

<b>Case Number:</b>	CM14-0081599		
<b>Date Assigned:</b>	07/18/2014	<b>Date of Injury:</b>	08/18/1999
<b>Decision Date:</b>	09/12/2014	<b>UR Denial Date:</b>	05/13/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/02/2014

### 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 Physical Medicine & Rehabilitation 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 patient sustained an injury on 8/18/1999 while employed by [REDACTED]. Request(s) under consideration include Fentora, 800mg #112, Zofran 8 mg, #60, and Methadone 5 mg, #60. Diagnoses include lumbago/ lumbosacral neuritis/radiculitis/ lumbosacral intervertebral disc degeneration/ postlaminectomy syndrome and s/p L1-S1 fusion (undated); s/p intrathecal pump placement in 2013; s/p spinal cord stimulator implantation in 2009. Report of 2/12/14 from the provider noted the patient experiencing severe pain and unable to get out of bed; had days of withdrawal; Fentanyl patch was decreased; however, family placed another patch of 75 ugm which helped with symptoms; having difficulty adjusting to pain pump medications with pain rated at 9/10. Exam noted "popping in low back." Treatment agreement and informed consent was re-established. Report of 4/29/14 noted no major changes in patient's condition and medications are working fair. Treatment plan included increasing Fentanyl patch to 25 ugm and will increase the pump dosing. Low dose of Methadone was used. Current medications list Fentora, Fioricet, Lyrica, Zofran. Exam showed ongoing baseline pain with popping sensation on movement; no new neurological changes. No withdrawal symptoms noted. Request(s) for Fentora 800mg, #112, Zofran 8 mg, #60, and Methadone 5 mg, #60 were non-certified on 5/13/14 citing guidelines criteria and lack of medical necessity.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Fentora, 800mg, #112:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids  
Page(s): 74-96.

**Decision rationale:** This patient sustained an injury on 8/18/1999 while employed by [REDACTED]. Request(s) under consideration include Fentora, 800mg #112, Zofran 8 mg, #60, and Methadone 5 mg, #60. Diagnoses include lumbago/ lumbosacral neuritis/radiculitis/ lumbosacral intervertebral disc degeneration/ postlaminectomy syndrome and s/p L1-S1 fusion (undated); s/p intrathecal pump placement in 2013; s/p spinal cord stimulator implantation in 2009. Report of 2/12/14 from the provider noted the patient experiencing severe pain and unable to get out of bed; had days of withdrawal; Fentanyl patch was decreased; however, family placed another patch of 75 ugm which helped with symptoms; having difficulty adjusting to pain pump medications with pain rated at 9/10. Exam noted "popping in low back." Treatment agreement and informed consent was re-established. Report of 4/29/14 noted no major changes in patient's condition and medications are working fair. Treatment plan included increasing Fentanyl patch to 25 ugm and will increase the pump dosing. Low dose of Methadone was used. Current medications list Fentora, Fioricet, Lyrica, Zofran. Exam showed ongoing baseline pain with popping sensation on movement; no new neurological changes. No withdrawal symptoms noted. Request(s) for Fentora 800mg, #112, Zofran 8 mg, #60, and Methadone 5 mg, #60 were non-certified on 5/13/14. Previous peer review had recommended tapering off oral Fentora, a scheduled II opioid agonist containing Fentanyl. The patient was recently certified Fentanyl patch in addition to treatment plan for increasing intrathecal pump medications. Per the MTUS Guidelines cited, opioid use in the setting of chronic, non-malignant, or neuropathic pain is controversial. Patients on opioids should be routinely monitored for signs of impairment and use of opioids in patients with chronic pain should be reserved for those with improved functional outcomes attributable to their use, in the context of an overall approach to pain management that also includes non-opioid analgesics, adjuvant therapies, psychological support, and active treatments (e.g., exercise). Submitted documents show no evidence that the treating physician is prescribing opioids in accordance to change in pain relief, functional goals with demonstrated improvement in daily activities, decreased in medical utilization or change in work status. There is no evidence presented of random drug testing or utilization of pain contract to adequately monitor for narcotic safety, efficacy, and compliance. The MTUS provides requirements of the treating physician to assess and document for functional improvement with treatment intervention and maintenance of function that would otherwise deteriorate if not supported. From the submitted reports, there is no demonstrated evidence of specific functional benefit derived from the continuing use of opioids with persistent severe pain. The Fentora 800mg, #112 is not medically necessary and appropriate.

**Zofran, 8 mg, #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Procedure Summary.

**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; Antiemetics (for opioid nausea), page 773: Not recommended for nausea and vomiting secondary to chronic opioid use. Recommended for acute use as noted below per FDA-approved indications (cancer pain).

