

Case Number:	CM15-0004389		
Date Assigned:	01/15/2015	Date of Injury:	06/04/2013
Decision Date:	03/17/2015	UR Denial Date:	12/09/2014
Priority:	Standard	Application Received:	01/08/2015

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: Preventive Medicine, Occupational 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:

This 42 year old male sustained a work related injury on 06/04/2013. According to a progress report dated 11/20/2014, the injured worker complained of low back pain, right-sided low back pain radiating to the right lumbosacral and right lower extremity and tingling and numbness radiating from the low back to right lower extremity down to his toes. Diagnoses included low back pain with degenerative disc disease, right sacroiliac joint arthropathy and insomnia. Comorbid conditions include obesity (wt 242). A MRI of the lumbar spine dated 06/02/2014 revealed 3 millimeter far right posterolateral disc protrusion at L3-L4 resulting in mild right L3-L4 neuroforaminal stenosis, 2 millimeter far right posterolateral disc protrusion at the level of L4-L5 with mild right L4-L5 foraminal stenosis and mild right L1-L2 facet joint arthropathy and mild lumbar spine levoscoliosis. Treatment plan included lumbar epidural steroid injection, motorized cold therapy unit, Tizanidine for muscle relaxation and help with insomnia secondary to pain and numbness, Norco for breakthrough pain and compound analgesic cream for symptomatic relief of pain in lumbosacral area. Documentation submitted for review did not include urine toxicology screen or evidence of objective functional improvement with the use of medications. On 12/09/2014, Utilization Review non-certified Tizanidine 4mg one to two tab every bedtime for muscle relaxation, Norco 10/325mg #60 and compound analgesic cream Tramadol 8 %, Gabapentin 10%, Menthol 2% and Camphor 2%. According to the Utilization Review physician in regards to compounds analgesic cream, there was no peer reviewed literature to support use of Gabapentin in a topical preparation. Guidelines do not recommend any compounded topical analgesic were at least one ingredient is not recommended. Regarding

Tizanidine, it was unclear how long he had been maintained on this medication and the functional benefit he derived from previous intake was not established. In regard to Norco, evidence of pain reduction and functional improvement had not been noted to justify continued treatment with this medication. Documentation of monitoring for appropriated medication use including recent urine drug screens had not been noted to validate the injured worker's compliance to his prescribed opioid regimen. Guidelines cited for this review included CA MTUS Low Back Complaints and Chronic Pain Medical Treatment Guidelines; Topical Analgesics, Antispasticity/Antispasmodic Drugs and Opioids. The decision was appealed for an Independent Medical Review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tizanidine 4mg one to two tab QHS for Muscle Relaxation: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants, Antispasticity/Antispasmodic Drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-6.

Decision rationale: Tizanidine (Zanaflex) is a central-acting sedating muscle relaxant used to treat skeletal muscle spasms. This class of medications can be helpful in reducing pain and muscle tension thus increasing patient mobility. Muscle relaxants as a group, however, are recommended for short-term use only as their efficacy appears to diminish over time. They are considered no more effective at pain control than non-steroidal anti-inflammatory medication (NSAIDs) and there is no study that shows combination therapy of NSAIDs with muscle relaxants has a demonstrable benefit. This patient has been on tizanidine therapy for over 2 weeks. Since there is no complaint of muscle spasms and documented muscle relaxant effect from this medication that would suggest a need for chronic use there is no indication to continue its use. If chronic insomnia treatment is the reason the provider has prescribed this medication then a full workup for the cause of insomnia should be done before deciding on therapy. Medical necessity for this medication has not been established.

Norco 10/325mg BID #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Criteria for Use.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 60, 74-96.

Decision rationale: Norco is a mixed medication made up of the opioid, hydrocodone, and acetaminophen, better known as tylenol. It is recommended for moderate to moderately severe pain with usual dosing of 5-10 mg hydrocodone per 325 mg of acetaminophen taken as 1-2 tablets every 4-6 hours. Maximum dose according to the MTUS is limited to 4 gm of

acetaminophen per day which is usually 120mg/day of hydrocodone. According to the MTUS, opioid therapy for control of chronic pain, while not considered first line therapy, is considered a viable alternative when other modalities have been tried and failed. Success of this therapy is noted when there is significant improvement in pain or function. The risk with this therapy is the development of addiction, overdose and death. The pain guidelines in the MTUS directly address this issue and have a number of recommendations to identify and prevent the significant problems of drug-related morbidity or mortality from occurring. The patient's provider has not documented that he is following these guidelines, however, and does not document improvement in pain or functioning while using this medication. The risk of chronic opioids to this patient's safety and health is real. Medical necessity for continued chronic opioid therapy has not been established.

Compound Analgesic Cream Tramadol 8%, Gabapentin 10%, Menthol 2%, Camphor 2%:
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Muscle Relaxants (for pain).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; Opioids; Anti-Epileptic Drugs Page(s): 18-9, 49, 60-1, 74-96, 111-13.

Decision rationale: Tramadol 8%/gabapentin 10%/menthol 2%/camphor 2% cream is a combination product formulated for topical use. It is made up of tramadol (a opiate), gabapentin (an anticonvulsant), menthol (an analgesic), and camphor (an anesthetic). The use of topical agents to control pain is considered by the MTUS to be an option in therapy of chronic pain although it is considered largely experimental, as there is little to no research to support their use. The MTUS does not address the topical use of tramadol or other topical opioid preparations. Gabapentin is an effective medication in controlling neuropathic pain, but the MTUS does not recommend its use topically. Menthol is a topical analgesic medication with local anesthetic and counter-irritant qualities. Camphor is a topical medication with local anesthetic and antimicrobial properties. It is important to note the MTUS states: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Since gabapentin is not recommended for topical use, this product is not recommended. Medical necessity has not been established for use of this medication.