

Case Number:	CM15-0161005		
Date Assigned:	08/27/2015	Date of Injury:	06/16/2006
Decision Date:	09/30/2015	UR Denial Date:	08/07/2015
Priority:	Standard	Application Received:	08/17/2015

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 41 year old female who sustained a work related injury June 16, 2006. Past history included fracture right ankle with an ORIF (open reduction internal fixation) repair. According to a primary treating physician's progress report, dated July 22, 2015, the injured worker presented with continued right ankle pain, rated 8 out of 10, with a burning sensation. She reports difficulty bearing weight and ambulating. She rates her pain 10 out of 10 without medication and 4 out of 10 with medication. There is a 50% reduction in pain with medication and she also reports to sometimes needing a cane or walker to ambulate. Physical examination revealed; disuse atrophy in the right ankle and thigh; allodynia to light touch and summation to pinprick; right lower extremity is cold to touch; 4 out of 5 weakness in dorsiflexion of the foot, plantar flexion, and right thigh flexion; reproducible pain with inversion of the ankle, otherwise full range of motion. Impressions are severe complex regional pain syndrome with allodynia symptoms with development of opioid dependence over the years; insomnia due to pain; neurogenic claudication leg cramps (stable, with as needed Robaxin); constipation; neuropathic pain (improved with Lyrica and Neurontin). Physician documented urine drug screens have been appropriate. At issue, is the request for authorization for Amitiza and Duragesic.

IMR ISSUES, DECISIONS AND RATIONALES

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

Amitiza 24mcg #60: Upheld

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

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®).

Decision rationale: The patient presents on 07/22/15 with right ankle pain rated 8/10 without medications, 4/10 with medications. The patient's date of injury is 06/16/06. Patient is status post open reduction and internal fixation of right ankle fracture at a date unspecified. The request is for AMITIZA 24MCG #60. The RFA is dated 07/27/15. Physical examination dated 07/22/15 reveals diffuse atrophy in the right ankle and thigh, allodynia to light touch, reduced temperature in the right lower extremity, pain elicitation upon inversion of the right ankle. The patient is currently prescribed Duragesic, Oxycodone, Rozerem, Doxepin, Cymbalta, Lyrica, Neurontin, Colace, Senokot, Amitiza, Miralax, Clonazepam, and Robaxin. Patient's current work status is not provided. 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 do not 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. In regard to the request for the continuation of Amitiza, the treater has not provided a reason for the request. This patient is currently taking at least 4 medications for opioid-induced constipation: Miralax, Colace, Senokot, and Amitiza. Guidelines provide firm support for medications intended to reduce opioid-induced constipation, however it not clear if this patient is intolerant of first line therapies or if they are not effective. Amitiza is considered by ODG to be a second-line medication for complaints of this nature, and is generally only used in cases where first-line medications are either ineffective or not tolerated. 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.

Duragesic 75mcg patch #15: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Duragesic (Fentanyl Transdermal System), Opioids Page(s): 44, 86.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain CRITERIA FOR USE OF OPIOIDS Page(s): 60, 61, 76-78, 88, 89.

Decision rationale: The patient presents on 07/22/15 with right ankle pain rated 8/10 without medications, 4/10 with medications. The patient's date of injury is 06/16/06. Patient is status post open reduction and internal fixation of right ankle fracture at a date unspecified. The request is for DURAGESIC 75MCG PATCH #15. The RFA is dated 07/27/15. Physical examination dated 07/22/15 reveals diffuse atrophy in the right ankle and thigh, allodynia to light touch, reduced temperature in the right lower extremity, pain elicitation upon inversion of the right ankle. The patient is currently prescribed Duragesic, Oxycodone, Rozerem, Doxepin, Cymbalta, Lyrica, Neurontin, Colace, Senokot, Amitiza, Miralax, Clonazepam, and Robaxin. Patient's current work status is not provided. MTUS Chronic Pain Medical Treatment Guidelines, page 44, states: "Duragesic-Fentanyl transdermal system- is not recommended as a first line therapy. Duragesic is a trade name of Fentanyl transdermal therapeutic system which releases Fentanyl, a potent opioid, slowly to the skin. For chronic opiate use, MTUS Guidelines pages 88 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 also requires documentation of the 4As (analgesia, ADLs, adverse side effects, and aberrant behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief." In regard to the request for additional Duragesic patches for the management of this patient's chronic intractable pain, the treater has not provided adequate documentation to substantiate continued use. Progress report dated 07/22/15/15 notes a reduction in pain from 8/10 without medications to 4/10 with medications. In regard to functional benefits, the note states "She states she cannot function without her medication regimen... 50% reduction in pain and functional improvement with the medications versus not taking them at all..." It is also noted that this patient's urine drug screening is consistent. Such vague documentation does not satisfy MTUS guidelines, which require documentation of analgesia via a validated scale, activity-specific functional improvements, consistent urine drug screening, and a stated lack of aberrant behavior. In this case, the provider has documented analgesia, but has not provided activity-specific functional improvements or a stated lack of aberrant behavior. Without such documentation, continuation of this medication cannot be substantiated. Owing to a lack of complete 4A's documentation as required by MTUS, continuation of this medication cannot be substantiated. The request IS NOT medically necessary.