

Case Number:	CM15-0218222		
Date Assigned:	11/10/2015	Date of Injury:	07/30/2004
Decision Date:	12/21/2015	UR Denial Date:	10/20/2015
Priority:	Standard	Application Received:	11/05/2015

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: Ohio, West Virginia

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Medical Toxicology

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 7-30-2004. Diagnoses include gastroesophageal reflux disease (GERD) - abdominal complaints, stress-anxiety, and gastritis versus peptic ulcer disease (PUD). Treatments to date include activity modification, medication therapy, psychotherapy, and home exercise. On 3-12-15, she complained of abdominal pain, occasional vomiting episodes, and persistent acid reflux. The physical examination documented abdominal tenderness in mid epigastric area. The plan of care included prescriptions for Ranitidine 150mg #60, Clonidine 0.1mg #5, and Docusate sodium, along with obtaining a gastrointestinal consultation. At re-evaluation, there was report of intermittent abdominal pain in times of high stress. The plan of care included Clonidine, Ranitidine, and the additional of Proctosol, and Prilosec. On 9-22-15, she continued to report acid reflux had worsened and wakes her up at night as well as hemorrhoid pain. The physical examination documented mid epigastric tenderness. The plan of care included a request for a gastrointestinal consultation, and prescriptions for Omeprazole 40mg, Proctosol, Clonidine 0.1mg #5, and Ranitidine 300mg #30. The appeal requested authorization for Proctosol Cream, Clonidine 0.1mg #5, and Ranitidine 300mg #30. The Utilization Review dated 10-20-15, denied the request.

IMR ISSUES, DECISIONS AND RATIONALES

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

Proctosol cream: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drugs.com.

MAXIMUS guideline: Decision based on MTUS General Approaches 2004, Section(s): Initial Approaches to Treatment, and Stress-Related Conditions 2004, Section(s): Treatment.

Decision rationale: Proctosol is a topical steroid intended for use as an anti-inflammatory and anti-pruritic. The available medical record does not provide an indication, a diagnosis or rationale for the use for this medication. As such the request for proctosol cream is deemed not medically necessary.

Clonidine 0.1mg #5: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS General Approaches 2004, Section(s): Initial Approaches to Treatment, and Stress-Related Conditions 2004, Section(s): Treatment. Decision based on Non-MTUS Citation Uptodate.com, hypertension treatment, JNC 8.

Decision rationale: Clonidine is a drug used for the treatment of hypertension. JNC 8 defines hypertension as Stage 1: systolic 140 to 159 mmHg or diastolic 90 to 99 mmHg. Stage 2: systolic 160 or diastolic 100 mmHg on two or more properly measured readings at each of two or more visits after an initial screen. The available medical record does not establish the diagnosis of hypertension. Progress notes did not objectively record systolic and diastolic blood pressure readings, which is critical in evaluation of hypertension. Medical records provided do not outline what lifestyle modification (weight loss, exercise, low sodium diet, etc) were tried initially and the results of those lifestyle interventions. Additionally, Clonidine is no longer used as a first line medication for the treatment of HTN and no documentation was provided that outlined which primary therapy was used initially. ACOEM guidelines state "Studies have shown that when NSAIDs are used for more than a few weeks, they can retard or impair bone, muscle, and connective tissue healing and perhaps cause hypertension." The treating physician does not address NSAID related hypertension in the progress notes. As such, the request for Clonidine 0.1mg #5 is deemed not medically necessary.

Ranitidine 300mg: Upheld

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

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), NSAIDs, GI symptoms & cardiovascular risk and Other Medical Treatment Guidelines Uptodate.com, NSAIDs (including aspirin): Primary prevention of gastroduodenal toxicity.

Decision rationale: Ranitidine is an H2 antagonist used for the treatment of stomach ulcers and gastroesophageal reflux. MTUS states, "Determine if the patient is at risk for gastrointestinal events: (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)." And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." Uptodate states regarding H2 antagonist for GI prophylaxis, "Standard doses of H2 receptor antagonists were not effective for the prevention of NSAID-induced gastric ulcers in most reports, although they may prevent duodenal ulcers [33]. Studies that detected a benefit on gastric ulcer prevention were short-term (12 to 24 weeks) and focused on endoscopic rather than clinical endpoints." This IW is receiving a PPI presumably for GI prophylaxis and as H2 blockers provided no additional protection from NSAID induced injury there is no clear indication for the use of ranitidine. As such, the request for Ranitidine 300mg is deemed not medically necessary. The patient does not meet the age recommendations for increased GI risk. The medical documents provided establish the patient has experienced GI discomfort, but is nonspecific and does not indicate history of peptic ulcer, GI bleeding or perforation. Medical records do not indicate that the patient is on ASA, corticosteroids, and/or an anticoagulant; or high dose/multiple NSAID. Additionally, uptodate suggests that H2 antagonist at this dose is not useful for to prevent ulcers. As such, the request for Ranitidine 150mg is not medically necessary.