

Case Number:	CM13-0032604		
Date Assigned:	12/11/2013	Date of Injury:	09/13/2005
Decision Date:	03/18/2014	UR Denial Date:	09/09/2013
Priority:	Standard	Application Received:	10/08/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Emergency Medicine and is licensed to practice in New York and Tennessee. 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 physician 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 patient is a 46 year old female who was injured on September 13, 2005. The injury occurred while the patient was lifting a box of watermelons. The patient continued to experience low back pain that radiates into her extremities. The patient states that the pain level is 8/10 with medications and 9/10 without medications. Physical examination showed decreased range of motion of the lumbar spine and spinal vertebral tenderness at L4-S1. MRI of the lumbar spine dated March 20, 2012 showed interbody fusion and posterior fusion with evidence of hardware removal at L4-5. Diagnoses include lumbar radiculopathy, cervical radiculopathy, myalgia/myositis and chronic pain. Treatments included acupuncture and medications. Requests for authorization for acupuncture weekly for 4 weeks, Excite C lotion, 120 ml, Ambien 10 mg, gabapentin 300 mg, lortab 7.5/500, naproxen sodium 550 mg, Protonix DR 20 mg, senokot-S tablet, tizanidine HCl 2 mg, Wellbutrin XL 150 mg, and ibuprofen 600 mg were submitted on September 4, 2013.

IMR ISSUES, DECISIONS AND RATIONALES

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

Acupuncture (1) times a week for (4) weeks: Upheld

Claims Administrator guideline: Decision based on MTUS Acupuncture Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Acupuncture Treatment Guidelines.

Decision rationale: There is documentation in this case that the patient had received prior acupuncture treatments with improved pain control and functional improvement. Functional improvement is defined as a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam. The functional improvement stated in this case is not defined. There is no documentation of the activities of daily living that have improved and there are no reductions in work restrictions. The acupuncture is not recommended.

Exoten C lotion 120ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines, Topical Analgesics. Page(s): 111.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 111-112.

Decision rationale: Exoten C lotion is a compounded topical analgesic medication that containing methyl salicylate, menthol, and capsaicin. Topical analgesics are recommended for neuropathic pain when anticonvulsants and antidepressants have failed. Compounded topical analgesics are commonly prescribed and there is little to no research to support the use of these compounds. Methyl salicylate is a topical salicylate and is recommended, being significantly better than placebo in chronic pain. Capsaicin is recommended only as an option in patients who have not responded or cannot tolerate other treatments. It is recommended for osteoarthritis, fibromyalgia, and chronic non-specific back pain and is considered experimental in high doses. There are no guidelines present for menthol and it cannot be recommended. The guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." This compounded product contains a drug that is not recommended and is, therefore, not recommended.

Ambien 10mg tablet: 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), Treatment Index, 11th Edition (web), 2013, Pain, Zolpidem.

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

Decision rationale: Zolpidem is a prescription short-acting non-benzodiazepine 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. 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, FDA now requires lower doses for zolpidem. The dose of zolpidem for women should be lowered from 10 mg to 5 mg for IR products. In this case the patient had been on Ambien since at least November 2012 and was still reporting difficulty sleeping. IN this case the medication is being use as a long term medication which is not recommended. Furthermore, documentation does not support its effectiveness. The medication is not recommended.

Gabapentin 300mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs), Outcome Page(s): 16-17.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 17-18.

Decision rationale: Gabapentin is an anti-epileptic medication. Gabapentin has been shown to be effective for treatment of diabetic painful neuropathy and post herpetic neuralgia and has been considered as a first-line treatment for neuropathic pain and has FDA approval for treatment of post-herpetic neuralgia. Gabapentin appears to be effective in reducing abnormal hypersensitivity, to have anti-anxiety effects, and may be beneficial as a sleep aid. Gabapentin has a favorable side-effect profile, few clinically significant drug-drug interactions and is generally well tolerated; however, common side effects include dizziness, somnolence, confusion, ataxia, peripheral edema, dry mouth, and weight gain. It has been recommended for the treatment of pain from spinal cord injury, fibromyalgia, lumbar spinal stenosis, CRPS, and fibromyalgia. Recommended trial period is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. If inadequate control of pain is found, a switch to another first-line drug is recommended. This patient had been treated with gabapentin since at least November 2012. Documentation in the medical record does not indicate that the medication has been effective. The patient's diagnoses did not include any of the indications for gabapentin. Medical necessity and efficacy have not been established.

Lortab 7.5-500mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-82.

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

Decision rationale: The Physician Reviewer's decision rationale: Lortab is the compounded medication containing the opioid hydrocodone and acetaminophen. Chronic Pain Medical

