

<b>Case Number:</b>	CM14-0081231		
<b>Date Assigned:</b>	08/08/2014	<b>Date of Injury:</b>	08/13/2001
<b>Decision Date:</b>	12/26/2014	<b>UR Denial Date:</b>	05/02/2014
<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 Occupational Medicine 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:

The claimant injured her low back on 08/13/01. She has lumbar postlaminectomy syndrome. She has required very high opioid dosages. Her medication use is highly complex and involve short acting, long acting and rapid onset opioids. On 01/03/14, she complained of chronic severe low back pain with bilateral leg pain. She had been seen last on 12/05/13 and she was in more pain because of the decrease in her pain medication at her last visit. Another epidural had been requested. She requested help in decreasing her medication. They discussed reducing the oxycodone in favor of Nucynta which would be easier to stop later. A possible spinal cord stimulator trial was recommended. She reported poor sleep quality. Her medications included Actiq, Celebrex, Cymbalta, fentanyl patches, Lyrica, methadone, prednisone, and tizanidine. She was in no acute distress with no signs of sedation or withdrawal. She had low back and neck pain. Her low back pain radiated from her buttocks to her toes and she also had a lot of right hip pain. Her pain was much worse that month. She is status post a fusion at L3-4 and L5-S1 with a new lesion at L4-5 per a myelogram. She has had three-level fusion and revision surgeries. She has also had bilateral SI joint fusions. She was to continue the fentanyl patch, methadone, and decrease the oxycodone. A trial of Nucynta IR was recommended. She was to continue prednisone, Cymbalta, Celebrex, Lyrica, and Zanaflex and Fiorinal. Fentora was decreased. On 01/13/14, she saw an orthopedic surgeon. She had a significantly forward flexed antalgic gait and was using a seated walker for ambulation. Tenderness was noted with hypersensitivity. Her strength was good. Her knee and ankle reflexes were absent except for the right ankle. She was to proceed with an SI joint block. She underwent bilateral SI joint injections on 01/22/14. On 02/03/14, she still had low back pain radiating into the bilateral buttocks and down the anterior and posterior thighs. She had pain in the SI joints at level 9/10. A CT scan of the pelvis was ordered. When she was seen on 02/07/13, she was using Actiq lozenges, Celebrex, Dilaudid,

Endocet, fentanyl patch, Fioricet with codeine, Lyrica, methadone, prednisone, and tizanidine. She was in a wheelchair. Bilateral SI joint fusion was planned and she was medically cleared. A CT scan of the pelvis dated 02/18/14 revealed postop hardware throughout the lower lumbar spine. There was osteolysis around the L4 vertebral body hardware. There was no evidence of hardware fracture. There were postop implants in the SI joints bilaterally. There was possible osteolysis and joint laxity. A bone scan was under consideration. She had extensive fractures of the iliac wings and left superior inferior pubic ramus. On 02/28/14, she was still using a walker. Her pain medications were controlling her pain well. A trial of Lazanda worked well. The increase in methadone to 3 times a day has helped control her baseline pain. Her sleep quality was good. She admitted that Actiq did not work very quickly and it was not very good for her. The Nucynta helped but made her feel "funky." She was to continue fentanyl patch, methadone, Nucynta IR and decreased the Actiq. She was on 2 long-acting opioids, one short-acting opioid, and one rapid onset opioid regimen. A spinal cord stimulator trial and a new CT scan of the lumbar spine were ordered. A drug screen dated 01/13/14 revealed the presence of codeine and morphine which were not prescribed. She also had norhydrocodone that was not prescribed. The oxycodone, oxymorphone, and noroxycodone were consistent and there was methadone and EDDP. There was no reported prescription for methadone.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Continue/Increase Fentanyl patch 100+50ugm, every (q) days, as needed, baseline pain #15 (long acting opioid (LAO)).:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Fentanyl patch Page(s): 78.

