

<b>Case Number:</b>	CM15-0197249		
<b>Date Assigned:</b>	10/12/2015	<b>Date of Injury:</b>	09/14/2012
<b>Decision Date:</b>	11/30/2015	<b>UR Denial Date:</b>	09/29/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/07/2015

### 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: Texas, California  
Certification(s)/Specialty: Family Practice

### 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 44 year old female, who sustained an industrial-work injury on 9-14-12. She reported initial complaints of neck, back, and shoulder pain. The injured worker was diagnosed as having cervical musculoligamentous strain-sprain, cervical spine discogenic disease, and bilateral shoulder impingement syndrome. Treatment to date has included medication, surgery (right shoulder on 11/28/14 with some relief), physical therapy (some benefit), and diagnostics. MRI results were reported on 3-19-15 of the left wrist that noted small cystic ganglion on the volar radial side of the wrist. MRI (magnetic resonance imaging) of the right wrist notes small amount of fluid in the extensor compartment tendon sheath, subcortical degenerative cyst at the proximal pole of the scaphoid, and 4 mm cystic ganglion at the floor of the flexor compartment. MRI (magnetic resonance imaging) of lumbar spine on 3-24-15 notes degenerative changes at multiple levels, moderate facet arthropathy, and disc protrusion at L5-S1 without canal stenosis. Currently, the injured worker complains of headaches, neck, back, and right shoulder pain along with depression, anxiety, and sleep difficulties on 5/29/15. She has pins and needles sensations in the upper back. Per the primary physician's progress report (PR-2) on 5-29-15, exam noted normal gait, tenderness to the anterior and lateral deltoid, biceps tendon, restrictions with range of motion, no instability, 2+ reflexes in upper extremities. The patient sustained the injury due to cumulative trauma. The patient had EMG of the bilateral upper extremities that revealed mild CTS and no radiculopathy on 9/30/15 and EMG of the bilateral lower extremities that revealed radiculopathy on 9/30/15. The medication list includes Tramadol and Diclofen. The patient does not have any complaints related to the gastrointestinal tract including nausea and vomiting. The patient had received an unspecified number of the PT visits for this injury.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Theramine #90 (1 bottle): Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Treatment Index, 8th Edition (web), Pain (updated 10/09/15), Theramine, Medical foods.

**Decision rationale:** Theramine #90 (1 bottle). ACOEM and CA MTUS does not address these medications. The contents of these medical food products are not recommended by ODG. Theramine is a proprietary formulation of neurotransmitter precursors (L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan), neurotransmitters (gamma-aminobutyric acid [GABA]), and a neuromodulator (L-serine). Per the cited guidelines, theramine is not recommended. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. See Medical food, Gamma-aminobutyric acid (GABA), where it says, "There is no high quality peer-reviewed literature that suggests that GABA is indicated."; Choline, where it says, "There is no known medical need for Choline supplementation."; L-Arginine, where it says, "This medication is not indicated in current references for pain or inflammation."; & L-Serine, where it says, "There is no indication for the use of this product." Until there are higher quality studies of the ingredients in Theramine, it remains not recommended." Therefore, this product still has limited scientific evidence for efficacy and safety profile for the management of pain. ODG quoting the FDA specifically states "To be considered the product must, at a minimum, meet the following criteria: (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements." There is no documented medical efficacy or benefit for these combinations or these doses when added to conventional medications. Therefore, there is no medical necessity for any medication containing these food supplements. Evidence of nutritional deficiency of the contents of this product was not specified in the records provided. The request for Theramine #90 (1 bottle) is not medically necessary.

**Flurbi (NAP) cream-LA (Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 5%) #180gm: 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:** Flurbi (NAP) cream-LA (Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 5%) #180gm. Flurbi (NAP) Cream contains Flurbiprofen, Lidocaine and Amitriptyline. According to the MTUS Chronic Pain Guidelines regarding topical analgesics, the use of topical analgesics is "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." MTUS guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve

symptoms. Intolerance or contraindication to oral medications was not specified in the records provided. Evidence of diminished effectiveness of oral medications was not specified in the records provided. Flurbiprofen is a NSAID. Per the cited guidelines, "Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration." Amitriptyline is an antidepressant. Per the cited guidelines, "Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants). There is little to no research to support the use of many of these agents." Per the cited guidelines, "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. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia." Evidence of post herpetic neuralgia or diabetic neuropathy is not specified in the records provided, in this patient. Therefore, topical Amitriptyline is not recommended by the cited guidelines. Per the cited guidelines, "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Topical Flurbiprofen, Lidocaine and Amitriptyline are not recommended in this patient for this diagnosis as cited. The request for Flurbi (NAP) cream-LA (Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 5%) #180gm is not medically necessary.

**Gabacyclotram (Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%) #180gm: 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:** Gabacyclotram (Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%) #180gm. According to the MTUS Chronic Pain Guidelines regarding topical analgesics, the use of topical analgesics is "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." MTUS guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve symptoms. A trial of antidepressants and anticonvulsants for these symptoms were not specified in the records provided. Intolerance or contraindication to oral medications was not specified in the records provided. Evidence of diminished effectiveness of oral medications was not specified in the records provided. Cyclobenzaprine is a muscle relaxant. Per the cited guidelines, "Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." The muscle relaxant Cyclobenzaprine in topical form is not recommended by MTUS. As per cited guideline "Gabapentin: Not recommended. There is no peer-reviewed literature to support use." In addition, as cited above, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Gabapentin and Cyclobenzaprine are not recommended in this patient for this diagnosis as cited. The request for Gabacyclotram (Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%) #180gm is not medically necessary.