

<b>Case Number:</b>	CM14-0163158		
<b>Date Assigned:</b>	10/14/2014	<b>Date of Injury:</b>	11/04/2013
<b>Decision Date:</b>	11/14/2014	<b>UR Denial Date:</b>	09/18/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/03/2014

### 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 Occupational Medicine 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:

This case is 55-year old female employee with a date of injury on 11/4/2013. A review of the medical records indicates that the patient is undergoing treatment for lumbar spine herniation of L3-4/L4-5 and low back pain. Subjective complaints (6/16/2014) low back pain with radiation to right leg, in addition to numbness, tingling, and weakness of that leg. Objective findings (6/16/2014) positive right straight leg test, tenderness to lumbar muscles, and decreased light touch to dorsal aspect of right foot. Lumbar X-ray reveals degenerative disc disease of L5-S1. MRI reveals disc herniation of L3-4/L4-5. Treatment has included medications (not specified in medical records). A utilization review dated 9/18/2014 non-certified the following:- Orphenadrine/Caffeine 50/10mg #60 due to not meeting guidelines- Hydrocodone/APAP/Ondan 10/300/2mg #40 due to lack of documented functional improvement- Orphenadrine/Caffeine 50/10mg #60 due to not meeting guidelines- Flurbiprofen/cyclo/menth cream 20%/10%/4% 180gm due to medication is not recommended- Keratek analgesic gel #4oz due to medication is not recommended- Omeprazole 10mg/Flurbiprofen 100mg #60 due to not meeting guidelines.

### IMR ISSUES, DECISIONS AND RATIONALES

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

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

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxant (non-sedating).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-65.

**Decision rationale:** Orphenadrine is classified as a muscle relaxant. MTUS states, "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment 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." Additionally, MTUS states "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)." MTUS guidelines recommend against the long term use of muscle relaxants. Medical records do not indicate the how long the patient has been on this medication. The treating physician has not provided documentation of acute muscle spasms, documentation of functional improvement while on Orphenadrine/Caffeine, and the treating physician has not provided documentation of trials and failures of first line therapies. As such the request for Orphenadrine/Caffeine 50/10mg #60 is not medically necessary.

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

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Hydrocodone Opioids Page(s): 51, 74-95. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Opioids

**Decision rationale:** ODG does not recommend the use of opioids for low back pain "except for short use for severe cases, not to exceed 2 weeks." Medical records do not indicate the length of time the patient has been on an opioid, but the date of injury does appear to be over a year old. MTUS does not discourage use of opioids past 2 weeks, but does state that "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." The treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, increased level of function, or improved quality of life. As such, the question for Hydrocodone/APAP/Ondan 10/300/2mg #40 is not medically necessary.

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

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (non-sedating).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-65.

**Decision rationale:** Orphenadrine is classified as a muscle relaxant. MTUS states, "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment 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." Additionally, MTUS states "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)." MTUS guidelines recommend against the long term use of muscle relaxants. Medical records do not indicate the how long the patient has been on this medication. The treating physician has not provided documentation of acute muscle spasms, documentation of functional improvement while on Orphenadrine/Caffeine, and the treating physician has not provided documentation of trials and failures of first line therapies. As such, the request for Orphenadrine/Caffeine 50/10mg #60 is not medically necessary.

**Flurbiprofen/cyclo/menth cream 20%/10%/4% 180gm:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Official Disability Guidelines (ODG) Pain, Compound creams Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams

**Decision rationale:** MTUS and ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "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. "FLURBIPROFEN: MTUS states that the only FDA- approved NSAID medication for topical use includes diclofenac, which is indicated for relief of osteoarthritis pain in joints. Flurbiprofen would not be indicated for topical use in this case. CYCLOBENZAPRINE: MTUS states regarding topical muscle relaxants, "Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Topical cyclobenzaprine is not indicated for this usage, per MTUS. MENTHOL: ODG only

comments on menthol in the context of cryotherapy for acute pain, but does state "Topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances because of serious burns, a new alert from the FDA warns." In this request MTUS does not recommend the use of Cyclobenzaprine and Flurbiprofen as topical agent. Per MTUS, if one compound is not recommended, the whole compound is not recommended. As such, the request for Flurbiprofen/cyclo/menth cream 20%/10%/4% 180gm is not medically necessary.

**Keratek anagesic gel #4oz: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate, Topical analgesic Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Salicylate topicals, Topical analgesics

**Decision rationale:** Kera-Tek Gel is the brand name version of a topical analgesic medication containing menthol and methyl salicylate. ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "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." ODG only comments on menthol in the context of cryotherapy for acute pain, but does state "Topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns, a new alert from the FDA warns." MTUS states regarding topical 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." The medical documents do not support the use of menthol and methyl salicylate this topical compound agent. As such, the request for Keratek anagesic gel #4oz is not medically necessary.

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

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk, NSAIDs, specific drug list & adverse effects, Flurbip. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk

**Decision rationale:** MTUS states "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)." And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease:(1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for

example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." The patient does not meet the age criteria and medical documents do not establish the patient has having documented GI bleeding, perforation, peptic ulcer, high dose NSAID, or other GI risk factors as outlined in MTUS. MTUS specifies four recommendations regarding NSAID use:1) Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain.2) Back Pain - Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP.3) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics.4) Neuropathic pain: There is inconsistent evidence for the use of these medications to treat longterm neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain.The medical documents do not indicate that the patient is being treated for osteoarthritis. Additionally, the treating physician does not document failure of primary (Tylenol) treatment. Progress notes do not indicate how long the patient has been on this NSAID, but the MTUS guidelines recommend against long-term use.As such, the request for Omeprazole 10mg/Flurbiprofen 100mg #60 is not medically necessary.