

Case Number:	CM15-0034904		
Date Assigned:	03/03/2015	Date of Injury:	05/29/2012
Decision Date:	04/14/2015	UR Denial Date:	02/13/2015
Priority:	Standard	Application Received:	02/24/2015

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: District of Columbia, Virginia
 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 35 year old male, who sustained an industrial injury on May 29, 2012. He has reported a low back injury. The diagnoses have included lumbar disc displacement without myelopathy. Treatment to date has included medications, and surgery. Currently, the IW complains of low back pain. He rates his pain as 6/10 without medications, and 3/10 with medications. Physical findings are noted as tenderness with muscle spasms in the lumbar region. Range of motion is decreased by 10 percent. The records indicate he was weaned from Norco, and now uses Tramadol. On February 13, 2015, Utilization Review non-certified Protonix Pantoprazole 20mg, one capsule twice daily for stomach irritation #60, and Fexmid Cyclobenzaprine 7.5mg, one tablet three times daily #60, and Ultram Tramadol HCL ER 150mg, one capsule every day #60, and Protonix Pantoprazole 20mg, one capsule twice daily for stomach irritation #60, and Fexmid Cyclobenzaprine 7.5mg, one tablet three times daily #60. The MTUS guidelines were cited. On February 23, 2015, the injured worker submitted an application for IMR for review of Fexmid Cyclobenzaprine 7.5 mg, one tablet three times daily, #60, and Protonix Pantoprazole 20mg, one capsule twice daily for stomach irritation #60, and Ultram Tramadol HCL ER 150mg, one capsule every day #60, Protonix Pantoprazole 20mg, one capsule twice daily for stomach irritation #60, and Fexmid Cyclobenzaprine 7.5mg, one tablet three times daily #60.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective request for Protonix Pantoprazole 20mg 1 cap BID #60: 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 9792
Page(s): 68.

Decision rationale: Per MTUS: NSAIDs, GI symptoms & cardiovascular risk-Recommend with precautions as indicated below. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (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. Recommendations: Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) Patients at intermediate risk for gastrointestinal events and no cardiovascular disease:(1) Anon-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. This patient had no issues with GERD and was not on any NSAIDS. There is no indication for this patient to be on this medication.

Retrospective request for Fexmid Cyclobenzaprine 7.5mg 1tab TID #60: 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 9792
Page(s): 64.

Decision rationale: Per MTUS: Cyclobenzaprine (Flexeril, Amrix, Fexmid, generic available): Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement. The greatest effect appears to be in the first 4 days of treatment. (Browning, 2001) (Kinkade, 2007) (Toth, 2004) See Cyclobenzaprine. Cyclobenzaprine has been shown to produce a modest benefit in treatment of fibromyalgia. Cyclobenzaprine-treated patients with fibromyalgia were 3 times more likely to report overall improvement and to report moderate

reductions in individual symptoms (particularly sleep). A meta-analysis concluded that the number needed to treat for patients with fibromyalgia was 4.8. (ICSI, 2007) (Tofferi, 2004) Side Effects: Include anticholinergic effects (drowsiness, urinary retention and dry mouth). Sedative effects may limit use. Headache has been noted. This medication should be avoided in patients with arrhythmias, heart block, heart failure and recent myocardial infarction. Side effects limit use in the elderly. (See, 2008) (Toth, 2004) Dosing: 5 mg three times a day. Can be increased to 10 mg three times a day. This medication is not recommended to be used for longer than 2-3 weeks. (See, 2008) This medication is indicated for short term usage. The patient had chronic issues with spasms and pain. This medication would not be indicated.

Retrospective request for Ultram Tramadol HCL ER 150mg 1 cap OD #60: 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 9792 Page(s): 82-84.

Decision rationale: Tramadol: A recent Cochrane review found that this drug decreased pain intensity, produced symptom relief and improved function for a time period of up to three months but the benefits were small (a 12% decrease in pain intensity from baseline). Adverse events often caused study participants to discontinue this medication, and could limit usefulness. There are no long-term studies to allow for recommendations for longer than three months. (Cepeda, 2006) Similar findings were found in an evaluation of a formulation that combines immediate-release vs. extended release Tramadol. Adverse effects included nausea, constipation, dizziness/vertigo and somnolence. (Burch, 2007) Opioids for neuropathic pain not recommended as a first-line therapy. Opioid analgesics and Tramadol have been suggested as a second-line treatment (alone or in combination with first-line drugs). A recent consensus guideline stated that opioids could be considered first-line therapy for the following circumstances: (1) prompt pain relief while titrating a first-line drug; (2) treatment of episodic exacerbations of severe pain; [&] (3) treatment of neuropathic cancer pain. (Dworkin, 2007) Response of neuropathic pain to drugs may differ according to the etiology of therapeutic pain. There is limited assessment of effectiveness of opioids for neuropathic pain, with short-term studies showing contradictory results and intermediate studies (8-70 days) demonstrating efficacy. (Eisenberg-Cochrane, 2006) (Eisenberg-JAMA, 2005) The results of short-term trials were mixed with respect to analgesia (less than 24 hours of treatment). Intermediate trials (average treatment duration of 28 days) showed statistical significance for reducing neuropathic pain by 20% to 30% (and 30% may be the threshold for describing a meaningful reduction of pain). This patient was on this medication, which is considered second line. From the clinical data provided, there is no evidence that the patient was tried on other medication prior to this. This medication would not be indicated.

Retrospective request for Protonix Pantoprazole 20mg 1 cap BID #60: 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 9792
Page(s): 68.

Decision rationale: Per MTUS: NSAIDs, GI symptoms & cardiovascular risk recommend with precautions as indicated below. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (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. Recommendations Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) Anon-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2selective agent plus a PPI if absolutely necessary.

Retrospective request for Fexmid Cyclobenzaprine 7.5mg 1tab TID #60: 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 9792
Page(s): 64.

Decision rationale: Per MTUS: Cyclobenzaprine (Flexeril & #130;, Amrix & #130; Fexmid, generic available): Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement. The greatest effect appears to be in the first 4 days of treatment. (Browning, 2001) (Kinkade, 2007) (Toth, 2004) See Cyclobenzaprine. Cyclobenzaprine has been shown to produce a modest benefit in treatment of fibromyalgia. Cyclobenzaprine-treated patients with fibromyalgia were 3 times more likely to report overall improvement and to report moderate reductions in individual symptoms (particularly sleep). A meta-analysis concluded that the number needed to treat for patients with fibromyalgia was 4.8. (ICSI, 2007) (Tofferi, 2004) Side Effects: Include anticholinergic effects (drowsiness, urinary retention and dry mouth). Sedative effects may limit use. Headache has been noted. This medication should be avoided in patients with arrhythmias, heart block, heart failure and recent myocardial infarction. Side effects limit use in the elderly. (See, 2008) (Toth, 2004) Dosing: 5 mg three times a day. Can be increased to 10 mg three times a day. This medication is not recommended to be used for longer

than 2-3 weeks. (See, 2008) This medication is indicated for short term usage. The patient had chronic issues with spasms and pain. This medication would not be indicated.