

<b>Case Number:</b>	CM13-0067822		
<b>Date Assigned:</b>	01/03/2014	<b>Date of Injury:</b>	05/19/2005
<b>Decision Date:</b>	04/21/2014	<b>UR Denial Date:</b>	11/13/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/18/2013

### 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 Physical Medicine & Rehabilitation and is licensed to practice in Illinois. 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 a male who reported an injury on May 19, 2005. The patient's diagnosis included rotator cuff syndrome, not otherwise specified. The documentation of October 25, 2013 revealed the patient had numbness, tingling, and radiating pain for the upper extremities and had radiating pain for the bilateral lower extremities. The patient's medications included Colace, tramadol cream, Cyclobenzaprine, and Flurbiprofen as of May 2013. The patient was taking hydrocodone as of January 2013. The treatment plan included continuation of Norco, Colace, and Omeprazole along with Flurbiprofen and Valium.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**VALIUM 10MG, #60 (DISPENSED: 10/25/2013): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepine Page(s): 24.

**Decision rationale:** The California MTUS guidelines do not recommend the use of benzodiazepines as treatment for patients with chronic pain for longer than three (3) weeks due to a high risk of psychological and physiological dependency. The duration of treatment could

not be established. However, the request for Valium 10mg, #60, would exceed the guideline recommendations for use no longer than three (3) weeks. Given the above and the lack of documentation of exceptional factors to warrant nonadherence to guideline recommendations, the request for Valium 10mg #60 dispensed 10/25/2013 is not medically necessary.

**NORCO 10/325MG, #60, WITH TWO (2) REFILLS:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic pain ongoing management Page(s): 60, 78.

**Decision rationale:** The California MTUS guidelines recommend opiates for chronic pain. There should be documentation of an objective improvement in function, an objective decrease in the visual analogue scale (VAS) score, and evidence that the patient is being monitored for aberrant drug behavior and side effects. The clinical documentation submitted for review indicated that the patient had been taking medication since January 2013. There is a lack of documentation of an objective improvement in function, and objective decrease in the VAS score and evidence the patient was being monitored for aberrant drug behavior and side effects. There is a lack of documentation indicating a necessity for two (2) refills without a re-evaluation. Given the above, the request for Norco 10/325mg, #60, with two (2) refills is not medically necessary.

**COLACE 100MG, #60, (DISPENSED: 10/25/2013):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic); and McKay SL, Fravel M, Scalmon C. Management of constipation. Iowa City (IA): University of Iowa Gerontological Nursing Interventions Research Center, Research Translation and Dissemination Core; 2009 Oct. 51p

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Initiation of Opioid Therapy Page(s): 77.

**Decision rationale:** According to the California MTUS Guidelines, when initiating opioid therapy, prophylactic treatment of constipation should be initiated. The clinical documentation submitted for review failed to provide documentation that the patient had constipation or that there was efficacy from the requested medication. Given the above, the request for Colace 100mg, #60, dispensed on 10/25/2013 is not medically necessary.

**ONE (1) 120GM TUBE OF 30MG FLURBIPROFEN 25% (DISPENSED: 10/25/2013):** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Flurbiprofen Page(s): 72, 111.

**Decision rationale:** The California MTUS Guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. The clinical documentation submitted for review indicated the patient had been on the medication since May 2013. There is a lack of documentation indicating that the patient had a trial and failure of antidepressants and anticonvulsants. Given the above and that the medication is not FDA approved for topical application, the request for a 120gm tube of 30mg of Flurbiprofen 25%, dispensed on 10/25/2013, is not medically necessary.

**ONE (1) 120GM TUBE OF 30GM CYCLOBENZAPRINE 10% TRAMADOL 10% (DISPENSED: 10/25/2013): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Topical Analgesics Tramadol Page(s): 42, 111, 82.

**Decision rationale:** The California MTUS Guidelines indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. They do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxant as there is no evidence for use of any other muscle relaxant as a topical product. The addition of cyclobenzaprine to other agents is not recommended. A thorough search of FDA.gov did not indicate there was a formulation of topical Tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption, which is not recommended as a first line therapy according to the California MTUS guidelines. The patient was on the medication since May 2013. The clinical documentation submitted for review failed to provide documentation that the patient had trialed and failed anticonvulsants and failed to indicate the patient had exceptional factors to warrant nonadherence to California MTUS Guidelines and FDA Guidelines. Given the above, the request for on e(1) 120g tube of 30gm Cyclobenzaprine 10% Tramadol 10% (Dispensed: 10/25/2013) is not medically necessary