

<b>Case Number:</b>	CM15-0044939		
<b>Date Assigned:</b>	03/17/2015	<b>Date of Injury:</b>	04/25/2007
<b>Decision Date:</b>	06/02/2015	<b>UR Denial Date:</b>	02/25/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/10/2015

### 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: Arizona, Michigan  
 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 45-year-old female, who sustained an industrial injury on April 25, 2007. She reported lifting a file box overhead and experienced neck pain over the course of the next week with pain extending into the right shoulder region. The injured worker was diagnosed as having cervical degenerative disc disease/degenerative joint disease with sprain, cervical-occipital headaches-greater occipital neuritis, right shoulder sprain with rotator cuff tear, lumbar sprain from MRI positioning, non-industrial mid back strain, and chronic pain. Treatment to date has included chiropractic treatments, x-rays, cortisone injection in the right shoulder, MRI of the right shoulder, bilateral C3-C5 radiofrequency ablation of medial branch nerve, and medication. Currently, the injured worker complains of neck pain with headaches. The Treating Physician's report dated February 12, 2015, noted the injured worker's injury had been going on for eight years, requiring continued treatment. Current medications were listed as Migranal nasal solution, Omeprazole, Trazodone HCL, Lidoderm patch, Amphetamine-Dextroamphetamine, Amphetamine-Dextroamphet ER, Naproxen Sodium, and Duexis. Physical examination was noted to show cervical rotation bilateral 30 degrees with pain to the left with crepitation, and sore left cervical thoracic paravertebral muscles.

### IMR ISSUES, DECISIONS AND RATIONALES

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

#### **Pain Management follow up QTY 4: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 174. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Neck & upper back (Acute & Chronic).

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 303. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic) / office visits.

**Decision rationale:** Per the MTUS/ACOEM Patients whose low back may be work related should receive follow-up care every three to five days by a midlevel practitioner, who can counsel them about avoiding static positions, medication use, activity modification, and other concerns. Take care to answer questions and make these sessions interactive so that patients are fully involved in their recovery. If the patient has returned to work, these interactions may be done on site or by telephone to avoid interfering with modified or full-work activities. Physician follow-up generally occurs when a release to modified, increased, or full duty is needed, or after appreciable healing or recovery can be expected, on average. Physician follow-up might be expected every four to seven days if the patient is off work and every seven to fourteen days if the patient is working. Per the ODG, office visits are recommended as determined to be medically necessary. Evaluation and management (E&M) outpatient visits to the offices of medical doctor(s) play a critical role in the proper diagnosis and return to function of an injured worker, and they should be encouraged. The need for a clinical office visit with a health care provider is individualized based upon a review of the patient concerns, signs and symptoms, clinical stability, and reasonable physician judgment. The determination is also based on what medications the patient is taking, since some medicines such as opiates, or medicines such as certain antibiotics, require close monitoring. As patient conditions are extremely varied, a set number of office visits per condition cannot be reasonably established. The determination of necessity for an office visit requires individualized case review and assessment, being ever mindful that the best patient outcomes are achieved with eventual patient independence from the health care system through self care as soon as clinically feasible. However, the rationale for why 4 visits would be necessary is not clear from a review of the injured workers medical records that are available to me and therefore the request for Pain Management follow up QTY 4 is not medically necessary.

#### **Sleep Study including PSG and sleep latency testing: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic).

**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) / Polysomnography.

**Decision rationale:** The MTUS / ACOEM did not address the use of polysomnography therefore, other guidelines were consulted. Per the ODG, Criteria for Polysomnography: Polysomnograms / sleep studies are recommended for the combination of indications listed below: (1) Excessive daytime somnolence; (2) Cataplexy (muscular weakness usually brought on by excitement or emotion, virtually unique to narcolepsy); (3) Morning headache (other causes have been ruled out); (4) Intellectual deterioration (sudden, without suspicion of organic dementia); (5) Personality change (not secondary to medication, cerebral mass or known psychiatric problems); (6) Sleep-related breathing disorder or periodic limb movement disorder is suspected; (7) Insomnia complaint for at least six months (at least four nights of the week), unresponsive to behavior intervention and sedative/sleep-promoting medications and psychiatric etiology has been excluded. A sleep study for the sole complaint of snoring, without one of the above mentioned symptoms, is not recommended; (8) Unattended (unsupervised) home sleep studies for adult patients are appropriate with a home sleep study device with a minimum of 4 recording channels (including oxygen saturation, respiratory movement, airflow, and EKG or heart rate). However a review of the injured workers medical records indicate that she has already had at least 2 sleep studies the results of which are not available for my review and it is unclear why she would need another one, therefore without the results of the previous studies and a clear rationale as to why additional sleep studies are needed the request for Sleep Study including PSG and sleep latency testing is not medically necessary.

**Omeprazole 20mg with 1refill:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation NSAIDs, GI symptoms and cardiovascular risk.

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

**Decision rationale:** Per the MTUS, Clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors according to specific criteria listed in the MTUS and a selection should be made based on these criteria (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). Per the ODG, PPI's are recommended for patients at risk for gastrointestinal events. Prilosec (omeprazole), Prevacid (lansoprazole) and Nexium (esomeprazole magnesium) are PPIs. Healing doses of PPIs are more effective than all other therapies, although there is an increase in overall adverse effects compared to placebo. Nexium and Prilosec are very similar molecules. (Donnellan, 2010) In this RCT, omeprazole provided a statistically significantly greater acid control than lansoprazole. (Miner, 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. 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 had been recommended before prescription Nexium therapy (before it went OTC). The other PPIs, Protonix, Dexilant, and Aciphex, should be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011). A review of the injured workers medical records that are available to me do not reveal gastrointestinal complaints or a past history of gastrointestinal issues that would increase the injured workers risk for gastrointestinal events, therefore the request for Omperazole 20mg with 1 refill is not medically necessary.

**Duexis (Famotidine and Ibuprofen): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Proton Pump Inhibitors (PPIs) / Duexis.

**Decision rationale:** Per the MTUS, Clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors according to specific criteria listed in the MTUS and a selection should be made based on these criteria (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). Per the ODG, PPI's are recommended for patients at risk for gastrointestinal events. Prilosec (omeprazole), Prevacid (lansoprazole) and Nexium (esomeprazole magnesium) are PPIs. Healing doses of PPIs are more effective than all other therapies, although there is an increase in overall adverse effects compared to placebo. Nexium and Prilosec are very similar molecules. (Donnellan, 2010) In this RCT, omeprazole provided a statistically significantly greater acid control than lansoprazole. (Miner, 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. 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 had been recommended before prescription Nexium therapy (before it went OTC). The other PPIs, Protonix, Dexilant, and Aciphex, should be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011). Per the ODG, Duexis is not recommended as a first-line drug. [REDACTED] recently announced the launch of Duexis, a combination of ibuprofen 800 mg and famotidine 26.6 mg, indicated for rheumatoid arthritis and osteoarthritis. (FDA, 2012) Ibuprofen (eg, Motrin, Advil) and famotidine (eg, Pepcid) are also available in multiple strengths OTC and other strategies are recommended to prevent stomach ulcers in patients taking NSAIDS. See NSAIDs, GI symptoms & cardiovascular risk, where Proton pump inhibitors (PPIs) are recommended. With less benefit and higher cost, using Duexis as a first-line therapy is not justified. A review of the injured workers medical records did not reveal that all other more cost effective NSAID's, PPI's and H2 blockers have been tried and failed and therefore the request for Duexis is not medically necessary.