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| <b>Case Number:</b>   | CM14-0137650 |                              |            |
| <b>Date Assigned:</b> | 09/08/2014   | <b>Date of Injury:</b>       | 10/06/2013 |
| <b>Decision Date:</b> | 10/10/2014   | <b>UR Denial Date:</b>       | 08/14/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 08/25/2014 |

### 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 Family Medicine 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:

This is a female patient who reported an industrial injury to the hand on 10/6/2013, one year ago, attributed to the performance of her usual and customary job tasks as a veterinarian reported as a cat bite. The patient was treated with a tenosynovectomy and debridement of the first and second dorsal compartment of the wrist. Electrodiagnostic testing was negative. The diagnosis was chronic neuropathic pain of the right thumb with chronic paresthesias and depression. The patient was prescribed a topical compounded analgesic and Gralise 300-600 mg at dinner. The patient was to continue the previously prescribed Gabapentin.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Cyclobenzaprine 10% / Gabapentin 10% cream:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): Table 3-1, Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines, and the FDA Guidelines

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines Topical Analgesics ; Anti-Inflammatory Medications Page(s): 112-113; 22, 67-68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--topical analgesics; topical analgesics compounded;

**Decision rationale:** The prescription for compounded topical Cyclobenzaprine 10% / Gabapentin 10% cream is not medically necessary for the treatment of the patient for pain relief for the orthopedic diagnoses of the patient. There is no clinical documentation submitted to demonstrate the use of the topical gels for appropriate diagnoses or for the recommended limited periods of time. It is not clear that the topical compounded medications are medically necessary in addition to prescribed oral medications. There is no provided subjective/objective evidence that the patient has failed or not responded to other conventional and recommended forms of treatment for relief of the effects of the industrial injury. Only if the subjective/objective findings are consistent with the recommendations of the ODG, then topical use of topical preparations is only recommended for short-term use for specific orthopedic diagnoses. There is no provided rationale supported with objective evidence to support the prescription of the topical compounded cream. There is no documented efficacy of the prescribed topical compounded analgesics with no assessment of functional improvement. The patient is stated to have reduced pain with the topical creams; however, there is no functional assessment and no quantitative decrease in pain documented. The use of topical NSAIDS is documented to have efficacy for only 2-4 weeks subsequent to injury and thereafter, is not demonstrated to be as effective as oral NSAIDS. There is less ability to control serum levels and dosing with the topicals. The patient is not demonstrated to have any GI issue at all with NSAIDS. There is no demonstrated medical necessity for topical NSAIDS for chronic pain for a prolonged period of time. The request for the topical NSAID compounded topical Cyclobenzaprine 10% / Gabapentin 10% cream is not medically necessary for the treatment of the patient for the diagnosis of the chronic pain to the right hand pain. The use of the topical gels/creams does not provide the appropriate therapeutic serum levels of medications due to the inaccurate dosing performed by rubbing variable amounts of gels on areas that are not precise. The volume applied and the times per day that the gels are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of gels to the oral medications in the same drug classes. There is no demonstrated evidence that the topicals are more effective than generic oral medications. The use of compounded topical Cyclobenzaprine 10% / Gabapentin 10% cream is not supported by the applicable evidence-based guidelines as cited above. The continued use of topical NSAIDS for the current clinical conditions is not otherwise warranted or demonstrated to be appropriate. There is no documented objective evidence that the patient requires both the oral medications and the topical analgesic medication for the treatment of the industrial injury.

**A trial of Gralise:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs). Decision based on Non-MTUS Citation Official Disability Guidelines

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drugs page 16; specific Anti-Epilepsy Drugs Gabapentin page 18 Page(s): 16; 18. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) chronic pain chapter 8/8/2008 page 110; Official Disability Guidelines (ODG) pain chapter-medications for chronic pain

**Decision rationale:** The Official Disability Guidelines and the CA MTUS state that there is insufficient evidence to support the use of Gabapentin for the treatment of non-neuropathic pain. The prescription for Gabapentin is prescribed for pain associated with nerve compression neuropathies for which there is a reported neurogenic pain issues due to a cat bite. The use of gabapentin is directed to subjective pain issues. Electrodiagnostic studies are negative. There is evidence of a nerve impingement radiculopathy or neuropathic pain to justify the use of Gabapentin. There is no demonstrated medical necessity for name brand Gralise. There is no rationale to support the medical necessity of both Gralise and Gabapentin. The prescription of Gabapentin (Gralise) for chronic right thumb pain s/p cat bite was not supported with objective findings on physical examination, as there were no demonstrated neurological deficits. There is no objective evidence on examination for significant neurogenic pain issues. The use of Gabapentin is not documented to be for neuropathic pain and is prescribed for right thumb pain s/p cat bite. The prescription of Gabapentin (Gralise) is recommended for neuropathic pain and is used to treat postherpetic neuralgia and painful polyneuropathy such as diabetic polyneuropathy. The patient is not demonstrated to have neuropathic pain. Anti-epilepsy drugs (AEDs) are recommended on a trial basis (Gabapentin/Pregabalin) as a first-line therapy for painful polyneuropathy such as diabetic polyneuropathy. The prescription of Gabapentin for neuropathic pain was not supported with objective findings on physical examination. There is no objective evidence that the recommended conservative treatment with the recommended medications have been provided prior to the prescription of Gabapentin for chronic pain. The use of Gabapentin should be for neuropathic pain. Presently, there is documented no objective evidence of neuropathic pain for which the use of Gabapentin is recommended. Mechanism of action: This medication appears to be effective in reducing abnormal hypersensitivity (allodynia and hyperalgesia), to have anti-anxiety effects, and may be beneficial as a sleep aid. Specific pain states: There is limited evidence to show that this medication is effective for postoperative pain, where there is fairly good evidence that the use of gabapentin and gabapentin-like compounds results in decreased opioid consumption. This beneficial effect, which may be related to an anti-anxiety effect, is accompanied by increased sedation and dizziness. (Peng, 2007) (Buvanendran, 2007) (Menigaux, 2005) (Pandey, 2005) Spinal cord injury: Recommended as a trial for chronic neuropathic pain that is associated with this condition. (Levendoglu, 2004) CRPS: Recommended as a trial. (Serpell, 2002) Fibromyalgia: Recommended as a trial. (Arnold, 2007) Lumbar spinal stenosis: Recommended as a trial, with statistically significant improvement found in walking distance, pain with movement, and sensory deficit found in a pilot study. (Yaksi, 2007) Side-Effect Profile: Gabapentin has a favorable side-effect profile, few clinically significant drug-drug interactions and is generally well tolerated; however, common side effects include dizziness, somnolence, confusion, ataxia, peripheral edema, and dry mouth. (Eisenberg, 2007) (Attal, 2006) Weight gain is also an adverse effect. It is believed that the pharmacology is related to its ability, documented in in-vitro experiments, to enhance the activity of gamma aminobutyric acid (GABA), the major inhibitory neurotransmitter in the central nervous system. These experiments have shown that tiagabine binds to recognition sites associated with the GABA uptake carrier. It is thought

that, by this action, tiagabine blocks GABA uptake into presynaptic neurons, permitting more GABA to be available for receptor binding on the surfaces of post-synaptic cells. Evidence is available that it operates as a selective GABA reuptake inhibitor. The prescription of Gabapentin/Gralise was not demonstrated to be medically necessary for the effects of the industrial injury.