

Case Number:	CM15-0020423		
Date Assigned:	02/10/2015	Date of Injury:	09/12/2001
Decision Date:	03/30/2015	UR Denial Date:	01/27/2015
Priority:	Standard	Application Received:	02/03/2015

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: California
 Certification(s)/Specialty: Internal 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 61 year old male, who sustained an industrial injury on 9/12/2001. The diagnoses have included failed back surgery syndrome, lumbar radiculopathy, cervical disc disease, and myofascial pain syndrome. Treatment to date has included surgical intervention, medications, and implanted Neurostimulation unit and activity modification. He underwent left shoulder arthroscopy (undated), followed by physical therapy. Currently, the IW complains of lower back pain, bilateral shoulder pain, and wrist and neck pain. Pain in the lower back is rated as 8-9/10. He has increasing tremors. Objective findings included tenderness of the AC joint of the bilateral shoulders. Manual testing of the rotator cuff reveals weakness with internal and external rotation. Pain was present during muscle testing. There is limited range of motion bilaterally. There is restricted range of motion and tenderness to palpation of the lumbar spine with muscle spasm and trigger points. Straight leg raise was positive. On 01/27/2015, Utilization Review non-certified a request for Flurbiprofen 30gm #1, Lidocaine 7.5gm #1 and Versapro cream 112.5 gm #1 noting that the lack of high quality evidence in support of topical compounds. The MTUS was cited. On 2/03/2015, the injured worker submitted an application for IMR for review of Flurbiprofen 30gm #1, Lidocaine 7.5gm #1 and Versapro cream 112.5 gm #1.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective Flurbiprofen powder 30 gm, quantity: 1 (date of service: 12/16/2014):
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 46, 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page 111-113. NSAIDs (non-steroidal anti-inflammatory drugs) Page 67-73..

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The efficacy in clinical trials of topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be either not superior to placebo after two weeks, or with a diminishing effect after two weeks. For osteoarthritis of the knee, topical NSAID effect appeared to diminish over time. There are no long-term studies of their effectiveness or safety for chronic musculoskeletal pain. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain as there is no evidence to support use. MTUS Chronic Pain Medical Treatment Guidelines addresses NSAIDs (non-steroidal anti-inflammatory drugs). All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Use of NSAIDs may compromise renal function. FDA package inserts for NSAIDs recommend periodic lab monitoring of a CBC complete blood count and chemistry profile including liver and renal function tests. Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. All NSAIDs have the potential to raise blood pressure in susceptible patients. Medical records indicate the long-term use of NSAIDs. Per MTUS, it is generally recommended that the lowest dose be used for NSAIDs for the shortest duration of time. The pain management consultation report dated 1/8/15 documented a diagnosis of hypertension. Blood pressure was elevated 152/72. Per MTUS, NSAIDs are associated with the risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. MTUS guidelines warn against the use of NSAIDs with patients with hypertension. MTUS guidelines do not support the use of topical NSAIDs. The request for a topical NSAID Flurbiprofen is not supported. Therefore, the request for Flurbiprofen powder is not medically necessary.

Retrospective Lidocaine 7.5 gm, quantity: 1 (date of service: 12/16/2014): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 46, 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Pages 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Compound drugs

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Besides Lidoderm, no other commercially approved topical formulation of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Further research is needed to recommend topical Lidocaine for chronic neuropathic pain disorders other than post-herpetic neuralgia. Topical Lidocaine is not recommended for non-neuropathic pain. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. Official Disability Guidelines (ODG) indicates that compound drugs are not recommended as a first-line therapy. ODG criteria for compound drugs requires that the compound drug is not a copy of a commercially available FDA-approved drug product. Lidocaine 7.5 grams was requested. The strength of Lidocaine were not specified. Medical records do not document a diagnosis of post-herpetic neuralgia, which is the only FDA approved indication for topical Lidocaine. The use of topical Lidocaine is not supported. Therefore, the request for Lidocaine 7.5 grams is not medically necessary.

Retrospective Versapro base cream 112.5 gm, quantity: 1 (date of service: 12/16/2014):
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 46, 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Compound drugs. VersaPro <http://www.versaprocreambase.com>

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Official Disability Guidelines (ODG) indicates that compound drugs are not recommended as a first-line therapy. Criteria for compound drugs were presented. Include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs. Is not a copy of a commercially available FDA-approved drug product. VersaPro cream base is an emollient cream. VersaPro cream base, without FDA-approved prescription drug active ingredients, was requested. Topical analgesics in general are not supported by MTUS guidelines. The request for VersaPro cream base is not supported by MTUS or ODG guidelines. Therefore, the request for VersaPro cream base is not medically necessary.