**Decision rationale:** The history and documentation do not objectively support the request to continue/increase Fentanyl patch 100+50ugm, every (q) days, as needed, baseline pain #15. The MTUS outlines several components of initiating and continuing opioid treatment and states "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." In these records, there is no documentation of trials and subsequent failure of or intolerance to first-line drugs such as acetaminophen or non steroidal anti-inflammatory drugs. MTUS further explains, "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." There is no indication that periodic monitoring of the claimant's pattern of use and specific response to this medication, including assessment of pain relief and functional benefit, has been done. There is no evidence that she has been involved in an ongoing rehab program to help maintain any benefits she receives from treatment measures. Additionally, the 4A's "analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors" should be followed and documented per the guidelines. The claimant's

pattern of use of fentanyl patch is unclear other than she uses it. It is not clear how the benefit to her of this particular medication has been determined. There is no evidence that a pain diary has been recommended and is being kept by the claimant and reviewed by the prescriber. As such, the medical necessity of the request to continue/increase Fentanyl patch 100+50ugm, every (q) days, as needed, baseline pain #15 (long acting opioid (LAO) has not been clearly demonstrated. Weaning of this type of medication is advisable.

**Continue Methadone 10mg 1 by mouth (PO), every (Q) 8 hours, #90 (from #60, long acting opioid (LAO)).:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Methadone Page(s): 95.

**Decision rationale:** The history and documentation do not objectively support the request to continue methadone 10mg 1 by mouth (PO), every (Q) 8 hours, #90 (from #60, long acting opioid (LAO). The MTUS outlines several components of initiating and continuing opioid treatment and states "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." In these records, there is no documentation of trials and subsequent failure of or intolerance to first-line drugs such as acetaminophen or non-steroidal anti-inflammatory drugs. MTUS further explains, "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." There is no indication that periodic monitoring of the claimant's pattern of use and specific response to this medication, including assessment of pain relief and functional benefit, has been done. There is no evidence that she has been involved in an ongoing rehab program to help maintain any benefits she receives from treatment measures. Additionally, the 4A's "analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors" should be followed and documented per the guidelines. The claimant's pattern of use of methadone is unclear other than she uses it. It is not clear how the benefit to her of this particular medication has been determined. There is no evidence that a pain diary has been recommended and is being kept by the claimant and reviewed by the prescriber. As such, the medical necessity of the request to continue methadone 10mg 1 by mouth (PO), every (Q) 8 hours, #90 (from #60, long acting opioid (LAO) has not been clearly demonstrated. The requested treatment is not medically necessary and appropriate.

**Continue Nucyta IR 100mg, 1-2 by mouth (PO), 4 times a day (QID), 6 times a day, #180 (from #120 short acting opioid (SAO)).:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG): Formulary - Nucynta

**Decision rationale:** The history and documentation do not objectively support the request to continue Nucynta IR 100mg, 1-2 by mouth (PO), 4 times a day (QID), 6 times a day, #180 (from #120 short acting opioid (SAO)). The MTUS do not address this type of medication and the ODG state Nucynta is recommended only as second line therapy for patients who develop intolerable adverse effects with first line opioids." The MTUS outlines several components of initiating and continuing opioid treatment and states "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." In these records, there is no documentation of trials and subsequent failure of or intolerance to first-line drugs such as acetaminophen or nonsteroidal anti-inflammatory drugs. MTUS further explains, "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." There is no indication that periodic monitoring of the claimant's pattern of use and specific response to this medication, including assessment of pain relief and functional benefit, has been done. There is no evidence that she has been involved in an ongoing rehab program to help maintain any benefits she receives from treatment measures. Additionally, the 4A's "analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors" should be followed and documented per the guidelines. The claimant's pattern of use of methadone is unclear other than she uses it. It is not clear how the benefit to her of this particular medication has been determined. There is no evidence that a pain diary has been recommended and is being kept by the claimant and reviewed by the prescriber. As such, the medical necessity of the request to continue Nucynta IR 100mg, 1-2 by mouth (PO), 4 times a day (QID), 6 times a day, #180 (from #120 short acting opioid (SAO)) has not been clearly demonstrated. The requested treatment is not medically necessary and appropriate.

**Continue/NO decrease Actiq 1600 ugm, 1, 4 times a day (QID), 6 times a day, #180 (from #120 short acting opioid (SAO)).:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Actiq Page(s): 42.

