MAXIMUS Federal Services

Case Number:	CM15-0124285		
Date Assigned:	07/08/2015	Date of Injury:	08/20/2009
Decision Date:	08/05/2015	UR Denial Date:	06/23/2015
Priority:	Standard	Application Received:	06/26/2015

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: Iowa, Illinois, Hawaii
Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive 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 60 year old male, who sustained an industrial injury on 8/20/2009. He reported hearing and feeling a pop in his lower back with increased pain radiating into the right buttock and leg. Diagnoses have included lumbar degenerative joint disease, chronic low back pain with disc protrusion L5-S1, chronic right sciatica and opioid-induced constipation. Treatment to date has included magnetic resonance imaging (MRI), epidural steroid injections, physical therapy and medication. According to the progress report dated 6/18/2015, the injured worker complained of low back pain with radiation to the right lower extremity. Physical exam was noted to be unchanged. Authorization was requested for Amitiza and Tegretol.

IMR ISSUES, DECISIONS AND RATIONALES

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

Amitiza 24mcg (Unspecified Quantity): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation WebMDFDA.com.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Opioid induced Constipation and Other Medical Treatment Guidelines http://www.webmd.com/drugs/drug-95153-Amitiza+Oral.aspx?drugid=95153http://www.amitiza.com/.

Decision rationale: MTUS is silent on Amitza. ODG discusses Amitza as a second line opioid induced constipation treatment. 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 non-cancer-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 non-cancer-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 a trial and failure of first line therapies (increased physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber; a trial of over the counter medication). Additionally, the treating physician has not provided the number of this medication being requested. As such the request for Amitiza 24mcg (Unspecified Quantity) is not medically necessary.

Tegretol 200mg (Unspecified Quantity): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs) Page(s): 16. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Anti-epilepsy drugs (AEDs) for pain.

Decision rationale: MTUS states that anti-epilepsy drugs are recommended, but do specify with caveats by medication. MTUS states "is among the AEDs most recently approved, while these drugs may be effective for neuropathic pain, the ultimate role of these agents for pain requires further research and experience (ICSI, 2007) (Knotkova, 2007) (Eisenberg, 2007). In the interim, these agents should be used to treat neuropathic pain only when carbamazepine, gabapentin, or lamotrigine cannot be used. (Guay, 2003)." ODG states "Carbamazepine (Tegretol, Tegretol-XR, Carbatrol, Epitol, Equetro", generic available) has been shown to be effective for trigeminal neuralgia (Backonja, 2002) (ICSI, 2007) (Finnerup, 2005) and has been FDA approved for this indication. The NNT for this medication for trigeminal neuralgia has been reported as 2.6. (Backonja, 2002) Side Effect Profile: Carbamazepine's use is often limited because of side-effects, (Knotkova, 2007) including ataxia, cognitive decreases (Namaka, 2004), dizziness, somnolence, CNS depression, hyponatremia, nausea and vomiting, skin rashes (rarely Stevens-Johnson Syndrome has been reported) and hematolgic disorders, including agranulycytosis and aplastic anemia. There is a black box warning regarding development of potentially fatal blood cell abnormalities following the use of carbamazepine, and the drug should be discontinued at the first sign of a rash. Pretreatment CBC should be obtained for monitoring purposes; other monitoring parameters include: CBC with platelet count, reticulocytes, serum iron, lipid panel, liver function tests, urinalysis, BUN, serum carbamazepine levels, thyroid function tests, serum sodium; ophthalmic exams (pupillary reflexes). Patient should also be observed for excessive sedation during initial therapy or when increasing dose. Additionally, a long-term effect of weight gain has been reported. This medication also has significant drug-drug interactions. The number needed to treat (NNT) for this medication for overall neuropathic pain is 2.5; while the number needed to harm found in the Cochrane review was 3.7. (Wiffen-Cochrane, 2005) Dosing Information: Trigeminal neuralgia "Begin with 100 mg twice daily with food; increase in increments of 100 mg twice daily as needed as tolerated. Usual dose is between 400-800 mg daily in two divided doses. Maximum dose 1200 mg/day." The medical documentation provided does not indicate the patient has been diagnosed with the conditions outlined above. Additionally, the treating physician has not specified the number of medication being requested, without this, the request cannot be certified. As such, the request for Tegretol 200mg (Unspecified Quantity) is not medically necessary.