Treatment Guidelines state that opioids are not recommended as a first line therapy. Opioid should be part of a treatment plan specific for the patient and should follow criteria for use. Criteria for use include establishment of a treatment plan, determination if pain is nociceptive or neuropathic, failure of pain relief with non-opioid analgesics, setting of specific functional goals, and opioid contract with agreement for random drug testing. If analgesia is not obtained, opioids should be discontinued. The patient should be screened for likelihood that he or she could be weaned from the opioids if there is no improvement in pain of function. It is recommended for short term use if first-line options, such as acetaminophen or NSAIDS have failed. Opioids are considered a second-line treatment for several reasons: (1) head-to-head comparisons have found that opioids produce more side effects than TCAs and gabapentin; (2) long-term safety has not been systematically studied; (3) long-term use may result in immunological and endocrine problems (including hypogonadism); (4) treatment may be associated with hyperalgesia; & (5) opioid use is associated with misuse/abuse. Opioids may be a safer choice for patients with cardiac and renal disease than antidepressants or anticonvulsants. Acetaminophen is recommended for treatment of chronic pain & acute exacerbations of chronic pain. Acetaminophen overdose is a well-known cause of acute liver failure. Hepatotoxicity from therapeutic doses is unusual. Renal insufficiency occurs in 1 to 2% of patients with overdose. The recommended dose for mild to moderate pain is 650 to 1000 mg orally every 4 hours with a maximum of 4 g/day. In this case, the patient had been receiving opioid medications since at least November, 2012. She was participating in a pain contract and had regular urine drug testing. However the patient was not obtaining analgesia. If analgesia is not obtained, opioids should be discontinued. The efficacy of the medication has not been established and is not recommended.

Naproxen sodium 500mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 68.

Decision rationale: Naproxen is a non-steroidal anti-inflammatory drug. Chronic Medical Treatment Guidelines state that "anti-inflammatory drugs are the traditional first line of treatment, but long term use may not be warranted". For osteoarthritis it was recommended that the lowest dose for the shortest length of time be used. It was not shown to be more effective than acetaminophen, and had more adverse side effects. Adverse effects for GI toxicity and renal function have been reported. Medications for chronic pain usually provide temporary relief. Medications should be prescribed only one at a time and should show effect within 1-3 days. Record of pain and function with the medication should be recorded. In this case the patient had been receiving the medication since at least November, 2012 and was not obtaining significant analgesia. Request for authorization for prescription for ibuprofen, another NSAID, was submitted at the same time. Two NSAIDS should not be prescribed concurrently. Risk of adverse effects increases without increase in analgesia. The medication is not recommended.

Protonix DR 20mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk Page(s): 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 68.

Decision rationale: Protonix is a proton pump inhibitor (PPI). PPIs are used in the treatment of peptic ulcer disease and may be prescribed in patients who are using non-steroidal anti-inflammatory drugs and are at high risk for gastrointestinal events. Risk factors for high-risk events are age greater than 65, history of peptic ulcer, GI bleeding or perforation, concurrent use of ASA, corticosteroids, and/or an anticoagulant, or high dose/multiple NSAID (e.g., NSAID + low-dose ASA). The patient in this case was using NSAID medication, but did not have any of the risk factors for a gastrointestinal event.

Senoket- S tablet: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 77.

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

Decision rationale: 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. If prescribing opioids has been determined to be appropriate, then ODG recommend that prophylactic treatment of constipation should be initiated. There is no documentation in the medical record that the patient was suffering from constipation. In addition the prescribed opioids have been determined to be inappropriate, obviating the need for a laxative. Medical necessity has not been established.

Tizanidine HCL 2mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain), Page(s): 66.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 63,65.

Decision rationale: Tizanidine is a muscle relaxant that acts centrally as an alpha2-adrenergic agonist that is FDA approved for management of spasticity. Side effects include somnolence, dizziness, dry mouth, hypotension, weakness, and hepatotoxicity. Non-sedating muscle

relaxants are recommended with caution as a second-line option for short-term (less than 2 weeks) treatment of acute exacerbations in patients with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Sedation is the most commonly reported adverse effect of muscle relaxant medications. The patient had been using the medication since at least November 2012 and had not obtained analgesia. Muscle relaxants are not indicated for long term use.

Wellbutrin XL 150mg: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain Page(s): 13-16.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 13-16.

Decision rationale: Wellbutrin is a second-generation non-tricyclic antidepressant. It has been shown to be effective in relieving neuropathic pain of different etiologies in a small trial, but there is no evidence of efficacy in patients with non-neuropathic chronic low back pain. Antidepressants are recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week. Assessment of treatment efficacy should include pain outcomes, an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. Side effects, including excessive sedation, should be assessed. It is recommended that these outcome measurements should be initiated at one week of treatment with a recommended trial of at least 4 weeks. The patient, in this case, had been taking Wellbutrin since at least November 2012. There is no documentation of functional improvement or changes in the use of analgesic medications. In addition, Wellbutrin is not a tricyclic which is the recommended first line therapy. The medication is not recommended.

Ibuprofen 600mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68,70.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 68.

Decision rationale: Ibuprofen is a non-steroidal anti-inflammatory drug. Chronic Medical Treatment Guidelines state that "anti-inflammatory drugs are the traditional first line of treatment, but long term use may not be warranted". For osteoarthritis it was recommended that the lowest dose for the shortest length of time be used. It was not shown to be more effective than acetaminophen, and had more adverse side effects. Adverse effects for GI toxicity and renal function have been reported. Medications for chronic pain usually provide temporary relief.

Medications should be prescribed only one at a time and should show effect within 1-3 days. Record of pain and function with the medication should be recorded. In this case the patient had been receiving NSAID since at least November, 2012 and was not obtaining significant analgesia. Request for authorization for prescription for naproxen, another NSAID, was submitted at the same time. Two NSAIDS should not be prescribed concurrently. Risk of adverse effects increases without increase in analgesia. The medication is not recommended.