

Case Number:	CM15-0168537		
Date Assigned:	09/09/2015	Date of Injury:	12/03/2012
Decision Date:	10/23/2015	UR Denial Date:	08/17/2015
Priority:	Standard	Application Received:	08/27/2015

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 55 year old female, who sustained an industrial injury on December 3, 2012. Several documents included in the submitted medical records are difficult to decipher. The injured worker's initial complaints and diagnoses are not included in the provided documentation. The injured worker was diagnosed as having status post lumbar decompression and fusion. Medical records (June 4, 2015 to July 28, 2015) indicate the injured worker underwent a L1-L5 (lumbar 1-lumbar 5) and a L4-L5 (lumbar 4-lumbar 5) fusion with allograft and instrumentation on June 4, 2015. The medical records refer to the injured worker undergoing postoperative physical therapy while in the hospital. Records also indicate the injured worker has a history of hypertension and her medications included antidepressant (Paroxetine), proton pump inhibitor (Omeprazole), and antiemetic (Reglan). She was treated with a full liquid diet, pain medication, and physical therapy. She was able to tolerate her diet, pain medication (Norco) controlled her pain, and ambulate independently prior to discharge to home on June 8, 2015. Records also indicate improvement of her lower back pain following surgery. Per the treating physician (July 7, 2015 report), the injured worker may return to work with restriction of no lifting greater than 20 pounds. The physical exam (July 7, 2015 to July 28, 2015) reveals the lumbar spine wound had healed, normal lordosis, limited flexion of 50 out of 60 degrees, extension of 25 out of 25 degrees, and bilateral bending of 25 out of 25 degrees, no tenderness to palpation over the spinous processes, unchanged range of motion of the bilateral lower extremities, strength of the bilateral lower extremities = 5, intact sensation in all dermatomes, 2+ reflexes in the patellae and Achilles, negative Achilles clonus, and negative straight leg raises.

The requested treatments included Ibuprofen, Paroxetine, Omeprazole, and Reglan. On August 17, 2015, the original utilization review non-certified requests for Ibuprofen #1, Paroxetine #1, Omeprazole #1, and Reglan #1.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ibuprofen, #1 pill: 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: Per the MTUS, NSAIDs are recommended at the lowest dose for the shortest period 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. A review of the injured workers medical records did not reveal documentation of pain and functional improvement with the use of ibuprofen, the requested quantity is also not clear, without this information it is not possible to establish medical necessity. Therefore, the request for ibuprofen is not medically necessary.

Paroxetine, #1 pill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): SSRIs (selective serotonin reuptake inhibitors).

Decision rationale: Per the MTUS SSRI's are "not recommended as a treatment for chronic pain, but SSRIs may have a role in treating secondary depression. Selective serotonin reuptake inhibitors (SSRIs), a class of antidepressants that inhibit serotonin reuptake without action on noradrenaline, are controversial based on controlled trials. It has been suggested that the main role of SSRIs may be in addressing psychological symptoms associated with chronic pain. More information is needed regarding the role of SSRIs and pain. SSRIs have not been shown

to be effective for low back pain." A review of the injured workers medical records did not reveal a clear rationale for the use of this medication, there was also no documentation of pain or functional benefit with the use of this medication. Without this information it is not possible to establish medical necessity, therefore the request for Paroxetine is not medically necessary.

Reglan, #1 pill: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Physician Desk Reference - Reglan Tablets (metoclopramide).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate / Reglan.

Decision rationale: The MTUS / ACOEM and ODG did not address the use of Reglan, therefore other guidelines were consulted. Per UpToDate, Reglan is an Antiemetic Prokinetic Gastrointestinal Agent used to treat GERD and in the prevention of nausea and vomiting with chemotherapy or post operatively. A review of the injured workers medical records did not reveal a current indication for the use of this medication, the requested quantity is also not clear, without this information medical necessity is not established; therefore, the request for Reglan is not medically necessary.

Omeprazole, #1 pill: 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 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 do not reveal that the injured worker is at increased risk for a gastrointestinal event according to guideline recommendations, therefore the request for omeprazole is not medically necessary.