

<b>Case Number:</b>	CM15-0064566		
<b>Date Assigned:</b>	04/10/2015	<b>Date of Injury:</b>	07/10/2013
<b>Decision Date:</b>	05/14/2015	<b>UR Denial Date:</b>	03/18/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/06/2015

### 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: Montana

Certification(s)/Specialty: Preventive Medicine, Occupational 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 42 year old female, who sustained an industrial injury on July 10, 2013. She has reported neck pain, right shoulder, wrist, hand, and finger pain. Diagnoses have included carpal tunnel syndrome, cervicalgia, and internal derangement of the shoulder. Treatment to date has included medications. A progress note dated February 2, 2015 indicates a chief complaint of worsening cervical spine pain radiating to the arms, associated headache, worsening right shoulder pain, and right wrist, hand, and long finger pain. The treating physician documented a plan of care that included tramadol, fenopfen, omeprazole, and cyclobenzaprine.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Fenopfen calcium (Nalfon) 400mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines non-steroidal anti-inflammatory drugs (NSAIDs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Non-steroidal anti-inflammatory drugs Page(s): 67-68.

**Decision rationale:** Fenoprofen is a non-steroidal anti-inflammatory drug (NSAID). The MTUS states that non-steroidal anti-inflammatory medications are recommended at the lowest dose for the shortest period possible in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008) Although NSAIDs are effective they can cause gastrointestinal irritation or ulceration. Studies also show that NSAID use for more than a few weeks can retard or impair bone, muscle, and connective tissue healing and may cause hypertension. Regarding neuropathic pain, the guidelines note inconsistent evidence for the use of these medications to treat long-term neuropathic pain but they may be useful to treat breakthrough pain. Fenoprofen (Nalfon, generic available): 200, 600 mg. Dosing: osteoarthritis; (off-label use for ankylosing spondylitis); 300 - 600mg PO 3 to 4 times per day (Max daily dose is 3200mg). Improvement may take as long as 2 to 3 weeks. Mild to moderate pain (off-label use for bone pain): 200mg PO every 4 to 6 hours as needed. In this case the records do document long term use of non-steroidal anti-inflammatory drugs, which are recommended for use at the lowest dose for the shortest period possible in patients with moderate to severe pain. There is no documentation of functional improvement related specifically to their use. The Utilization Review of 3/18/15 notes that there is no documentation of functional benefit. The request for fenoprofen calcium (Nalfon) 400 mg #120 is not consistent with the guidelines and is not medically necessary.

**Omeprazole 20mg #120:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Non-steroidal anti-inflammatory drugs, GI symptoms and cardiovascular risk Page(s): 68.

**Decision rationale:** Omeprazole (Prilosec) is a proton pump inhibitor (PPI) indicated for use in gastroesophageal reflux disease, erosive and non-erosive esophagitis, gastric ulcer, duodenal ulcer, hypersecretory conditions, H pylori infection and gastric ulcer prophylaxis associated with nonsteroidal anti-inflammatory drug use. The MTUS states that patients at risk for gastrointestinal events may use proton pump inhibitors. Those at risk include age greater than 65 years, history of peptic ulcer, GI bleeding or perforation, and concurrent use of aspirin, corticosteroids and/or anticoagulants or use of high-dose multiple non-steroidal anti-inflammatory drugs. The ODG guidelines state that, in general, the use of PPIs should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. In this case the medical records do not document risk factors as noted above. There is no

indication in the medical records of peptic ulcer, GI bleeding or perforation or any current gastrointestinal symptoms or side effects from medication use. The requested NSAID medication has been determined to be not medically necessary. The criteria for use of proton pump inhibitors are not met. The request for omeprazole 20mg #120 is not medically necessary.

**Cyclobenzaprine hydrochloride 7.5mg #120:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants Page(s): 63-64.

**Decision rationale:** The MTUS notes that cyclobenzaprine is an antispasmodic medication, recommended for a short course of therapy with the greatest benefit occurring within the first 4 days. Cyclobenzaprine is not recommended to be used for longer than 2-3 weeks. The MTUS recommends non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. Cyclobenzaprine is recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement. The greatest effect appears to be in the first 4 days of treatment. In this case, the medical records show that cyclobenzaprine was prescribed at least since at least May 2014. There is no evidence of any clinical or functional improvement related to its use. The continued use of cyclobenzaprine is not consistent with the MTUS guidelines which state that it is recommended for short-term use only. The request for cyclobenzaprine 7.5 mg #120 is not medically necessary.