

<b>Case Number:</b>	CM14-0040006		
<b>Date Assigned:</b>	06/27/2014	<b>Date of Injury:</b>	09/17/2012
<b>Decision Date:</b>	08/19/2014	<b>UR Denial Date:</b>	03/05/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/04/2014

### 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 Occupational 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:

The patient is a 28-year-old male who has submitted a claim for right shoulder pain status post right shoulder arthroscopy, subacromial decompression, distal clavicle excision and partial synovectomy associated with an industrial injury date of 09/17/2012. Medical records from 08/29/2013 to 02/24/2014 were reviewed and showed that patient complained of right shoulder pain ( grade not specified) with no reported radiation. There was occasional numbness of the thumb and index finger distribution. Physical examination revealed well-healed incisions with no tenderness to palpation. Right shoulder active ROM was within normal limits. Hawkins and Neer signs were mildly positive. Obrien's test was mildly positive. MRI of the right shoulder dated 11/13/2012 revealed right acromioclavicular joint arthropathy with capsular hypertrophy as well as hypertrophic spur from the inferior aspect of the right lateral clavicle. X-ray of the right shoulder dated 07/11/2013 revealed no calcification or other abnormalities. Treatment to date has included right shoulder arthroscopy, subacromial decompression, distal clavicle excision, partial synovectomy, and rotator cuff repair (05/20/2013), Kenalog and lidocaine injection (11/29/2012), physical therapy, home exercise program, and pain medications and creams. Utilization review dated 03/05/2014 denied the request for prescription of LidoPro ointment 120g #2 because there records did not demonstrate exhaustive trials of standard oral care medications to support the request for an investigational topical analgesic. Utilization review dated 03/05/2014 denied the request for prescription of Flexeril 10mg tablet #30 because the use of Flexeril was not supported by the guidelines. Utilization review dated 03/05/2014 modified the request for prescription of Norco 10/325mg #30 with one refill to Norco 10/325mg #30 with zero refills because Norco was medically necessary for acute exacerbation of pain. Utilization review dated 03/05/2014 modified the request for prescription of Ultram 50mg #30 with 1 refill to Ultram 50mg #30 with zero refills for the purpose of weaning.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**LidoPro Ointment 120g #2 - apply 4 times a day as needed (prescribed 01-31-14): Upheld**

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

**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 Chapter, Topical Salicylates.

**Decision rationale:** Lidopro Ointment contains 4 active ingredients; Capsaicin in a 0.0325% formulation, Lidocaine in a 4.5% formulation, Menthol in a 10% formulation, and Methyl Salicylate in a 27.5% formulation. As stated on pages 111-113 of the California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. Regarding the Menthol and Methyl Salicylate components, CA MTUS does not cite specific provisions, but the Official Disability Guidelines (ODG) Pain Chapter issued an FDA safety warning which identifies rare cases of serious burns that have been reported to occur on the skin where over-the-counter (OTC) topical muscle and joint pain relievers were applied. These products contain the active ingredients menthol, methyl salicylate, or capsaicin. Regarding the capsaicin component, the guideline states there is no current indication that an increase over a 0.025% formulation would provide any further efficacy. In this case, the patient has been prescribed LidoPro ointment since 10/30/2013. However, there was no complaint of gastrointestinal disturbance or oral pain medication intolerance. There was also no documentation of pain relief with LidoPro. It is unclear as to why topical analgesia is needed. Capsaicin in 0.0325% formulation is likewise not recommended. Therefore, the request for LidoPro Ointment 120g #2 - apply 4 times a day as needed (prescribed 01-31-14) is not medically necessary.

**Flexeril 10mg tablet #30 +1 refill - 1 tablet orally every 12 hours as needed for spasms (prescribed 01-31-14): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41-42.

**Decision rationale:** According to page 41-42 of the California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines, sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. The effect is greatest in the first 4 days of

treatment, suggesting that shorter courses may be better and treatment should be brief. In this case, the patient has been prescribed Flexeril (quantity and frequency not made available) since 09/20/2012. The long-term use of Flexeril is not in conjunction with guidelines recommendation. Therefore, the request for Flexeril 10mg tablet #30 +1 refill - 1 tablet orally every 12 hours as needed for spasms (prescribed 01-31-14) is not medically necessary.

**Norco 10/325mg #30 +1 refill - 1-2 tabs orally every 4-6 hours as needed for pain (prescribed 01-31-14): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Hydrocodone Bitartrate and Acetaminophen (Norco).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78.

**Decision rationale:** According to page 78 of the California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines state that ongoing opioid treatment should include monitoring of analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors; these outcomes over time should affect the therapeutic decisions for continuation. In this case, the patient has been prescribed Norco 10/325 mg #30 since 01/31/2014. However, there was no documentation of analgesia, functional improvement, or urine toxicology review. There was no discussion as to why continuation of Norco use is needed. Therefore, the request for Norco 10/325mg #30 +1 refill - 1-2 tabs orally every 4-6 hours as needed for pain (prescribed 01-31-14) is not medically necessary.

**Ultram 50mg tablet #30 +1 refill - 1-2 tabs orally every 4-6 hours as needed for pain: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol (Ultram).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78.

**Decision rationale:** As stated on page 78 of California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines, there are 4 A's (analgesia, activities of daily living, adverse side effects and aberrant drug-taking behaviors) for ongoing monitoring of opioid use: pain relief, side effects, physical and psychosocial functioning and the occurrence of any potentially aberrant drug-related behaviors. The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. In this case, the patient has been prescribed Ultram (quantity and frequency not made available) since 10/03/2012. There was no objective evidence of episodic severe pain exacerbations or documentation of analgesia or functional improvement. It is unclear as to why continuation of Ultram use is needed. Therefore, the request for Ultram 50mg tablet #30 +1 refill - 1-2 tabs orally every 4-6 hours as needed for pain is not medically necessary.