

<b>Case Number:</b>	CM15-0216973		
<b>Date Assigned:</b>	11/06/2015	<b>Date of Injury:</b>	06/05/2013
<b>Decision Date:</b>	12/22/2015	<b>UR Denial Date:</b>	10/29/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/04/2015

### 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: California

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 49 year old female injured worker suffered an industrial injury on 6-5-2013. The diagnoses included history of fracture, left knee with open reduction and internal fixation for fracture of tibia and fibula 7-2009 and subsequent fall injury with aggravation from 2013, low back pain and bilateral knee pain. On 8-18-2015, the treating provider noted there was indeed an updated opiate agreement on file with a urine drug screen on 5-26-2015 that was consistent. Medications in use were Norco, Tizanidine, Etodolac, Lorazepam, Neurontin and Sertraline. The provider recommended a trial of Percocet as the injured worker was in severe pain. On exam, the injured worker appeared in mild distress with difficulty with walking and arising from a seated position. She was walking with the assistance of a cane. There was tenderness across the joint line in the left knee and there was crepitus by the kneecap with range of motion. On 10-13-2015, the provider reported left thigh pain, bilateral knee pain and lower back pain. The Percocet continued to bring her pain from 10 out of 10 down to 6 out of 10. The injured worker noted the Zanaflex that was given to her the last visit was helpful and would like to increase it as it was not adequate through the day. She would like to see if she can get some for night time as she kept waking up with a lot of pain. On exam, she continued to walk slowly with the cane. On 10-14-2015 the provider noted decreased range of motion in the lumbar spine, pelvic rack and sustained hip flexions were positive. The Patellar ballottement increased the pain. Prior treatments included pool physical therapy. Diagnostics included urine drug screen 5-26-2015 that was consistent per the provider. Norco had been in use since at least 6-23-2015. The documentation provided did include evidence of a comprehensive pain evaluation with pain levels with and without

medications, but no evidence of functional improvement with treatment and no aberrant risk assessment except for urine drug screen and opiate agreement. There was no evidence of muscle spasms on exam that would indicate treatment with Zanaflex or objective evidence of effectiveness. Request for Authorization date was 10-22-2015. Utilization Review on 10-29-2015 determined non-certification for Percocet 10-325mg #90 with no refills and modification for Zanaflex 4mg #120 with no refills to #20.

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

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

**Percocet 10-325mg #90 with no refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic): Opioids for chronic pain.

**Decision rationale:** Based on ODG guidelines, the opioids for chronic pain is not recommended as a first-line treatment for chronic non-malignant pain, and not recommended in patients at high risk for misuse, diversion, or substance abuse. Opioids may be recommended as a 2nd or 3rd line treatment option for chronic non-malignant pain, with caution, especially at doses over 100 mg morphine equivalent dosage/day (MED). Risks of adverse effects are documented in the literature at doses as low as 50 MED. At this dose of MED, prescribing clinicians should begin to use caution in terms of any additional escalation of dose. At doses of 100 mg MED it is recommended that reassessment of use of this class of drugs should be made due to limited evidence for improved pain control and function with continued use as well as evidence of substantial adverse risks with higher MEDs. Escalation of doses beyond the 50 to 100 MED range should be done with caution, and generally under the care of pain specialists. In certain cases, addiction specialists may need to evaluate patients, with the understanding that many patients who progress to chronic opioid therapy have underlying psychiatric disease and substance abuse issues. See Opioid, dosing for details on how these values were derived based on current literature. Risk-benefit of use should be carefully weighed for substance abuse and overdose risks, including risk of death, and this information should be provided to the patient as part of informed decision-making. Extreme caution is required for any opioid use in patients with the following: (1) Individuals with a high risk for misuse or diversion; (2) Individuals with evidence of substance abuse issues; (3) Individuals with a family history of substance abuse; (4) Individuals with underlying psychiatric disease. An accurate diagnosis should be established. At the minimum, screening for opioid risk and psychological distress inventories should occur before starting this class of drugs and a psychological evaluation is strongly recommended. While long-term opioid therapy may benefit some patients with severe suffering that has been refractory to other medical and psychological treatments, it is not generally effective in achieving the original goals of complete pain relief and functional restoration. For patients now on high opioid doses who are not benefiting from this class of drugs there is some evidence that dose reduction does not increase pain levels or decrease function, and in fact, may provide

improvement of these outcomes. (DiBenedetto, 2014) (Baron, 2006) See Weaning of medications. To prevent new patients from getting caught in this cycle, ODG recommends consideration of a one-month limit on opioids for new chronic non-malignant pain patients in most cases. Use for specific disease states -- Neuropathic pain: Opioids have been suggested for neuropathic pain that has not responded to first-line recommendations (antidepressants, anticonvulsants). There are no trials of long-term use. There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant neuropathy. See Opioids for neuropathic pain, where opioids are not recommended as a first-line therapy. (McNicol, 2013)- Chronic back pain: Opioids appear to be efficacious but should be limited for short-term pain relief in patients with acute low back pain. Long-term efficacy is unclear (>16 weeks), and there is also limited evidence for the use of opioids for chronic low back pain. (Martell-Annals, 2007) (White, 2011) (Franklin, 2009) Failure of activity level to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicates that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. (Martell-Annals, 2007) (Chou, 2007) There are three studies comparing tramadol to placebo that have reported pain relief, but this did not necessarily improve function. (Deshpande, 2007) See also the Low Back Chapter for recommendations in acute pain, where opioids are not recommended except for short use for severe cases, not to exceed 2 weeks. In this case, the patient has been on percocet for at least 4 months, which is the limit for use of opioids for chronic pain. Opioids should not be used long term for chronic low back pain. She was approved a reduced number of pills for weaning purposes. Therefore, based on ODG guidelines and the evidence in this case, the request for Percocet 10-325 mg #90 with no refills is not medically necessary.

**Zanaflex 4mg #20 with no refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

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

**Decision rationale:** Based on ODG guidelines, muscle relaxants are recommend non-sedating muscle relaxants with caution as a second-line option for short-term (less than two weeks) treatment of acute LBP and for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) See the Low Back Chapter. 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. (Schnitzer, 2004) (Van Tulder, 2004) (Airaksinen, 2006) 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) Classifications: Muscle relaxants are a broad range of medications that are generally divided into antispasmodics, antispasticity drugs, and drugs with both actions. Antispasticity/ Antispasmodic Drugs: Tizanidine (Zanaflex, generic available) is a centrally acting alpha<sub>2</sub>-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 subacute and 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. In this case, the patient has been on zanaflex at least a couple of months and there is no documented evidence of muscle spasms on examination. No more than 2 weeks of treatment with muscle relaxants is indicated for acute low back pain or acute exacerbations of low back pain. Therefore, based on the ODG guidelines and the evidence in this case, the request for Zanaflex 4 mg #20 with no refills is not medically necessary.