

Case Number:	CM15-0119387		
Date Assigned:	06/29/2015	Date of Injury:	12/18/2007
Decision Date:	09/24/2015	UR Denial Date:	06/02/2015
Priority:	Standard	Application Received:	06/19/2015

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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 male who sustained an industrial injury on 12/18/07. The injured worker was diagnosed as having failed back surgery syndrome of the lumbar spine with residual left lower extremity complex regional pain syndrome with low back pain, status post right femoral nerve injury with intravenous filter placement, knee degenerative joint disease, constipation. Currently, the injured worker was with complaints of pain in the lower back and lower extremity. Previous treatments included epidural steroid injection, oral muscle relaxant, oral pain medication, intrathecal pain pump, use of a wheel chair. Previous diagnostic studies are not included in the provided documentation. The injured workers pain level was noted as 8/10. Physical examination was notable for bilateral legs edematous to the knees with decreased sensation of the left leg with stasis changes from the knee down. The plan of care was for Amitiza 8 micrograms quantity of 60 and Gralise 600 milligrams quantity of 90.

IMR ISSUES, DECISIONS AND RATIONALES

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

Amitiza 8mcg #60: 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 Official Disability Guidelines (ODG) Pain Chapter, under Lubiprostone (Amitiza®), Opioid-induced constipation treatment.

Decision rationale: The patient presents on 06/02/15 with pain in the lower back and hips. The handwritten progress note is poorly scanned and handwritten, illegible in some portions. The patient's date of injury is 12/18/07. Patient is status post multiple lumbar spine surgeries, cancer, and several serious operative complications and infections. The request is for AMITIZA 8MCG #60. The RFA was not provided. Physical examination dated 06/02/15 is almost entirely illegible, the legible findings include edematous lower extremities, and decreased sensation in the left lower extremity. The patient's current medication regimen is illegible. Patient is currently disabled. Official Disability Guidelines, Pain Chapter, under Lubiprostone (Amitiza): Recommended only as a possible second-line treatment for opioid-induced constipation. Official Disability Guidelines, under Opioid-induced constipation treatment provides clearer guidance: 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. In regard to the request for the continuation of Amitiza, the treater has not provided a reason for the request. This patient presents with a significant medical and surgical history, and is currently utilizing an opioid pain pump. Guidelines provide firm support for medications intended to reduce opioid-induced constipation, however it not clear why this patient is tolerant of first line therapies. Without a clear rationale as to why first-line constipation therapies are insufficient or not tolerated by this patient, the request cannot be substantiated. Therefore, the request IS NOT medically necessary.

Gralise 600mg #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 Gabapentin, Medications for chronic pain Page(s): 18-19, 64.

Decision rationale: The patient presents on 06/02/15 with pain in the lower back and hips. The handwritten progress note is poorly scanned and handwritten, illegible in some portions. The patient's date of injury is 12/18/07. Patient is status post multiple lumbar spine surgeries, cancer, and several serious operative complications and infections. The request is for GRALISE 600MG #90. The RFA was not provided. Physical examination dated 06/02/15 is almost entirely illegible, the legible findings include edematous lower extremities, and decreased sensation in the left lower extremity. The patient's current medication regimen is illegible. Patient is currently disabled. MTUS Guidelines, Gabapentin section on pg 18, 19 has the following: Gabapentin - Neurontin, Gabarone, generic available 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. MTUS Guidelines, Medications for chronic pain section, page 64 also states: "A record of pain and function with the medication should be recorded," when medications are used for chronic pain. In regard to the continuation of Gralise for this patient's neuropathic pain, the requesting physician has not provided adequate documentation of analgesia. This patient has been prescribed Gabapentin long term for lower back pain with a neurological component, and presents with a significant medical/surgical history. Progress report dated 06/02/15 has the following regarding analgesia: "unsatisfactory." The remaining progress note is handwritten, poorly scanned, and very difficult to decipher. Given this patient's significant surgical history and presentation, this medication would generally be considered a first-line treatment modality. However, MTUS guidelines require at least some clear documentation of medication efficacy to substantiate continuation. In this case, no such clear documentation is provided. The request IS NOT medically necessary.