

Case Number:	CM14-0016005		
Date Assigned:	06/04/2014	Date of Injury:	12/31/2011
Decision Date:	07/21/2014	UR Denial Date:	01/17/2014
Priority:	Standard	Application Received:	02/07/2014

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 & Rehabilitation and is licensed to practice in Illinois. 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 56-year-old male who reported an injury on 12/31/2011. The mechanism of injury was reported as the lifting of an elderly person. Per the orthopedic spine evaluation dated 08/07/2013, the cervical spine revealed negative Hoffman's and Spurling's test; however, there was slight tenderness noted with slight spasms and mildly decreased range of motion. Examination of the bilateral shoulders revealed no tenderness, negative impingement, normal resisted abduction and stability test, and no decreased range of motion. Examination of the bilateral wrists revealed negative tinel's, phalen's, and finklestein's, as well as no tenderness and normal range of motion. The thoracic spine revealed slight tenderness on palpation, moderate tenderness, and moderate muscle spasms. Lumbar range of motion was noted as forward flexion of 30 degrees, extension of 5 degrees, bilateral rotation of 20 degrees, with a negative straight leg raise. Per the clinical note dated 04/25/2014, the injured worker reported a constant moderate, sharp headache with severe migraines and memory loss. The injured worker also reported frequent moderate, dull, sharp, stabbing, throbbing, burning pain to the cervical, thoracic and lumbar spine with heaviness, numbness, tingling, and weakness throughout. The injured worker was prescribed condrolite, cyclobenzaprine, hydrocodone/apap, naproxen, omeprazole, zolpidem, flurbiprofen/tramadol in mediderm base, and Gabapentin/dextromethorphan/amitriptyline in mediderm base. The diagnoses for the injured worker included headache, cervical sprain and strain, thoracic and lumbar sprain and strain, and lumbar radiculopathy. Prior treatments for the injured worker included trigger point injections. The request for authorization for medical treatment for the tramadol/l-carnitine, baclofen/flurbiprofen/acetyl-carnitine, flurbiprofen/tramadol in mediderm base, gabapentin/amitriptyline/dexamethopphan in mediderm base was dated 05/16/2014. The provider's rationale for the request was not provided within the documentation.

IMR ISSUES, DECISIONS AND RATIONALES

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

TRAMADOL/L-CARNITINE 40/125MG #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG (OFFICIAL DISABILITY GUIDELINES) COMPOUNDED MEDICATIONS.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for chronic pain, Tramadol Page(s): 80-81,83-84,113. Decision based on Non-MTUS Citation <http://ods.od.nih.gov/factsheets/Carnitine-HealthProfessional/>.

Decision rationale: Per the ca mtus guidelines, tramadol is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. A recent cochrane review found that this drug decreased pain intensity, produced symptom relief and improved function for a time period of up to three months but the benefits were small. There are no long-term studies to allow for recommendations for longer than three months. Tramadol is reported to be effective in managing neuropathic pain and osteoarthritis. 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 is a lack of documentation regarding the efficacy of this medication, including clinical findings of decreased pain or increased functionality. In addition, the documentation submitted does not indicate the injured worker has findings that would support that she is at risk for carnitine deficiency. Additionally, the submitted documentation does not indicate the injured worker has findings that would support a diagnosis of neuropathic pain. The frequency of the medication is not provided in the submitted request. Therefore, the request for tramadol/l- carnitine 40/125 mg # 90 is non-certified.

BACLOFEN/FLURIPROFEN/ACETYL-CARNITINE 7/60/125MG #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG (OFFICIAL DISABILITY GUIDELINES) COMPOUNDED MEDICATIONS.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants,NSAID's Page(s): 63-64,72. Decision based on Non-MTUS Citation <http://ods.od.nih.gov/factsheets/Carnitine-HealthProfessional/>.

Decision rationale: The CA MTUS guidelines recommend non-sedating 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 in pain and overall improvement. In addition, efficacy appears to diminish over time,

and prolonged use of some medications in this class may lead to dependence. Baclofen is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Flurbiprofen is recommended for osteoarthritis and mild to moderate pain. 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 is a lack of documentation regarding the efficacy of this medication, including clinical findings of decreased pain or increased functionality. There is a lack of documentation regarding muscle spasms or a spasticity that would warrant the need for a muscle relaxant. In addition, the documentation submitted does not indicate the injured worker has findings that would support he has a diagnosis of multiple sclerosis. Additionally, the submitted documentation did not indicate the injured worker has a spinal cord injury. The request as submitted fails to provide the frequency of the medication. There is no documentation which indicates why a compounded medication is needed as opposed to the separated medications which are available. Therefore, the request for baclofen/flurbiprofen/acetyl-carnitine 7/60/175 mg quantity of 90 is non-certified.

