

Case Number:	CM15-0169900		
Date Assigned:	09/10/2015	Date of Injury:	12/04/2001
Decision Date:	11/02/2015	UR Denial Date:	08/19/2015
Priority:	Standard	Application Received:	08/28/2015

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: Emergency 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 39 year old female who sustained an injury on 12-4-01 resulting when she fell at work picking up a box from overhead. Her chair tipped over and she fell on top of the chair with her back and neck hyper-extended. Diagnoses include lumbago; sacroiliitis; lumbar myofascial pain; lumbar spondylosis; anxiety; depression; chronic pain syndrome; opioid dependence; bipolar disease. The qualified medical examination on 2-6-12 indicates prescriptions Cymbalta 90 mg every night; Geodon 80 mg; Colace 200 mg and Senna 8.6 mg. were prescribed and on 5-4-15 she was to continue with Cymbalta 60 mg; Geodon 80 mg; (through her psychiatrist); Colace 250 mg and Senna 8.6 for constipation due to opioid use. She was to continue working with her psychiatrist in the treatment of bipolar disease and the anxiety associated with that. The examination on 6-1-15 indicates she is on chronic opioid management for a back problem and sacroiliitis and being prescribed Geodon 80 mg once a day as a mood stabilizer and Cymbalta 60 mg once a day as an anti-depressant; Colace 250 mg and Senna 8.6 for constipation due to opioids. Her mood is good, anxiety is low and attitude is positive. She continues to have painful areas in her lower back and SI joints. She is to continue to work on yoga, physical therapy, exercises, walking and diet. The review of symptoms report negative gastrointestinal stomach upset, abdominal cramps, nausea, vomiting, diarrhea, constipation, tarry stool or loss of bowel control. The abdomen is soft and non-tender with good bowel sounds heard throughout. Currently as indicated on 8-10-15 she has back pain that is being managed by opioid medication which she states is helping her a lot. She works 20-30 hours per week and states without these medications she would not be able to take care of herself or work. Oxycodone 10 mg and Dilaudid were prescribed and the report indicates she was stable on Geodon and

Cymbalta and her present medication regimen. Current requested treatments: Senna 8.6 quantity 60 with 5 refills; Colace 250 mg quantity 60 with 5 refills; Geodon 80 mg quantity 30 with 5 refills; Cymbalta 60 mg quantity 30 with 5 refills. Her utilization review 8-19-15 Senna 8.6 #60 with 5 refills was modified to 1 prescription Senna 8.6 #60 with no refills; Colace 250 mg #60 with 5 refills modified to 1 prescription of Colace 250 mg with no refills; Geodon 80 mg #30 with 5 refills was modified to 1 prescription with no refills; Cymbalta 60 mg #30 with 5 refills was modified to 1 prescription with no refills.

IMR ISSUES, DECISIONS AND RATIONALES

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

Senna 8.6 quantity 60 with five refills: Upheld

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

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

Decision rationale: The request is for a medication to aid in constipation. The Official Disability Guidelines state the following regarding this topic: Recommended as indicated below: In the section, Opioids, criteria for use, if prescribing opioids has been determined to be appropriate, then ODG recommends, under Initiating Therapy, that Prophylactic treatment of constipation should be initiated. Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral opioid receptors in the gastrointestinal (GI) tract results in absorption of electrolytes, such as chloride, with a subsequent reduction in small intestinal fluid. Activation of enteric opioid receptors also results in abnormal GI motility. Constipation occurs commonly in patients receiving opioids and can be severe enough to cause discontinuation of therapy. 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% 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 non-cancer-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 non-cancer-related pain. There was an 80% improvement in response with the 450 mg dose and a 55% 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. (Bader, 2013) (Gras-Miralles, 2013) See also Tapentadol (Nucynta), which has improved gastrointestinal tolerability for patients complaining of constipation, nausea, and/or vomiting. The FDA has approved methylnaltrexone bromide (Relistor) subcutaneous injection 12 mg/0.6 mL for the treatment of opioid-induced constipation in patients taking opioids for non-cancer pain. (FDA, 2014) As stated above, measures to combat constipation for patients on opioids are needed. In this case, the use of this medication is not certified. This is secondary to poor documentation of first-line therapy which includes activity and dietary measures including increased water intake. The request is not medically necessary.

Colace 250mg quantity 60 with five refills: Upheld

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

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

Decision rationale: The request is for a medication to aid in constipation. The Official Disability Guidelines state the following regarding this topic: Recommended as indicated below: In the section, Opioids, criteria for use, if prescribing opioids has been determined to be appropriate, then ODG recommends, under Initiating Therapy, that Prophylactic treatment of constipation should be initiated. Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral opioid receptors in the gastrointestinal (GI) tract results in absorption of electrolytes, such as chloride, with a subsequent reduction in small intestinal fluid. Activation of enteric opioid receptors also results in abnormal GI motility. Constipation occurs commonly in patients receiving opioids and can be severe enough to cause discontinuation of therapy. 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% 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 non-cancer 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 non-cancer-related pain. There was an 80% improvement in response with the 450 mg dose and a 55% 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. (Bader, 2013) (Gras-Miralles, 2013) See also Tapentadol (Nucynta), which has improved gastrointestinal tolerability for patients complaining of constipation, nausea, and/or vomiting. The FDA has approved methylnaltrexone bromide (Relistor) subcutaneous injection 12 mg/0.6 mL for the treatment of opioid-induced constipation in patients taking opioids for non-cancer pain. (FDA, 2014) As stated above, measures to combat constipation for patients on opioids are needed. In this case, the use of this medication is not certified. This is secondary to poor documentation of first-line therapy which includes activity and dietary measures including increased water intake. The request is not medically necessary.

Geodon 80mg quantity 30 with five refills: Overturned

Claims Administrator guideline: Decision based on MTUS Stress-Related Conditions 2004.

MAXIMUS guideline: Decision based on MTUS Stress-Related Conditions 2004, Section(s): General Approach.

Decision rationale: The request is for the use of an antipsychotic medication. The ACOEM guidelines state the following regarding this topic: Medications generally have a limited role. Limit use of anti-anxiety agents to short periods of time, i.e., periods when overwhelming anxiety limits the patient's ability to work or effectively perform the activities of daily living. Anti-depressant or anti-psychotic medication may be prescribed for major depression or psychosis; however, this is best done in conjunction with specialty referral. Also, the guidelines state the following: Continuing an established course of antipsychotics is important, but they can decrease motivation and effectiveness at work. If a referral is made, it is still important to plan how the patient using these drugs will manage at work or return to work even after being referred for specific psychiatric treatment. In this case, the use of an antipsychotic medication is appropriate based on the guidelines. Anti-psychotic medications require screening measures for potential side-effects incurred. As such, there should be documentation of an adequate response and lack of significant side effects seen for continued use. The request is medically necessary.

Cymbalta 60mg quantity 30 with five refills: Overturned

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): Antidepressants for chronic pain.

Decision rationale: The request is for the use of the medication Cymbalta which is in the category of a Selective serotonin and norepinephrine reuptake inhibitor. The MTUS guidelines state this drug is FDA-approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. It has been used off-label for neuropathic pain and radiculopathy. Duloxetine is recommended as a first-line option for diabetic neuropathy. (Dworkin, 2007) No high quality evidence is reported to support the use of Duloxetine for lumbar radiculopathy. In this case, there is adequate documentation of a diagnosis, which would qualify use of this medication. The patient has shown positive effects related to depression and anxiety with no described significant side effects. As such, the request is medically necessary.