

Case Number:	CM13-0065054		
Date Assigned:	01/03/2014	Date of Injury:	10/10/2003
Decision Date:	07/03/2014	UR Denial Date:	11/15/2013
Priority:	Standard	Application Received:	12/12/2013

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 & Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in Minnesota. 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 61-year-old female who reported an injury on 10/10/2003. The mechanism of injury was reported to be her right knee being jammed into a gear shift on a bus. Per the evaluation dated 08/09/2013, the injured worker reported continuing severe low back pain with radiation into the left hip, thigh and down the left lower extremity. The injured worker reported pain to the right lower extremity as well particularly in the calf area. The injured worker was noted to be wearing a lumbar support brace. On physical examination, the injured worker was reported to have decreased flexion of the lumbar spine with forward flexion at 20 degrees and lateral flexion 10 degrees bilaterally. The injured worker was also reported to have paraspinous myospasm with myofascial trigger points with twitch response and referral of pain to the lumbosacral area. Examination of the left hip revealed pain with deep palpation over the left greater trochanter. Reflex and motor strength were normal and sensation was intact bilaterally. Straight leg raise was positive on the right. An MRI from 07/2013 revealed evidence of a decompression laminectomy with pedicle screws and fusion. There was a 3.5 mm disc protrusion at L5-S1 with mild thecal sac indentation. Per the progress note dated 11/06/2013, the injured worker reported left shoulder pain. The injured worker reported her left total knee replacement was doing well. The injured worker was reported to have had a caudal epidural steroid injection to the L5-S1 on the left. The Request for Authorization for medical treatment for Zolpidem, Hydrocodone/Acetaminophen, Tizanidine, Lorazepam, and 3 compound medications was dated 11/08/2013. The provider's rationale for the request for those medications was not provided within the documentation. Previous treatments for the injured worker included physical therapy, epidural steroid injection, aquatic therapy and lumbar fusion and medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

ZOLPIDEM TARTRATE 10MG #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

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.

Decision rationale: Per Official Disability Guidelines, Zolpidem is a prescription short-acting nonbenzodiazepine hypnotic, which is approved for short term usually 2 to 6 week's treatment of insomnia. While sleeping pills, so called minor tranquilizers, and anti anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long term use. They can be habit-forming and they may impair function and memory more than opioid pain medications. In laboratory studies, 15% of women and 3% of men who took a 10 mg dose of Ambien had potentially dangerous concentrations of the drug in their blood 8 hours later. There is also concern that they may increase pain and depression over the long term. There was a lack of documentation regarding the time frame the injured worker had been utilizing this medication. There was a lack of documentation regarding the efficacy of this medication. There was a lack of documentation regarding any potential aberrant behavior or use of this medication by the injured worker. There was a lack of documentation regarding the intended function of this medication, for sleep or for pain. In addition, the request did not include frequency information for the medication. Therefore, the request for Zolpidem tartrate 10 mg quantity of 30 is not medically necessary.

HYDROCODONE BIT/ACET 10/500MG #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chapter Opioids Page(s): 91.

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

Decision rationale: The California MTUS Guidelines state opioids are seen as an effective method in controlling chronic pain. They are often used for intermittent or breakthrough pain; however, for continuous pain extended release opioids are recommended. The 4 domains for ongoing monitoring are pain relief, side effects, physical and psychosocial functioning, and the occurrence of any aberrant behavior. Monitoring of these outcomes overtime should effect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. Opioids appear to be efficacious but limited for short term pain relief and long term efficacy is unclear but also appears limited. Failure 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 that opioids showed long term benefit or improvement in function when used as treatment for chronic back pain. The guidelines recommend that opioid dosing not exceed 120

mg of oral morphine equivalence per day, and for patients taking more than 1 opioid the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose. There was a lack of documentation regarding the time frame the injured worker had been utilizing this medication. There was a lack of documentation regarding the efficacy of this medication, including decreased pain or increased functionality. There was a lack of documentation regarding any potential aberrant use of this medication by the injured worker. In addition, the request did not include frequency information for the medication. Therefore, the request for Hydrocodone/Acetaminophen 10/500 mg quantity of 60 is not medically necessary.

TIZANIDINE 4MG #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chapter Muscle Relaxants (For Pain Page(s): 66.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain), Tizanidine Page(s): 63, 66.

Decision rationale: The California MTUS Guidelines recommend nonsedating muscle relaxants with caution as a second line option for short term treatment of acute exacerbations in patients with chronic low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most low back pain cases, they show no benefit beyond NSAIDS and pain in overall improvement. Also, there are no additional benefits shown in combination with NSAIDS. Efficacy appears to diminish over time and prolonged use of some medications in this class may lead to dependence. Per the guidelines, Tizanidine is essentially acting of 2 adrenergic agonist that is FDA approved for management of spasticity and unlabeled use for low back pain. There was a lack of documentation regarding the time frame the injured worker had been utilizing this medication. There was a lack of documentation regarding the efficacy of this medication, including decreased pain or increased functionality. There was a lack of documentation regarding potential aberrant behavior with this medication by the injured worker. In addition, the request did not include frequency information for the medication. Therefore, the request for Tizanidine 4 mg quantity of 60 is not medically necessary.

