

Case Number:	CM13-0071047		
Date Assigned:	01/08/2014	Date of Injury:	06/24/2009
Decision Date:	06/05/2014	UR Denial Date:	12/06/2013
Priority:	Standard	Application Received:	12/26/2013

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 Anesthesiology, has a subspecialty in Pain Management 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:

The patient is an employee of [REDACTED] and has submitted a claim for right shoulder pain, and sleep problems associated with an industrial injury date of June 24, 2009. Treatment to date has included physical therapy, aquatic therapy, acupuncture, and intake of the following medications: tramadol/L-carnitine, cyclobenzaprine, hydrocodone/APAP, naproxen, Restone, and topical medications. Medical records from 2012 to 2013 were reviewed showing that patient complained of occasional to constant mild, dull, right shoulder pain with tingling. This resulted to loss of sleep. Patient stated that his sleep duration was 5 hours without medication, and 8 to 9 hours if with medication. Physical examination showed presence of "WHSS" at the right shoulder. There was tenderness at the right acromioclavicular joint, lateral shoulder, and posterior shoulder. Utilization review from December 6, 2013 denied the requests for Capsaicin 0.025%, Flurbiprofen 30%, Methyl Sallcylate 4%, Lipoderm Base 30gm Jar; Flurbiprofen 30%, Tramadol 20%, Lipoderm Base 30gm jar; and Capsaicin 0.0375%, Diclofenac 20%, Tramadol 20%, Flurbiprofen 10% 240gm jar because there was no clearly stated rationale for requesting 3 topical formulations that contain repetition of active ingredients and of different dosage strengths. the request for restone 3/100MG #30 was likewise denied due to lack of documentation on patient's sleep history, including onset and duration of sleep disturbance, associated symptoms, and initial attempts at non-pharmacologic management.

IMR ISSUES, DECISIONS AND RATIONALES

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

CAPSAICIN 0.025%, FLURBIPROFEN 30%, METHYL SALICYLATE 4%, LIPODERM BASE 30GM JAR: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Shoulder Complaints, Page Topical Analgesics..

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain, Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter; Salicylate Topicals.

Decision rationale: Pages 111-113 of MTUS Chronic Pain Medical Treatment Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Compounded Flurbiprofen and NSAIDs in general do not show consistent efficacy and are not FDA approved. Page 28 states that capsaicin cream is recommended only as an option in patients who have not responded or are intolerant to other treatments. The ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain methyl salicylate, or capsaicin, may in rare instances cause serious burns. Lidocaine topical is only approved as a dermal patch formulation. In this case, patient has been prescribed with this medication since August 2013. The documentation submitted for review is insufficient to indicate that the patient has failed a trial of oral pain medications prior to proceeding with the use of topical analgesic. Furthermore, there is no discussion regarding the need for multiple topical medications of similar components being prescribed to the patient. Any compounded product that contains at least one drug (drug class) that is not recommended is not recommended. Therefore, the request for Capsaicin 0.025%, Flurbiprofen 30%, Methyl Salicylate 4%, Lipoderm Base 30gm Jar is not medically necessary.

FLURBIPROFEN 30%, TRAMADOL 20%, LIPODERM BASE 30GM JAR: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Shoulder Complaints, Page Topical Analgesics..

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

Decision rationale: Pages 111-113 of the MTUS Chronic Pain Medical Treatment Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Lidocaine topical is only approved as a dermal patch formulation. Tramadol is indicated for moderate to severe pain, however CA MTUS does not recommend its topical formulation. In this case, patient has been prescribed with this medication since August 2013. The documentation submitted for review is insufficient to indicate that the patient has failed a trial of oral pain medications prior to proceeding with the use of topical analgesic. Furthermore, there is no discussion regarding the need for multiple topical medications of similar components being prescribed to the patient. Any compounded product that contains at least one drug (drug class) that is not recommended is not recommended. Therefore, the request for Flurbiprofen 30%, Tramadol 20%, Lipoderm Base 30gm jar is not medically necessary.

CAPSAICIN 0.0375%, DICLOFENAC 20%, TRAMADOL 20%, FLURBIPROFEN 10% 240GM JAR: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Shoulder Complaints, Page Topical Analgesics..

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-11.

Decision rationale: Pages 111-113 of MTUS Chronic Pain Medical Treatment Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Compounded Flurbiprofen and NSAIDs in general do not show consistent efficacy and are not FDA approved. Page 28 states that capsaicin cream is recommended only as an option in patients who have not responded or are intolerant to other treatments. Tramadol is indicated for moderate to severe pain, however CA MTUS does not recommend its topical formulation. Diclofenac as topical analgesic is indicated for relief of osteoarthritis pain in ankle, elbow, foot, hand, knee, and wrist joints only. In this case, patient has been prescribed with this medication since August 2013. The documentation submitted for review is insufficient to indicate that the patient has failed a trial of oral pain medications prior to proceeding with the use of topical analgesic. Furthermore, there is no discussion regarding the need for multiple topical medications of similar components being prescribed to the patient. Any compounded product that contains at least one drug (drug class) that is not recommended is not recommended. Therefore, the request for Capsaicin 0.0375%, Diclofenac 20%, Tramadol 20%, Flurbiprofen 10% 240gm jar is not medically necessary.

RESTONE 3/100MG #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Shoulder Complaints, Page Topical Analgesics..

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

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Official Disability Guidelines, Pain Chapter was used instead. It states that Restone is a proprietary blend of melatonin 3mg and L-tryptophan 100mg. As a medical food, 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety, and sleep disorders. In this case, patient has been complaining of sleep difficulties with a sleep duration of 5 hours. Intake of Restone has resulted to prolonged sleep lasting 8 to 9 hours. However, there was no discussion regarding patient's sleep hygiene aside from the information stated above. It is likewise unknown if the patient was given non-pharmacologic management to assist in sleep prior to prescribing medications. The medical necessity of Restone has not been established. Therefore, the request for Restone 3/100mg, #30 is not medically necessary.