FLURBIPROFEN 20%, TRAMADOL 20% IN MEDIDERM BASE 240GM: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical NSAIDS. Decision based on Non-MTUS Citation ODG (Official Disability Guidelines), Topical NSAIDS.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-112. Decision based on Non-MTUS Citation http://medi-derm.net/?page_id=11; effectiveness of topical administration of opioids in palliative care: a systematic review. B Lebon, G Zeppetella, Ij Higginson - Journal of pain and symptoms, 2009- Elsevier.

Decision rationale: Per the CA MTUS guidelines, topical analgesics are recommended as an option; however, they are largely experimental in use, with few randomized trials to determine efficacy or safety and is 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. The guidelines recommend topical NSAIDS for osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDS for treatment of osteoarthritis of the spine, hip or shoulder. Medi-derm consists of methyl salicylate, menthol and capsaicin. Topical salicylates are recommended as significantly better than placebo in chronic pain. Capsaicin is recommended only as an option in patients who have not responded to 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. Medi-derm can aid in the treatment of inflammation, muscle pain, muscle soreness, joint pain, stiffness, backache, strains, nerves, and pain associated with arthritis. There is a lack of documentation regarding a diagnosis of neuropathic pain. There is a lack of documentation regarding failed trials of antidepressants and anticonvulsants. There is a

lack of documentation regarding the use of oral medications for pain and the efficacy and side effects reported by the injured worker. There is a lack of documentation regarding a diagnosis of osteoarthritis or tendinitis for the injured worker. There is a lack of documentation regarding the utilization of this topical medication and the efficacy of the medication. There is a lack of documentation within the request regarding dosing instructions including location for administration of the topical. Therefore, the request for flurbiprofen 20%, tramadol 20% in mediderm base quantity 240 grams is non-certified.

GABAPENTIN 10% AMITRIPTYLIN 10%, DEXAMETHORPHAN 10% IN MEDIDERM BASE 240GM: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation (ODG) Official Disability Guidelines, Compound Topical Creams.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113. Decision based on Non-MTUS Citation http://the-medical-dictionary.com/dextromethorphan_article_2.htm; <http://onlinelibrary.wiley.com/doi/10.1111/j.1533-2500.2011.00477.x/full>.

Decision rationale: Per the ca mtus guidelines, topical analgesics are recommended as an option; however, they are largely experimental in use, with few randomized trials to determine efficacy or safety and is 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. There is no peer-reviewed literature to support the use of gabapentin as a topical agent; therefore, it is not recommended. Per the online research high dose topical amitriptyline, 5% and 10%, might be a useful adjunct to treat severe and intractable neuropathic pain. Although previous trials were inconsistent in reporting efficacy of topical amitriptyline cream, in a dose range from 1% to 5%, we believe the dose range has to be further explored, targeting the lowest therapeutic plasma concentration of amitriptyline as amitriptyline 10% can induce systemic adverse effects. The effect of an antidepressant, such as amitriptyline, in combination with other classes of drugs has not been well researched. Per the medical dictionary when topical compounds are applied to the site of pain every 1 to 2 hours as needed, even as little as three times a day on a regular basis, the results are encouraging. Topical dextromethorphan 5% to 10% in a gel is effective without concern for side effects and/or possible interactions with concomitant medications." Medi-derm consists of methyl salicylate, menthol and capsaicin. Topical salicylates are recommended as significantly better than placebo in chronic pain. Capsaicin is recommended only as an option in patients who have not responded to or are intolerant to other treatments. Medi-derm can aid in the treatment of inflammation, muscle pain, muscle soreness, joint pain, stiffness, backache, strains, nerves, and pain associated with arthritis. There is a lack of documentation regarding a diagnosis of neuropathic pain. There is a lack of documentation regarding failed trials of antidepressants and anticonvulsants. There is a lack of documentation regarding the utilization and efficacy of this medication. There is a lack of documentation regarding current oral medications and the efficacy and side effects of those meds. As the guidelines note that topical gabapentin is not recommended and any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended, the medication would not be indicated. In addition, there is a lack of documentation within the request regarding dosing instructions including location for administration of the topical. Therefore, the request for gabapentin 10%, amitriptyline 10%, dextromethorphan 10% in mediderm base 240 grams is non-certified.