LORAZAPAM 2MG #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 24.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

Decision rationale: Per California MTUS Guidelines, Lorazepam is not recommended for long term use because long term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. The range of action includes sedative hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance of hypnotic effects develops rapidly. Tolerance of anxiolytic

effects occurs within months and long term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is antidepressants. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. Not recommended due to rapid development of tolerance and dependence. There appears to be little benefit for the use of this class of drugs over nonbenzodiazepines for the treatment of spasm. There was a lack of documentation regarding the time frame the injured worker had been using this medication. There was a lack of documentation regarding the efficacy of this medication including decreased pain or increased functionality. There was a lack of documentation regarding potential aberrant behavior associated with this medication. There was a lack of documentation regarding the intended function of this medication whether for anticonvulsants, muscle relaxant, or sleep. In addition, the request did not include frequency information for the medication. Therefore, the request for Lorazepam 2 mg quantity of 30 is not medically necessary.

COMPOUND MEDICATION GABAPENTIN 550MG / ACETYL-L-CARNITE 75MG:
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chapter Specific Anti-Epilepsy Drugs Page(s): 18-19.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 18. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://ods.od.nih.gov/factsheets/Carnitine-HealthProfessional/>.

Decision rationale: Per CA MTUS guidelines Gabapentin has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. Recommendations involving combination therapy require further study. Per the national institute of health two types of Carnitine deficiency states exist. Primary Carnitine deficiency is a genetic disorder of the cellular Carnitine-transporter system that usually manifests itself by five years of age with symptoms of Cardiomyopathy, skeletal-muscle weakness, and hypoglycemia. Secondary Carnitine deficiencies may occur due to certain disorders (such as chronic renal failure) or under particular conditions (e.g., use of certain antibiotics) that reduce Carnitine absorption or increase its excretion. There is scientific agreement on Carnitine's value as a prescription product for treating such deficiencies. The kidneys efficiently conserve carnitine, so even Carnitine-poor diets have little impact on the body's total Carnitine content. There was a lack of documentation regarding Carnitine deficiency for the injured worker. There was a lack of documentation regarding a diagnosis of diabetic neuropathy or postherpetic neuralgia per the injured worker. The guidelines do not recommend combination therapy regarding Gabapentin. In addition, the request did not include frequency information for the medication. Therefore, the request for compound medication Gabapentin 550 mg and acetyl-l-Carnitine 75 mg is not medically necessary.

COMPOUND MEDICATION FLURBIPROFEN 25% LIDOCAINE5%: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-114.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics, Non-steroidal antiinflammatory agents (NSAIDs), Lidocaine Page(s): 111-112.

Decision rationale: Per California MTUS Guidelines topical analgesics are recommended as an option; however, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. The efficacy of NSAIDs in clinical trials for topical treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to a placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward or with a diminishing effect over another 2 week period. Topical Lidocaine in the formulation of a dermal patch has been designated for orphan status by the FDA for neuropathic pain and used off-label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine whether creams, lotions or gels are indicated for neuropathic pain. There was a lack of documentation regarding a diagnosis of neuropathic pain, osteoarthritis or diabetic neuropathy for the injured worker. There was a lack of documentation regarding failed trials of antidepressants or anticonvulsants. In addition, dosing information including location for application of this medication was not provided in the request. Therefore, the request for compound medication Flurbiprofen 25% and Lidocaine 5% is not medically necessary.

COMPOUND MEDICATION TRAMADOL 15% DETROL 10% CAP 0.025%: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-114.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics, Capsaicin. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:

http://www.rsds.org/pdfsall/conference%20speakers%202011%20pdfs/Roberto%20perez_NMDA%20receptor%20antagonists.pdf.

Decision rationale: Per CA MTUS guidelines topical analgesics are recommended as an option; however, they are largely experimental in use, with few randomized control trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Per the guidelines Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful in patients whose pain has not been controlled successfully with conventional therapy. Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine

(whether creams, lotions or gels) are indicated for neuropathic pain. Per the American academy of pain medicine Dextromethorphan is an NMDA Receptor Antagonist. Based on systematic review, no conclusions can yet be made about the efficacy of NMDA receptor antagonists on neuropathic pain. There was a lack of documentation regarding a diagnosis of neuropathic pain, osteoarthritis, or diabetic neuropathy for the injured worker. There was a lack of documentation regarding failed trials of antidepressants or anticonvulsants. There is a lack of clinical evidence to recommend Dextromethorphan for topical use for neuropathic pain. In addition, dosing information including location for application of the medication was not provided in the request. Therefore, the request for a compounded medication Tramadol, Detrol and Capsaicin is not medically necessary.