

Case Number:	CM14-0020686		
Date Assigned:	04/30/2014	Date of Injury:	06/18/2011
Decision Date:	07/08/2014	UR Denial Date:	02/03/2014
Priority:	Standard	Application Received:	02/19/2014

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, 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 58-year-old who reported an injury on June 18, 2011. The mechanism of injury was not provided in the documentation. Per the progress note dated January 17, 2014, the injured worker reported constant moderate to severe dull achy right wrist pain. On physical exam there was 3 tenderness to palpation of the anatomical snuff box, dorsal radial wrist, dorsal wrist and thenar. There is muscle spasm of the thenar. Finkelstein's is positive. An x-ray of the right wrist had reported osteopenia of the visualized bony structures. The diagnosis reported for the injured worker included right De Quervain's disease and right wrist tenosynovitis. The request for authorization for medical treatment and the provider's rationale for the request(s) for cartivisc, 2 topical creams, tramadol/L-carnitine, and baclofen/flurbiprofen/acetyl-carnitine was not provided in the documentation.

IMR ISSUES, DECISIONS AND RATIONALES

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

CARTIVISC 500/200/150MG #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine and Chondroitin Sulfate Page(s): 50.

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines, Glucosamine and Chondroitin Sulfate are recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Cartivisc is Glucosamine, Chondroitin Sulfate, and Methylsulfonylmethane. Per an online review Methylsulfonylmethane (MSM) is taken because some believe it helps support health ligaments, MSM has not undergone any significant test to support its use. The theory is that the sulfur in MSM helps the body maintain healthy, flexible ligaments. The FDA has not reviewed this product for safety or effectiveness. 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 did not indicate the injured worker had findings that would support arthritis. The request did not specify dosing for this medication. The request for cartivisc 500/200/150mg, ninety count, is not medically necessary or appropriate.

MEDICAL COMPOUND CREAM: GABAPENTIN 10%, LIDOCAINE 5%, TRAMADOL 15% - 240gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment Guidelines, page(s) 111-113, as well as the Non-MTUS article Effectiveness of Topical Administration of Opioids in Palliative Care: A Systematic Review, by B LeBon, G Zeppetella, IJ Higginson, from the Journal of Pain and Symptoms, 2009.

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines, topical analgesics are recommended as an option as indicated below. 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 one drug (or drug class) that is not recommended is not recommended. Gabapentin is not recommended as a topical agent. 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. Tramadol is a centrally acting synthetic opioid analgesic. Peer reviewed literature states that there is a deficiency of higher quality evidence on the role of topical opioids and that more robust primary studies are required to inform practice recommendations. There was a lack of documentation regarding the efficacy of this medication including clinical findings of decreased pain or increased functionality. In addition, the documentation submitted did not indicate the injured worker had findings that would support a diagnosis of neuropathic pain. As guidelines state any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended, the requested compound is not supported. The request for medical compound cream: gabapentin 10%, lidocaine 5%, tramadol 15%, 240 grams, is not medically necessary or appropriate.

MEDICAL COMPOUND CREAM: CAPSAICIN 0.0375%, DICLOFENAC 20%, TRAMADOL 10%, KETOPROFEN 10%, CAMPHOR 2%, MENTHOL 2% - 240gm:
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-112. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: 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: According to the Chronic Pain Medical Treatment Guidelines, topical analgesics are recommended as an option as indicated below. 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 one drug (or drug class) that is not recommended is not recommended. Recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Indications: 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. Ketoprofen is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. Voltaren Gel 1% (diclofenac) is indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). Tramadol is a centrally acting synthetic opioid analgesic. Peer reviewed literature states that there is a deficiency of higher quality evidence on the role of topical opioids and that more robust primary studies are required to inform practice recommendations. There was a lack of documentation regarding the efficacy of this medication including clinical findings of decreased pain or increased functionality. In addition, the documentation submitted did not indicate the injured worker had findings that would support a diagnosis of osteoarthritis, fibromyalgia, or chronic non-specific back pain. The guidelines note there is no current indication the increase of capsaicin at 0.0375% would provide any further efficacy. As guidelines state any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended, the requested compound is not supported. The request for medical compound cream: capsaicin 0.0375%, diclofenac 20%, tramadol 10%, ketoprofen 10%, camphor 2%, menthol 2%, 240 grams, is not medically necessary or appropriate.

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

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol Page(s): 84, 113. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://ods.od.nih.gov/factsheets/Carnitine-HealthProfessional/>.

Decision rationale: According to the Chronic Pain Medical Treatment 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 did not indicate the injured worker had findings that would support she was at risk for carnitine deficiency. Additionally, the submitted did not indicate the injured worker had findings that would support a diagnosis of osteoarthritis or neuropathic pain. The frequency of the medication was not provided in the request as submitted. The request for tramadol/l-carnitine 40/125mg, ninety count, is not medically necessary or appropriate.

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

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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 Other Medical Treatment Guideline or Medical Evidenc <http://ods.od.nih.gov/factsheets/Carnitine-HealthProfessional/>.

Decision rationale: The Chronic Pain Medical Treatment 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 (non-steroidal anti-inflammatory drugs) 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 was a lack of documentation regarding muscle spasms or or spasticity that would warrant the need for a muscle relaxant. In addition, the documentation submitted did not indicate the injured worker had findings that would support she was at risk for multiple sclerosis. Additionally, the submitted documentation did not indicate the injured worker had findings that would support a diagnosis of spinal cord injuries or low back pain. The request as submitted failed to provide the frequency of the medication. The request for baclofen/flurbiprofen/acetyl-carnitine 7/60/125mg, ninety count, is not medically necessary or appropriate.