

<b>Case Number:</b>	CM15-0081181		
<b>Date Assigned:</b>	05/01/2015	<b>Date of Injury:</b>	10/04/2011
<b>Decision Date:</b>	06/08/2015	<b>UR Denial Date:</b>	04/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/28/2015

### 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: Maryland, Texas, Virginia

Certification(s)/Specialty: Internal Medicine, Allergy and Immunology, Rheumatology

### 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 64-year-old male, who sustained an industrial injury on 10/4/11. He reported pain in the neck, lower back, and left wrist. The injured worker was diagnosed as having L4-5 spondylolisthesis, facet arthropathy at C3-6, and L5-S1 degenerative disc disease with severe disc space collapse, chronic intractable pain, C3-T1 severe degenerative disc disease, and C5-6 disc degeneration with significant osteophyte formation. Treatment to date has included 6 physical therapy sessions for the neck, back, and hands. Other treatment included the use of a back brace/support, heat application, and medications. A physician's report dated 8/25/14 noted the injured worker was taking Norco 10/325, Ultram 50mg, and Amitiza 24mcg. A physician's report dated 2/23/15 noted pain was rated as 10/10 without medications and 8/10 with medications. A physician's report dated 3/31/15 noted pain was rated as 8-10/10 but was reduced to 7-8/10 with medications. Amitiza was noted to have made a difference and the injured worker was having daily bowel movements. A physician's report dated 4/6/15 noted pain was rated as 8/10 with medications and 10/10 without medications. Currently, the injured worker complains of neck pain and low back pain with bilateral lower extremity numbness and weakness. The treating physician requested authorization for Tramadol 50mg #90, Norco 10/325mg #120, Amitiza 24mcg #60.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**90 Tablets of Tramadol 50mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 75.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Tramadol, Ultram Page(s): 74-96, 113, 123. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) - Medications for acute pain (analgesics), Tramadol (Ultram).

**Decision rationale:** Tramadol is classified as central acting synthetic opioids. MTUS states regarding tramadol "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. MTUS states "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, increased level of function, or improved quality of life. As such, the request for 90 Tablets of Tramadol 50mg is not medically necessary.

**120 tablets of Norco 10mg/325mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Short Acting Opioids Page(s): 78.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck and Upper Back (Acute and Chronic), Low Back - Lumbar & Thoracic (Acute & Chronic), Shoulder, Pain, Opioids.

**Decision rationale:** ODG does not recommend the use of opioids for neck, low back, and shoulder pain "except for short use for severe cases, not to exceed 2 weeks." The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include current pain; the least reported pain over the period since last assessment; average

pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, increased level of function, or improved quality of life. Additionally, medical documents indicate that the patient has been on Norco in excess of the recommended 2- week limit. As such, the request for 120 tablets of Norco 10/325mg is not medically necessary.

### **60 Capsules of Amitiza 24mcg: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment Index 11th Edition web, 2014, pain.

**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=95153> <http://www.amitiza.com/>.

**Decision rationale:** MTUS is silent on Amitiza. ODG discusses Amitiza 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 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 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). As such, the request for 60 Capsules of Amitiza 24mcg is not medically necessary.