

<b>Case Number:</b>	CM14-0181336		
<b>Date Assigned:</b>	11/07/2014	<b>Date of Injury:</b>	04/29/2013
<b>Decision Date:</b>	12/11/2014	<b>UR Denial Date:</b>	10/01/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/31/2014

### 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 Family Medicine 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:

This is a 35-year-old male patient who reported an industrial injury to the left shoulder on 4/29/2013, 20 months ago, attributed to the performance of his usual and customary job tasks. The patient received conservative treatment but subsequently went to surgery for arthroscopy of the left shoulder. The patient has been diagnosed with left shoulder subluxation and left shoulder partial tear of the rotator cuff tendon. The patient complained of persistent left shoulder pain. The patient complained of left shoulder limited ROM (range of motion) and that the shoulder dislocated easily. The objective findings on examination included TTP and reduced ROM. A QME assessment recommended a MR arthrogram of the left shoulder with a second surgical intervention with reconstructive surgery. The patient was recommended to have an open capsulorrhaphy or a Putt-Platt procedure. The patient was noted to have a computerized range of motion study performed on 8/6/2014, with documented limited range of motion to the left shoulder. The patient was continued TTD. The patient was prescribed two (2) separate topical compounded creams.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Lido/Gaba/Tram, CPD Cream (Dos 8/6/14): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines anti-inflammatory medications, muscle relaxants, topical analgesics Page(s): 22, 67-68, 63, 111-. Decision based on Non-MTUS Citation ACOEM Pain Chapter (2008), pages 128 Official Disability Guidelines (ODG) pain chapter cyclobenzaprine; muscle relaxants; topical analgesics; topical analgesics compounded

**Decision rationale:** There is clinical documentation submitted to demonstrate the use of the topical gels for appropriate diagnoses or for the recommended limited periods of time. It is not clear that the topical compounded medications are medically necessary in addition to prescribed oral medications. There is no provided subjective/objective evidence that the patient has failed or not responded to other conventional and recommended forms of treatment for relief of the effects of the industrial injury. Only if the subjective/objective findings are consistent with the recommendations of the ODG, then topical use of topical preparations is only recommended for short-term use for specific orthopedic diagnoses. There is no provided rationale supported with objective evidence to support the prescription of the topical compounded cream. There is no documented efficacy of the prescribed topical compounded analgesics with no assessment of functional improvement. The patient is stated to have reduced pain with the topical creams; however, there is no functional assessment and no quantitative decrease in pain documented. Evidence-based guidelines report that compounded drugs are not evaluated for safety or efficacy by the federal FDA. According to the FDA, compounded drugs carry significant health risk that can lead to permanent injury or death. The California state legislature stated: "the legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods." The prescribed topical analgesic is not demonstrated to be medically necessary for the treatment of the cited diagnoses of this patient. The use of topical compounded analgesics is documented to have efficacy for only 2-4 weeks subsequent to injury and thereafter is not demonstrated to be as effective as oral NSAIDs. There is less ability to control serum levels and dosing with the topicals. The patient is not demonstrated to have any GI issue at all with NSAIDs or the prescribed analgesics. There is no demonstrated medical necessity for topical NSAIDs for chronic pain for a prolonged period of time. There is no demonstrated evidence that the topicals are more effective than generic oral medications. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or demonstrated to be appropriate. There is no documented objective evidence that the patient requires both the oral medications and the topical analgesic medication for the treatment of the industrial injury. The prescription of Lidocaine 6%, Gabapentin 19%, Tramadol 10%, 180 grams refill x2 DOS 8/6/14 is not recommended by the CA MTUS; ACOEM guidelines, and the Official Disability Guidelines. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or appropriate - noting the specific comment that "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder." The objective findings in the clinical documentation provided do not support the continued prescription of Lidocaine 6%, Gabapentin 19%, Tramadol 10%, 180 grams refill x2 DOS 8/6/14 for the treatment of chronic pain. Therefore, the request is not medically necessary.

