MAXIMUS Federal Services

Case Number:	CM15-0011764		
Date Assigned:	01/29/2015	Date of Injury:	09/02/2011
Decision Date:	03/30/2015	UR Denial Date:	01/09/2015
Priority:	Standard	Application Received:	01/20/2015

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: District of Columbia, Virginia
Certification(s)/Specialty: Internal 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 57 year old male, who sustained an industrial injury on 09/02/2011. The diagnoses have included bilateral hand and wrist pain and bilateral carpal tunnel. Treatments to date have included bilateral carpal tunnel release surgeries, exercise program, and medications. Diagnostics to date have included electromyography/nerve conduction studies on 05/03/2013 showed bilateral carpal tunnel. In a progress note dated 12/04/2014, the injured worker presented with complaints of continued bilateral wrist and hand pain. The treating physician reported the injured worker continues to do well on his current medications. Utilization Review determination on 01/09/2015 modified the request for Gralise 600mg x 90 x 4 refills, Prilosec 20mg x 30 x 4 refills, and Ibuprofen 800mg x 60 x 4 refills to Gralise 600mg x 90 x 2 refills, Prilosec 20mg x 30 x 2 refills, and Ibuprofen 800mg x 60 x 2 refills citing Medical Treatment Utilization Schedule Chronic Pain Medical Treatment Guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gralise 600mg #90 with 4 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 18-19. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter and PDR

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792 Page(s): 18-19.

Decision rationale: Per MTUS: Gabapentin (Neurontin , Gabarone TM, generic available) has been shown to be effective fortreatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. (Backonja, 2002) (ICSI, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Attal, 2006). This RCT concluded that gabapentin monotherapy appears to be efficacious for the treatment of pain and sleep interference associated with diabetic peripheral neuropathy and exhibits positive effects on mood and quality of life. (Backonja, 1998). It has been given FDA approval for treatment of post-herpetic neuralgia. The number needed to treat (NNT) for overall neuropathic pain is 4. It has a more favorable side-effect profile than Carbamazepine, with a number needed to harm of 2.5. (Wiffen2-Cochrane, 2005) (Zaremba, 2006). Gabapentin in combination with morphine has been studied for treatment of diabetic neuropathy and postherpetic neuralgia. When used in combination the maximum tolerated dosage of both drugs was lower than when each was used as a single agent and better analgesia occurred at lower doses of each. (Gilron-NEJM, 2005). Recommendations involving combination therapy require further study. Mechanism of action: This medication appears to be effective in reducing abnormal hypersensitivity (allodynia and hyperalgesia), to have anti-anxiety effects, and may be beneficial as a sleep aid. (Arnold, 2007). Specific pain states: There is limited evidence to show that this medication is effective for postoperative pain, where there is fairly good evidence that the use of gabapentin and gabapentin-like compounds results in decreased opioid consumption. This beneficial effect, which may be related to an anti-anxiety effect, is accompanied by increased sedation and dizziness. (Peng, 2007) (Buvanendran, 2007) (Menigaux, 2005) (Pandey, 2005) Lumbar spinal stenosis: Recommended as a trial, with statistically significant improvement Dosing Information:Diabetic neuropathy (off-label indication) Gabapentin dosages range from 900 mg to 3600 mg Recommended Trial Period: One recommendation for an adequate trial with gabapentin is three package insert).This medication should not be used over 3 month's duration for neuropathic pain. The patient had some clinical findings which were suggestive of neuropathy. However, the dose duration prescribed is not medically necessary.

