

<b>Case Number:</b>	CM15-0184212		
<b>Date Assigned:</b>	09/24/2015	<b>Date of Injury:</b>	04/21/2014
<b>Decision Date:</b>	11/24/2015	<b>UR Denial Date:</b>	09/16/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/18/2015

### 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: Tennessee, Florida, Ohio  
 Certification(s)/Specialty: Surgery, Surgical Critical Care

### 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 46 year old female with an industrial injury date of 04-21-2014. Medical record review indicates she is being treated for shoulder burase and tendon disorders and cervicalgia. Subjective complaints (09-01-2015) included neck pain, lower back pain and right shoulder pain radiating to the left shoulder, right arm, right elbow, right forearm, right hand and right thigh. The pain is documented as "burning, sharp, shooting, stabbing and throbbing." The injured worker described her pain as "moderate" and rated the pain as 8 out of 10. Aggravating factors are documented as activity, movement, lifting, lying on the affected side and overhead use. Relieving factors include application of cold, application of heat, application of topical painkiller, medication, rest and stretching. The treating physician documented the injured worker tolerated the medications well, showed no evidence of developing medication dependency and stated the medications were helping. The treating physician also documented that the patient stated before medication her pain level is an 8 out of 10 and afterwards it is a 6 out of 10 and lasts for 4-6 hours. "Pain level has increased since last visit." "Patient has left shoulder surgery scheduled 09-16-2015." Progress notes dated 07-06-2015 and 08-03-2015 also document pain rating as 8 out of 10. Her medications included Ultracet, Lidopro Ointment, Diclofenac and Pantoprazole. The injured worker had been on the listed medications at least since 05-04-2015. Her work status on 09-01-2015 was documented as "temporarily totally disabled" Prior treatment included lumbar epidural steroid injection lumbar 5-sacral 1, physical therapy and medications. The treating physician documented in the 09-01-2015 note MRI of the right shoulder as showing a full thickness tear. Physical exam (09-01-2015) revealed cervical

spine range of motion was restricted with tenderness at the trapezius. Cervical facet loading was positive on the right side. Lumbar range of motion was restricted. Right shoulder movements were restricted. Urine drug screen on 05-04-2015 revealed negative findings for all items tested. The injured worker stated she had not had her Ultracet filled. The treatment request is for: Retrospective Ultracet 37.5-325 mg #60 (DOS 09/01/2015); Retrospective Pantoprazole Sod DR 20 mg #60 (DOS 09/01/2015); Retrospective Lidopro ointment #1 (DOS 09/01/2015); Retrospective Diclofenac Sod ER 100 mg #60 (DOS 09/01/2015) On 09-16-2015 the requested treatments below were non-certified by utilization review: Retrospective Ultracet 37.5-325 mg #60 (DOS 09/01/2015); Retrospective Pantoprazole Sod DR 20 mg #60 (DOS 09/01/2015); Retrospective Lidopro ointment #1 (DOS 09/01/2015); Retrospective Diclofenac Sod ER 100 mg #60 (DOS 09/01/2015).

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **Retrospective Ultracet 37.5/325mg #60 (DOS 09/01/2015): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use, Opioids for chronic pain.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. Ultracet is a combination medication of tylenol and ultram. Per MTUS guidelines, "Tramadol is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. Tramadol may increase the risk of seizure especially in patients taking SSRIs, TCAs and other opioids. Do not prescribe to patients that at risk for suicide or addiction." Per ODG, Tramadol is associated with an increased risk for hypoglycemia requiring hospitalization. Although rare, tramadol-induced hypoglycemia is a potentially fatal, adverse event. "Hypoglycemia adds to mounting concerns about tramadol, a weak opioid, that counter the perception that it is a safer alternative to full opioids." This patient has cervical pain, which is currently being treated with opioids. The patient is at risk for addiction due to his current opioid use. Therefore, based on the submitted medical documentation, the request for tramadol is not medically necessary.

#### **Retrospective Lidopro ointment #1 (DOS 09/01/2015): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Lidoderm (lidocaine patch).

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. Lidopro is a topical agent, which is composed of:

capsaicin/lidocaine/menthol/methyl salicylate. Topical lidocaine, in the formulation of a dermal patch, has been designated for neuropathic pain by the FDA. No other commercially approved topical formulation of lidocaine is indicated for neuropathic pain. The clinical information submitted for review fails to provide evidence of a failure to respond to antidepressants or anticonvulsants prior to the request for an initiation of a topical analgesic. Hence, the request for lidopro is not or indicated by MTUS guidelines. Therefore, based on the submitted medical documentation, the request for lidopro is not medically necessary.

**Retrospective Diclofenac Sod ER 100mg #60 (DOS 09/01/2015): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of treatment of this medication for this patient. The California MTUS guidelines address the topic of NSAID prescriptions by stating, "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." The MTUS guidelines do not recommend routine use of NSAIDs due to the potential for adverse side effects (GI bleeding, ulcers, renal failure, etc). The medical records do not support that the patient has a contraindication to other non-opioid analgesics. Therefore, medical necessity for diclofenac sodium ER 100mg prescription has not been established. The request is not medically necessary.

**Retrospective Pantoprazole Sod DR 20mg #60 (DOS 09/01/2015): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of the requested prescription for this patient. The clinical records submitted do not support the fact that this patient has refractory GERD resistant to H2 blocker therapy or an active h. pylori infection. The California MTUS guidelines address the topic of proton pump prescription. In accordance with California MTUS guidelines, PPI's (Proton Pump Inhibitors) can be utilized if the patient is concomitantly on NSAIDs and if the patient has gastrointestinal risk factors. This patient is not on NSAIDs. Additionally, per the Federal Drug Administration's (FDA) prescribing guidelines for PPI use, chronic use of a proton pump inhibitor is not recommended due to the risk of developing atrophic gastritis. Short-term GERD symptoms may be controlled effectively with an H2 blocker unless a specific indication for a

proton pump inhibitor exists. This patient's medical records do not support that she has GERD. The reason for this medication is unclear. The patient has no documentation of why chronic PPI therapy is necessary. There is no history of GERD that is refractory to H2 blocker therapy and she has no records that indicate an active h. pylori infection. Therefore, based on the submitted medical documentation, the request for Pantoprazole prescription is not medically necessary.