

Case Number:	CM15-0112889		
Date Assigned:	06/19/2015	Date of Injury:	11/30/2014
Decision Date:	07/20/2015	UR Denial Date:	05/21/2015
Priority:	Standard	Application Received:	06/11/2015

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: New Jersey, Alabama, California
 Certification(s)/Specialty: Neurology, Neuromuscular 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 42 year old female, who sustained an industrial injury on 11/30/14. She reported mid back pain, right sided neck and shoulder pain radiating to the right arm. The injured worker was diagnosed as having fibromyositis, cervicalgia, pain in thoracic spine and inflammation of rotator cuff tendon. Treatment to date has included acupuncture treatment, physical therapy sessions, trigger point injections, home exercise program, activity restrictions and oral medications including Ibuprofen. Currently, the injured worker complains of mid back pain, right sided neck and shoulder pain radiating to right arm, rated 7/10. She notes physical therapy sessions and trigger point injections were not very helpful. Decreased sensation of right upper extremity is also noted along with decreased range of motion in neck. She may currently work with restrictions. Physical exam noted tenderness of right trapezius muscle, deltoid muscle and upper extremity muscles, tenderness of right rotator cuff and restricted range of motion or fight shoulder. The treatment plan included prescriptions for Zorvolex and Omeprazole.

IMR ISSUES, DECISIONS AND RATIONALES

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

Zorvolex 18mg #90 with 1 refill: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Zorvolex (diclofenac). <http://www.odg-twc.com/index.html>.

Decision rationale: According to ODG guidelines, Zorvolex (diclofenac) "Not recommended except as a second-line option, because diclofenac products are not recommended as first-line choices due to potential increased adverse effects. See Diclofenac. In late 2013 FDA approved diclofenac capsules (Zorvolex, ██████████) at 18-mg and 35-mg doses for the treatment of mild to moderate acute pain in adults. These dosages are 30% lower in strength than the 25-mg and 50-mg diclofenac products already on the market. The FDA also approved another lower-dose NSAID from ██████████, indomethacin capsules (Tivorbex). While diclofenac has potent anti-inflammatory and analgesic properties, research has linked this drug to sometimes-serious adverse outcomes, including cardiovascular thrombotic events, myocardial infarction, stroke, gastrointestinal ulcers, gastrointestinal bleeding, and renal events (such as acute renal failure). (FDA, 2014) This new formulation of diclofenac does not present any apparent advantages versus other medications of the class. Zorvolex is pure acid versus salt in other formulations, resulting in faster dissolution using SoluMatrix Fine Particle Technology. However, it has the same side effect profile while more expensive than other NSAIDs that are available as generics. It is an expensive, brand name only, second-line medication with little to no place in the treatment of workers compensation injuries. (FDA, 2013)" There is no documentation that the patient failed first line NSAID. There is no documentation of the advantage of using Zorvolex rather than other NSAID. There is no documentation that the drug has a less side effect profile than other NSAID. Therefore, the request for Zorvolex 18mg #90 with 1 refill is not medically necessary.

Omeprazole 20mg #30 with 3 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

Decision rationale: According to MTUS guidelines, Omeprazole is indicated when NSAID are used in patients with intermediate or high risk for gastrointestinal events. The risk for gastrointestinal events are: (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. There is no documentation that the patient has GI issue that requires the use of prilosec. There is no documentation in the patient's chart supporting that she is at intermediate or high risk for developing gastrointestinal events. Therefore, the request for Omeprazole 20mg #30 with 3 refills is not medically necessary.