04/10/2015	<b>UR Denial Date:</b>	11/13/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/11/2014

### 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. 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: District of Columbia, Virginia  
Certification(s)/Specialty: Internal Medicine

### 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 49 year old female with an industrial injury dated 07/08/2011. Her diagnoses include lumbar radiculopathy, and internal derangement of the left knee. No recent diagnostic testing was submitted or discussed. Previous treatments have included conservative care and medications. In a progress note dated 11/03/2014, the treating physician reports worsening neck pain. The objective examination revealed tenderness to the paravertebral muscles with noted spasms, restricted range of motion in the lumbar spine, positive straight leg raises on the left, joint effusion to the left knee, tenderness to palpation of the medial aspect of the left knee, and positive McMurray's test. The treating physician is requesting multiple medications which were denied by the utilization review. On 11/13/2014, Utilization Review non-certified a prescription for hydrocodone/APAP (Norco) 10/325mg, noting there was no documented improvement in the injured worker's pain levels with this medication. The MTUS Guidelines were cited. On 11/13/2014, Utilization Review non-certified a prescription for, zolpidem tartrate 10mg with 3 refills, noting that the medication can be habit forming, lead to depression and impair function, and is not recommended for long term use. The ODG Guidelines were cited. On 11/13/2014, Utilization Review non-certified a prescription for orphenadrine ER 100mg, noting that the medication is not recommended for long term use since the efficacy diminishes over time. The MTUS Guidelines were cited. On 11/13/2014, Utilization Review non-certified a prescription for Medrox pain relief ointment with 2 refills, noting that the medication contains menthol which has no recommended use. The MTUS ACOEM ODG Guidelines were cited. On 12/11/2014, the injured worker submitted an application for IMR for review of

hydrocodone/APAP (Norco) 10/325mg, zolpidem tartrate 10mg with 3 refills, orphenadrine ER 100mg, and Medrox pain relief ointment with 2 refills.

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

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

**1 prescription of hydrocodone/ APAP (Norco) 10/325mg: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792 Page(s): 75,124,91.

**Decision rationale:** Per MTUS: Short-acting opioids: also known as "normal-release" or "immediate-release" opioids are seen as an effective method in controlling chronic pain. They are often used for intermittent or breakthrough pain. These agents are often combined with other analgesics such as acetaminophen and aspirin. These adjunct agents may limit the upper range of dosing of short-acting agents due to their adverse effects. The duration of action is generally 3-4 hours. Shortacting opioids include Morphine (Roxanol), Oxycodone (OxyIR, Oxyfast), Endocodone, Oxycodone with acetaminophen, (Roxilox, Roxicet, Percocet, Tylox, Endocet), Hydrocodone with acetaminophen, (Vicodin, Lorcet, Lortab, Zydone, Hydrocet, Norco), Hydromorphone (Dilaudid, Hydrostat). (Baumann, 2002)Per review of clinical data provided, this would not be indicated for long term usage. A weaning process should be initiated. Hydrocodone/Acetaminophen (Anexsia, Co-Gesic, Hycet; Lorcet, Lortab; Margesic-H, Maxidone; Norco, Stagesic, Vicodin, Xodol, Zydone; generics available): Indicated for moderate to moderately severe pain. Note: there are no FDA-approved hydrocodone products for pain unless formulated as a combination. Side Effects: See opioid adverse effects. Analgesic dose: The usual dose of 5/500mg is 1 or 2 tablets PO every four to six hours as needed for pain (Max 8 tablets/day). For higher doses of hydrocodone (>5mg/tab) and acetaminophen (>500mg/tab) the recommended dose is usually 1 tablet every four to six hours as needed for pain. Hydrocodone has a recommended maximum dose of 60mg/24 hours. The dose is limited by the dosage of acetaminophen, which should not exceed 4g/24 hours.

**1 prescription of zolpidem tartrate 10mg (refill x 3): 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)- Mental Illness and Stress.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Ogd- insomnia.

**Decision rationale:** Per ODG guidelines, Ambien is a short-acting sedative hypnotic. It is used to treat insomnia for about 2-6 weeks. Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain. Various medications may provide short term benefit. While sleeping pills, so called minor tranquilizers and anti-anxiety agents are commonly

prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit forming and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long term(Feinberg20008). See insomnia treatment. Ambien CR offers no significant clinical advantage over regular release ambien. Ambien CR is approved for chronic use, but chronic use of hypnotics in general is discourage, as outline in insomnia treatment. (ambien and ambien CR package insert). Cognitive behavioral therapy(CBT) should be an important part of an insomnia treatment plan. A study of patients with persistent insomnia found that the addition of zolpiden immediate release to CBT was modestly beneficial during acute(first 6 weeks) therapy but better long-term outcomes were achieved when ambien IR was discontinued and maintenance of CBT continued(Morin 2009). Per guidelines, this medication would not be indicated.

### **1 prescription of orphenadrine ER 100mg: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792 Page(s): 65.

**Decision rationale:** Per MTUS: Orphenadrine (Norflex, Banflex, Antiflex, Mio-Rel, Orphenate, generic available): This drug is similar to diphenhydramine, but has greater anticholinergic effects. The mode of action is not clearly understood. Effects are thought to be secondary to analgesic and anticholinergic properties. This drug was approved by the FDA in 1959.Side Effects: Anticholinergic effects (drowsiness, urinary retention, 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. (Shariatmadari, 1975) Dosing: 100 mg twice a day; combination products are given three to four times a day. (See, 2008)Per reference cited, this would not be indicated for long term usage.

### **1 prescription of Medrox pain relief ointment (refill x 2): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792.2-.26 Page(s): 28,38,105,111.

**Decision rationale:** Medrox contains capsaicin/menthol/methyl salicylate ointment. Per MTUS, Recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations: Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and

chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The number needed to treat in musculoskeletal conditions was 8.1. The number needed to treat for neuropathic conditions was 5.7. (Robbins, 2000) (Keitel, 2001) (Mason-BMJ, 2004) The results from this RCT support the beneficial effects of 0.025% capsaicin cream as a first-line therapy for OA pain. (Altman, 1994) Mechanism of action: Capsaicin, which is derived from chili peppers, causes vasodilation, itching, and burning when applied to the skin. These actions are attributed to binding with nociceptors, which causes a period of enhanced sensitivity followed by a refractory period of reduced sensitivity. Topical capsaicin is superior to placebo in relieving chronic neuropathic and musculoskeletal pain. Capsaicin produces highly selective regional anesthesia by causing degeneration of capsaicin-sensitive nociceptive nerve endings, which can produce significant and long lasting increases in nociceptive thresholds. (Maroon, 2006). Adverse reactions: Local adverse reactions were common (one out of three patients) but seldom serious (burning, stinging, erythema). Coughing has also been reported. See also CRPS, medications; Topical analgesics. For stimulus-independent pain, Mexiletine, lidocaine patches and capsaicin are used but efficacy is not convincing. Methyl salicylate: Recommended. Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. (Mason-BMJ, 2004) See also Topical analgesics; & Topical analgesics, compounded. In MTUS section addressing topical analgesics, it is recommended as an option as indicated below. 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. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) 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. The role of capsaicin is still not recommended for the chronic pain. It, being a part of Medrox formulation, is therefore, is not indicated. Therefore, this is not medically indicated for this patient's condition.