

<b>Case Number:</b>	CM15-0132957		
<b>Date Assigned:</b>	07/21/2015	<b>Date of Injury:</b>	06/18/2013
<b>Decision Date:</b>	09/15/2015	<b>UR Denial Date:</b>	06/11/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/09/2015

### 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: Arizona, Michigan

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 73 year old male, who sustained an industrial injury on 6/18/13. Documentation did not include the mechanism of injury. The injured worker was diagnosed as having headaches, status post right shoulder surgery, right shoulder internal derangement, right hip sprain-strain, depression and adjustment disorder. Treatment to date has included right shoulder surgery (2/13/14), home exercise program, activity restrictions and cardio-pulmonary testing. Currently on 4/8/15, the injured worker complains of intermittent headache rated 5-6/10, occasional chest wall pain rated 4-5/10 and constant low back pain rated 5-6/10. The injured worker noted approximately 80% improvement following right shoulder surgery. Work status is noted to be temporarily totally disabled. Physical exam performed on 4/8/15 revealed tenderness to palpation over the acromial joint on the right, tenderness over the trapezius muscle with spasms and positive impingement sign along with restricted range of motion of right shoulder. The treatment plan included request for authorization for neurological evaluation, Theramine #180, Terocin 120ml, Genicin #90 and Somnicin #30 and on 3/25/15 a request for cardio-respiratory testing was submitted.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbi (NAP) Cream - LA 180gms: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113.

**Decision rationale:** According to the California MTUS Guidelines (2009), Topical Analgesics are primarily recommended for neuropathic pain when trials of anti-depressants and anti-convulsants 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 anti-depressants. In this case, there is no documentation provided necessitating Flurbi 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). Medical necessity for the requested Flurbi cream has not been established. The requested treatment is not medically necessary.

**Terocin 120ml (Capsaicin 0.025%): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113.

**Decision rationale:** There is no documentation provided necessitating the use of the requested topical medication, Terocin. According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of anti-depressants and anti-convulsants 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, local anesthetics or antidepressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case there is no documentation provided necessitating Terocin. This medication contains methyl salicylate, capsaicin, menthol, and lidocaine. MTUS states that capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Menthol is not recommended. Lidocaine is recommended for localized peripheral pain. Lidoderm has been designated by the FDA for neuropathic pain; no other form of Lidocaine is indicated. Salicylate topicals are recommended by the CA MTUS. There is no documentation of intolerance to other previous medications. Medical necessity for the requested topical medication has not been established. The requested treatment is not medically necessary.

**Gabaclotram 180mgs:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

**Decision rationale:** According to the California MTUS Guidelines (2009), Topical Analgesics are primarily recommended for neuropathic pain when trials of anti-depressants and anti-convulsants 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 anti-depressants. In this case there is no documentation supporting Gabaclotram, there is no documentation of failed trials of anti-depressants and anti-convulsants. Therefore, the request for Gabaclotram is not medically necessary.

**Somnicin #30 capsules:** 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), Pain, Somnicin.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Somnicin.

**Decision rationale:** Somnicin is a nutritional supplement which contains Melatonin, Magnesium oxide, Oxitriptan, 5-Hydroxytryptophan, Tryptophan and Vitamin B6. It is used to treat insomnia, anxiety and depression. It is not a hypnotic and treatment for insomnia is inconclusive. ODG does not recommend use of Somnicin. Therefore, the request for Somnicin is not medically necessary.

**Theramine, QTY: 180:** 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), Pain, Theramine.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Theramine.

**Decision rationale:** ODG does not recommend Theramine for the treatment of chronic pain. It is a medical food that is used in pain management for acute pain, chronic pain, fibromyalgia, neuropathic pain and inflammatory pain. "Theramine is composed of 5-hydroxytryptophan, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine and GABA and there is no role for these supplements as treatment for chronic pain." Therefore, the request for Theramine is not medically necessary.

**Genicin, QTY: 90 capsules:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate) Page(s): 50.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine and Chondroitin sulfate Page(s): 50.

**Decision rationale:** According to CA MTUS, Genicin (Glucosamine) is "recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH). Symptomatic efficacy described in multiple studies performed with glucosamine sulphate (GS) support continued consideration in the OA therapeutic armamentarium. Results obtained with GS may not be extrapolated to other salts (hydrochloride) or formulations (OTC or food supplements) in which no warranty exists about content, pharmacokinetics and pharmacodynamics of the tablets." The injured worker did not have a diagnosis of arthritis and notes 80% relief in pain following right shoulder surgery. There is lack of documentation to support the request. Therefore, the request for Genicin is not medically necessary.

**Cardio Respiratory Testing - Autonomic Function Assessment:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.ncbi.nlm.nih.gov/pubmed/16464634>.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Autonomic nervous system function testing /CRPS, diagnostic tests.

**Decision rationale:** The MTUS / ACOEM did not specifically address the use of autonomic function testing in the injured worker, therefore other guidelines were consulted. Autonomic function testing is "not generally recommended as a diagnostic test for CRPS", recommend assessment of clinical findings as the most useful method of establishing the diagnosis. Specific procedures are not generally recommended. A gold standard for diagnosis of CRPS has not been established and no test has been proven to diagnose this condition. Assessment of clinical findings is currently suggested as the most useful method of establishing the diagnosis. A review of the injured workers medical records that are available to me did not reveal a clear rationale for ordering this test, without this information it is not possible to establish medical necessity, therefore the request for Cardio Respiratory Testing - Autonomic Function Assessment is not medically necessary.

