

Case Number:	CM14-0090813		
Date Assigned:	09/10/2014	Date of Injury:	05/31/2006
Decision Date:	10/03/2014	UR Denial Date:	05/30/2014
Priority:	Standard	Application Received:	06/16/2014

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 Anesthesiology, has a subspecialty in Pain Medicine and is licensed to practice in Massachusetts. 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:

According to the documents available for review, the patient is a 60 year old female. The date of injury is May 31, 2006. The patient sustained injury to the lumbar spine. The exact mechanism of injury was not elaborating on in the notes available for review. The patient carries a current diagnosis of displacement of intravertebral disc without myelopathy. Patient complains of ongoing lumbar back pain with decreased range of motion in the lumbar spine. The patient is maintained any multimodal pain medication regimen including gabapentin, Norco, Prilosec, Topiramate Zanaflex. A request for gabapentin, Norco, Prilosec, Topiramate, Zanaflex and a urine drug screen was denied.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gabapentin 600mg, #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs: Neuropathic pain Page(s): 16.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 18.

Decision rationale: According to the MTUS, Gabapentin (Neurontin, Gabarone generic available) has been shown to be effective for treatment of diabetic painful neuropathy and

postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. Gabapentin is also recommended for spinal cord injury, CRPS, fibromyalgia, and lumbar spinal stenosis. According to the documents available for review, the patient has none of the aforementioned MTUS approved indications for the use of this medication. Therefore, at this time, the request is not medically necessary.

Norco 10/325mg, #180: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 80,81.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, On-Going Management Page(s): 74-97.

Decision rationale: According to the MTUS Chronic Pain Medical Treatment Guidelines section on Opioids, On-Going Management, p 74-97, (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; 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. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. (f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion). (g) Continuing review of overall situation with regard to non-opioid means of pain control. (h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Additionally, the MTUS states that continued use of opioids requires (a) the patient has returned to work, (b) the patient has improved functioning and pain. There is no current documentation of baseline pain, pain score with use of opioids, functional improvement on current regimen, side effects. Therefore, at this time, the request is not medically necessary.

Prilosec 20mg, #60: 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 PPI Page(s): 68-69.

Decision rationale: The MTUS makes the following recommendations for the use of proton pump inhibitors. 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) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 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. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI. Cardiovascular disease: A non-pharmacological choice should be the first option in patients with cardiac risk factors. It is then suggested that acetaminophen or aspirin be used for short term needs. An opioid also remains a short-term alternative for analgesia. Major risk factors (recent MI, or coronary artery surgery, including recent stent placement): If NSAID therapy is necessary, the suggested treatment is naproxyn plus low-dose aspirin plus a PPI. Mild to moderate risk factors: If long-term or high-dose therapy is required, full-dose naproxen (500 mg twice a day) appears to be the preferred choice of NSAID. If naproxyn is ineffective, the suggested treatment is (1) the addition of aspirin to naproxyn plus a PPI, or (2) a low-dose Cox-2 plus ASA. According to the records available for review the patient does not meet any of the guidelines required for the use of this medication therefore, at this time, the request is not medically necessary.

Zanaflex 4mg, #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Zanaflex Page(s): 63-66.

Decision rationale: According to the MTUS, Tizanidine (Zanaflex, generic available) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity;

unlabeled use for low back pain. (Malanga,2008) Eight studies have demonstrated efficacy for low back pain. (Chou, 2007) One study(conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. (Malanga, 2002) May also provide benefit as an adjunct treatment for fibromyalgia. (ICSI, 2007) Side effects: somnolence, dizziness, dry mouth, hypotension, weakness, hepatotoxicity (LFTsshould be monitored baseline, 1, 3, and 6 months). (See, 2008) Dosing: 4 mg initial dose; titrate gradually by 2 - 4 mg every 6 - 8 hours until therapeutic effect with tolerable side-effects; maximum 36 mg per day. (See, 2008) Use with caution in renal impairment; should be avoided in hepatic impairment. Tizanidine use has been associated withhepatic aminotransaminase elevations that are usually asymptomatic and reversible with discontinuation. However, according to the MTUS, Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (VanTulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) 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. Also there is no additional benefit shown in combination with NSAIDs. 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. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, methocarbamol, dantrolene and baclofen. (Chou, 2004) According to a recent review in American Family Physician, skeletal muscle relaxants are the most widely prescribed drug class for musculoskeletal conditions (18.5% of prescriptions), and the most commonly prescribed antispasmodic agents are carisoprodol, cyclobenzaprine, metaxalone, and methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. (See2, 2008) According to the documents available for review, the patient has been utilizing zanaflex for long-term treatment of chronic pain condition. This is in contrast to the MTUS recommendations for short-term treatment of acute exacerbations. Therefore, at this time, the request is not medically necessary.

Urine Drug Screen (UDS): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Drug Testing Page(s): 43.

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), Drug Testing

Decision rationale: UDT is Recommended as a tool to monitor compliance with prescribed substances, identify use of undisclosed substances, and uncover diversion of prescribed substances. The test should be used in conjunction with other clinical information when decisions are to be made to continue, adjust or discontinue treatment. This information includes clinical observation, results of addiction screening, pill counts, and prescription drug monitoring reports. The prescribing clinician should also pay close attention to information provided by

family members, other providers and pharmacy personnel. The frequency of urine drug testing may be dictated by state and local laws. Indications for UDT: At the onset of treatment: (1) UDT is recommended at the onset of treatment of a new patient who is already receiving a controlled substance or when chronic opioid management is considered. Urine drug testing is not generally recommended in acute treatment settings (i.e. when opioids are required for nociceptive pain). (2) In cases in which the patient asks for a specific drug. This is particularly the case if this drug has high abuse potential, the patient refuses other drug treatment and/or changes in scheduled drugs, or refuses generic drug substitution. (3) If the patient has a positive or "at risk" addiction screen on evaluation. This may also include evidence of a history of comorbid psychiatric disorder such as depression, anxiety, bipolar disorder, and/or personality disorder. See Opioids, screening tests for risk of addiction & misuse. (4) If aberrant behavior or misuse is suspected and/or detected. See Opioids, indicators for addiction & misuse. Ongoing monitoring: (1) If a patient has evidence of a "high risk" of addiction (including evidence of a comorbid psychiatric disorder (such as depression, anxiety, attention-deficit disorder, obsessive-compulsive disorder, bipolar disorder, and/or schizophrenia), has a history of aberrant behavior, personal or family history of substance dependence (addiction), or a personal history of sexual or physical trauma, ongoing urine drug testing is indicated as an adjunct to monitoring along with clinical exams and pill counts. See Opioids, tools for risk stratification & monitoring. (2) If dose increases are not decreasing pain and increasing function, consideration of UDT should be made to aid in evaluating medication compliance and adherence. According to the documents available for review, regarding the applicability of urine drug screen for ongoing monitoring, the patient has none of the aforementioned indications for use of such screening. Therefore, at this time, the request is not medically necessary.