

Case Number:	CM14-0150987		
Date Assigned:	09/19/2014	Date of Injury:	07/01/2006
Decision Date:	10/22/2014	UR Denial Date:	09/06/2014
Priority:	Standard	Application Received:	09/16/2014

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. The expert reviewer is Board Certified in Neurology; has a subspecialty Neuromuscular Medicine and is licensed to practice in New Jersey. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 patient is a 50-year-old man who sustained a work related injury on July 1, 2006. Subsequently, he developed chronic low back pain. According to a progress report dated September 16, 2014, the patient did complain of lower back pain radiating to both lower extremities. He described the pain as constant, sharp, tabbing, cramping, spasm pain. He rated the pain as an 8/10. He also was complaining of constipation, change of bowel habits, abdominal pain, depression, and anxiety. Cervical examination revealed diffuse tenderness and limited range of motion. There is diffuse weakness due to pain. The patient was not able to dorsiflex the ankle due to pain. There is normal sensation to pin prick in the upper and lower extremities. There is normal vibratory sensation in the upper and lower extremities. There is no evidence for sensory loss. Deep tendon reflexes in the upper and lower extremities are decreased but equal. His diagnoses include chronic pain, facet arthropathy of the lumbar spine, sacroiliac joint dysfunction, lumbar radiculopathy left greater than right, and muscle spasm. The provider requested authorization for Naltrexone.

IMR ISSUES, DECISIONS AND RATIONALES

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

Naltrexone 50 mcg/1cc, QTY: 100 cc: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Institute for Clinical Systems Improvement (ICSI); 2014 Jan. 44p.(76 references)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Naltrexone 50 mcg/1cc, QTY: 100 cc. <http://www.worklossdatainstitute.verioiponly.com/odgtwc/pain.htm>

Decision rationale: According to ODG guidelines, naltrexone < Recommended as an option for patients who are at risk for abuse of opioids by altering recommended oral use. This includes crushing or dissolving meds allowing for ingestion nasally (insufflation), chewing and /or intravenous use. Other tamper resistant agents on the market include Suboxone (buprenorphine/naloxone), Opana (oxymorphone), Exalgo (hydromorphone), and OxyContin (oxycodone controlled release). [REDACTED] has temporarily recalled Embeda because a prespecified stability requirement was not met during testing, but they are committed to making Embeda available as soon as possible once this issue is resolved. (Embeda, 2012) The FDA has approved morphine sulfate and naltrexone hydrochloride extended-release capsules (Embeda) for once- or twice-daily use in the management of moderate to severe pain when continuous, around-the-clock opioid analgesic therapy is warranted for an extended period. The capsules contain morphine pellets with a sequestered inner core of the opioid antagonist naltrexone that is released when the product is crushed or chewed, thereby discouraging tampering and drug abuse. Approval of the product was based on data from 12 clinical studies, including a phase 3 study showing that its use provided significant pain relief compared with placebo in patients with severe pain caused by osteoarthritis of the hip or knee. (FDA, 2009) In this RCT pain relief was statistically significantly superior for those treated with Embeda compared to the control group (Trevino, 2009) The FDA's latest list of drugs to monitor after having identified potential signs of serious risks or new safety information includes Embeda for withdrawal symptoms not associated with misuse. (FDA, 2011) Black Box Warning: Embeda is not intended for PRN use. Embeda can be abused in a manner similar to other opioid agonists. It is only recommended for opioid tolerant patients. Patients on this drug should not ingest alcohol, including that included in prescription and non-prescription medications. Fatal respiratory depression can occur with use. There is no clear documentation that the patient is suffering from opioid abuse and its use may precipitate opioid withdraw. Therefore, the request for Naltrexone 50 mcg/1cc, QTY: 100 cc is not medically necessary.