

Case Number:	CM15-0161183		
Date Assigned:	08/28/2015	Date of Injury:	03/13/2010
Decision Date:	10/13/2015	UR Denial Date:	07/23/2015
Priority:	Standard	Application Received:	08/18/2015

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 53 year old female, who sustained an industrial injury on March 13, 2010. Several documents are included in the submitted medical records are difficult to decipher. She reported head, neck, upper and mid back, low back, right shoulder, left elbow, right wrist, and bilateral thumb injuries due to cumulative trauma. The injured worker was diagnosed as having cervical spine sprain and strain, lumbar spine sprain and strain, right shoulder sprain and strain, left elbow sprain and strain, right wrist carpal tunnel syndrome, and right wrist sprain and strain. Diagnostic studies to date have included MRIs, x-rays, and electrodiagnostic studies. On January 12, 2015, the agreed medical evaluator noted that x-rays of the bilateral shoulders revealed thinning of the acromion with scalloped appearance on the undersurface of the acromium, consistent with a subacromial decompression. The agreed medical evaluator noted that x-rays of the cervical spine revealed some narrowing, but not advanced, at C5-6 (cervical 5-6) and C6-7 (cervical 6-7). Surgeries to date have included right shoulder arthroscopic rotator cuff surgery on April 23, 2014 and left shoulder arthroscopic surgery on July 2, 2014. Treatment to date has included physical therapy, acupuncture, shockwave treatments, aquatic therapy, psychotherapy, a transcutaneous electrical nerve stimulation (TENS) unit, a lumbar support, cervical epidural steroid injections, work modifications, right elbow and wrist braces, and medications including opioid analgesic, anti-epilepsy, muscle relaxant, proton pump inhibitor, and non-steroidal anti-inflammatory. There were no noted previous injuries or dates of injury. Comorbid diagnoses included history of anxiety, depression, and stress. On July 13, 2015, the injured worker reported right shoulder pain, heartburn, reflux, abdomen pain, and

bloating. The physical exam revealed tenderness of the right shoulder. The injured worker was to remain off work. The requested treatments included Prevacid, Flector 13% topical patch, Flurbiprofen 30%- Lidocaine 10%, and Maalox.

IMR ISSUES, DECISIONS AND RATIONALES

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

Prevacid 30mg #30: 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): Prevacid (lansoprazole); Proton pump inhibitors (PPIs); NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: Per the California Medical Treatment Utilization Schedule (CMTUS) guidelines, proton pump inhibitor medication is recommended when the injured worker is at intermediate or high risk for gastrointestinal events without cardiovascular disease and at high risk for gastrointestinal events with cardiovascular disease while being treated with non-steroidal anti-inflammatory drugs (NSAIDs). The patient is at risk for a gastrointestinal event when they are older than 65 years, have a history of peptic ulcer, GI bleeding or perforation; use ASA, corticosteroids, and-or an anticoagulant concurrently; or use high dose or multiple NSAID (e.g., NSAID + low-dose ASA). The Official Disability Guidelines (ODG) recommends Lansoprazole (Prevacid), a proton pump inhibitor, for first-line treatment of injured workers at risk for gastrointestinal events. There is lack of evidence that the injured worker is at intermediate or high risk for gastrointestinal events. The injured worker is younger than 65 years. There was lack of documentation of a history peptic ulcer, GI bleeding or perforation, concurrent use of ASA, corticosteroids, and-or an anticoagulant; or are on high dose or multiple NSAID (e.g., NSAID + low-dose ASA). There was documentation of the injured worker having reported heartburn, reflux, abdomen pain, and bloating. However, there was a lack of objective evidence of gastrointestinal issues. Therefore, the Prevacid is not medically necessary.

Flector 13% topical patch #60: 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): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic): Flector patch (diclofenac epolamine); Topical Analgesics.

Decision rationale: The California Medical Treatment Utilization Schedule (CMTUS) guidelines recommend topical non-steroidal anti-inflammatory drugs (NSAIDs) for "osteoarthritis and tendinitis in particular, that of the knee and elbow or other joints that are

amenable to topical treatment". The OGD recommends Flector patch as a second-line treatment, after oral NSAID failure or oral NSAIDs are contraindicated when, for osteoarthritis. The Food and Drug Administration (FDA) has approved Flector patch for treatment of "acute strains, sprains, and contusions". There is a lack of approved diagnosis for treatment with Flector patch. There is a lack of documentation of failed oral NSAID treatment. The medical record shows that the injured worker was prescribed an oral NSAID in addition to the Flector patch. Therefore, the Flector 13% topical patch is not medically necessary.

Flurbiprofen 30%/Lidocaine 10% 240mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Topical analgesic.

MAXIMUS guideline: Decision based on MTUS Elbow Complaints 2007, Section(s): Basic Principles, Contusion, and Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: The requested medication is Flurbiprofen 30%-Lidocaine 10%. This compounded topical medication contains Flurbiprofen 30%-and Lidocaine 10%. Flurbiprofen is a non-steroidal anti-inflammatory medication and Lidocaine is a topical anesthetic. The California Medical Treatment Utilization Schedule (CMTUS) guidelines primarily recommended topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. In addition, CMTUS does not recommend any compound product that contains at least one drug (or drug class) that is not recommended. The CMTUS recommends topical non-steroidal anti-inflammatory drugs (NSAIDs) for "osteoarthritis and tendinitis in particular, that of the knee and elbow or other joints that are amenable to topical treatment". Per the CMTUS, Lidocaine is indicated for the treatment of Neuropathic pain and the only approved formulation of topical lidocaine is a dermal patch. Per the ACOEM (American College of Occupational and Environmental Medicine) guidelines, topical non-steroidal anti-inflammatory drugs are recommended for lateral and medial epicondylalgia. The treating physician did not discuss the failure of standard oral medications, including antidepressants and anticonvulsants. The use of topical Flurbiprofen is inappropriate as there is lack of evidence that the injured worker is being treated for lateral or medial epicondylalgia. This topical compound contains Lidocaine, which is only approved for use in a dermal patch formulation. Therefore, the request for Flurbiprofen 30%-Lidocaine 10% is not medically necessary.

Maalox: Overturned

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 based on Non-MTUS Citation UpToDate / Aluminum hydroxide and magnesium hydroxide.

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)" Maalox is an antacid indicated for the relief of heartburn, acid indigestion, sour stomach and GI upset associated with these symptoms. The injured worker is reporting symptoms of heartburn, the use of Maalox appears appropriate and is medically necessary.