

<b>Case Number:</b>	CM15-0112637		
<b>Date Assigned:</b>	06/24/2015	<b>Date of Injury:</b>	09/01/2014
<b>Decision Date:</b>	09/22/2015	<b>UR Denial Date:</b>	06/03/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/11/2015

### 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: Maryland, Texas, Virginia

Certification(s)/Specialty: Internal Medicine, Allergy and Immunology, Rheumatology

### 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 61 year old male, who sustained an industrial injury on September 1, 2014. He reported an injury to his right elbow with radiation of pain from the right shoulder to the right hand. Treatment to date has included topical analgesics, oral medications, MRI of the right shoulder, home exercise and physical therapy. Currently, the injured worker complains of right shoulder and right elbow pain. On physical examination the injured worker has a decreased range of motion of the right elbow, right shoulder and his acromioclavicular joint is tender to palpation. The diagnoses associated with the request include right shoulder sprain/strain and right elbow sprain/strain. The treatment plan includes exercise, analgesic topical creams, orthopedic evaluation, Norco, Diclofenac sodium, Xanax and Duexis.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective Diclofenac Sodium 100mg #60 - DOS 5/21/15: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Diclofenac.

**Decision rationale:** Volteran/Zipsor is the name brand version of Diclofenac, which is an NSAID. MTUS specifies four recommendations regarding NSAID use: 1) Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. 2) Back Pain - Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. 3) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. 4) Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain. The medical documents do not indicate that the patient is being treated for osteoarthritis. The treating physician does not document failure of primary (Tylenol) treatment. Importantly, ODG also states that Diclofenac is "Not recommended as first line due to increased risk profile . . . If using Diclofenac then consider discontinuing as it should only be used for the shortest duration possible in the lowest effective dose due to reported serious adverse events." Medical documents indicate that the patient has been on Diclofenac since 2014, which given the treatment history does not appear to be the shortest duration possible. As such, the request for Retrospective Diclofenac Sodium 100mg #60-DOS 5/21/15 is not medically necessary.

**Retrospective Pantoprazole 20mg #60 - DOS 5/21/15: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** Protonix is the brand name version of Pantoprazole, which is a proton pump inhibitor. MTUS states, "Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA)." And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg Omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." ODG states, "If a PPI is used, omeprazole OTC tablets or lansoprazole 24HR OTC are recommended for an equivalent clinical efficacy and significant

cost savings. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), Lansoprazole (Prevacid), Omeprazole (Prilosec), Pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of Omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011)." The patient does not meet the age recommendations for increased GI risk. The medical documents provided do not indicate history of peptic ulcer, GI bleeding or perforation. Medical records do not indicate that the patient is on ASA, corticosteroids, and/or an anticoagulant; or high dose/multiple NSAID. Additionally per guidelines, Pantoprazole is considered second line therapy and the treating physician has not provided detailed documentation of a failed trial of Omeprazole and/or Lansoprazole. As such, the request for retrospective Pantoprazole 20mg #60-DOS 5/21/15 is not medically necessary.

**Retrospective Gabapentin 10%, Cyclobenzaprine 6%, Bupivacaine 5% in cream base 240gms - DOS 5/21/15: Upheld**

**Claims Administrator guideline:** Decision based on MTUS 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, Compound creams.

**Decision rationale:** MTUS and ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Gabapentin/Pregabalin (not recommended) - MTUS states that topical Gabapentin is "Not recommended." And further clarifies, "anti-epilepsy drugs: There is no evidence for use of any other anti-epilepsy drug as a topical product." Cyclobenzaprine or Muscle Relaxants (not recommended)-MTUS states regarding topical muscle relaxants, "Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Topical Cyclobenzaprine is not indicated for this usage, per MTUS. This topical analgesic contains multiple components that are not recommended. As such, the request for Retrospective Gabapentin 10%, Cyclobenzaprine 6%, Bupivacaine 5%, in cream base 240 gms-DOS 5/21/15 is not medically necessary.

**Retrospective Flurbiprofen 20%, Baclofen 5%, Dexamethasone 2%, Menthol 12%, Camphor 2%, Capsaicin 0.025% in cream base 240gm - DOS 5/21/15: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, Topical Analgesics Page(s): 28, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams.

**Decision rationale:** MTUS and ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Flurbiprofen (not recommended)-MTUS states that the only FDA-approved NSAID medication for topical use includes Diclofenac, which is indicated for relief of osteoarthritis pain in joints. Flurbiprofen would not be indicated for topical use in this case. Baclofen (not recommended)-MTUS states that topical Baclofen is "Not recommended." Capsaicin (recommended after failure of 1st line)-MTUS recommends topical capsaicin "only as an option in patients who have not responded or are intolerant to other treatments." There is no indication that the patient has failed oral medication or is intolerant to other treatments. Additionally, ODG states "Topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns, a new alert from the FDA warns." This topical analgesic contains multiple components that are not recommended. As such, the request for Retrospective Flurbiprofen 20%, Baclofen 5%, Dexamethasone 2%, Menthol 12%, Camphor 2%, Capsaicin-DOS 5/21/15 is not medically necessary.

**Retrospective confirmation ordered for medication monitoring and management purpose - DOS 5/21/15:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-48.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids and Substance abuse Page(s): 74-96, 108-109. Decision based on Non-MTUS Citation University of Michigan Health System Guidelines for Clinical Care: Managing Chronic Non-terminal Pain, Including Prescribing Controlled Substances (May 2009), pg 32 Established Patients Using a Controlled Substance.

**Decision rationale:** MTUS states that use of urine drug screening for illegal drugs should be considered before therapeutic trial of opioids are initiated. Additionally, "Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion) would indicate need for urine drug screening. There is insufficient documentation provided to suggest issues of abuse, addiction, or poor pain control by the treating physician. University of Michigan Health System Guidelines for Clinical Care: Managing Chronic Non-terminal Pain, Including Prescribing Controlled Substances (May 2009) recommends for stable patients without red flags-twice yearly urine drug screening for all chronic non-malignant pain patients receiving opioids - once during January-June and another July-December". The patient has been on chronic opioid therapy. The treating physician has not indicated why a urine drug screen is necessary at this time and has provided no evidence of red flags. As such, the request for Retrospective confirmation ordered for medication monitoring and management purposes-DOS

5/21/15 is not medically necessary.