

<b>Case Number:</b>	CM15-0188674		
<b>Date Assigned:</b>	09/30/2015	<b>Date of Injury:</b>	04/18/2014
<b>Decision Date:</b>	12/09/2015	<b>UR Denial Date:</b>	09/24/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/24/2015

### 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 68-year-old female who sustained an industrial injury on 4-18-2014. Diagnoses have included lumbar facet syndrome and lumbar sprain or strain. In the 7-7-2015 note the physician states "back pain secondary to combination of facet disease which created an anterolisthesis at L4-L5 and a very marginal disc at L5-S1." This was noted from an MRI of unknown date. Past treatments include an epidural steroid injection at L5-S1 on 9-2014 stated to "not have worked," and the physician's note of 7-7-2015 states "multiple and extensive medical care with very poor results." No other treatments were discussed in the medical records provided, including medication. A urine drug screen was performed 7-7-2015 and Ranitidine was the only medication shown as being detected. Length of time or purpose of this medication was not provided. On 9-1-2015, the progress note states the injured worker had a "major significant exacerbation" of back pain, mostly in the left distal joint. There was tenderness of her SI joint and her range of motion could not be tested according to the note because she was in pain. There was no pain rating provided, nor description of character of pain. The treating physician's plan of care includes a request for authorization submitted on 9-1-2015 for Tramadol HCL 50 mg. 90 were requested, and this was modified to 60. On the same date, Pantoprazole, Diclofenac, and compound creams: CL- cyclobenzaprine 10 percent plus lidocaine 20 percent; FL- Flurbiprofen 20 percent and lidocaine 5 percent; and, GAC- gabapentin 10 percent, amitriptyline 50 percent and capsaicin 0.025 percent were all request, but denied. Determination was made on 9-24-2015. She is noted to be on work restrictions only.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**CL 150 g (cyclobenzaprine 10 % + lidocaine 2 %) QTY 1.00: 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), Topical Analgesics.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines address the topic of compound medication prescriptions. In accordance with California MTUS guidelines, topical analgesics are considered largely experimental in use with few randomized controlled trials to determine efficacy or safety. Guidelines go on to state that, there is little to no research to support the use of many of these agents. The guideline specifically says, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Compounded medications are not subject to FDA oversight for purity or efficacy. Therefore, based on the submitted medical documentation, the request for a CL150g prescription is not medically necessary.

**FL 150 g (flurbiprofen 20 % + lidocaine 5%) QTY 1.00: 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 prescription for this patient. The California MTUS guidelines address the topic of compound medication prescriptions. In accordance with California MTUS guidelines, topical analgesics are considered largely experimental in use with few randomized controlled trials to determine efficacy or safety. Guidelines go on to state that, there is little to no research to support the use of many of these agents. The guideline specifically says, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Compounded medications are not subject to FDA oversight for purity or efficacy. Therefore, based on the submitted medical documentation, the request for an FL150g prescription is not medically necessary.

**GAC 150 g (gabapentin 10% + amitriptyline 5% + capsaicin .025% QTY 1.00: 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): Topical Analgesics.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines address the topic of compound medication prescriptions. In accordance with California MTUS guidelines, topical analgesics are considered largely experimental in use with few randomized controlled trials to determine efficacy or safety. Guidelines go on to state that, there is little to no research to support the use of many of these agents. The guideline specifically says, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Compounded medications are not subject to FDA oversight for purity or efficacy. Therefore, based on the submitted medical documentation, the request for a GAC 150g prescription is not medically necessary.

**Pantoprazole sodium DR (Protonix) 20 mg QTY 60.00: 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. Likewise, the patient has no documentation of why chronic PPI therapy is necessary. GERD is not documented to be refractory to H2 blocker therapy and she has not records that indicate an active h. pylori infection. Therefore, based on the submitted medical documentation, the request for Protonix prescription is not medically necessary.

**Tramadol HCL (Ultram) 50 mg QTY 90.00: 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.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. 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 back pain which is currently exacerbated with activity. Safer alternative opioid medications exist for acute on chronic back pain. Therefore, based on the submitted medical documentation, the request for tramadol is not medically necessary.

**Diclofenac sodium ER (Voltaren XR) 100 m QTY 60.00:** 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 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 Voltaren XR prescription is not medically necessary.