

Case Number:	CM15-0075864		
Date Assigned:	04/27/2015	Date of Injury:	04/21/2004
Decision Date:	07/03/2015	UR Denial Date:	04/07/2015
Priority:	Standard	Application Received:	04/21/2015

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: Maryland, Texas, Virginia

Certification(s)/Specialty: Internal Medicine, Allergy and Immunology, Rheumatology

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 64 year old female who sustained an industrial injury on 4/21/04. She has reported initial complaints of neck, shoulder, wrist, and knee pain after a fall. The diagnoses have included cervical spondylosis, sprain of the knee and leg, sprain of the wrist, muscle spasm and fibromyositis. Treatment to date has included medications, diagnostics, injections, bracing and home exercise program (HEP). The current medications included Prozac, Wellbutrin, Abilify, Adderall, Amitiza, Duexis, Percocet, Soma, Ambien, Xanax and OxyContin. Currently, as per the physician progress note dated 3/25/15, the injured worker complains of pain in the left knee, neck and right shoulder which is constant, aching, and sharp. The average pain level is 5/10 on pain scale which is unchanged from previous visits. The medications prescribed currently allow her to function and perform her activities of daily living (ADL). The physical exam revealed decreased cervical range of motion with pain and tenderness. There was tenderness in the right shoulder region and diffuse upper extremity weakness was noted. The urine drug screen dated 11/5/15 was consistent with prescribed medications. The physician noted that she has ongoing chronic, intractable pain in the left knee, neck and right shoulder and she reports relief with use of medications which allow her to perform her activities of daily living (ADL). The physician requested treatments included Soma 350mg #90, Percocet 10/325mg #180, OxyContin extended release (ER) 30mg #90, Amitiza 24mcg #60, and Duexis 26.6mg-800mg, #90.

IMR ISSUES, DECISIONS AND RATIONALES

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

Soma 350mg, #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol (Soma), Weaning of Medications.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol (Soma) and Muscle relaxants (for pain) Page(s): s 29 and 63-66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Soma (Carisoprodol).

Decision rationale: Soma is the brand name version of the muscle relaxant Carisoprodol. MTUS guidelines state that Soma is, not recommended. This medication is not indicated for long-term use. MTUS continues by discussing several severe abuse, addiction, and withdrawal concerns regarding Soma. Soma is not recommended for longer than a 2 to 3 week period and that weaning of medication should occur, according to MTUS. The request for Soma 350mg #90 is in excess of the guidelines and weaning should occur. As such, the request for 1 prescription for Soma 350mg #90 is not medically necessary.

Percocet 10/325mg, #180: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for chronic pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back- Lumbar & Thoracic (Acute & Chronic), Opioids.

Decision rationale: Percocet (oxycodone with acetaminophen) is a short-acting opioid. Chronic pain guidelines and ODG does not recommend opioid, except for short use for severe cases, not to exceed 2 weeks. Routine long-term opioid therapy is not recommended and ODG recommends consideration of a one-month limit on opioids for new chronic non-malignant pain patients in most cases, as there is little research to support its use. The research available does not support overall general effectiveness and indicates numerous adverse effects with long-term use. The latter includes the risk of ongoing psychological dependence with difficulty weaning. Medical documents indicate that the patient has been on Percocet for several months, in excess of the recommended 2-week limit. Additionally, indications for when opioids should be discontinued include, if there is no overall improvement in function and unless there are extenuating circumstances. Medical records indicate that the overall pain level has increased over the last several months and there is lack of documentation of overall improvement in function or indications of when an opioid should be discontinued. As such, the request for Percocet 10/325MG #180 is not medically necessary.

Oxycontin extended release (ER) 30mg, #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Oxycontin (Oxycodone).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): s 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic) and Pain, Opioids.

Decision rationale: Oxycodone is the generic version of Oxycontin, which is a pure opioid agonist. ODG does not recommend the use of opioids for neck pain except for short use for severe cases, not to exceed 2 weeks. The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects is recommended. Pain assessment should include: current pain; the least reported pain over the period since last assessment, average pain and intensity of pain after taking the opioid, how long it takes for pain relief, and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. The treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, increased level of function, or improved quality of life. As such the request for Oxycontin extended release (ER) 30mg #90 is not medically necessary.

Amitiza 24mcg, #60: 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), Lubiprostone (Amitiza), Opioid-induced constipation treatment.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic pain, Opioid induced constipation <http://www.webmd.com/drugs/drug-95153-Amitiza+Oral.aspx?drugid=95153> <http://www.amitiza.com/>.

Decision rationale: MTUS is silent on Amitiza. ODG discusses Amitiza as a second line opioid induced constipation treatment. ODG states, First-line: When prescribing an opioid, and especially if it will be needed for more than a few days, there should be an open discussion with the patient that this medication may be constipating, and the first steps should be identified to correct this. Simple treatments include increasing physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber. These can reduce the chance and severity of opioid-induced constipation and constipation in general. In addition, some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Second-line: If the first-line treatments do not work, there are other second-line options. About 20 percent of patients on opioids develop constipation, and some of the traditional constipation medications don't work as well with these patients, because the problem is not from the gastrointestinal tract but from the central nervous system, so treating these patients is different from treating a traditional patient with constipation. An oral formulation of

methylnaltrexone (Relistor) met the primary and key secondary end points in a study that examined its effectiveness in relieving constipation related to opioid use for noncancer-related pain. The effectiveness of oral methylnaltrexone in this study was comparable to that reported in clinical studies of subcutaneous methylnaltrexone in subjects with chronic noncancer-related pain. There was an 80 percent improvement in response with the 450 mg dose and a 55 percent improvement with 300 mg. Constipation drug Lubiprostone (Amitiza) shows efficacy and tolerability in treating opioid-induced constipation without affecting patients' analgesic response to the pain medications. Lubiprostone is a locally acting chloride channel activator that has a distinctive mechanism that counteracts the constipation associated with opioids without interfering with the opiates binding to their target receptors. The treating physician has not provided documentation of a trial and failure of first line therapies which are (increased physical activity, maintaining appropriate hydration by drinking enough water, advising the patient to follow a proper diet, rich in fiber, or a trial of over the counter medication). As such the request for AMITIZA 24MCG #60 is not medically necessary.

Duexis 26.6mg-800mg, #90: 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): s 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk and Other Medical Treatment Guidelines Uptodate.com, NSAIDs (including aspirin): Primary prevention of gastroduodenal toxicity.

Decision rationale: Duexis is famotidine and ibuprofen. Ranitidine is an H2 antagonist used for the treatment of stomach ulcers and gastroesophageal reflux. MTUS states, "Determine if the patient is at risk for gastrointestinal events: (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)." And, "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-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 (greater than a 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." Uptodate states regarding H2 antagonist for GI prophylaxis states, "Standard doses of H2 receptor antagonists were not effective for the prevention of NSAID-induced gastric ulcers in most reports, although they may prevent duodenal ulcers [33]. Studies that detected a benefit on gastric ulcer prevention were short-term (12 to 24 weeks) and focused on endoscopic rather than clinical endpoints." The patient does not meet the age recommendations for increased GI risk. The medical documents provided do not indicate history of peptic ulcer, GI bleeding, or perforation. Medical records do not indicate that the patient is on ASA, corticosteroids, and/or an anticoagulant; or high dose/multiple NSAID. Additionally, uptodate suggests that H2 antagonist at this dose is not useful to prevent ulcers. As such, the request for Duexis 26.6mg-800mg #90 is not medically necessary.