

Case Number:	CM15-0200445		
Date Assigned:	10/15/2015	Date of Injury:	12/03/2014
Decision Date:	11/25/2015	UR Denial Date:	10/05/2015
Priority:	Standard	Application Received:	10/13/2015

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: New York

Certification(s)/Specialty: Anesthesiology

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 64 year old female, who sustained an industrial injury on 12-3-2014. The injured worker is undergoing treatment for: cumulative trauma of the neck, upper extremity and low back. On 9-18-2015, she reported neck, upper extremity and low back pain. She indicated being unable to sleep through the night and needing to take Norco during the night. There is notation of increased restless legs with Theramine and this side effect subsiding. She indicated Theramine to help with increased energy. She rated her pain 6 out of 10, maximum pain 8 out of 10, minimum pain 4 out of 10, and acceptable pain 2 out of 10. Physical findings revealed tenderness, spasms in the cervical spine and trapezius muscles, tenderness in the low back, decreased cervical range of motion, decreased lumbar range of motion, and decreased bilateral shoulders range of motion and strength. There is notation of no aberrant behaviors or adverse side effects. Pain is noted to have been decreased with medications. She reported that over the counter topical creams have not worked for her. The treatment and diagnostic testing to date has included: lumbar fusion (date unclear) bilateral carpal tunnel surgery (dates unclear), ergonomic work station, medications, work restrictions, hot packs, magnetic resonance imaging of the lumbar (3-19-08), CT scan of the lumbar (5-11-09), magnetic resonance imaging of the cervical spine (5-22-09, 7-3-12), CURES (5-8-15), urine toxicology screen (5-8-15). Medications have included: Theramine, Gabapentin, Cymbalta, Lidocaine patches, and Flurbiprofen cream. There is notation on 9-18-15 that she is unable to take more Gabapentin due to dizziness and balance problems. She is noted to be unable to take oral non-steroidal anti-inflammatory drugs due to cardiac issues and gastritis. Lidocaine patches are noted as prescribed due to allodynia and radicular symptoms that are not controlled by 100mg of Gabapentin. The

records indicate she has utilized Theramine, Cymbalta, Gabapentin, Flurbiprofen cream, and Lidocaine patches since July 2015, possibly longer. Current work status: not documented. The request for authorization is for: Theramine quantity 90, Gabapentin 100mg quantity 30, Cymbalta 30mg quantity 60, Lidocaine patches quantity 30, Flurbiprofen cream quantity 2. The UR dated 10-5-2015: Certified Cymbalta 30 quantity 60; and non-certified Theramine quantity 90, Gabapentin 100mg quantity 30, Lidocaine patches quantity 30, and Flurbiprofen cream quantity 2.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine Qty: 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 (ODG)- TWC Pain last updated 09/08/2015.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medscape Internal Medicine (2014).

Decision rationale: According to the ODG, Theramine is an FDA regulated medical food designed to address the increased nutritional requirements associated with chronic pain syndromes and low back pain. Its mechanism of action is the production of neurotransmitters that help manage and improve the sensory response to pain and inflammation. This medication contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa. There is no medical literature that supports the use of this medication for the treatment of chronic pain. Medical necessity for the requested medication has not been established. The requested medication is not medically necessary.

Gabapentin 100mg Qty: 30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Gabapentin (Neurontin).

Decision rationale: Gabapentin (Neurontin) is an anti-epilepsy drug, which has been shown to be effective for treatment of diabetic painful neuropathy and post-herpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. There is no documentation of objective findings consistent with current neuropathic pain to necessitate the use of Gabapentin. In addition, there is no documentation of benefit from the previous use of Gabapentin. Medical necessity for Gabapentin has not been established. The requested medication is not medically necessary.

Lidocaine patches Qty: 30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Lidoderm (lidocaine patch).

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics, such as the Lidoderm 5% patch, are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically 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, for example, NSAIDs, opioids, or antidepressants. Lidoderm is the brand name for a lidocaine patch. Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants, or an AED, such as gabapentin or Lyrica). Lidoderm patches are not a first-line treatment and are only FDA approved for post-herpetic neuralgia. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. In this case, medical necessity of the requested medication has not been established. The requested topical analgesic is not medically necessary.

Flurbiprofen cream Qty: 2.00: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically 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, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. In this case, there is no documentation provided necessitating Flurbiprofen cream. There is no documentation of intolerance to other previous medications. Flurbiprofen, used as a topical NSAID, has been shown in a meta-analysis to be superior to placebo during the first two weeks of treatment for osteoarthritis but either, not afterward, or with diminishing effect over another two-week period. There are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). In addition, there is no specified dosage or quantity of Flurbiprofen cream requested. Medical necessity for the requested Flurbiprofen cream has not been established. The requested treatment is not medically necessary.