**Decision rationale:** The history and documentation do not objectively support the request to continue/NO decrease Actiq 1600 ugm, 1, 4 times a day (QID), 6 times a day, #180 (from #120 short acting opioid (SAO)). The MTUS state "Actiq (fentanyl lollipop) is not recommended for musculoskeletal pain. Actiq (oral transmucosal fentanyl citrate), a fast-acting highly potent "lollipop" painkiller produced by Cephalon, is indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Actiq is not for use in

chronic pain; and it has a Black Box warning for abuse potential." The MTUS outlines several components of initiating and continuing opioid treatment and states "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." In these records, there is no documentation of trials and subsequent failure of or intolerance to first-line drugs such as acetaminophen or non-steroidal anti-inflammatory drugs. MTUS further explains, "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." There is no indication that periodic monitoring of the claimant's pattern of use and specific response to this medication, including assessment of pain relief and functional benefit, has been done. There is no evidence that she has been involved in an ongoing rehab program to help maintain any benefits she receives from treatment measures. Additionally, the 4A's "analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors" should be followed and documented per the guidelines. The claimant's pattern of use of Actiq is unclear other than she uses it. It is not clear how the benefit to her of this particular medication has been determined. There is no evidence that a pain diary has been recommended and is being kept by the claimant and reviewed by the prescriber. As such, the medical necessity of the request to continue/NO decrease Actiq 1600 ugm, 1, 4 times a day (QID), 6 times a day, #180 (from #120 short acting opioid (SAO)) has not been clearly demonstrated. The requested treatment is not medically necessary and appropriate.

**Continue Prednisone 5mg, 1 by mouth (PO), every (Q) 12 hours, #60 (from #90): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Federal Drug Administration (FDA)

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG): Formulary - oral corticosteroids

**Decision rationale:** The history and documentation do not objectively support the request to continue prednisone 5mg, 1 by mouth (PO), every (Q) 12 hours, #60 (from #90). The MTUS do not address its use and the Official Disability Guidelines (ODG) state "Criteria for the Use of Corticosteroids (oral/parenteral for low back pain):(1) Patients should have clear-cut signs and symptoms of radiculopathy;(2) Risks of steroids should be discussed with the patient and documented in the record;(3) The patient should be aware of the evidence that research provides limited evidence of effect with this medication and this should be documented in the record;(4) Current research indicates early treatment is most successful; treatment in the chronic phase of injury should generally be after a symptom-free period with subsequent exacerbation or when there is evidence of a new injury. In this case, the claimant has chronic pain and not exacerbations and remissions. Chronic use of prednisone is not supported by the ODG. It is not clear what benefit the claimant has received from the chronic use of prednisone or what the indications are. The medical necessity of the continuation of prednisone 5mg, 1 by mouth (PO), every (Q) 12 hours, #60 (from #90) has not been clearly demonstrated. The requested treatment is not medically necessary and appropriate.

**May continue Fiorinal #3, #80, by mouth, per primary care physician (PCP): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Barbituate containing alalgesics.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: PDR, 2014. Fiorinal

**Decision rationale:** The history and documentation do not objectively support the request for Fiorinal #3, #80, by mouth, per primary care physician (PCP). The MTUS do not address its use and the PDR recommends it for treatment of tension headaches. There is no evidence that this medication has been recommended for headaches. The indication for its use is not clearly stated in the records and none can be ascertained from the records. Specific measurable objective and functional benefit to the claimant from the use of Fiorinal has not been described in the records. The medical necessity of the continued use of Fiorinal #3, #80, by mouth, per primary care physician (PCP) has not been clearly demonstrated. The requested treatment is not medically necessary and appropriate.

**Contine/reRX: Lazanda 400 ugm, 1 NS, per every day (QD) to twice a day (BID), as needed (PRN), severe break through (b/t) pain, #8 x 8 doses = 64 doses (from 32 doses, decreasing the Actiq from 8 to 4/day now; but have a true rapid acting opiod (ROO), Kazabda at 2.dat as wekk as fir titak if 6/ROO d: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG): Formulary - Lazanda

**Decision rationale:** The history and documentation do not objectively support the request to continue/reRX: Lazanda 400 ugm. The MTUS do not address its use and the ODG state is it "not recommended for musculoskeletal pain." The medical necessity of the continuation/reRX: Lazanda 400 ugm, 1 NS, per every day (QD) to twice a day (BID), as needed (PRN), severe break through (b/t) pain, #8 x 8 doses = 64 doses (from 32 doses, decreasing the Actiq from 8 to 4/day now; but have a true rapid acting. The requested treatment is not medically necessary and appropriate.