

<b>Case Number:</b>	CM15-0126850		
<b>Date Assigned:</b>	07/13/2015	<b>Date of Injury:</b>	05/13/2008
<b>Decision Date:</b>	08/10/2015	<b>UR Denial Date:</b>	05/30/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/01/2015

### 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, Indiana, New York  
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 41 year old male, who sustained an industrial injury on 5/13/2008. The mechanism of injury is unknown. The injured worker was diagnosed as having left shoulder impingement, adhesive capsulitis and chronic pain syndrome. There is no record of a recent diagnostic study. Treatment to date has included shoulder surgery, physical therapy and medication management. In a progress note dated 4/13/2015, the injured worker complains of left shoulder pain radiating to the neck with a pain rating of 7-8/10 without medications and 3/10 with medications. Physical examination showed left shoulder decreased range of motion due to pain. The treating physician is requesting retrospective compound topical medications dispensed on 4/23/15 (Flurbiprofen/Diclofenac/Lidocaine/Cyclobenzaprine/Piroxicam/cream base and retrospective compound topical medications, dispensed on 4/23/15, Octinoxate/Fluticasone Propionate/Tranilast/Tamoxifen Citrate/Caffeine/Alpha Lipoic Acid/Captracin/cream base.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective compound topical medication (Flurbiprofen/Diclofenac/Lidocaine/Cyclobenzaprine/Piroxicam/cream base) (DOS: 4/23/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM, Chronic Pain Treatment Guidelines topical analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain section, Topical analgesics.

**Decision rationale:** Pursuant to the Chronic Pain Medical Treatment Guidelines and the Official Disability Guidelines, retrospective compound topical medication (Flurbiprofen/diclofenac/lidocaine/cyclobenzaprine/piroxicam/cream base) Date of service: April 23, 2015 is not medically necessary. Topical analgesics are largely experimental with few controlled trials to determine efficacy and safety. They 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. In this case, the injured worker's working diagnoses are impingement syndrome shoulder; and adhesive capsulitis shoulder. Subjectively, the injured worker has complaints of shoulder pain. Objectively there is tenderness to palpation and decreased range of motion. 42 of progress note dated February 24, 2015, the injured worker was prescribed Norco, naproxen and tramadol. According to a follow-up progress note dated April 13, 2015, the injured worker had adverse effects to both tramadol and naproxen. The treating provider increased the Norco dose and added topical compounds. Flurbiprofen is not FDA approved for topical use. Diclofenac is indicated for relief of osteoarthritis pain in the joint that lends itself to topical treatment (ankle, elbow, foot, hand, knee and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Topical cyclobenzaprine is not recommended. Any compounded product that contains at least one drug (Flurbiprofen, cyclobenzaprine and diclofenac) that is not recommended is not recommended. Consequently, retrospective topical compound (Flurbiprofen/diclofenac/lidocaine/cyclobenzaprine/piroxicam/cream base) is not recommended. Based on the clinical information in the medical record and the peer-reviewed evidence-based guidelines, retrospective compound topical medication (Flurbiprofen/diclofenac/lidocaine/cyclobenzaprine/piroxicam/cream base) Date of service: April 23, 2015 is not medically necessary.

**Retrospective compound topical medication (Octinoxate/Fluticasone Propionate/Tranilast/Tamoxifen Citrate/Caffeine/Alpha Lipoic Acid/Captracin/cream base) (DOS: 4/23/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM, Chronic Pain Treatment Guidelines topical analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain section, Topical analgesics and Other Medical Treatment Guidelines <http://www.ncbi.nlm.nih.gov/pubmed/19019027><http://www.nlm.nih.gov/medlineplus/druginfo/meds/a695002.html>.

**Decision rationale:** Pursuant to the Chronic Pain Medical Treatment Guidelines and the Official Disability Guidelines, retrospective compound topical medication (octinoxate, fluticasone propionate/Tranilast/tamoxifen citrate/caffeine/alpha lipoic acid/captracin in cream base), Date of service: April 23, 2015 is not medically necessary. Topical analgesics are largely experimental with few controlled trials to determine efficacy and safety. They 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. Other than Lidoderm, no other commercially approved topical formulation of lidocaine whether cream, lotions or gels are indicated for neuropathic pain. Captracin contains menthol and capsaicin 0.0375%. Capsaicin is generally available as a 0.025% formulation. There have been no studies of a 0.0375% formulation and there is no current indication that an increase over 0.025% formulation would provide any further efficacy. Alpha-lipoic acid (LA), a naturally occurring dithiol compound, has long been known as an essential cofactor for mitochondrial bioenergetic enzymes. LA is a very important micronutrient with diverse pharmacologic and antioxidant properties. In this case, the injured worker's working diagnoses are impingement syndrome shoulder; and adhesive capsulitis shoulder. Subjectively, the injured worker has complaints of shoulder pain. Objectively there is tenderness to palpation and decreased range of motion. According to a progress note dated February 24, 2015, the injured worker was prescribed Norco, naproxen and tramadol. According to a follow-up progress note dated April 13, 2015, the injured worker had adverse effects to both tramadol and naproxen. The treating provider increased the Norco dose and added topical compounds. Capsaicin 0.0375% is not recommended. Any compounded product that contains at least one drug (Capsaicin 0.0375%) that is not recommended is not recommended. Consequently, retrospective compound octinoxate, fluticasone propionate/Tranilast/tamoxifen citrate/caffeine/alpha lipoic acid/captracin in cream base is not recommended. Based on clinical information in the medical record and the peer-reviewed evidence-based guidelines, retrospective compound topical medication (octinoxate, fluticasone propionate/Tranilast/tamoxifen citrate/caffeine/alpha lipoic acid/captracin in cream base), Date of service: April 23, 2015 is not medically necessary.