

Case Number:	CM14-0091403		
Date Assigned:	07/25/2014	Date of Injury:	02/06/1981
Decision Date:	09/15/2014	UR Denial Date:	06/06/2014
Priority:	Standard	Application Received:	06/17/2014

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 Orthopedic Surgery and is licensed to practice in California. 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:

This is a 54-year old female with a date of injury of 2/6/81. The mechanism of injury was not noted. On 5/29/14 she complained of a lot more pain, 8/10 with medications and 10/10 without. She had left knee surgery on 5/15/14, using a walker and attending rehab. She is on Methadone 10mg 4-5 tabs per day #150, Percocet-10 every 4 hours as needed #180, Baclofen 20mg three times daily #90, and uses Fentora 400mcg. On 6/24/14, it was noted that she take Fentora 400mcg 6/day. Both notes are handwritten and somewhat illegible. There was a urine drug screen on 1/15/14, but results were not noted. On exam her knee was healing well but with restricted range of motion. The diagnostic impression is CRPS of the right upper extremity, s/p left knee surgery, s/p reversed left shoulder arthroplasty placement. Treatment to date: surgery, spinal cord stimulator, medication management. A UR decision dated 6/6/14 denied the requests for Methadone and Fentora. The Methadone and Fentora were denied because the only medical report submitted for this review is the progress note dated 5/29/14, which was mostly illegible handwritten notes, and the patient's medication history and response to treatment were not discussed. Guidelines state that a satisfactory response to opioid treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. However, this was not adequately documented in the sole report submitted for review. The last urine drug screen was on 1/15/14 but the result is not clearly seen in the report. In addition Fentora is not recommended for musculoskeletal pain, and it is currently approved for the treatment of breakthrough pain in certain cancer patients, and no diagnosis of cancer is mentioned in this patient. Also guidelines recommends that a patient's Morphine Equivalent Dose (MED) not exceed 120mg oral morphine equivalents per day. This patient's MED is 680/day, not including the Fentora, or about 5.7 times the recommended ceiling. The current notes indicate the patient is allowed up to 6 doses of Fentora 400mcg per day. The MED of

Fentora 2400mcg/day is not known. This MED significantly exceeds the guideline recommendation, of 120mg oral morphine equivalents per day, not including the Fentora dose of 2400mcg/day.

IMR ISSUES, DECISIONS AND RATIONALES

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

150 tablets of Methadone 10 mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opiates Page(s): 78-81.

Decision rationale: CA MTUS Chronic Pain Medical Treatment Guidelines do not support ongoing opioid treatment unless prescriptions are from a single practitioner and are taken as directed; are prescribed at the lowest possible dose; and unless there is ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. However, there is no documentation of functional benefit or continued analgesia with the use of opiates. There is no documentation of the lack of adverse side effects or aberrant behavior. There is no documentation of a CURES Report or a signed opiate contract. In addition, the patient is on 6 tablets of Percocet 10/325mg per day, Methadone 50mg/day and Fentora 400mcg, 6 tablets per day. The MED for the prescribed medications is 590, not including the Fentora, which the MED is not known. Guidelines recommend that the MED not exceed 200. This patient's MED is 590, which far exceeds the recommended ceiling of MED of 200. This 590 does not include the Fentora dose of 2400mcg/day the patient is also using. Therefore, the request for 150 tablets of Methadone 10mg was not medically necessary.

1 month supply of Fentora 400 mcg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Fentora Page(s): 47.

Decision rationale: Not recommended for musculoskeletal pain. Fentora is an opioid painkiller currently approved for the treatment of breakthrough pain in certain cancer patients. Cephalon had applied to the FDA for approval to market the drug for patients with other pain conditions such as chronic low back pain and chronic neuropathic pain, but approval was not obtained. However, there is no documentation of functional improvement or continued analgesia with the use of opiates. There is no documentation of lack of adverse side effects or aberrant behavior. There is no documentation of a Cures Report or an opiate pain contract. In addition, the patient is on a 6 tablets of Percocet 10/325mg per day, Methadone 50mg/day, and Fentora 400mcg, 6 tablets per day or 2400mcg/day. The MED for this patient's pain regimen is 590, not including

the Fentora 2400mg/day. The MED for Fentora 2400mcg is not known. The guidelines recommend a ceiling of MED of 200. This far exceeds that ceiling of MED of 200, which does not include the Fentora 2400mcg/day. In addition, the FDA does not approve of the use of Fentora for musculoskeletal pain. It is approved for cancer patients over the age of 18 years. The patient does not have a diagnosis of cancer. In addition, the quantity needed for a 1-month supply of Fentora 400mcg was not indicated. Therefore, the request for 1-month supply of Fentora 400mcg was not medically necessary.