

Case Number:	CM14-0107676		
Date Assigned:	08/01/2014	Date of Injury:	03/17/2014
Decision Date:	10/21/2014	UR Denial Date:	06/17/2014
Priority:	Standard	Application Received:	07/11/2014

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 Occupational Medicine, and is licensed to practice in Texas. 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:

This injured worker is a 51 year old woman involved in a work related injury from 3/17/14. There is scant data provided for review. The injured worker was complaining of some stress at work, and also had some neck pain with complaints of pain radiating to the upper extremities. A request was made for topical compounded medication creams.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen 20% Capsaicin 0.025% Methyl Salicylate 4% in Lipoderm Base 180gms:
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (<http://www.odg-twc.com/odgtwc/pain.htm#>)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111.

Decision rationale: There is no data to support the use of these topical compounds. There is little data in the file addressing any musculoskeletal problems and no data about failure of first line medications. In addition, from the guidelines, we note, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety and primarily

recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control (including non-steroidal anti-inflammatory drugs [NSAIDs], opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). There is little to no research to support the use of many these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Non-steroidal anti-inflammatory agents (NSAIDs) are recommended for the following indications: Acute pain: recommended for short-term use (one to two weeks), particularly for soft tissue injuries such as sprain/strains. According to a recent review, topical non-steroidal anti-inflammatory drugs (NSAIDs) can provide good levels of pain relief for sprains, strains, and overuse injuries, with the advantage of limited risk of systemic adverse effects as compared to those produced by oral non-steroidal anti-inflammatory drugs (NSAIDs). They are considered particularly useful for individuals unable to tolerate oral administration, or for whom it is contraindicated. Food and Drug Administration (FDA)-approved agents: At this time, the only available Food and Drug Administration (FDA)-approved topical non-steroidal anti-inflammatory drugs (NSAID) is diclofenac. Lidocaine is recommended for a trial if there is evidence of localized pain that is consistent with a neuropathic etiology. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the Food and Drug Administration (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. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Baclofen is not recommended. There is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer injured workers for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen. Other muscle relaxants there is no evidence for use of any other muscle relaxant as a topical product. Gabapentin is not recommended. There is no peer-reviewed literature to support use. Other anti-epilepsy drugs, there is no evidence for use of any other anti-epilepsy drug as a topical product. Ketamine is under study: The guideline criteria have not been met as there are insufficient large-scale, randomized, controlled references showing the safety and efficacy of the requested compound prescription in this injured worker's clinical scenario. It is not clear that the injured worker is intolerant of oral medications. The compounded substance is composed of drugs that have, in many instances, no Food and Drug Administration (FDA) approval for a topical form, have no identified clinical application in topical form, or both.

Gabapentin 5% Ketoprofen 10% Tramadol 5% Cyclobenzaprine 2.5% in Lipoderm base 180gms: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (<http://www.odg-twc.com/odgtwc/pain.htm#>)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111.

Decision rationale: There is no data to support the use of these topical compounds. There is little data in the file addressing any musculoskeletal problems and no data about failure of first line medications. In addition, from the guidelines, we note: 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. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control (including non-steroidal anti-inflammatory drugs (NSAIDs), opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). There is little to no research to support the use of many these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Non-steroidal anti-inflammatory agents (NSAIDs) are recommended for the following indications: Acute pain: Recommended for short-term use (one to two weeks), particularly for soft tissue injuries such as sprain/strains. According to a recent review, topical non-steroidal anti-inflammatory drugs (NSAIDs) can provide good levels of pain relief for sprains, strains, and overuse injuries, with the advantage of limited risk of systemic adverse effects as compared to those produced by oral non-steroidal anti-inflammatory drugs (NSAIDs). They are considered particularly useful for individuals unable to tolerate oral administration, or for whom it is contraindicated. Food and Drug Administration (FDA)-approved agents: At this time, the only available Food and Drug Administration (FDA)-approved topical non-steroidal anti-inflammatory drug (NSAID) is diclofenac. Lidocaine is recommended for a trial if there is evidence of localized pain that is consistent with a neuropathic etiology. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the Food and Drug Administration (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. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Baclofen is not recommended. There is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer injured workers for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen. Other muscle relaxants: there is no evidence for use of any other muscle relaxant as a topical product. Gabapentin is not recommended. There is no peer-reviewed literature to support use. Other antiepilepsy drugs: There is no evidence for use of any other anti-epilepsy drug as a topical product. Ketamine is under study. The guideline criteria have not been met as there are insufficient large-scale, randomized, controlled references showing the safety and efficacy of the requested compound prescription in this injured worker's clinical scenario. It is not clear that the injured worker is intolerant of oral medications. The compounded substance is composed of drugs that have, in many instances, no Food and Drug Administration (FDA) approval for a topical form, have no identified clinical application in topical form, or both. Therefore, this request is not indicated as medically necessary at this time, and is not medically necessary.

