

Case Number:	CM15-0091501		
Date Assigned:	05/18/2015	Date of Injury:	10/10/2007
Decision Date:	06/17/2015	UR Denial Date:	04/20/2015
Priority:	Standard	Application Received:	05/13/2015

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: California
 Certification(s)/Specialty: Family Practice

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 43-year-old male who sustained an industrial injury on October 10, 2007. He has reported back pain and has been diagnosed with sacroiliitis, radiculopathy spine/lumbar/ leg, and herniated nucleus pulposus. Treatment has included medical imaging, medications, and chiropractic care. Subjective complaints note moderate back pain rarely to the hips and legs. Objective findings note a negative straight leg raising bilaterally, slight spasm, slight limits horizontal torsion and lateral bend. MRI dated October 13, 2008 revealed at L5-S1 there is a 5mm left paracentral disc herniation, which narrows the left lateral recess and left neural foramen. There is bilateral facet joint arthropathy and at L4-5, there is bilateral facet joint arthropathy. The treatment request included Vimovo.

IMR ISSUES, DECISIONS AND RATIONALES

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

Vimovo 500/20 MG #20 with 1 Refill: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs and NSAIDs/GI Symptoms & Cardiovascular Risk Page(s): 67-69.

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of NSAIDs and proton pump inhibitors (PPIs). Vimovo is a combination medication including an NSAID plus a PPI. Regarding the use of an NSAID, the MTUS guidelines state the following: Specific recommendations: Osteoarthritis (including knee and hip): 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. 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. Back Pain: Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. Back Pain: Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain. Regarding the use of PPIs in combination with an NSAID, the MTUS guidelines state the following: Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. 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). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDs to develop gastroduodenal lesions. Recommendations Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e. g. , ibuprofen, naproxen, etc.) 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). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardio-protection) and a PPI. If cardiovascular risk is greater than GI risk, the suggestion is naproxyn plus low-dose aspirin plus a PPI. In this case, the records indicate that Vimovo is being used as a strategy to provide long-term treatment with an NSAID to this patient. Long-term use is not consistent with the above-cited guidelines. Specifically, NSAIDs should only be used in the short-term for relief of acute symptoms. Further, there is no evidence in the medical records

to indicate that this patient is at risk for a significant gastrointestinal event. As noted in the above-cited guidelines, without the presence of risk factors the use of a PPI is not indicated. In summary, there is insufficient evidence in the medical records in support of the long-term use of an NSAID; further, there is insufficient evidence that the patient is at risk for a serious gastrointestinal event. Given that Vimovo is a combination of an NSAID and a PPI, the use of Vimovo is not medically necessary.