MAXIMUS Federal Services

Case Number:	CM15-0072758		
Date Assigned:	04/23/2015	Date of Injury:	02/21/2012
Decision Date:	05/26/2015	UR Denial Date:	04/08/2015
Priority:	Standard	Application Received:	04/16/2015

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:

This 63 year old man sustained an industrial injury on 2/21/2012 due to a fall. Diagnoses include lumbar spinal stenosis and left shoulder pain. Treatment has included oral medications, shoulder surgery, physical therapy, and chiropractic treatment. Evaluations include a lumbar spine MRIs dated 7/23/2014 and 10/26/2012. Physician notes from 11/6/14 document persistent severe back pain. Medications included naproxen, pantoprazole, quetiapine, and tramadol. Work restrictions were noted to include restriction of lifting to 10 pounds, restriction of no use at or above the left shoulder, and alternating between standing and sitting. Physician notes dated 1/26/2015 show continued complaints of back and leg pain. Protonix was noted to be used for gastrointestinal (GI) side effects of non-steroidal anti-inflammatory drugs (NSAIDS) with some symptoms of gastritis, and Seroquel was noted to be used for sleeplessness. GI review of systems was negative. Physical examination showed normal strength, tenderness over the L3-5 facet joints bilaterally, and symmetrical deep tendon reflexes. Work restrictions were noted to include restriction of lifting to 10 pounds, restriction of no use at or above the left shoulder, and alternating between standing and sitting. Recommendations include continued meds including Naproxen, Protonix, Seroquel, and Tramadol, and consultation with a surgeon as a second opinion. At visits on 3/9/15 and 4/6/15, the injured worker denied any significant changes in his pain complaints. Tramadol was noted to provide a 30-40% reduction in pain with increased ability to carry out activities such as standing and walking. Examination and work restrictions were unchanged. On 4/8/15, Utilization Review non-certified or modified requests for pantoprazole, quetiapine, tramadol, and naproxen, 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:

Pantoprazole (Protonix) 20mg #60 with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69.

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

Decision rationale: This injured worker has been prescribed naproxen, a non-steroidal anti-inflammatory medication (NSAID), and protonix (pantoprazole), a proton pump inhibitor (PPI). Per the MTUS, co-therapy with a non-steroidal anti-inflammatory medication (NSAID) and a proton pump inhibitor (PPI) is not indicated in patients other than those at intermediate or high risk for gastrointestinal events (including age > 65 years, history of peptic ulcer, gastrointestinal (GI) bleeding or perforation, concurrent use of aspirin, corticosteroids and/or an anticoagulant, or high dose/multiple NSAIDS such as NSAID plus low dose aspirin). None of these risk factors were noted for this injured worker. Long term proton pump inhibitor (PPI) use (> 1 year) has been shown to increase the risk of hip fracture. The injured worker has been prescribed pantoprazole for at least 5 months. Symptoms of gastritis were noted, without further discussion or documentation of evaluation. There are no medical reports which adequately describe signs and symptoms of possible GI (gastrointestinal) disease. There is no examination of the abdomen on record. There are many possible etiologies for GI symptoms; the available reports do not provide adequate consideration of these possibilities. Empiric treatment after minimal evaluation is not indicated. If one were to presume that a medication were to be the cause of the un-described gastrointestinal symptoms, the treating physician would be expected to change the medication regime accordingly, at least on a trial basis to help determine causation. The associated NSAID has been determined to be not medically necessary. Due to lack of specific indication and lack of documentation of GI evaluation, the request for pantoprazole is not medically necessary.

Naproxen sodium (Anaprox) #60 with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs), Naproxen Page(s): 67-68, 73.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 67-73.

