

<b>Case Number:</b>	CM15-0056595		
<b>Date Assigned:</b>	04/01/2015	<b>Date of Injury:</b>	01/05/2005
<b>Decision Date:</b>	05/19/2015	<b>UR Denial Date:</b>	03/13/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/25/2015

### 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: Pennsylvania

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 59-year-old male who sustained an industrial injury on 01/05/2005. Diagnoses include history of lumbosacral sprain/strain, lumbar degenerative disc disease with facet arthrosis and left radicular symptoms, left hip pain, left shoulder sprain/strain, and history of reactive depression. Treatment has included medications, home exercise program, and use of a cane for ambulation. Magnetic resonance imaging of the lumbar spine showed degenerative disc disease at L5-S1 with facet arthrosis and foraminal stenosis. Work status was noted as not working/medically retired on Social Security and disability. Medications in May 2012 included Vicodin, Lodine, and Omeprazole for dyspepsia secondary to Lodine. Vicodin, Lodine, and Omeprazole were continued in 2012 and 2013. A progress note from July 2013 noted that the injured worker had a narcotics contract with the treating physician's office, that urine drug screens have been appropriate. The injured worker reported at least 50% functional improvement with the medications, but the specific results related to any particular medication were not discussed. Some non-steroidal anti-inflammatory agents (NSAIDS) were noted to cause gastrointestinal (GI) upset. Back pain was rated at 8/10 in severity during most of 2012, 2013, and 2014. Nucynta and Mobic were prescribed in November 2013. Progress note of April 2014 notes that the injured worker continued to take Nucynta, and that he cannot take Norco or Tylenol with codeine as these medications made him sick in the past. Norco was prescribed in May 2014 and on 5/29/14, the physician documented that the injured worker found Norco helpful in the past. Medications in June 2014 included Vimovo and Xartemis; in July 2014, medications were Naprosyn and Norco. Medications in November 2014 were Naprosyn and Nucynta. On

2/26/15, the injured worker continued to report severe back pain with radiation to the hip. A 50% improvement in pain and 50% functional improvement with activities of daily living were reported with medications. Specific activities of daily living were not discussed. Examination showed decreased lumbar range of motion, inability to stand up straight, positive bilateral straight leg raise, and 4/5 weakness in the left thigh flexion, knee extension, and great toe extension. There was sensory loss to light touch and pinprick in the left lateral calf and bottom of the foot. The left hip was tender over the greater trochanter with a positive fabere maneuver. Left shoulder examination revealed decreased range of motion with crepitus noted and a positive impingement sign. Abdomen was soft, non-tender, with positive bowel sounds. Medications were Zorvolex, Omeprazole, and Norco. It was noted that the injured worker remained on Social Security disability. The physician documented that there was a narcotic contract and that urine drug screens were appropriate. No results or dates of urine drug screens were present in the documentation submitted. On 3/13/15, Utilization Review (UR) non-certified requests for Zorvolex 35 mg #90, Zorvolex 35 mg #30 sample tablets, Omeprazole 20 mg #30 sample, and Norco 10/325 #90, citing the MTUS and ODG.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **1 Prescription of Zorvolex 35mg #90: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, Medications for chronic pain; NSAIDs for Back Pain - Acute exacerbations of chronic pain; Back Pain - Chronic low back pain; NSAIDs, specific drug list & adverse effects Page(s): 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter: zorvolex, diclofenac.

**Decision rationale:** Per the MTUS for chronic pain, page 60, medications should be trialed one at a time, and there should be functional improvement with each medication. No reports show any specific benefit, functional or otherwise from using non-steroidal anti-inflammatory agents (NSAIDs). The treating physician refers to unspecified improvements in function and pain as a result of using all medications as a group. The specific results of any single medication are not apparent from the reports. The actual functions that are described are "not working" status, disability extreme enough to exit the work force and receive permanent benefits, and very poor ambulation ability. These are not good evidence of functional improvement with any of the treatments. Systemic toxicity is possible with NSAIDs. The FDA and MTUS recommend monitoring of blood tests and blood pressure. There is no evidence that the prescribing physician is adequately monitoring for toxicity as recommended by the FDA and MTUS, as there are no blood tests prescribed or discussed. This is particularly important for users of diclofenac, which has an FDA warning for liver toxicity among other effects. The MTUS does not recommend chronic NSAIDs for low back pain. NSAIDs should be used for the short term only. Acetaminophen is the drug of choice for flare-ups, followed by a short course of NSAIDs. The MTUS states that NSAIDs for arthritis are "Recommended at the lowest dose for the shortest

period in patients with moderate to severe pain." The MTUS does not specifically reference the use of NSAIDs for long term treatment of chronic pain in other specific body parts. NSAIDs are indicated for long term use only if there is specific benefit, symptomatic and functional, and an absence of serious side effects. As noted above, specific functional benefit has not been described. The Official Disability Guidelines, per the citation above, state that Zorvolex is not recommended except as a second-line option, because diclofenac products are not recommended as first-line choices due to potential increased adverse effects. 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. It is an expensive, brand name only, second-line medication with little to no place in the treatment of workers compensation injuries. For Diclofenac, the ODG states 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%. For a patient who has a 5% to 10% risk of having a heart attack that is a significant increase in absolute risk, particularly if there are other drugs that don't seem to have that risk. For people at very low risk, it may be an option. This injured worker has been treated with various NSAIDs from 2012-2015. The treating physician noted nonspecific functional improvement as a result of medications in general, but no specific improvement in activities of daily living was discussed, and the injured worker remained on Social Security disability and was not working. There was no documentation of the reason for prescription of Zorvolex instead of any other NSAID. Due to lack of documentation of specific functional improvement as a result of NSAID use and due to risk of toxicity, the request for Zorvolex is not medically necessary.

