

Case Number:	CM14-0156773		
Date Assigned:	09/26/2014	Date of Injury:	05/18/2007
Decision Date:	10/27/2014	UR Denial Date:	08/26/2014
Priority:	Standard	Application Received:	09/24/2014

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. The expert reviewer is Board Certified in Occupational Medicine and is licensed to practice in Montana. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 sustained a back injury on 5/18/07 when lifting a 35 pound bucket. His diagnoses include thoracic and lumbosacral neuritis/radiculitis, lumbar postlaminectomy syndrome and fibromyalgia. The treatment note of 8/22/14 documents complaint of low back pain with leg pain. The primary treating physician has requested Norco, Opana ER, Ambien, Miralax, Soma, and Xanax.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ambien 10mg HS #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Mental Illness & Stress; Insomnia treatment

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Drug Formulary, Zolpidem (Ambien)

Decision rationale: The ODG guidelines note that zolpidem (Ambien) is a prescription short-acting nonbenzodiazepine hypnotic, which is approved for the short-term (usually two to six weeks) treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain

and often is hard to obtain. Various medications may provide short-term benefit. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They 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. Ambien CR offers no significant clinical advantage over regular release zolpidem. Ambien CR is approved for chronic use, but chronic use of hypnotics in general is discouraged. Ambien CR causes a greater frequency of dizziness, drowsiness, and headache compared to immediate release zolpidem. Cognitive behavioral therapy (CBT) should be an important part of an insomnia treatment plan. A study of patients with persistent insomnia found that the addition of zolpidem immediate release to CBT was modestly beneficial during acute (first 6 weeks) therapy, but better long-term outcomes were achieved when zolpidem IR was discontinued and maintenance CBT continued. Due to adverse effects the FDA now requires lower doses for zolpidem. Even at the lower dose of Ambien CR now recommended by the FDA, 15% of women and 5% of men still had high levels of the drug in their system in the morning. 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. In this case the medical records document use of Ambien well beyond the two to six weeks (short-term) recommendation for treatment. The request for Ambien 10mg at HS #30 is not medically necessary.

Miralax 17 gram once a day #4-6 grams: 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 Opioids, Initiating therapy Page(s): 77. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Opioid induced constipation treatment

Decision rationale: Miralax is an osmotic laxative (polyethylene glycol) used for treatment of constipation. It is recommended for use for the shortest possible duration to avoid electrolyte disorders and laxative dependence. The MTUS does note that with initiation of opioid therapy prophylactic treatment of constipation should be initiated. Prophylactic treatment would include advising physical activity, maintaining appropriate hydration, and a proper diet rich in fiber. The ODG guidelines recommend opioid induced constipation treatment as indicated below. 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 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% 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. See also Tapentadol (Nucynta), which has improved gastrointestinal tolerability for patients complaining of constipation, nausea, and/or vomiting. In this case the medical records have not documented any issues with constipation or address first-line treatments noted above. Use of a laxative would not be indicated without documentation of constipation, unresponsive to first-line treatments. Additionally, the ODG recommends several other medications that might be more effective in opioid induced constipation. The request for Miralax is not medically necessary.

Opana ER 5mg 1-2 Q 12 hrs #120: 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 Opioids, Specific drug list, Oxymorphone (Opana). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Drug Formulary, Oxymorphone

Decision rationale: Opana ER is an extended release formulation of oxymorphone. The MTUS notes that Opana ER is not intended for PRN use. Patients are to avoid alcohol while on Opana ER due to increased (possibly fatal) plasma levels. The ODG guidelines note that oxymorphone (Opana) is not recommended. Due to issues of abuse and Black Box FDA warnings, oxymorphone is recommended as second line therapy for long acting opioids. Oxymorphone products do not appear to have any clear benefit over other agents and have disadvantages related to dose timing (taking the IR formulation with food can lead to overdose), and potential for serious adverse events (when the ER formulation is combined with alcohol use a potentially fatal overdose may result). (Opana FDA labeling) Since oxymorphone is recommended only as a second line therapy with significant potential for serious adverse events, the request for Opana ER 5 mg 1-2 Q 12 hours #120 is not medically necessary.