**Decision rationale:** This patient sustained an injury on 8/18/1999 while employed by [REDACTED]. Request(s) under consideration include Fentora, 800mg #112, Zofran 8 mg, #60, and Methadone 5 mg, #60. Diagnoses include lumbago/ lumbosacral neuritis/radiculitis/ lumbosacral intervertebral disc degeneration/ postlaminectomy syndrome and s/p L1-S1 fusion (undated); s/p intrathecal pump placement in 2013; s/p spinal cord stimulator implantation in 2009. Report of 2/12/14 from the provider noted the patient experiencing severe pain and unable to get out of bed; had days of withdrawal; Fentanyl patch was decreased; however, family placed another patch of 75 ugm which helped with symptoms; having difficulty adjusting to pain pump medications with pain rated at 9/10. Exam noted "popping in low back." Treatment agreement and informed consent was re-established. Report of 4/29/14 noted no major changes in patient's condition and medications are working fair. Treatment plan included increasing Fentanyl patch to 25 ugm and will increase the pump dosing. Low dose of Methadone was used. Current medications list Fentora, Fioricet, Lyrica, Zofran. Exam showed ongoing baseline pain with popping sensation on movement; no new neurological changes. No withdrawal symptoms noted. Request(s) for Fentora 800mg, #112, Zofran 8 mg, #60, and Methadone 5 mg, #60 were non-certified on 5/13/14. Previous peer review of 1/22/14 had partial-certification of Zofran to #60 pending documentation of clear GI complaints and/or efficacy. The Zofran is provided as medication causes recurrent nausea and vomiting. Ondansetron (Zofran) is an antiemetic, serotonin 5-HT<sub>3</sub> receptor antagonist FDA- approved and prescribed for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, radiotherapy, and in severe postoperative nausea and/or vomiting, and for acute gastroenteritis. Common side effects include headaches, dizziness, malaise, and diarrhea amongst more significant CNS extra-pyramidal reactions, and hepatic disease including liver failure. None of these indications are industrially related to accepted low back claim for this 1999 injury. The medical report from the provider has not adequately documented the medical necessity of this antiemetic medication prescribed from nausea and vomiting side effects of chronic pain medications. A review of the MTUS-ACOEM Guidelines, McKesson InterQual Guidelines are silent on its use; however, ODG Guidelines does not recommend treatment of Zofran for nausea and vomiting secondary to chronic opioid use. The Zofran 8 mg, #60 is not medically necessary and appropriate.

**Methadone, 5 mg, #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

**Decision rationale:** This patient sustained an injury on 8/18/1999 while employed by [REDACTED]. Request(s) under consideration include Fentora, 800mg #112, Zofran 8 mg, #60, and Methadone 5 mg, #60. Diagnoses include lumbago/ lumbosacral neuritis/radiculitis/ lumbosacral intervertebral disc degeneration/ postlaminectomy syndrome and s/p L1-S1 fusion (undated); s/p intrathecal pump placement in 2013; s/p spinal cord stimulator implantation in 2009. Report of 2/12/14 from the provider noted the patient experiencing severe pain and unable to get out of bed; had days of withdrawal; Fentanyl patch was decreased; however, family placed another patch of 75 ugm which helped with symptoms; having difficulty adjusting to pain pump medications with pain rated at 9/10. Exam noted "popping in low back." Treatment agreement and informed consent was re-established. Report of 4/29/14 noted no major changes in patient's condition and medications are working fair. Treatment plan included increasing Fentanyl patch to 25 ugm and will increase the pump dosing. Low dose of Methadone was used. Current medications list Fentora, Fioricet, Lyrica, Zofran. Exam showed ongoing baseline pain with popping sensation on movement; no new neurological changes. No withdrawal symptoms noted. Request(s) for Fentora 800mg, #112, Zofran 8 mg, #60, and Methadone 5 mg, #60 were non-certified on 5/13/14. MTUS provides requirements of the treating physician to assess and document for functional improvement with treatment intervention and maintenance of function that would otherwise deteriorate if not supported. From the submitted reports, there is no demonstrated evidence of specific functional benefit derived from the continuing use of opioids with persistent severe pain. Guidelines do not support chronic use of opioids and pain medications are typically not useful in the subacute and chronic phases, impeding recovery of function in patients. Methadone, a synthetic opioid, may be used medically as an analgesic, in the maintenance anti-addictive for use in patients with opioid dependency and in the detoxification process (such as heroin or other morphine-like drugs) as a substitute for seriously addicted patients because of its long half-life and less profound sedation and euphoria. The patient is prescribed multiple opiates including current intrathecal pain medications, Fentanyl patch, Fentora, along with Methadone. Guidelines do not support chronic use of Opioid, Methadone. Submitted reports have not adequately identified significant clinical findings or red-flag conditions to continue high doses of opiates for this unchanged chronic injury of 1999. The Methadone 5 mg, #60 is not medically necessary and appropriate.