Decision rationale: This injured worker has chronic back pain. Naproxen has been prescribed for at least 5 months. Per the MTUS, non-steroidal anti-inflammatory drugs (NSAIDs) are recommended as a second line treatment after acetaminophen for treatment of acute exacerbations of chronic back pain. NSAIDs are noted to have adverse effects including gastrointestinal side effects and increased cardiovascular risk; besides these well-documented

side effects of NSAIDs, NSAIDs have been shown to possibly delay and hamper healing in all the soft tissues including muscles, ligaments, tendons, and cartilage. NSAIDs can increase blood pressure and may cause fluid retention, edema, and congestive heart failure; all NSAIDS are relatively contraindicated in patients with renal insufficiency, congestive heart failure, or volume excess. They are recommended at the lowest dose for the shortest possible period in patients with moderate to severe pain. The MTUS does not recommend chronic NSAIDs for low back pain; NSAIDs should be used for the short term only. 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. There was no documentation of functional improvement as a result of naproxen. Work restrictions remain unchanged, there was no discussion of improvement in activities of daily living as a result of naproxen, and there was no documentation of decrease in medication use or decrease in frequency of office visits. Due to length of use in excess of the guidelines, lack of functional improvement and potential for toxicity, the request for naproxen is not medically necessary.

Quetiapine fumarate (Seroquel) 25mg #60 with 3 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 (ODG), Mental Illness & Stress, Atypical antipsychotics.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 15 Stress Related Conditions Page(s): 388. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) mental illness/stress chapter: Seroquel, atypical antipsychotics; pain chapter: anxiety medications in chronic pain; pain chapter: insomnia treatment.

Decision rationale: The ACOEM states that antidepressant or antipsychotic medication may be prescribed for major depression or psychosis, and that this is best done in conjunction with specialty referral. The ODG states that Seroquel is not recommended as a first line agent. There is insufficient evidence to recommend atypical antipsychotics for conditions covered in the ODG. Adding an atypical antipsychotic (such as quetiapine) to an antidepressant provides limited improvement in depressive symptoms in adults. A meta-analysis showed that the benefits of antipsychotics in terms of quality of life and improved functioning are small to nonexistent, and there is abundant evidence of potential treatment-related harm. In this case, the documentation indicates that seroquel was prescribed for insomnia. The ODG states that antipsychotics should be far down on the list of medications that should be used for insomnia as there is no good evidence to support this. The MTUS does not address the use of hypnotics other than benzodiazepines. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. For the treatment of insomnia, pharmacologic agents should only be used after careful evaluation of potential causes of sleep disturbance. Specific components of insomnia should be addressed. There was no documentation of evaluation of sleep disturbance in the injured worker, and components insomnia was not addressed. The treating physician has not addressed major issues affecting sleep in this patient, including the use of other psychoactive agents like opioids, which significantly impair sleep

architecture, and depression. Due to insufficient evaluation of sleep disturbance, and lack of recommendation of this agent by the guidelines, the request for seroquel is not medically necessary.

Tramadol HCL ER 100mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Criteria for Use, Weaning of Medications Page(s): 76-80, 124.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 74-96.

Decision rationale: This injured worker has chronic back pain. Tramadol has been prescribed for at least 5 months. Tramadol is a centrally acting synthetic opioid analgesic which is not recommended as a first line oral analgesic. Multiple side effects have been reported including increased risk of seizure especially in patients taking selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs) and other opioids. It may also produce life-threatening serotonin syndrome. 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, and opioid contract. There was no documentation of opioid contract, random drug testing, or functional goals. Per the MTUS, opioids are minimally indicated, if at all, for chronic non-specific pain, osteoarthritis, mechanical and compressive etiologies, "and chronic back pain. The MTUS states that a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. There is no evidence that the treating physician has utilized a treatment plan NOT using opioids, and that the patient has failed a trial of non-opioid analgesics." Ongoing management should reflect four domains of monitoring, including analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors. The documentation does note an improvement in pain as a result of tramadol. Improvement in standing and walking were also noted. However, there was no documentation of decrease in work restrictions, decrease in medication use, or decrease in frequency of office visits. This does not support decreased in dependence on medical care, which is required for the documentation of functional improvement. Screening for aberrant drug-taking behaviors was not documented. The MTUS recommends urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. There is no record of a urine drug screen program performed according to quality criteria in the MTUS and other guidelines. As currently prescribed, tramadol does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary.