

Case Number:	CM15-0059721		
Date Assigned:	04/06/2015	Date of Injury:	06/18/2009
Decision Date:	09/22/2015	UR Denial Date:	03/03/2015
Priority:	Standard	Application Received:	03/30/2015

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: Indiana

Certification(s)/Specialty: Preventive Medicine, Occupational 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 61 year old male who sustained an industrial injury on 06/18/2009. Mechanism of injury was not documented. Diagnoses include severe cervical spondylosis with bilateral upper extremity radiating symptoms, bilateral knee internal derangement; status post left knee arthroscopy, status post left carpal tunnel released, severe gastritis and sleep disorder. He also has severe gastritis, irritable bowel syndrome/diverticulitis and ulcerative colitis. Treatment to date has included diagnostic studies, medications, surgery, cold therapy, physical therapy, and epidural blocks. The injured worker is not working, and is permanent and stationary. The most recent physician progress note, a Qualified Medical Re-Evaluation, dated 07/15/2014 documents the injured worker complains of pain in the neck radiating down through the arms with an achy pain. Pain in both knees and knee buckles, left side is worse than the right, carpal tunnel syndrome left, released in 2009 but the left hand fingers including the thumb are still numb. He has pain in his neck, shoulders, arms, hand and finger numbness and pack pain and bilateral knee pain. Pain is constant. It is sometimes achy and stabbing and sharp. He feels discomfort most of the time. He rates his pain as 6-8 out of 10 on the pain schedule with the maximum pain being 10. He has weakness in his hands and knees, and swelling in his hands, knees and fingers. His neck and knees pop and grind. Fingers and knees lock, and knees give out. Treatment requested is for Celebrex 200mg tablet #30, Dexilant 60mg tablet #30, Levsin 0.125mg #30, Lyrica 75mg tablet #90, Tizanidine 4mg #90, and Tramadol 50mg #120.

IMR ISSUES, DECISIONS AND RATIONALES

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

Celebrex 200mg tablet #30: 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 NSAIDs; anti-inflammatory medications Page(s): 22, 30, 70. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: Anti-inflammatory medications are the traditional first line treatment for pain, but COX-2 inhibitors (Celebrex) should be considered if the patient has risk of GI complications, according to MTUS. The medical documentation provided does not indicate a reason for the patient to be considered high risk for GI complications. Risk factors for GI bleeding according to ODG include: (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 or multiple NSAID (e.g., NSAID + low-dose ASA). Additionally, the medical records do not indicate that he is undergoing treatment for any of the FDA approved uses such as osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis in patients 2 years and older, ankylosing spondylitis, acute pain, and primary dysmenorrhea. As such, the request is not medically necessary.

Tramadol 50mg #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; Tramadol Page(s): 74-123. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) - Medications for acute pain (analgesics), Tramadol (Ultram®).

Decision rationale: Ultram is the brand name version of tramadol, which is classified as central acting synthetic opioids. MTUS states regarding tramadol that "A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals". ODG further states, "Tramadol is not recommended as a first-line oral analgesic because of its inferior efficacy to a combination of Hydrocodone/acetaminophen". The treating physician did not provide sufficient documentation that the patient has failed a trial of non-opioid analgesics at the time of prescription or in subsequent medical notes. Additionally, no documentation was provided which discussed the setting of goals for the use of tramadol prior to the initiation of this medication. The original utilization review recommended weaning and modified the request, which is appropriate. As such, the request for tramadol #120 is not medically necessary.

Dexilant 60mg tablet #30: 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 NSAIDs; GI risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: 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 (200g 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 patient does not meet the age recommendations for increased GI risk. The medical documents provided establish the patient has experienced GI discomfort, but is nonspecific and does not indicate history of peptic ulcer, GI bleeding or perforation. Medical records do not indicate that the patient is on ASA, corticosteroids, and/or an anticoagulant; or high dose/multiple NSAID. Additionally per guidelines, Dexilant 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 is not medically necessary.

Lyrica 75mg tablet #90: 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 anti-epilepsy drugs; Lyrica Page(s): 16-17; 99. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Anti-epilepsy drugs (AEDs) for pain.

Decision rationale: MTUS and ODG state that "Pregabalin (Lyrica) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. Pregabalin was also approved to treat fibromyalgia. See Anti-epilepsy drugs (AEDs) for general guidelines, as well as specific

Pregabalin listing for more information and references". MTUS additionally comments "Anti-epilepsy drugs (AEDs) are also referred to as anti-convulsants. Recommended for neuropathic pain (pain due to nerve damage) . . . A 'good' response to the use of AEDs has been defined as a 50% reduction in pain and a 'moderate' response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the 'trigger' for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails. (Eisenberg, 2007) (Jensen, 2006) After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use". The patient appears to have established neuropathic pain for which Lyrica is an appropriate medication. The medical records provided do not detail any objective improvement over the last several months. Overall, pain improvement has not been documented. Given the lack of subjective and objective improvement, a request more Lyrica is not appropriate. As such, the request is not medically necessary.

Tizanidine 4mg #90: 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 Zanaflex Page(s): 63-67.

Decision rationale: Zanaflex is the brand name version of tizanidine, which is a muscle relaxant. MTUS states concerning muscle relaxants "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) (Van Tulder, 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. (Homik, 2004) 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. (See 2, 2008)". MTUS further states, "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)". In this case, there is no medical documentation of an acute exacerbation, since the original injury occurred in 2009. Therefore, the request is not medically necessary.

Levain 0.125mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation WebMD: Levain: <http://www.webmd.com/drugs/2/drug-13766/hyoscyamine-oral/details>.

Decision rationale: MTUS and ODG do not address Levain. The above cited reference states the following: "Hyoscyamine is used to treat a variety of stomach/intestinal problems such as cramps and irritable bowel syndrome. It is also used to treat other conditions such as bladder and bowel control problems, cramping pain caused by kidney stones and gallstones, and Parkinson's disease. In addition, it is used to decrease side effects of certain medications (drugs used to treat myasthenia gravis) and insecticides. This medication works by decreasing acid production in the stomach, slowing down the natural movements of the gut, and relaxing muscles in many organs (e.g., stomach, intestines, bladder, kidney, gall bladder). Hyoscyamine also lessens the amount of certain body fluids (e.g., saliva, sweat). This medication belongs to a class of drugs known as anticholinergics/antispasmodics." There is no medical documentation that the employee has any of the above conditions and has failed first line therapy for them. Therefore, the request is not medically necessary.