Soma 350mg BID #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants, Carisoprodol (Soma) Page(s): 65. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Muscle relaxants, Soma

Decision rationale: The MTUS notes that Soma is not recommended for longer than a 2 to 3 week period. It is metabolized to meprobamate, which requires classification as a schedule IV drug in some states. Withdrawal symptoms may occur with sudden discontinuation. It is suggested that its main effect is due to generalized sedation as well as treatment of anxiety. In this case the medical records document use of Soma for at least 3 months or longer, well beyond the 2 to 3 week recommendation. The request for Soma 350mg #60 is not medically necessary.

Xanax 0.25mg 1-2 tablets BID #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines, Muscle relaxants, Benzodiazepines Page(s): 24;66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Benzodiazepines

Decision rationale: Xanax is a benzodiazepine medication. Its range of action includes sedative/hypnotic, anxiolytic, anticonvulsant and muscle relaxant. Chronic benzodiazepines are the treatment of choice and very few conditions. The MTUS notes that benzodiazepines are not recommended due to rapid development of tolerance and dependence. There appears to be little benefit for the use of this class of drugs over non-benzodiazepines for treatment of spasm. The ODG guidelines note that benzodiazepines are not recommended for long-term use because long-term efficacy is unproven and there is a risk of psychological and physical dependence or frank addiction. Most guidelines limit use to 4 weeks. Benzodiazepines are a major cause of overdose, particularly as they act synergistically with other drugs such as opioids (mixed overdoses are often a cause of fatalities). Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly (3-14 day). Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. Tolerance to lethal effects does not occur and a maintenance dose may approach a lethal dose as the therapeutic index increases. The best prevention for substance use disorders due to benzodiazepines is careful prescribing. Adults who use hypnotics, including benzodiazepines such as temazepam, have a greater than 3-fold increased risk for early death, according to results of a large matched cohort survival analysis. The risks associated with hypnotics outweigh any benefits of hypnotics, according to the authors. Benzodiazepines are Not Recommended as first-line medications by ODG. Criteria for use if provider & payor agree to prescribe anyway: 1) Indications for use should be provided at the time of initial prescription. 2) Authorization after a one-month period should include the

specific necessity for ongoing use as well as documentation of efficacy. In this case there is no documentation of specific indications for use and necessity for ongoing use as recommended in the ODG guidelines. The records show that Xanax has been used for at least 3 months which is not consistent with the MTUS and ODG guidelines. The request for Xanax 0.25 mg 1-2 tablets BID #120 is not medically necessary.

Norco 10mg/325mg 1 tablet q 4-6pm #160: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 75, 78 and 91.

Decision rationale: Norco is a combination medication including hydrocodone, a short-acting opioid analgesic, and acetaminophen. The MTUS states that opioids are not recommended as first line therapy for neuropathic pain. Opioids are suggested for neuropathic pain that has not responded to first line recommendations including antidepressants and anticonvulsants. The MTUS states that reasonable alternatives to opioid use should be attempted. There should be a trial of non-opioid analgesics. When subjective complaints do not correlate with clinical studies a second opinion with a pain specialist and a psychological assessment should be obtained. The lowest possible dose should be prescribed to improve pain and function. Ongoing use of Norco requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: the least reported pain over the period since the last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Norco has a recommended maximum dose of 60 mg per 24 hours. The medical records document decreases in pain level up to 60% and increased function of 50%. His current Norco dose does not exceed the 60 mg per 24 hours which is the recommended maximum dose. There is no evidence for abuse or diversion. At this time there is adequate evidence for efficacy of his current treatment regimen which has been used for several months. I am reversing the prior UR decision. The request for Norco 10/325 mg 1 tablet Q 4-6 hrs PRN #160 is medically necessary.

