

Case Number:	CM14-0074329		
Date Assigned:	09/05/2014	Date of Injury:	06/06/2006
Decision Date:	10/21/2014	UR Denial Date:	04/23/2014
Priority:	Standard	Application Received:	05/21/2014

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 Physical Medicine and Rehabilitation, has a subspecialty in Pain 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:

The injured worker is a 59 year-old female with a date of injury of 6/6/2006. The patient's industrially related diagnoses include lumbar disc disorder, lumbar facet syndrome, knee pain, and mood disorder. The disputed issues are Zanaflex 4mg #60 with 1 refill and Norco 10/325mg #30 with 1 refill. A utilization review determination on 4/23/2014 had modified these requests to Zanaflex 4mg #60 with 0 refills and Norco 10/325mg #30 with 0 refills. The stated rationale for the partial certification of Zanaflex 4mg was: "Based on the reported pain and functional benefits a further one month supply is supported with needed blood monitoring for adverse effects and a refill is not supported." The stated rationale for the partial certification of Norco 10/325mg was "there is no documentation of functional improvements in ADLs as a result of hydrocodone/APAP use. Opioid monitoring is not documented with evidence of opioid contract; urine drug testing. These benefits are not adequately documented and provider reports a pain contract and compliance with latest urine drug screen 2/13/14 was compliant. There is use of only one tablet daily with pain and functional benefit and the MD is encouraged to document the above and a one month further supply is supported."

IMR ISSUES, DECISIONS AND RATIONALES

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

Zanaflex 4mg, #60 with 1 refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain), Antispasticity/antispasmodic drugs, page 63, 66.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-64, 66.

Decision rationale: Zanaflex is a centrally acting alpha2-adrenergic agonist that is FDA approved for the management of spasticity and is used off-label for low back pain. According to the Chronic Pain Medical Treatment Guidelines, eight studies have demonstrated efficacy for low back pain and one study showed significant decrease in pain associated with chronic myofascial pain syndrome. The authors of that study recommended Zanaflex as a first line option to treat myofascial pain. However, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. Zanaflex use has been associated with hepatic aminotransaminase elevations that are usually asymptomatic and reversible with discontinuation. A possible side effect is hepatotoxicity, therefore LFTs should be monitored at baseline, 1, 3, and 6 months. In general, the CPMT guidelines recommend the use of "non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP." Efficacy appears to diminish over time. Zanaflex was first prescribed on 1/18/2010 for muscle spasms and insomnia. Regarding Zanaflex, the treating physician documented on 4/10/2014 that the pain is reduced from a pain level of 10/10 to 7/10 with the use of Zanaflex and the injured worker is able to walk for 30 minutes with medication versus 10 minutes without medication. The medication helped the piriformis pain, which significantly increased mobility. A trial of generic Zanaflex caused nausea and was ineffective. Although the treating physician documented improvement with the use of Zanaflex, muscle relaxants are recommended only for short term-term treatment of acute exacerbations of chronic low back pain. However, the injured worker has been on Zanaflex for over 4 years demonstrating chronic use. Furthermore, there are no laboratory results available for review monitoring LFTs for risk of hepatotoxicity. Therefore medical necessity for Zanaflex 4mg #60 with 1 refill cannot be established.

Norco 10/325mg, #30 with 1 refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids and On going management Page(s): 74-82.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Page(s): 76-80.

Decision rationale: Norco 10/325mg is an opioid that is recommended for moderate to severe pain. With regard to the use of Norco, the California Chronic Pain Medical Treatment Guidelines states the following about on-going management with opioids: "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." The guidelines indicated that discontinuation of opioids would be appropriate if there was no

functional improvement. In the progress report dated 4/10/2014, the treating physician documented that the pain level had remained unchanged since the last visit and the injured worker's activity level had remained the same. The treating physician did not document the pain level without the use of Norco compared to the pain level with the use of Norco. Regarding functional level, there was no documented objective functional improvement with the use of Norco. In a subsequent progress report dated 6/5/2014, the treating physician documented that the pain level had increased since the last visit and the activity level had decreased. Addressing adverse events, the injured worker reported no side effects. Regarding the evaluation for aberrant behavior, in March 2014, the treating physician stated that the UDS (urine drug screen) was consistent. Based on the guidelines referenced above, all four domains (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behavior) should be monitored. The medical documentation did not adequately address all four domains with regards to the use of Norco 10/325mg. Due to the lack of documentation, Norco 10/325mg #30 with 1 refill is not medically necessary at this time.