Prilosec 20mg #30 with 4 refills: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation proton pump inhibitors

Decision rationale: MTUS does not address this medication. Per ODG: proton pump inhibitors (PPI) are recommended for patients at risk for gastrointestinal events. See NSAIDS, GI symptoms and cardiovascular risk. Prilosec(omeprazole), Prevacid(lansoprazole) and

nexium(esomeprazole) are PPIs. Omeprazole provides a statistically significantly greater acid control than lansoprazole (Miner 2010). Healing doses of PPIs are more effective than all other therapies although there is an increase in overall adverese effects to placebo. Nexium and Prilosec are very similar molecules. For many people, Prilosec is more affordable than nexium. Nexium is not available in a generic(as in Prilosec). Also, prilosec is more available as an over the counter product while nexium is not. (Donnellan 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose or the shortest possible amount of time. PPIs are more effective 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. If a PPI is used , omeprazole OTC tablets or lansoprazole 24 HR OTC are 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, including nexium, prevacid, prilosec, protonix , dexilant and aciphex (Shi 2008). A trial of omeprazole or lansoprazole is recommended before nexium therapy. The other PPIs, protonix, dexilant, aciphex should also be second line. According to the latest AHRQ comparative effectiveness research, all of the commercially available PPIs appeared to be similarly effective (AHRQ 2011) (Pain Chapter).The patient had indications for prilosec but the duration would exceed that which is recommended. Therefore, this current regimen would not be recommended.

Ibuprofen 800mg #60 with 4 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 47. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792 Page(s): 67,72,22.

Decision rationale: Per MTUS: PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007) Cardiovascular disease: A non-pharmacological choice should be the first option in patients with cardiac risk factors. It is then suggested that acetaminophen or aspirin be used for short-term needs. An opioid also remains a short-term alternative for analgesia. Major risk factors (recent MI, or coronary artery surgery, including recent stent placement): If NSAID therapy is necessary, the suggested treatment is naproxyn plus low-dose aspirin plus a PPI.Mild to moderate risk factors: If long-term or high-dose therapy is required, full-dose naproxen (500 mg twice a day) appears to be the preferred choice of NSAID. If naproxyn is ineffective, the suggested treatment is (1) the addition of aspirin to naproxyn plus a PPI, or (2) a low-dose Cox-2 plus ASA. Cardiovascular risk does appear to extend to all non-aspirin NSAIDs, with the highest risk found for the Cox-2 agents. (Johnsen, 2005) (Lanas, 2006) (Antman, 2007) (Laine, 2007) Use with Aspirin for cardioprotective effect:In terms of GI protective effect: The GI protective effect of Cox-2 agents is diminished in patients taking low-dose aspirin and a PPI may be required for those patients with GI risk factors. (Laine, 2007) In terms of the actual cardioprotective effect of aspirin: Traditional NSAIDs (both ibuprofen and naproxen) appear to attenuate the antiplatlet effect of enteric-coated aspirin and should be taken

30 minutes after ASA or 8 hour s before. (Antman, 2007) Cox-2 NSAIDs and diclofenac (a traditional NSAID) do not decrease anti-platelet effect. (Laine, 2007) Use of NSAIDs and SSRIs: The concurrent use of SSRIs and NSAIDs is associated with moderate excess relative risk of serious upper GI events when compared to NSAIDs alone. This risk was higher for non-selective NSAIDs when compared to Cox-2 selective agents (adjustedod ds ratio of 1.77 and 1.33, respectively). (Helin-Salmivaara, 2007) Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI.Ibuprofen (Motrin, Advil [otc], generic available): 300, 400, 6 00, 800 m g. Dosing: Osteoarthritis and off-label for ankylosing spondylitis: 1200 mg to 3200 mg daily. Individual patients may show no better response to 3200 mg as 2400 m g, and sufficient clinical improvement should be observed to offset potential risk of treatment with the increased dose. Higher doses are generally recommended for rheumatoid arthritis: 400-800 mg PO 3-4 times a day, use the lowest effective dose. Higher doses are usually necessary for osteoarthritis. Doses should not exceed 3200 m g/day. Mild pain to moderate pain: 400 mg PO every 4-6 hours as needed. Doses greater than 400 mg have not provided greater relief of pain.This medication would be recommended for only short term usage and is not medically necessary.