

<b>Case Number:</b>	CM15-0115366		
<b>Date Assigned:</b>	06/23/2015	<b>Date of Injury:</b>	02/06/2012
<b>Decision Date:</b>	07/23/2015	<b>UR Denial Date:</b>	05/20/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/15/2015

### 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:

The injured worker is a 54 year old female, who sustained an industrial injury on 2/6/12. The injured worker was diagnosed as having myalgia and myositis, internal derangement of the knee and backache. Treatment to date has included use of an H-wave device, physical therapy, chiropractic treatment, acupuncture, and medication. The injured worker had been using Gabapentin and Cyclobenzaprine topical cream since at least 1/21/15. Currently, the injured worker complains of total body pain, chronic fatigue, and problems sleeping. The treating physician requested authorization for Cyclobenzaprine 10%/Gabapentin 5%/Lidocaine 5%/Capsaicin 0.025%, Gabapentin 250mg/Pyridoxine 100mg #81, and a functional capacity evaluation.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Cyclobenzaprine 10%/Gabapentin 5%/Lidocaine 5%/Capsaicin 0.025% quantity unspecified: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Section, Topical Capsaicin Section Page(s): 28, 111-113.

**Decision rationale:** The MTUS Guidelines recommend the use of topical analgesics as an option for the treatment of chronic pain, however, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. The MTUS Guidelines state that there is no evidence for use of muscle relaxants, such as Cyclobenzaprine, as a topical product. The MTUS Guidelines do not recommend the use of topical gabapentin, as there is no peer-reviewed literature to support use. Topical lidocaine is used primarily for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. There is no clear evidence in the clinical reports that this injured worker has neuropathic pain that has failed treatment with trials of antidepressants and anticonvulsants. Topical capsaicin is recommended by the MTUS Guidelines 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. As one of the medications in the requested compounded medication is not recommended, the request for Cyclobenzaprine 10%/Gabapentin 5%/Lidocaine 5%/Capsaicin 0.025% quantity unspecified is not medically necessary.

**Gabapentin 250mg/Pyridoxine 100mg quantity 81:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine, Chapter 6; Official Disability Guidelines, Pain (chronic).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy Drugs (AEDs) Section Page(s): 16-21. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/B vitamins & vitamin B complex Section.

**Decision rationale:** The MTUS Guidelines recommend the use of anti-epilepsy drugs for neuropathic pain. Most randomized controlled trials for the use of anti-epilepsy drugs for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy, with polyneuropathy being the most common example. There are few RCTs directed at central pain, and none for painful radiculopathy. A good response to the use of anti-epilepsy drugs has been defined as a 50% reduction in pain and a moderate response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response to this magnitude may be the trigger for switching to a different first line agent, or combination therapy if treatment with a single drug fails. After initiation of treatment, there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of anti-epilepsy drugs depends on improved outcomes versus tolerability of adverse effects. 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. Per the ODG, vitamin B 6 is not recommended for the treatment of chronic pain unless this is associated with documented vitamin deficiency. It is frequently used for treating peripheral neuropathy but its efficacy is not clear. A recent meta-analysis concluded that there are only limited data in randomized trials testing the efficacy of vitamin B for treating peripheral neuropathy (diabetic and alcoholic). Evidence was insufficient to determine whether specific B vitamins or B complex for these conditions was beneficial or harmful. The available documentation does not explain why the injured worker needs a combination drug of gabapentin and vitamin B6. There is no indication that the injured worker has a vitamin b deficiency. The request for Gabapentin 250mg/Pyridoxine 100mg quantity 81 is not medically necessary.

**Functional Capacity Evaluation:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Work Conditioning, Work Hardening Section Page(s): 125, 126. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Fitness for Duty Chapter/Functional Capacity Evaluation (FCE) Section.

**Decision rationale:** The MTUS Guidelines state that a functional capacity evaluation (FCE) may be required for admission to a work hardening program, but do not provide specific recommendations regarding the FCE alone. The ODG recommends the use of FCE prior to admission to a work hardening program. The ODG provides specific guidelines for performing an FCE and state to consider an FCE if: 1) case management is hampered by complex issues such as: prior unsuccessful RTW attempts; conflicting medical reporting on precautions and/or fitness for modified job; injuries that require detailed exploration of a worker's abilities; 2) timing is appropriate: close or at MMI/all key medical reports secured; additional/secondary conditions clarified. It is recommended to not proceed with an FCE if: 1) the sole purpose is to determine a worker's effort or compliance; 2) the worker has returned to work and an ergonomic assessment has not been arranged. There is no indication in the available documentation that the injured worker is being considered for a work hardening program. The request for functional capacity evaluation is not medically necessary.