

<b>Case Number:</b>	CM15-0119454		
<b>Date Assigned:</b>	07/06/2015	<b>Date of Injury:</b>	10/16/2012
<b>Decision Date:</b>	09/17/2015	<b>UR Denial Date:</b>	06/16/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/22/2015

### 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: New York, Tennessee  
Certification(s)/Specialty: Emergency 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 59 year old female, who sustained an industrial injury on 10/16/2012. Diagnoses have included right shoulder status post remote rotator cuff repair, acromioplasty with partial distal claviclectomy and right shoulder recurrent tear involving the anterior half of the supraspinatus and subscapularis tendon with early rotator cuff arthroplasty. Treatment to date has included medication. According to the progress report dated 5/19/2015, the injured worker complained of increasing pain in her right shoulder with diminished range of motion. Exam of the right shoulder revealed decreased range of motion and positive impingement. Authorization was requested for Topical Analgesic (Containing Ketoprofen 10%, Gabapentin 6%, Bupivacaine 5%, Baclofen 2%, Cyclobenzaprine 2%, Clonidine 0.2% And Hyaluronic Acid 2% 300 Grams), Norco, Tramadol, Anaprox and Keflex.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Topical Analgesic (Containing Ketoprofen 10%, Gabapentin 6%, Bupivacaine 5%, Baclofen 2%, Cyclobenzaprine 2%, Clonidine 0.2% And Hyaluronic Acid 2% 300 Grams:**  
Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 111-112. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee & Leg, Hyaluronic Acid Pain: Clonidine and Other Medical Treatment Guidelines UpToDate: Drug Information, Bupivacaine.

**Decision rationale:** This medication is a compounded topical analgesic containing ketoprofen, gabapentin, bupivacaine, baclofen, cyclobenzaprine, clonidine, and hyaluronic acid. Topical analgesics are recommended for neuropathic pain when anticonvulsants and antidepressants have failed. Compounded topical analgesics are commonly prescribed and there is little to no research to support the use of these compounds. Furthermore, the guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Ketoprofen is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. Absorption of the drug depends on the base it is delivered in. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. Gabapentin is not recommended. There is no peer-reviewed literature to support use. Baclofen is not recommended. Bupivacaine is a local anesthetic used in nerve blocks and spinal anesthesia. It is not recommended as a topical preparation. There is no peer-reviewed literature to support the use of topical baclofen. Cyclobenzaprine is a muscle relaxant. There is no evidence for use of any muscle relaxant as a topical product. Intrathecal clonidine is recommended as an end-stage treatment alternative for selected patients for specific conditions, and only after a short-term trial indicates pain relief in patients refractory to opioid monotherapy or opioids with local anesthetic. It is not recommended as a topical preparation. Hyaluronic acid is recommended as an injection for severe osteoarthritis of the knees. It is not recommended as a topical medication. This medication contains drugs that are not recommended. Therefore the medication cannot be recommended. The request is not medically necessary.

**Norco 10/325mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 11, 74-96.

**Decision rationale:** Norco is the compounded medication containing hydrocodone and acetaminophen. Chronic Pain Medical Treatment Guidelines state that opioids are not recommended as a first line therapy. Opioid should be part of a treatment plan specific for the patient and should follow criteria for use. Criteria for use include establishment of a treatment plan, determination if pain is nociceptive or neuropathic, failure of pain relief with non-opioid analgesics, setting of specific functional goals, and opioid contract with agreement for random drug testing. If analgesia is not obtained, opioids should be discontinued. The patient should be screened for likelihood that he or she could be weaned from the opioids if there is no

improvement in pain of function. It is recommended for short-term use if first-line options, such as acetaminophen or NSAIDS have failed. Opioids may be a safer choice for patients with cardiac and renal disease than antidepressants or anticonvulsants. Acetaminophen is recommended for treatment of chronic pain & acute exacerbations of chronic pain. Acetaminophen overdose is a well-known cause of acute liver failure. Hepatotoxicity from therapeutic doses is unusual. Renal insufficiency occurs in 1 to 2% of patients with overdose. The recommended dose for mild to moderate pain is 650 to 1000 mg orally every 4 hours with a maximum of 4 g/day. In this case, there is no documentation of benefit or duration of treatment with Norco. Urine drug testing is negative for hydrocodone, which is inconsistent with prescription history. Criteria for opioid use have not been met. The request is not medically necessary.

**Tramadol ER 50 Mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 74-96.

**Decision rationale:** Tramadol is a synthetic opioid affecting the central nervous system. It has several side effects, which include increasing the risk of seizure in patients taking SSRI's, TCA's and other opioids. Chronic Pain Medical Treatment Guidelines state that opioids are not recommended as a first line therapy. Opioid should be part of a treatment plan specific for the patient and should follow criteria for use. Criteria for use include establishment of a treatment plan, determination if pain is nociceptive or neuropathic, failure of pain relief with non-opioid analgesics, setting of specific functional goals, and opioid contract with agreement for random drug testing. If analgesia is not obtained, opioids should be discontinued. The patient should be screened for likelihood that he or she could be weaned from the opioids if there is no improvement in pain of function. It is recommended for short-term use if first-line options, such as acetaminophen or NSAIDS have failed. In this case, there is no documentation of benefit or duration of treatment with Tramadol. Criteria for opioid use have not been met. The request is not medically necessary.

**Anaprox 550mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 67-68.

**Decision rationale:** Anaprox is naproxen, a non-steroidal anti-inflammatory drug (NSAID). Chronic Medical Treatment Guidelines state, "anti-inflammatory drugs are the traditional first line of treatment, but long term use may not be warranted." For osteoarthritis it was recommended that the lowest dose for the shortest length of time be used. It was not shown to be

more effective than acetaminophen, and had more adverse side effects. Adverse effects for GI toxicity and renal function have been reported. Medications for chronic pain usually provide temporary relief. Medications should be prescribed only one at a time and should show effect within 1-3 days. Record of pain and function with the medication should be documented. In this case, the quantity of medication indicates long-term use of anaprox. There is no documentation that the medication is effective. The duration of treatment increases the risk of adverse effects with little benefit. The request is not medically necessary.

**Keflex 500mg #28:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Treatment Guidelines from the Medical Letter, Issue 131, July 1, 2013: Drugs for Bacterial Infections.

**Decision rationale:** Keflex is cephalexin a first generation cephalosporin. First generation cephalosporins are used in the treatment of non-MRSA skin infections and pharyngitis. In this case, documentation in the medical record does not support the presence of infection. Antibiotics are not indicated. The request is not medically necessary.