

Case Number:	CM15-0001584		
Date Assigned:	01/12/2015	Date of Injury:	09/05/2012
Decision Date:	03/10/2015	UR Denial Date:	12/09/2014
Priority:	Standard	Application Received:	01/05/2015

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:

This 52-year-old building inspector reported a low back injury as a result of slipping and twisting his back without falling on 9/5/12. Treatment has included medications, physical therapy, epidural steroid injections, a medial branch block and TENS. Except for periods of pain exacerbation, he has remained at work in a modified capacity since the injury. Past medical history is notable for hypertension. It is unclear whether or not the patient smokes. Most of the progress notes state that he is a non-smoker or has a remote history of smoking. However, a pamphlet on how to stop smoking was dispensed to him on 8/28/14.. The patient is listed as taking multiple medications at each visit. Since 7/29/14, these have included Voltaren, omeprazole, Norco, Medrol Dosepak, Advil, Codeine Sulfate, metoprolol, Lexapro, lorazepam 1 mg, and lorzepam 0.5 mg. An identical medication list is documented on 9/30/14 and 11/18/14. Documented rationales for Voltaren include only the statement that the treater is prescribing "an anti-inflammatory medication to address the persistent inflammatory component of their pain". Documented rationales for omeprazole include preventing GI upset from Voltaren and prevention of the possibility of developing gastritis or ulcers. On 11/18/14 the progress note contained a generic, obviously templated statement that the patient "is able to provide a specific example of functional improvement due to their use of pain relieving medications", but no such specific example is actually documented. A minimal physical exam is recorded, which includes no abnormal findings. Diagnoses include lumbago and sciatica. The plan is to continue the patient's medications (as listed above). No work status is documented, although it appears likely from previous notes that the patient is working at modified status. Requests for Voltaren and

omeprazole were non-certified in UR on 12/9/14. MTUS Chronic Pain, NSAIDs, was cited as the rationale for both non-certifications.

IMR ISSUES, DECISIONS AND RATIONALES

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

Voltaren 100mg #30 refill: 2: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-73.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, page 60; NSAIDs (non-steroidal anti-inflammatory drugs), Chronic I.

Decision rationale: Voltaren is brand-name diclofenac, which is a non-steroidal anti-inflammatory medication (NSAID). Per the first reference cited above, medications should be trialed one at a time while other treatments are held constant, with careful assessment of function, and there should be functional improvement with each medication in order to continue it. The NSAID references state that NSAIDs are recommended at the lowest dose for the shortest period possible for patients with moderate to severe pain due to osteoarthritis. There is no evidence to recommend one drug over another in terms of efficacy or pain relief. Cardiovascular risk occurs with all NSAIDs, and there is no evidence of long-term effectiveness for pain or function. NSAIDs are recommended as an option for short-term symptomatic relief of chronic low back pain. There is inconsistent evidence to support their use for neuropathic pain. All NSAIDs have the potential to raise blood pressure in susceptible patients. The greatest risk appears to occur in patients taking ACE inhibitors, ARBs, beta-blockers or diuretics. The clinical documentation in this case does not support the use of Voltaren for this patient. He has been taking it for months without any documentation of significant improvements in functional status. The time period for which he has been taking it exceeds any period likely to be due to an acute exacerbation of his back pain. The provider has not provided any documentation that supports his statement that the patient has a persistent inflammatory component of his pain. The record does not include any documentation by the provider of the patient's risk for GI or cardiovascular events. At each recent clinic visit, this patient is documented as taking a steroid (Medrol) and another NSAID (Advil) as well as Voltaren. Although it seems likely that this represents an accidental carryover of medications which have been discontinued, at a minimum it is unacceptably sloppy documentation. If really being prescribed, this combination would put the patient at high risk for GI side effects such as ulcers. The patient has a history of hypertension, he is over 50 and is possibly a smoker. All of these factors put him at increased risk for a cardiac event such as a heart attack. This risk is increased if he is taking an NSAID, especially if it is combined with another NSAID. He is taking metoprolol, a beta blocker, for his hypertension. Voltaren combined with metoprolol is likely to increase his blood pressure and therefore his cardiovascular risk as well. Based on the MTUS citations above and on the clinical information provided for my review, Voltaren 100 mg #30 with 2 refills is not medically necessary. It is not medically necessary because long-term use of an NSAID is not indicated or likely to be helpful, because there is no documentation that the patient's functional status has

improved with its use, because there is no evidence that it is being used for an acute exacerbation of back pain, because it may be being prescribed with both a steroid and another NSAID which puts the patient at unacceptably high GI risk, and because its use increases that patient's risk for a cardiovascular event.

Omeprazole DR 20mg #60 refill: 2: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk, pages 68-69 Page(s): 68-69. Decision based on Non-MTUS Citation UpToDate, an evidence-based online review service for clinicians, (www.uptodate.com); Omeprazole: drug information

Decision rationale: Omeprazole is a proton pump inhibitor (PPI). The first guideline cited above states that clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. They should determine if the patient is at risk for GI events. Risk factors include age over 65 years; history of peptic ulcer, GI bleeding or perforation; concurrent use of aspirin, corticosteroids, or an anticoagulant; or high-dose or multiple NSAIDs, or an NSAID combined with aspirin. Patients with no GI risk factors and no cardiovascular disease may be prescribed a non-selective NSAID. Those at intermediate risk for GI disease should receive a non-selective NSAID plus a proton pump inhibitor (PPI) or misoprostol; or a Cox-2 selective NSAID. Patients at high GI risk should receive a Cox-2 selective NSAID and a PPI if an NSAID is absolutely necessary. This reference notes that long-term PPI use has been shown to increase the risk of hip fracture. The Up to Date reference cited above lists the indications for omeprazole as active duodenal ulcer, gastric ulcer, erosive esophagitis, helicobacter pylori eradication, pathological hypersecretory conditions (such as Zollinger-Ellison syndrome), frequent heartburn, GERD or other acid-related disorders, NSAID-induced ulcer treatment, NSAID-induced ulcer prophylaxis, and stress ulcer prophylaxis in ICU patients. The last three indications are off label. Significant side effects include hepatic disease and hepatic failure. Risks of long-term (usually over one year) use include atrophic gastritis, increased incidence of gastric carcinoid tumors, clostridium difficile-associated diarrhea, increased incidence of osteoporosis-related fractures of the hip, spine, or wrist; hypomagnesemia and Vitamin B12 deficiency. The usual dosage for omeprazole is 20 mg/day. The clinical documentation in this case does not support the provision of omeprazole to this patient. The provider's stated rationales, that it is being prescribed to reduce GI upset caused by Voltaren and to reduce the risk of gastritis or ulcers, appear to be generic statements unrelated to this specific patient. There is no actual documentation of the patient's GI risk. (The risk would have been unacceptably high if the Voltaren were being taken in conjunction with Medrol and Advil, which would argue that the medication documentation was in error). The records do not contain documentation of symptoms of gastritis, of ulcers or of "GI upset". There is no documentation of any concern for another diagnosis that would require the use of a PPI. The patient has been taking omeprazole at twice the usual dosage for at least 4 months, and probably for much longer. This long-term use puts him at increased risk for the side effects described above, some of which may be life threatening. Based on the clinical information provided for my review and the evidence-base

citations above, omeprazole 20 mg #30 is not medically necessary. It is not medically necessary because the provider has not documented symptoms compatible with any condition that would require its use, because the provider has not documented any risk factors for GI events that would require its use, and because its long-term use puts the patient at unacceptable risk for serious side effects.