

Case Number:	CM15-0193957		
Date Assigned:	10/07/2015	Date of Injury:	06/05/2006
Decision Date:	11/19/2015	UR Denial Date:	09/24/2015
Priority:	Standard	Application Received:	10/02/2015

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 61 year old male, who sustained an industrial-work injury to the left shoulder and upper extremity on 6-5-06. A review of the medical records indicates that the injured worker is undergoing treatment for pain in joint of the shoulder and chronic pain syndrome. Treatment to date has included pain medication, Pantoprazole, Lidopro cream, and Terocin patch since at least 9-9-15, two left shoulder surgeries 2006 and 2007, heat and cold therapy, physical therapy, acupuncture, home exercise program (HEP) and other modalities. Medical records dated 9-9-15 indicate that the injured worker complains of neck and left shoulder pain. The pain radiates to the left arm and hand. The associated symptoms are numbness, tingling and weakness. The pain is aggravated by activities and decreased with medications, heat and cold applications, rest and topical analgesics. The injured worker is able to walk 5 blocks, sit 2 hours, and stand 1 hour. He has little difficulty performing household chores, doing yard work and socializing with friends. He reports that he lies down 2-3 times a day due to his pain. Per the treating physician report dated 9-9-15, the injured worker has not returned to work. The physical exam dated 9-9-15 reveals that the left shoulder exam movements are restricted by pain, shoulder crossover test is positive, and there is tenderness noted in the acromioclavicular joint (AC). The left wrist has positive Tinel's, motor exam is decreased on the left and light touch sensation is decreased over the hand on the left side. The physician indicates that Naproxen was discontinued and prescription was given for Diclofenac, Lidopro ointment, Pantoprazole and Terocin patch. The current medications included Naproxen and Lisinopril. The trialed medications include Hydrocodone, Naproxen and Celebrex. The treating physician

indicates that the urine drug test result dated 9-9-15 was consistent with the medication prescribed. The requested services included Pantoprazole sod Dr 20mg #60 times 1, Lidopro 4% ointment #1 tube, and Terocin patch 4-4% #30. The original Utilization review dated 9-24-15 non-certified- the request for Pantoprazole sod Dr 20mg #60 times 1, Lidopro 4% ointment #1 tube, and Terocin patch 4-4% #30.

IMR ISSUES, DECISIONS AND RATIONALES

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

Pantoprazole sod Dr 20mg #60 times 1: 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, Proton pump inhibitors.

Decision rationale: Pantoprazole (Protonix) is a proton pump inhibitor (PPI) used primarily for gastroesophageal reflux disease, esophagitis, hypersecretory conditions, upper GI bleeding and H. pylori infection. 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 recommend proton pump inhibitors for patients at risk for gastrointestinal events. Healing doses of PPIs are more effective than all other therapies, although there is an increase in overall adverse effects compared to placebo. 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. If a PPI is used, omeprazole OTC tablets or lansoprazole 24HR OTC is recommended for an equivalent clinical efficacy and significant cost savings. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses. A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line. In this case, the medical records do not note a history of heartburn or a diagnosis of gastritis. The records do not show that a first-line PPI agent, has been prescribed. Since Pantoprazole is not a first-line PPI, the request for Protonix/Pantoprazole Sodium DR 20mg, #60 is not consistent with the MTUS guidelines and is not medically necessary.

Lidopro 4% ointment #1 tube: 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 rationale: The MTUS states that topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Their use is largely experimental with few randomized controlled trials to determine efficacy or safety. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine are indicated for neuropathic pain. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than postherpetic neuralgia. The ODG guidelines also state that Lidoderm patches are not a first-line treatment and are FDA approved only for postherpetic neuralgia. In this case, the medical records do not indicate that the injured worker has post herpetic neuralgia. There is no indication of failure of first line treatments such as anti-depressants and anticonvulsants. Lidoderm patches are the only commercially approved topical formulations of lidocaine indicated for neuropathic pain. The request for Lidopro 4% ointment #1 tube is not consistent with the MTUS guidelines and is not medically necessary.

Terocin patch 4-4% #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): Topical Analgesics.

Decision rationale: Terocin is a combination medication containing methyl salicylate, lidocaine, capsaicin and menthol. The MTUS notes that use of topical analgesics is largely experimental with few trials to determine efficacy or safety. Specifically, topical lidocaine is recommended only for neuropathic pain after a trial of first-line therapy. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Methyl salicylate is a volatile oil with a characteristic wintergreen odor and taste, used as a flavoring agent and as a topical counterirritant for muscle pain. The salicylate component is an anti-inflammatory agent. Topical non-steroidal anti-inflammatory agents have shown inconsistent efficacy in clinical trials with most studies being small and of short duration. The use of menthol is not supported in the MTUS. The use of lidocaine is only supported in the form of a dermal patch. The MTUS does state that if a compounded product contains at least one component that is not recommended, the compounded treatment itself is not recommended. As such, the request for Terocin Patch 4% #30 is not consistent with the MTUS guidelines and is not medically necessary.