

Case Number:	CM15-0185172		
Date Assigned:	09/25/2015	Date of Injury:	07/03/2005
Decision Date:	11/09/2015	UR Denial Date:	09/10/2015
Priority:	Standard	Application Received:	09/21/2015

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 52-year-old female with an industrial injury dated of 07-03-2005. Medical records indicate she is being treated for status post lumbar discectomy at lumbar 5-sacral, anxiety, depression and low back pain. Subjective findings (08-25-2015) included "radicular symptoms down the left lower extremity." The treating physician documented the injured worker needed refills of Voltaren, Prilosec, Zolofit and Ambien. Current medications continue to bring her pain level down from 8 out of 10 to 5 out of 10. Work status on 08-25-2015 is documented as: "No heavy lifting. No frequent bending, stooping." Prior progress note dated 05-05-2015 documented: "Pain level with Nucynta is 4 out of 10, without 8 out of 10." "When she is able she does help with quick meal preparation, dishes and laundry but activities are limited secondary to pain." "Prilosec helps with gastrointestinal upset." "Voltaren helps with inflammation." Prior treatment included physical therapy and medications. Current medications included Nucynta, Voltaren, Prilosec, Zolofit and Ambien. Review of prior records indicates the injured worker has been taking Voltaren, Nucynta and Prilosec at least since 12-14-2014. She was also receiving Ambien (12-14-2014) however, the treating physician noted in the 03-10-2015 note Ambien had been denied and Trazodone was requested. Objective findings (08-25-2015) included ongoing tenderness to lumbar paraspinal muscles with positive left leg lift. The treatment plan included Voltaren XR, Prilosec, Zolofit and Ambien. Other treatment plan included second opinion spine surgeon consultation and return in 3 months. The treatment note dated 05-05-2015 documented random urine drug screen today (05-05-2015) was consistent. We have updated signed pain agreement on file. The treatment request is for: Voltaren XR

100 mg #30 with three refills; Prilosec 20 mg #60 with three refills; Ambien 5 mg #30 with three refills. On 09-10-2015 utilization review non-certified the following requests: Voltaren XR 100 mg #30 with three refills; Prilosec 20 mg #60 with three refills; Ambien 5 mg #30 with three refills;

IMR ISSUES, DECISIONS AND RATIONALES

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

Voltaren XR 100mg #30 with three refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-inflammatory medications. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Diclofenac.

Decision rationale: According to the MTUS guidelines, anti-inflammatories are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. In addition, per ODG, Diclofenac 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%. 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 do not seem to have that risk. For people at very low risk, it may be an option. (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) In this nationwide cohort study the traditional NSAID diclofenac was associated with the highest increased risk of death or recurrent myocardial infarction (hazard ratio, 3.26; 95% confidence interval, 2.57 to 3.86 for death/MI at day 1 to 7 of treatment) in patients with prior MI, an even higher cardiovascular risk than the selective COX-2 inhibitor rofecoxib, which was withdrawn from the market due to its unfavorable cardiovascular risk profile. (Schjerning, 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. Diclofenac is associated with a significantly increased risk of cardiovascular complications and should be removed from essential-medicines lists, according to a new review. The increased risk with diclofenac was similar to Vioxx, a drug withdrawn from worldwide markets because of cardiovascular toxicity. Rofecoxib, etoricoxib, and diclofenac were the three agents that were consistently associated with a significantly increased risk when compared with nonuse. With diclofenac even in small doses, it increases the risk of cardiovascular events. They recommended naproxen as the NSAID of choice. (McGettigan, 2013) As noted above,

diclofenac containing agents are not supported due to increased risks. The request for Voltaren XR 100mg #30 with three refills is not medically necessary and appropriate.

Prilosec 20mg #60 with three refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: According to the MTUS guidelines, proton pump inhibitors may be indicated for the following cases: (1) age greater than 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). In this case, the request for NSAID Voltaren has not been deemed medically necessary and appropriate. Additionally, it should be noted that per the MTUS guidelines long-term use of proton pump inhibitors leads to an increased risk of hip fractures. ODG also address risks for proton pump inhibitors and notes that the potential adverse effects of long-term PPI use include B12 deficiency; iron deficiency; hypomagnesemia; increased susceptibility to pneumonia, enteric infections, and fractures; hypergastrinemia and cancer; and more recently adverse cardiovascular effects. The request for Prilosec 20mg #60 with three refills is not medically necessary and appropriate.

Ambien 5mg #30 with three refills: 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 Chapter.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Ambien.

Decision rationale: According to ODG, Zolpidem (Ambien) is a prescription short-acting nonbenzodiazepine hypnotic, which is recommended for short-term (7-10 days) treatment of insomnia. Per ODG, these medications can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. According to SAMHSA, zolpidem is linked to a sharp increase in ED visits, so it should be used safely for only a short period of time. The request for Ambien 5mg #30 with three refills is therefore not medically necessary and appropriate.