

<b>Case Number:</b>	CM15-0201224		
<b>Date Assigned:</b>	10/16/2015	<b>Date of Injury:</b>	11/19/2009
<b>Decision Date:</b>	11/30/2015	<b>UR Denial Date:</b>	09/30/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/13/2015

### 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: Montana

Certification(s)/Specialty: Preventive Medicine, Occupational 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 52 year old, male who sustained a work related injury on 11-19-09. A review of the medical records shows he is being treated for neck pain. In the progress notes dated 7-24-15, 8-21-15 and 9-22-15, the injured worker reports neck pain that has not significantly changed with physical therapy and medications. He rates his pain level a 3-4 out of 10 with medication and use of TENS unit. On physical exam dated 9-22-15, he has full cervical range of motion without pain. He has some tenderness over C7-T1 spinous process. Treatments have included chiropractic treatments, 12 sessions of physical therapy without significant benefit, 20 sessions of acupuncture with each session providing one day for relief, TENS unit therapy with some benefit, and medications. Current medications include Voltaren gel and Norco. He has been taking the Norco since July 2015. There is no documentation on how this medication is effective for decreasing pain or improving functional capabilities. No notation of working status. The treatment plan includes requests for Voltaren gel, Norco and start Relafen, Prevacid and a compounded ointment. The Request for Authorization dated 9-22-15 has requests for Norco, Prevacid, Relafen, and a compound ointment. In the Utilization Review dated 9-30-15, the requested treatments of Relafen 500mg. #90 and compound ointment of Diclofenac 5%-Beclomethasone 2%-Lidocaine 5% and Arnica Montana-100gm x 4 tubes are not medically necessary. The requested treatment of Norco 10-325mg. #240 is modified to Norco 10-325mg. #59.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Norco 10/325mg qty: 240.00: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids (Classification), Opioids for neuropathic pain, Weaning of Medications.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for neuropathic pain, Opioids, dealing with misuse & addiction, Opioids, long-term assessment, Opioids, pain treatment agreement, Opioids, screening for risk of addiction (tests), Opioids, specific drug list.

**Decision rationale:** Norco is a brand name for hydrocodone, a short-acting opioid analgesic, combined with acetaminophen. The MTUS states that opioids are not recommended as first line therapy for neuropathic pain. Opioids are suggested for neuropathic pain that has not responded to first line recommendations including antidepressants and anticonvulsants. The MTUS states that reasonable alternatives to opioid use should be attempted. There should be a trial of non-opioid analgesics. When subjective complaints do not correlate with clinical studies a second opinion with a pain specialist and a psychological assessment should be obtained. The lowest possible dose should be prescribed to improve pain and function. Ongoing use of hydrocodone/acetaminophen requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include the least reported pain over the period since the last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. In this case, there continues to be deficiency in documentation of specific functional improvement, decreased pain, side effects, pain contract and aberrant pain behaviors. Additionally the request is for #240 and it is unclear whether this represents increased dosage or duration of treatment. The injured worker does have chronic pain and, with appropriate documentation as noted in the MTUS, the opioid could be justified. At this time, the request for Norco 10/325mg qty: 240.00 is not medically necessary.

**Relafen 500mg qty: 90.00: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-inflammatory medications, NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, GI symptoms & cardiovascular risk, NSAIDs, hypertension and renal function, NSAIDs, specific drug list & adverse effects.

**Decision rationale:** The MTUS states that anti-inflammatories are the traditional first line of treatment to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. Relafen is a non-steroidal anti-inflammatory medication (NSAID). NSAIDs are 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. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). NSAIDs may cause borderline elevations of one or more liver enzymes in up to 15% of patients taking NSAIDs. Renal: Use of NSAIDs may compromise renal function. FDA Medication Guide is provided by FDA mandate on all prescriptions dispensed for NSAIDS. Routine Suggested Monitoring: Package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile (including liver and renal function tests). There has been a recommendation to measure liver transaminases within 4 to 8 weeks after starting therapy, but the interval of repeating lab tests after this treatment duration has not been established. Routine blood pressure monitoring is recommended. Overall Dosing Recommendation: It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time consistent with the individual patient treatment goals. In this case, the Relafen has been used on a long-term basis (since at least 4-8-15, without specific documentation of functional improvement or monitoring as recommended above. Without this documentation, the request for Relafen 500mg qty: 90 is not medically necessary.

**Compounded ointment: 5% Diclofenac/2% Beclomethasone/5% Lidocaine/5% Amica Montana-100gm (tubes) qty: 4.00: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The MTUS, in the ACOEM guidelines, states that, for initial treatment, topical medications are not recommended. The Chronic Pain Medical Treatment Guidelines note 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. This topical analgesic contains diclofenac, which is a non-steroidal anti-inflammatory medication (NSAID). The MTUS states that topical non-steroidal anti-inflammatory agents have not been shown to be effective in long-term studies. Topical non-steroidal anti-inflammatory agents have shown inconsistent efficacy in clinical trials and most studies are small and of short duration. Topical NSAIDs have been shown in meta- analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study, the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These

medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). Voltaren Gel 1% (diclofenac): 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. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus. Topical treatment can result in blood concentrations and systemic effects comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. (Krummel 2000) The MTUS states that topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off label for diabetic neuropathy. 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. The ODG guidelines also state that Lidoderm patches are not a first-line treatment and are FDA approved only for postherpetic neuralgia. ODG Criteria for use of Lidoderm patches include: (a) Recommended for a trial if there is evidence of localized pain that is consistent with a neuropathic etiology. (b) There should be evidence of a trial of first-line neuropathy medications (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). (c) This medication is not generally recommended for treatment of osteoarthritis or treatment of myofascial pain/trigger points. (d) An attempt to determine a neuropathic component of pain should be made if the plan is to apply this medication to areas of pain that are generally secondary to non-neuropathic mechanisms (such as the knee or isolated axial low back pain). One recognized method of testing is the use of the Neuropathic Pain Scale. (e) The area for treatment should be designated as well as number of planned patches and duration for use (number of hours per day). (f) A Trial of patch treatment is recommended for a short-term period (no more than four weeks). (g) It is generally recommended that no other medication changes be made during the trial period. (h) Outcomes should be reported at the end of the trial including improvements in pain and function, and decrease in the use of other medications. If improvements cannot be determined, the medication should be discontinued. In this case, the injured worker does not have diabetic neuropathy, neuropathic pain or postherpetic neuralgia. The request for compounded ointment: 5% Diclofenac/2% Beclomethasone/5% Lidocaine/5% Amica Montana-100gm (tubes) qty: 4.00 is not supported by the MTUS and is not medically necessary.