

<b>Case Number:</b>	CM15-0185012		
<b>Date Assigned:</b>	09/25/2015	<b>Date of Injury:</b>	08/09/2001
<b>Decision Date:</b>	12/10/2015	<b>UR Denial Date:</b>	09/09/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/21/2015

### 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: California, District of Columbia, Maryland  
 Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 64 year old female, who sustained an industrial injury on 8-9-01. Her diagnoses or physician impression is pain in joint-hand. Her work status was not addressed. Notes dated 7-22-15 and 8-19-15 reveals the injured worker presented with complaints of constant shoulder pain described as sharp, throbbing, burning and aching and is rated at 7 out of 10. She reports her pain is decreased by medication. The note dated 7-22-15 states the injured worker was evaluated at a hospital for confusion and determined to be suffering from polypharmacy. It also states the injured worker experiences decreased pain and improved functioning with her medication. She is able to engage in activities of daily living, shop, socialize and do light housework. A physical examination dated 8-19-15 revealed shoulder and arm pain and swelling. Treatment to date has included surgical intervention and medications; Fentanyl patches, Gabapentin, Baclofen (discontinued), Naproxen, Pepcid, Topamax, Percocet and Vimovo. Diagnostic studies to date have included x-rays and urine toxicology screen. A request for authorization dated 8-27-15 for prospective usage of Vimovo 500-20 mg #60, Gabapentin 300 mg #180, Pepcid 20 mg #90, Percocet 10-325 mg #120 and Fentanyl patch 12 mcg per hour #10 are all non-certified, per Utilization Review letter dated 9-9-15.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Prospective usage of Vimovo 500/20 Mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation ODG.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Vimovo (esomeprazole magnesium/naproxen).

**Decision rationale:** The MTUS is silent on the use of this medication. Per the ODG guidelines: Not recommended as a first-line therapy. See Proton pump inhibitors (PPIs) & Naproxen. In May 2010 FDA approved Vimovo, a fixed-dose tablet combination of delayed-release enteric-coated naproxen and immediate-release esomeprazole magnesium (Nexium). The NSAID/PPI combo is indicated to relieve signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis while decreasing the risk for NSAID-related gastric ulcers in susceptible patients. (FDA, 2010) As with Nexium, a trial of omeprazole and naproxen or similar combination is recommended before Vimovo therapy. Per the medical records submitted for review, there was no documentation indicating that the injured worker was refractory to treatment with naproxen and omeprazole. There is no indication for combination tablet. The request is not medically necessary.

**Prospective usage of Gabapentin 300 Mg #180: Overturned**

**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): Antiepilepsy drugs (AEDs).

**Decision rationale:** With regard to antiepilepsy drugs, the MTUS CPMTG states "Fibromyalgia: Gabapentin and pregabalin have been found to be safe and efficacious to treat pain and other symptoms. (Arnold, 2007) (Crofford, 2005) Pregabalin is FDA approved for fibromyalgia." Per MTUS CPMTG, "Gabapentin (Neurontin) has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain." Per MTUS CPMTG p17, "After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects." Per the documentation submitted for review, it was noted that the injured worker experienced decreased pain and improved functioning with her medication. She is able to engage in activities of daily living, shop, socialize, and do light housework. I respectfully disagree with the UR physician's assertion that there was no evidence of functional gains with the use of this medication. The request is medically necessary.

**Prospective usage of Pepcid 20 Mg #90: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** The MTUS is silent on the use of Pepcid (famotidine). Per [REDACTED] famotidine is used to treat stomach ulcers (gastric and duodenal), erosive esophagitis (heartburn or acid indigestion), and gastroesophageal reflux disease (GERD). GERD is a condition where the acid in the stomach washes back up into the esophagus. It is also used to treat certain conditions where there is too much acid in the stomach (e.g., Zollinger-Ellison syndrome, endocrine tumors). Famotidine belongs to the group of medicines known as histamine H2-receptor antagonists or H2-blockers. It works by decreasing the amount of acid produced by the stomach. The documentation submitted for review does not provide information supporting the medical necessity of an H2-blocker. There is no documentation of peptic ulcer, GI bleeding or perforation, or cardiovascular disease in the records available for my review, the injured worker's risk for gastrointestinal events is low. Furthermore, a PPI would be first line therapy. It is noted per the medical records that the injured worker uses omeprazole. The request is not medically necessary.

**Prospective usage of Percocet 10/325 Mg #120:** Overturned

**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:** Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding ongoing management of opioids "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: Pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug related behaviors. These domains have been summarized as the "4 A's" (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking 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." Per the documentation submitted for review, it was noted that the injured worker experienced decreased pain and improved functioning with her medication. She is able to engage in activities of daily living, shop, socialize, and do light housework. She denied any intolerable side effects. Efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. UDS dated 3/27/15 was positive for oxycodone, tramadol, and fentanyl. The injured workers morphine equivalent dose is less than 120MED. I respectfully disagree with the UR physician's assertion that there was no evidence of functional gains with the use of this medication. The request is medically necessary.

**Prospective usage of Fentanyl Patch 12mcg /hr # 10:** Overturned

**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): Duragesic (fentanyl transdermal system).

**Decision rationale:** Per MTUS CPMTG with regard to Duragesic: "Not recommended as a first-line therapy. Duragesic is the trade name of a fentanyl transdermal therapeutic system, which releases fentanyl, a potent opioid, slowly through the skin. It is manufactured by [REDACTED] and marketed by [REDACTED] (both subsidiaries of [REDACTED]). The FDA-approved product labeling states that Duragesic is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by other means." Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding on-going management of opioids "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: Pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug related behaviors. These domains have been summarized as the "4 A's" (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking 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." Per the documentation submitted for review, it was noted that the injured worker experienced decreased pain and improved functioning with her medication. She is able to engage in activities of daily living, shop, socialize, and do light housework. She denied any intolerable side effects. Efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. UDS dated 3/27/15 was positive for oxycodone, tramadol, and fentanyl. The injured workers morphine equivalent dose is less than 120MED. I respectfully disagree with the UR physician's assertion that there was no evidence of functional gains with the use of this medication. The request is medically necessary.