MAXIMUS Federal Services

Case Number:	CM15-0203007		
Date Assigned:	10/19/2015	Date of Injury:	05/15/2012
Decision Date:	12/02/2015	UR Denial Date:	09/23/2015
Priority:	Standard	Application Received:	10/15/2015

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, California
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 56 year old female who sustained an industrial injury on 5-15-12. The medical records indicate that the injured worker is being treated for posttraumatic right shoulder, left shoulder, right elbow, left elbow pain; status post surgery, right shoulder (2011); status post left elbow surgery (12-2-14). She currently (9-8-15) complains of severe left shoulder pain with a pain level of 10 out of 10 at times. She had an MRI done under anesthesia and she was on her left shoulder. The left shoulder pain is causing her to lose sleep. On physical exam there was tenderness of the right and left shoulders and right and left elbows with painful movement. She has undergone an MRI of the left shoulder (8-3-15). Treatments to date include physical therapy; medication: tramadol, Nexium, Amitriptyline, Zoloft, Norco. In the 9-8-15 progress note the treating provider gave the injured worker a prescription for Naloxone with instructions for use. The request for authorization was not present. On 9-23-15 Utilization Review non-certified the request for Naloxone 0.4mg #2.

IMR ISSUES, DECISIONS AND RATIONALES

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

Naloxone 0.4mg QTY: 2: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.uptodate.com/; Naloxone monograph; Pharmacotherapy for opioid use disorder.

Decision rationale: Naloxone: Drug information Brand Names: US: EvzioBrand Names: Canada: Naloxone Hydrochloride Injection;Pharmacologic Category: Antidote; Opioid Antagonist Dosing: Adult Opioid overdose (with standard ACLS protocols): IV, IM, SubQ: Initial: 0.4 to 2 mg; may need to repeat doses every 2 to 3 minutes; after reversal, may need to readminister dose(s) at a later interval (ie, 20 to 60 minutes) depending on type/duration of opioid. If no response is observed after 10 mg total, consider other causes of respiratory depression. Note: May be given endotracheally (off-label route) as 2 to 2.5 times the initial IV dose (ie, 0.8 to 5 mg) (Neumar, 2010). Reversal of respiratory depression with therapeutic opioid doses: IV, IM, SubQ. Initial: 0.04 to 0.4 mg; may repeat until desired response achieved. If desired response is not observed after 0.8 mg total, consider other causes of respiratory depression. Note: May be given endotracheally (off-label route) as 2 to 2.5 times the initial IV dose (ie, 0.08 to 1 mg) (Neumar, 2010). Pharmacotherapy for opioid use disorder SUMMARY AND RECOMMENDATIONS. "Patients with opioid use disorder who achieve abstinence through medically supervised withdrawal or other means often require long-term treatment to prevent relapse. Treatment options include long-term medication maintenance with an opioid agonist or an opioid antagonist, or abstinence-based therapy, a nonmedication treatment. (See 'Overview' above.) For patients with a moderate to severe opioid use disorder, we suggest maintenance treatment with medication rather than abstinence-based therapy (Grade 1B). (See 'Opioid agonists' above.) For most patients treated with medication for a moderate to severe opioid use disorder, we suggest use of Buprenorphine rather than other medications (Grade 2B). While methadone may have slightly better capacity to retain patients in treatment, it has a higher risk of lethal overdose. (See 'Opioid agonist versus antagonist medication' above and 'Buprenorphine versus methadone' above.) Buprenorphine is taken in a combined formulation with Naloxone to discourage abuse. Following training and certification, clinicians in the United States can prescribe Buprenorphine in an office-based practice setting. Buprenorphine can be started at 4 mg (with 1 mg of Naloxone), sublingually. Most patients will stabilize on up to 16 mg/day, although selected patients may need higher doses. (See 'Buprenorphine' above.) For patients who continue to use opioids despite Buprenorphine treatment, or have a history of a prior poor response to, misuse or diversion of Buprenorphine, we suggest treatment with methadone rather than other medications (Grade 2C). Methadone cannot not be prescribed for self-administration in the United States; patients receive the medication in treatment at an opioid treatment program (ie, a methadone clinic). Naltrexone is suggested as third-line medication treatment for moderate to severe opioid use disorder in patients who have had poor responses to Buprenorphine and methadone. (See 'Buprenorphine versus methadone' above and 'Opioid agonist versus antagonist medication' above and 'Naltrexone' above.Most patients treated with methadone do best on doses between 80 to 120 mg/day, which is typically sufficient to block a euphoric response if the patients self-administer additional opioids; however, patients vary in their response to methadone dosing, which should be based upon the patient's clinical response rather than a particular target dose. (See 'Methadone' above.) For most patients with a mild

opioid use disorder, we suggest treatment with naltrexone rather than other treatments (Grade 2C). For patients with a mild form of the disorder who are highly motivated to participate in treatment and prefer a nonmedication approach, abstinence-based therapy is a reasonable alternative. (See 'Naltrexone' above.) For patients with opioid use disorder in safety-sensitive occupat ions that prohibit opioid agonist use, we suggest naltrexone as first line medication treatment rather than other medications. (Grade 2C). To ensure adherence, administration of oral naltrexone should be supervised. (See 'Oral naltrexone' above.) Oral naltrexone is taken as a single 50 mg tablet once daily, but can be started at 25 mg/day for one to three days to minimize side effects. Long-acting naltrexone can be used in patients who have problems with adherence to daily medications. Patients who fail treatment with naltrexone should be treated with an opioid agonist. (See 'Opioid agonist versus antagonist medication' above and 'Oral naltrexone' above and 'Long-acting injectable naltrexone' above.) For patients who are treated with medication for opioid use disorder, we suggest adjunctive treatment with addiction counseling and participation in a mutual help group such as Narcotics Anonymous (Grade 2B). Methadone programs in the United States (opioid treatment programs) are required to provide drug counseling. Clinicians who prescribe Buprenorphine in an office-based practice are required to have the capability to provide or refer patients for drug counseling.Naloxone is not prescribed as needed. It is prescribed for opioid overdose and may be utilized to treat patients with opioid addiction or abuse.” Evidence based guidelines do not recommend it for as needed pain control. As such the request for Naloxone 0.4mg QTY: 2 is not medically necessary.