**Flurbi/Cyclo/Baclo/Lido CPD Cream (Dos 8/6/14): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines anti-inflammatory medications, muscle relaxants, topical analgesics Page(s): 22, 67-68, 63, 111-. Decision based on Non-MTUS Citation ACOEM Pain Chapter (2008), page 128 Official Disability Guidelines (ODG) pain chapter cyclobenzaprine; muscle relaxants; topical analgesics; topical analgesics compounded

**Decision rationale:** There is clinical documentation submitted to demonstrate the use of the topical gels for appropriate diagnoses or for the recommended limited periods of time. It is not clear that the topical compounded medications are medically necessary in addition to prescribed oral medications. There is no provided subjective/objective evidence that the patient has failed or not responded to other conventional and recommended forms of treatment for relief of the effects of the industrial injury. Only if the subjective/objective findings are consistent with the recommendations of the ODG, then topical use of topical preparations is only recommended for short-term use for specific orthopedic diagnoses. There is no provided rationale supported with objective evidence to support the prescription of the topical compounded cream. There is no documented efficacy of the prescribed topical compounded analgesics with no assessment of functional improvement. The patient is stated to have reduced pain with the topical creams; however, there is no functional assessment and no quantitative decrease in pain documented. Evidence-based guidelines report that compounded drugs are not evaluated for safety or efficacy by the federal FDA. According to the FDA, compounded drugs carry significant health risk that can lead to permanent injury or death. The California state legislature stated: "the legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods." The prescribed topical analgesic is not demonstrated to be medically necessary for the treatment of the cited diagnoses of this patient. The use of topical compounded analgesics is documented to have efficacy for only 2-4 weeks subsequent to injury and thereafter is not demonstrated to be as effective as oral NSAIDs. There is less ability to control serum levels and dosing with the topicals. The patient is not demonstrated to have any GI issue at all with NSAIDs or the prescribed analgesics. There is no demonstrated medical necessity for topical NSAIDs for chronic pain for a prolonged period of time. The use of the topical gels does not provide the appropriate therapeutic serum levels of medications due to the inaccurate dosing performed by rubbing variable amounts of gels on areas that are not precise. The volume applied and the times per day that the gels are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of gels to the oral medications in the same drug classes. There is no demonstrated evidence that the topicals are more effective than generic oral medications. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or demonstrated to be appropriate. There is no documented objective evidence that the patient requires both the oral medications and the topical analgesic medication for the treatment of the industrial injury. The prescription of Flurbiprofen 15%, cyclobenzaprine 2%, Lidocaine 5% 180 grams refill x2 DOS 8/6/14 is not recommended by the CA MTUS; ACOEM guidelines, and the Official Disability Guidelines. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or appropriate - noting the

specific comment, "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder." The objective findings in the clinical documentation provided do not support the continued prescription of the topical compounded analgesic Flurbiprofen 15%, cyclobenzaprine 2%, Lidocaine 5% 180 grams refill x2 DOS 8/6/14 for the treatment of chronic pain. Therefore, the request is not medically necessary.

**Computer Rom Testing (Dos 8/6/14): Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) Chapter 7 pages 137-138 Official Disability Guidelines (ODG) fitness for duty chapter-functional capacity evaluation Other Medical Treatment Guideline or Medical Evidence: General Medical Guidelines for the practice of medicine

**Decision rationale:** There is no rationale by the treating physician for the medical necessity of the ROM or MMT strength testing in relation to the treatment for this patient or for the diagnoses cited or for the analysis of the cited industrial injury. There are no objective findings on examination other than limited range of motion and tenderness to palpation with the diagnoses of left shoulder rotator cuff tear and subluxation s/p (status post) arthroscopy. There is no objective evidence to support the medical necessity for ROM and MMT for the treatment of the patient 20 months status post date of injury. There was no rationale to support the medical necessity of computerized range of motion and muscle testing over the standard documentation of objective findings on physical examination. There were no provided objective findings on examination and no rationale for the use of the provided analysis for strength and ROM instead of the physical examination. There was no objective evidence to support the medical necessity of the performed assessment for the effects of the industrial injury. The computerized muscle testing (CMT) or MMT testing is not demonstrated to be medically necessary and has not been requested by the employer. There is no objective medically based evidence provided to support the medical necessity of the requested MMT for the effects of the reported industrial injury. There is no indication that the CMT or MMT is required to establish the patient current status over the generally accepted findings on physical examination. The procedure was not requested by the employer and is not demonstrated to be medically necessary in addition to the documented objective findings on physical examination. There is no objective evidence provided to support the medical necessity of the CMT and MMT over the objective findings documented on physical examination. There was no provided report to support the testing that was not medically necessary for the treatment of the effects of the industrial injury. Therefore, the request is not medically necessary.