

<b>Case Number:</b>	CM14-0189729		
<b>Date Assigned:</b>	11/20/2014	<b>Date of Injury:</b>	04/06/1994
<b>Decision Date:</b>	01/09/2015	<b>UR Denial Date:</b>	10/27/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/13/2014

### 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 Preventive Medicine, has a subspecialty in Occupational Medicine and is licensed to practice in Iowa. 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 is a 61 year old patient with date of injury of 04/06/1994. Medical records indicate the patient is undergoing treatment for chronic neck pain, status post right carpal tunnel release, and lumbar discogenic pain,. Subjective complaints include neck and low back pain rated 9/10 without medications 7/10 with medications, pain radiates down bilateral legs posteriorly intermittently and right sided neck pain. Objective findings include tenderness in the lumbar paraspinal muscles bilaterally with decreased range of motion in all planes at the waist with bilateral positive leg lifts, decreased cervical and lumbar range of motion, pain with range of motion, increased tenderness over the right paraspinal muscles and paraspinal tenderness. MRI dated 10/11/2012 showed disc endplate degeneration and mild facet ligamentum hypertrophy from L3-L4 to L5-S1. Also disc narrowing with endplate edema at L5-S1, mildly efface the axillary recesses from L3-L4 to L5-S2 without definite impingement. Moderate bilateral L5-S1 narrowing potentially impinging on the LS nerve root, right greater than left. Treatment has consisted of massage therapy, TENS unit, use of cane, brace for left knee, cervical fusion, cervical discectomy, right carpal tunnel release and right shoulder surgery, . Medications have included Norco, Lunesta, Ambien, Colace, Lactulose, Lyrica, Biofreeze, Zanaflex and Tizanide. The utilization review determination was rendered on 10/27/2014 recommending non-certification of Norco 10/325mg #360, Biofreeze Gel 2 bottles, Tizanidine 4mg, #240 and Ambien 10mg #30.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Norco 10/325mg #360:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck and Upper Back (Acute and Chronic), Low Back - Lumbar & Thoracic (Acute & Chronic), Shoulder, Pain, Opioids

**Decision rationale:** ODG does not recommend the use of opioids for neck, low back, and shoulder pain "except for short use for severe cases, not to exceed 2 weeks." The patient has exceeded the 2 week recommended treatment length for opioid usage. 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 increased level of function, or improved quality of life. Additionally, medical documents indicate that the patient is not receiving adequate pain relief from this medication and the risks appear to outweigh the benefits. Also, this patient has been on Norco in excess of the recommended 2-week limit and the treating physician did not document a new injury or a re-injury . As such, the question for Norco 10/325mg #360 is not medically necessary.

**Biofreeze Gel 2 bottles:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Biofreeze cryotherapy gel

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

**Decision rationale:** MTUS and ODG recommend 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." Analgesics and Biofreeze Biofreeze is a compound topical analgesic containing camphor and menthol. 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." ACOEM and

MTUS are silent regarding the use of camphor. ODG states in the low back chapter regarding biofreeze, "recommended as an optional form of cryotherapy for acute pain. See also Cryotherapy, Cold/heat packs. Biofreeze is a nonprescription topical cooling agent with the active ingredient menthol that takes the place of ice packs. Whereas ice packs only work for a limited period of time, Biofreeze can last much longer before reapplication. This randomized controlled study designed to determine the pain-relieving effect of Biofreeze on acute low back pain concluded that significant pain reduction was found after each week of treatment in the experimental group. (Zhang, 2008)". Medical documents do not indicate that is patient has an acute injury, which is the indication for use per ODG. As such, the request for Biofreeze Gel 2 bottles is not medically necessary.

**Tizanidine 4mg, #240:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxant Page(s): 63.64.66.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants, Zanaflex Page(s): 63-67.

**Decision rationale:** Zanaflex is the brand name version of Tizanidine, which is a muscle relaxant. MTUS states concerning muscle relaxants "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (VanTulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) 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. (Homik, 2004) 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. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, methocarbamol, dantrolene and baclofen. (Chou, 2004) According to a recent review in American Family Physician, skeletal muscle relaxants are the most widely prescribed drug class for musculoskeletal conditions (18.5% of prescriptions), and the most commonly prescribed antispasmodic agents are carisoprodol, cyclobenzaprine, metaxalone, and methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. (See2, 2008)."MTUS further states, "Tizanidine (Zanaflex, generic available) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. (Malanga, 2008) Eight studies have demonstrated efficacy for low back pain. (Chou, 2007) One study (conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. (Malanga, 2002) May also provide benefit as an adjunct treatment for fibromyalgia. (ICSI, 2007)." The medical documentation provided does not indicate that this patient is getting significant relief in symptoms from the utilization of this medication. Studies show that prolonged use of this

medication decreases its efficacy. As such, the request for Tizanidine 4mg, #240 is not medically necessary.

**Ambien 10mg #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Insomnia treatment

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Zolpidem, insomnia treatment

**Decision rationale:** The CA MTUS is silent regarding this topic. ODG states that zolpidem is a prescription short acting non-benzodiazepine hypnotic, which is approved for short-term treatment of insomnia. In this case, the patient has been taking this medication in excess of the guideline recommendation of short-term use. There has been no discussion of the patient's sleep hygiene or the need for variance from the guidelines, such as "a) Wake at the same time everyday; (b) Maintain a consistent bedtime; (c) Exercise regularly (not within 2 to 4 hours of bedtime); (d) Perform relaxing activities before bedtime; (e) Keep your bedroom quiet and cool; (f) Do not watch the clock; (g) Avoid caffeine and nicotine for at least six hours before bed; (h) Only drink in moderation; & (i) Avoid napping." Medical documents also do not include results of these first line treatments, if they were used in treatment of the patient's insomnia. ODG additionally states "The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning." Medical documents provided do not detail these components. As such, the request for Ambien 10mg #30 is not medically necessary at this time.