### **1 Prescription of Zorvolex 35mg #30 Sample Tablets: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, Medications for chronic pain, NSAIDs for Back Pain - Acute exacerbations of chronic pain, Back Pain - Chronic low back pain, NSAIDs, specific drug list & adverse effects Page(s): 60 and 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter: zorvolex, diclofenac.

**Decision rationale:** Per the MTUS for chronic pain, page 60, medications should be trialed one at a time, and there should be functional improvement with each medication. No reports show any specific benefit, functional or otherwise from using NSAIDs. The treating physician refers to unspecified improvements in function and pain as a result of using all medications as a group. The specific results of any single medication are not apparent from the reports. The actual functions that are described are "not working" status, disability extreme enough to exit the work force and receive permanent benefits, and very poor ambulation ability. These are not good evidence of functional improvement with any of the treatments. Systemic toxicity is possible

with NSAIDs. The FDA and MTUS recommend monitoring of blood tests and blood pressure. There is no evidence that the prescribing physician is adequately monitoring for toxicity as recommended by the FDA and MTUS, as there are no blood tests prescribed or discussed. This is particularly important for users of diclofenac, which has an FDA warning for liver toxicity among other effects. The MTUS does not recommend chronic NSAIDs for low back pain. NSAIDs should be used for the short term only. Acetaminophen is the drug of choice for flare-ups, followed by a short course of NSAIDs. The MTUS states that NSAIDs for arthritis are "Recommended at the lowest dose for the shortest period in patients with moderate to severe pain." The MTUS does not specifically reference the use of NSAIDs for long term treatment of chronic pain in other specific body parts. NSAIDs are indicated for long term use only if there is specific benefit, symptomatic and functional, and an absence of serious side effects. As noted above, specific functional benefit has not been described. The Official Disability Guidelines, per the citation above, state that Zorvolex is "not recommended except as a second-line option, because diclofenac products are not recommended as first-line choices due to potential increased adverse effects 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. It is an expensive, brand name only, second-line medication with little to no place in the treatment of workers compensation injuries." For diclofenac, the ODG states "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%. For a patient who has a 5% to 10% risk of having a heart attack that is a significant increase in absolute risk, particularly if there are other drugs that don't seem to have that risk. For people at very low risk, it may be an option." The treating physician has not adequately addressed the toxicity of Diclofenac. This NSAID is not medically necessary.

### **1 Prescription of Omeprazole 20mg #30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines GI symptoms & cardiovascular risk Page(s): 68 and 69.

**Decision rationale:** Per the MTUS, co-therapy with an NSAID is not indicated in patients other than those at high risk. The treating physician has noted the dyspepsia associated with using NSAIDs, which is an accepted indication for a proton pump inhibitor (PPI). However, the current NSAID is not medically necessary as discussed above. This PPI is therefore not medically necessary as a result.

### **1 Prescription of Omeprazole 20mg #30 sample: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms and cardiovascular risk Page(s): 68 and 69.

**Decision rationale:** Per the MTUS, co-therapy with an NSAID is not indicated in patients other than those at high risk. The treating physician has noted the dyspepsia associated with using NSAIDs, which is an accepted indication for a proton pump inhibitor (PPI). However, the current NSAID is not medically necessary as discussed above. This PPI is therefore not medically necessary as a result.

### **1 Prescription of Norco 10/325mg #90: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioid management; Opioids, steps to avoid misuse/addiction, indications, Chronic back pain, Mechanical and compressive etiologies, Medication trials Page(s): 94, 80, 81 and 60.

**Decision rationale:** There is insufficient evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, opioid contract, and there should be a prior failure of non-opioid therapy. The treating physician refers to drug testing, but no results are presented in the reports since 2012. Per the MTUS for chronic pain, page 60, medications should be trialed one at a time, and there should be functional improvement with each medication. No reports show any specific benefit, functional or otherwise from using opioids. The treating physician refers to unspecified improvements in function and pain as a result of using all medications as a group. The specific results of any single medication are not apparent from the reports. The actual functions that are described are "not working" status, disability extreme enough to exit the work force and receive permanent benefits, and very poor ambulation ability. These are not good evidence of functional improvement with any of the treatments. The prescribing physician describes this patient as disabled and not working, which fails the "return-to-work" criterion for opioids in the MTUS, and represents an inadequate focus on functional improvement. As currently prescribed, this opioid does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary.