MAXIMUS Federal Services

Case Number:	CM14-0136919		
Date Assigned:	09/05/2014	Date of Injury:	10/18/2009
Decision Date:	10/28/2014	UR Denial Date:	07/31/2014
Priority:	Standard	Application Received:	08/25/2014

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 Preventative Medicine, has a subspecialty in Occupational Medicine and is licensed to practice in Hawaii. 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:

This patient is a 57 year old employee with date of injury of 10/18/2009. Medical records indicate the patient is undergoing treatment for s/p left shoulder surgery; adhesive capsulitis of the bilateral shoulder with tendinitis; displacement of cervical intervertebral disc without myelopathy; multiple level disc disease in cervical spine; thoracic or lumbosacral neuritis or radiculitis unspecified; multiple level disc disease in lumbar spine with right sided lumbar radiculopathy; hernia of other specified sites without obstruction on gangrene; IBS; esophageal reflux and gastro esophageal reflux secondary to NSAIDS; Lumbar spine AME (11/18/2013); abdominal pain generalized and hemorrhaged of rectum and anus. She ran out of PPI and used Naproxen and her GERD flared up. Her IBS returned when she ran out of Citrucel. Subjective complaints include frequent pain in her head, rated 4/10. Her neck pain is constant, throbbing and radiates to bilateral upper extremities with numbness and tingling. She rates this pain a 5/10. In her lower back, she describes burning, stabbing and sharp pain that radiates from the right lower back to the bilateral legs. She has numbness and tingling in her buttocks. She rates this pain as 6/10. She says she has abdominal pain that she associates with taking medicine, rated 5/10. She says she has difficulty sleeping, increased anxiety and symptoms of depression. Her pain is aggravated by prolonged sitting, standing, walking, repetitive lifting and bending. She gets relief with rest, activity modification, heat/cold. Currently, the physiotherapy was helpful temporarily but her pain has been increasing, not decreasing. Objective findings include nonspecific tenderness to palpation in the right shoulder. Neer's test and impingement maneuver reveal pain on the left shoulder. She has nonspecific tenderness at both wrists. At the cervical spine there is no loss of sensibility, abnormal sensation or pain on the left or corresponding to the C5 dermatome. There is no loss of sensibility, abnormal sensation or pain on the left or right corresponding to the C7 or C8 dermatome. There is paraspinal tenderness to palpation at C1-2,

C2-3, C3-4, C5-6 and C6-7 and C7-T1. There is subocoipital tenderness bilaterally. There is no loss of sensibility, abnormal sensation or pain on the left or right corresponding to the T1 dermatome. There is paraspinal tenderness to palpation bilaterally, left greater than right at T1-2, T2-3, T3-4, T5-6 and T6-7, T7-8 and C7-T1. The upper trapezius has tenderness bilaterally, left greater than right. Forminal compression test reveals pain on both sides. There is no loss of sensibility, abnormal sensation or pain on the left or right corresponding to the L2, L3, L4, L5, S1 or S2 dermatomes. There is paraspinal tenderness to palpation bilaterally with spasm at T2-3, L3-4, L4-5 and L5-S1 and S1.Treatment has consisted of Vicodin, Tizanidine, Gabapentin, Levothyroxin, Tylenol, Chamomile tea for insomnia, Mint leaf for pain relief, Dexilant, Gaviscon and Citrucel. On 6/16/2014, she had a right and left lumbar translaminar L4-L5, L5-S1 epidural injection. The utilization review determination was rendered on 7/31/2014 recommending non-certification of for Gaviscon, 1 teaspoon 3 x daily, 1 bottle with 2 refills; Citrucel, 3 x daily with 2 refills and Dexilant 60mg #30, 1 capsule daily with 2 refills.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gaviscon, 1 teaspoon 3 x daily, 1 bottle with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms and Cardiovascular Risk Page(s): 68-69.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk http://www.webmd.com/drugs/2/drug-18801-2123/gaviscon-oral/calciumcarbonateantacid-oral/details

Decision rationale: Gaviscon is an over the counter medication used to treat heartburn, upset stomach, and acid reflux. It contains aluminum hydroxide and magnesium carbonate. MTUS states "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)." 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 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)." The medical documents provided do not establish the patient has having documented GI bleeding, perforation, peptic ulcer, high dose NSAID, or other GI risk factors as outlined in MTUS. The treating physican also requested Dexilant, a second line PPI. As such, the request for Gaviscon , 1 teaspoon 3 x daily, 1 bottle with 2 refills is not medically necessary.

Citrucel, 3 x daily with 2 refills: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Chronic Pain, Opioid induced Constipation http://www.webmd.com/drugs/2/drug-6149/citrucel-oral/details

Decision rationale: Cirtucel is an over the counter medication used to treat constipation by adding bulk to the stool. 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% 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." The treating physician has not provided documentation of recommending increased physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber. As such the request for Citrucel, 3 x daily with 2 refills is not medically necessary

Dexilant 60mg #30, 1 capsule daily with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms and Cardiovascular Risk Page(s): 68-69.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk

Decision rationale: Dexilant is the brand name version of dexlansoprazole, which is a proton pump inhibitor. MTUS states, "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)." 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 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)." ODG states, "If a PPI is used, omeprazole OTC tablets or lansoprazole 24HR OTC are recommended for an equivalent clinical efficacy and significant cost savings. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011)." The medical documents provided do not establish the patient as having documented GI bleeding/perforation/peptic ulcer or other GI risk factors as outlined in MTUS. Additionally, there is no evidence provided to indicate the patient suffers from dyspepsia because of the present medication regiment. Per guidelines, Dexlansoprazole is considered second line therapy and the treating physician has not provided detailed documentation of a failed trial of omeprazole and/or lansoprazole. As such, the request for Dexilant 60mg #30, 1 capsule daily with 2 refills is not medically necessary