

<b>Case Number:</b>	CM14-0021913		
<b>Date Assigned:</b>	05/09/2014	<b>Date of Injury:</b>	03/07/2005
<b>Decision Date:</b>	07/29/2014	<b>UR Denial Date:</b>	02/19/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/21/2014

### 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 Anesthesiology, has a subspecialty in Pain Management 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 is a 58-year-old male with a 03/07/2005 date of injury. A specific mechanism of injury was not described. The 2/19/14 determination was modified. A certification was rendered for Exalgo and Cymbalta. There was a non-certification of testosterone replacement therapy evaluate and treat, given no documentation that the patient developed sexual dysfunction or had low levels of testosterone that would require replacement therapy. A partial certification was given from Soma 350mg qty 75 + 1 refill to #20 with no refills to provide initiation of downward titration and complete discontinuation of the medication. A partial certification from Norco 10/325mg qty 210 + 1 refill to Norco #180 with no refills to allow opportunity for submission of medication compliance guidelines. A partial certification from Baclofen 10mg qty 90 to #20 for initiation of downward titration and complete discontinuation. A partial certification from Ambien CR 6.25mg qty 45 + 1 refill to qty 30 with no refills for initiation of downward titration and complete discontinuation. 4/12/13 medical report identifies that the medication are being renewed and monitor for adherence with UDS, CURES and routine labs. Increase Exalgo to replace OxyContin. Recommendations are also to taper onto baclofen from Soma. Consider decreasing Norco and Ambien. There is also indication that the patient's testosterone was low and a referral was needed for maintenance. The patient was getting the testosterone replacement from [REDACTED]. The patient trialed the Exalgo by itself and stopped Norco for a day. The patient was advised not to trial his own dosage adjustments with these medications. The patient was still asking for more Soma as he feels this was the only muscle relaxer that helped. Baclofen and tizanidine were ineffective. He was adamant that his pain was reduced to a 2/10 with 8 Norco per day and his Soma. He stated that he needed this medications in order to go on walks with grandkids. The patient also wanted OxyContin back because it worked for his pain and the Exalgo had not yet at the 8mg QD. He could not take OxyContin after his morning dose because

he finds it stimulating making sleeping more difficult. The provider did not feel that taking OxyContin once a day, in the morning and then 8 Norco over the rest of the day, because OxyContin later in the day wires him was a good plan. The Exalgo was to be increased until he has stable 24hr pain control so the Norco could be decreased. The patient also had an elevated GGT and he was counseled that this may be due to the high APAP and his occasional ETOH consumption. The risks of pain medications were discussed. The patient choose to continue COAT as it allows to retain IADLs/ADLs and improved quality of life. The patient's daily morphine equivalent was 125mg. A trial of Exalgo was recommended to replace OxyContin, so the patient could utilize a long-acting medication around the clock. Laboratory report from 11/22/13 identify a testosterone level of 23.1 (normal range reported from 46-224). 2/10/14 medical report identified the same concerns regarding the medications as on December. There was still indication of continued increase in Exalgo to decrease Norco, and still the concern regarding OxyContin and Soma. 4/8/14 medical report identified that the patient had run out of his medications early and appeared to require escalating dosages. Despite higher doses, the functional status remained marginal. The recommendation was to continue to taper the medications. It was indicated that Soma was to be weaned off over the next month. Ambien was decreased. The Norco, Exalgo, and Baclofen were renewed without changes.

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

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

#### **Testosterone Replacement Therapy Evaluation And Treatment: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone Replacement For Hypogonadism. Related to Opioids Page(s): 74.

**Decision rationale:** The California MTUS states that testosterone replacement for hypogonadism (related to opioids) is recommended in limited circumstances for patients taking high-dose long-term opioids with documented low testosterone levels. The prior determination was non-certified due to no indication of low testosterone levels. There is now a laboratory report provided from November 2013 which indicates a testosterone level of 23, for which replacement therapy is appropriate. However, the specific route of administration (e.i gel, oral, patch) and dosage was not indicated. There was also indication that the patient was getting the testosterone replacement from [REDACTED]. There was no indication for the necessity of additional evaluation and treatment of testosterone replacement in this context. The request is not medically necessary.

#### **Soma 350mg #75 With 1 Refill: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol (Soma) Page(s): 29, 65.

**Decision rationale:** The California MTUS states that SOMA is not recommended. Carisoprodol is metabolized to meprobamate an anxiolytic that is a schedule IV controlled substance. The patient had been under chronic treatment of Soma, several medical reports indicate that the patient was adamant to continue with the medication and there was intention to discontinue since December. However, this medication was continuously refilled and the actual tapering did not take place until May 2014. There was no rationale for the continued prescription of medication, or objective documentation of benefit.

**NORCO 10/325MG #210 WITH 1 REFILL:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 79-81.

**Decision rationale:** The California MTUS Chronic Pain Medical Treatment Guidelines do not support ongoing opioid treatment unless prescriptions are from a single practitioner and are taken as directed; are prescribed at the lowest possible dose; and unless there is ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. There has been apparently appropriate medication monitoring from the provider. However, there is no clear indication for the continuation of Norco, more so, given the concern for the amount of medication taken. There were several medical reports indicating that Exalgo dose was being escalated to initiate decrease in Norco, however, the dosage of Norco has not changed. There was no clear indication to continue Norco at the same dosage and intake given repeated concerns for high dosage. While tapering was appropriately recommended at the time of the previous determination, the request as made, was not medically necessary.

**Baclofen 10MG #90:** Upheld

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

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

**Decision rationale:** The California MTUS Chronic Pain Medical Treatment Guidelines recommends non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP, however, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. There indication that baclofen was not efficient for the patient. There is no clear indication for the prescription of this medication in that regard, and also given the continued Soma prescription. The medical necessity was not substantiated. A modified certification was appropriate given at the time of prior

determination to allowed weaning of the medication. However, the request as presented was not medically necessary.

**Ambien CR 6.25mg #45 With 1 Refill:** Upheld

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

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

**Decision rationale:** The ODG and the FDA state that Ambien is approved for the short-term (usually two to six weeks) treatment of insomnia. Additionally, pain specialists rarely, if ever, recommend Ambien for long-term use. There was no clear indication of sleep difficulties specifically identifying insomnia with difficulty with sleep initiation. There was no indication if the patient was following a sleep hygiene routine and this was insufficient to address any possible sleep issues. There was insufficient documentation to support this request. A modified certification was appropriate given at the time of prior determination to allowed weaning of the medication. However, the request as presented was not medically necessary.