

Case Number:	CM14-0143822		
Date Assigned:	09/12/2014	Date of Injury:	06/08/2011
Decision Date:	12/24/2014	UR Denial Date:	08/11/2014
Priority:	Standard	Application Received:	09/05/2014

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. The expert reviewer is Board Certified in Occupational Medicine and is licensed to practice in Montana. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a 52 year old male patient with a reported date of injury as 06/08/2011. The mechanism of injury is not described. The patient was diagnosed with cervicalgia. A primary treating physician note dated 07/14/2014 described a history of intermittent pain in the cervical spine that is aggravated by repetitive motions of the neck such as lifting, pushing, pulling, forward reaching and working at or above the shoulder level. The pain noted described as dull with radiation to bilateral upper extremities. There are also associated headaches and tension between the shoulder blades. The pain is noted as unchanged and rated three out of ten on a pain scale. Physical examination showed palpable paravertebral muscle tenderness with spasm. Both Spurling's and axial loading compression tests noted with negative findings. He returned to work on modified duty. A request for authorization of medications dated 07/28/2014 was denied as described on 08/11/2014 Utilization Review determination.

IMR ISSUES, DECISIONS AND RATIONALES

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

Diclofenac Sodium ER100mg, #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs. Decision based on Non-MTUS Citation Official Disability Guidelines: Drug Formula

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Nonsteroidal Anti-inflammatory Drugs Page(s): 67 and 71. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Diclofenac

Decision rationale: Diclofenac is a nonsteroidal anti-inflammatory drug (NSAID). The MTUS and ODG guidelines note that 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. Diclofenac Sodium (Voltaren, Voltaren-XR) is not recommended as first line due to increased risk profile. A large systematic review of available evidence on NSAIDs confirms that diclofenac, a widely used NSAID, poses an equivalent risk of cardiovascular events to patients as did rofecoxib (Vioxx), which was taken off the market. According to the authors, this is a significant issue and doctors should avoid diclofenac because it increases the risk by about 40%. (McGettigan, 2011) Another meta-analysis supported the substantially increased risk of stroke with diclofenac, further suggesting it not be a first-line NSAID. (Varas-Lorenzo, 2011) (Schjerning, 2011) If using diclofenac then consider discontinuing as it should only be used for the shortest duration possible in the lowest effective dose due to reported serious adverse events. Post marketing surveillance has revealed that treatment with all oral and topical diclofenac products may increase liver dysfunction, and use has resulted in liver failure and death. Physicians should measure transaminases periodically in patients receiving long-term therapy with diclofenac. (FDA, 2011) In 2009 the FDA issued warnings about the potential for elevation in liver function tests during treatment with all products containing diclofenac sodium. (FDA, 2009) With the lack of data to support superiority of diclofenac over other NSAIDs and the possible increased hepatic and cardiovascular risk associated with its use, alternative analgesics and/or non pharmacological therapy should be considered. With diclofenac even in small doses it increases the risk of cardiovascular events. They recommended naproxen as the NSAID of choice. In this case 120 diclofenac sodium ER tablets are requested. This would indicate relatively long-term use of the medication that has a significantly adverse risk profile. The request for diclofenac sodium ER 100mg, #120 is not medically necessary.

Omeprazole 20mg, #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Nonsteroidal Anti-inflammatory Drugs, GI symptoms and cardiovascular risk Page(s): 68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Proton pump inhibitors (PPIs)

Decision rationale: Prilosec is a proton pump inhibitor (PPI) indicated for use in gastroesophageal reflux disease, erosive and non-erosive esophagitis, gastric ulcer, duodenal ulcer, hypersecretory conditions, H pylori infection and gastric ulcer prophylaxis associated with nonsteroidal anti-inflammatory drug use. 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 nonsteroidal anti-inflammatory drugs. The ODG guidelines state that, in general, the use of PPIs should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. The medical records show that Prilosec has been used on at least an intermittent basis since November 2012. The records provided do not document history of peptic ulcer, GI bleeding or perforation. Additionally there is no indication in the medical records of any current gastrointestinal symptoms or side effects from medication use. The criteria for use of proton pump inhibitors are not met. The request for omeprazole 20mg, #120 is not medically necessary.

Ondansetron 8mg, #30: 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 States that Antiemetics (for Opioid Nausea)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, ondansetron and on Other Medical Treatment Guideline or Medical Evidence: Product information for ondansetron

Decision rationale: The MTUS does not specifically address treatment with ondansetron. The ODG Guidelines note that ondansetron is not recommended for nausea and vomiting secondary to chronic opioid use. Product information documents the following indications;Prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin 50 mg/m².Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.Prevention of nausea and vomiting associated with radiotherapy in patients receiving total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.Prevention of postoperative nausea and/or vomiting. As with other antiemetics, routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided postoperatively, Ondansetron tablets, USP are recommended even where the incidence of postoperative nausea and/or vomiting is low.The medical records do not provide evidence of indications for this medication as noted above. The request for on ondansetron 8mg, #30 is not medically necessary.

Cyclobenzaprine Hydrochloride 7.5mg, #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants for Pain. Decision based on Non-MTUS Citation Official Disability Guidelines: Muscle Relaxants for Short Term use.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antispasmodics, Cyclobenzaprine Page(s): 64.

Decision rationale: The MTUS notes that cyclobenzaprine is an antispasmodic medication, recommended for a short course of therapy with the greatest benefit occurring within the first 4 days. Flexeril is not recommended to be used for longer than 2-3 weeks. The medical records indicate at least intermittent use of Flexeril since at November 2012. The continued use of Flexeril is not consistent with the MTUS guidelines. The Utilization Review on 8/11/14 did modify the request for cyclobenzaprine 7.5mg, #120 to allow 20 tablets, since long-term use of this medication is not recommended. The request for cyclobenzaprine 7.5mg, #120 is not medically necessary.

Tramadol ER 150mg, #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 75, 78 and 93-94.

Decision rationale: The MTUS notes that tramadol is a central acting opioid analgesic that may be used to treat chronic pain and neuropathic pain. The MTUS states that opioids are not recommended as first line therapy for neuropathic pain. Opioids are suggested for neuropathic pain that has not responded to first line recommendations including antidepressants and anticonvulsants. The MTUS states that reasonable alternatives to opioid use should be attempted. There should be a trial of non-opioid analgesics. When subjective complaints do not correlate with clinical studies a second opinion with a pain specialist and a psychological assessment should be obtained. The lowest possible dose should be prescribed to improve pain and function. Ongoing use of tramadol requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: the least reported pain over the period since the last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Opioid use for chronic pain appears to be effective for short-term pain relief but long-term benefit is unclear. Tramadol specifically is found to have a small benefit (12% decrease in pain intensity baseline) for up to 3 months. No long-term studies allow for recommended use beyond 3 months. The injured worker has apparently been using tramadol at least on an intermittent basis since November 2012. The medical records do not document pain relief, functional improvement, appropriate medication use, and side effects. There is no pain assessment that includes: the least reported pain over the period since the last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. The medical records do not support use of tramadol within the MTUS guidelines noted above. The Utilization Review of 8/11/14 did modify the request for tramadol ER 150mg, #90 to allow for 60 tablets. This would allow adequate time for tapering off the medication or documentation to support continued use. The request for tramadol ER 150mg, #90 is not medically necessary.