

<b>Case Number:</b>	CM14-0219295		
<b>Date Assigned:</b>	01/09/2015	<b>Date of Injury:</b>	11/15/2000
<b>Decision Date:</b>	03/10/2015	<b>UR Denial Date:</b>	12/15/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/31/2014

### 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. 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: Texas, California  
 Certification(s)/Specialty: Family Practice

### 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 57 year old female, who sustained an industrial injury on 11/15/00. She has reported neck and low back pain. She sustained the injury in a MVA. The diagnoses have included thoracic/lumbosacral radiculopathy, post laminectomy syndrome and cervicgia. Treatment to date has included laminectomy, physical therapy, epidural injections, pain management and medications. Diagnostic studies have included x-rays, (MRI) magnetic resonance imaging of lumbar and cervical spine and EMGs. Currently, the IW complains of neck, low back and right leg pain. The injured worker continues to have neck and low back pain with poor sleep due to pain and continues to use Fentanyl patch, Fentora, Nucynta and has also used Lyrica, Cymbalta, Celebrex, naprelan and Rozerem. Per the doctor's note dated 12/4/14 patient had complaints of neck, low back and right leg pain at 5-9/10. Physical examination revealed she was using walker, neck and back pain and tenderness over SI joint bilaterally. The MRI of the lumbar spine revealed s/p laminectomy, spinal canal stenosis, and MRI of the cervical spine revealed s/p discectomy and fusion and foraminal stenosis. She has had a urine drug toxicology report on 7/31/14. The patient's surgical history include back surgery laminectomy and cervical spine laminectomy. Patient has received an unspecified number of PT and aquatic therapy visits for this injury.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Fentanyl patch, fifteen count, provided on December 4, 2014, with one refill dispensed on December 31, 2014:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 47, 78, and 93.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use: Other Guidelines Page(s): 75-80.

**Decision rationale:** According to MTUS guidelines fentanyl/ duragesic, is an opioid analgesic with potency eighty times that of morphine. Weaker opioids are less likely to produce adverse effects than stronger opioids such as fentanyl. According to MTUS guidelines fentanyl / Duragesic is not recommended as a first-line therapy. The FDA-approved product labeling states that Duragesic is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by other means. In addition, according to CA MTUS guidelines cited below, 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. The records provided do not specify that that patient has set goals regarding the use of opioid analgesic. A treatment failure with non-opioid analgesics is not specified in the records provided. Other criteria for ongoing management of opioids are: The lowest possible dose should be prescribed to improve pain and function. Continuing review of overall situation with regard to nonopioid means of pain control. Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Consider the use of a urine drug screen to assess for the use or the presence of illegal drugs. The records provided do not provide a documentation of response in regards to pain control and functional improvement to opioid analgesic for this patient. The continued review of overall situation with regard to non-opioid means of pain control is not documented in the records provided. As recommended by MTUS a documentation of pain relief, functional status, appropriate medication use, and side effects should be maintained for ongoing management of opioid analgesic, these are not specified in the records provided. MTUS guidelines also recommend urine drug screen to assess for the use or the presence of illegal drugs in patients using opioids for long term. With this, it is deemed that, based on the clinical information submitted for this review and the peer reviewed guidelines referenced, this patient does not meet criteria for ongoing continued use of opioids analgesic. The medical necessity of Fentanyl patch, fifteen count, provided on December 4, 2014, with one refill dispensed on December 31, 2014 is not established for this patient.

**Nucynta IR 75 mg, 120 count, provided on December 4, 2014, with one refill dispensed on December 31, 2014:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78 and 86.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Central acting analgesics, Opioids for neuropathic pain Page(s): 75, 82.

**Decision rationale:** Nucynta, is a centrally acting analgesic with a dual mode of action as an agonist of the  $\mu$ -opioid receptor and as a norepinephrine reuptake inhibitor. It is similar to tramadol in its dual mechanism of action. According to MTUS guidelines, Central acting analgesics: an emerging fourth class of opiate analgesic that may be used to treat chronic pain. This small class of synthetic opioids (e.g., Tramadol) exhibits opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Central analgesics drugs such as Tramadol (Ultram) are reported to be effective in managing neuropathic pain. (Kumar, 2003) Cited guidelines also state that, A recent consensus guideline stated that opioids could be considered first-line therapy for the following circumstances: (1) prompt pain relief while titrating a first-line drug; (2) treatment of episodic exacerbations of severe pain; [ & ] (3) treatment of neuropathic cancer pain. Nucynta use is recommended for treatment of episodic exacerbations of severe pain. The diagnoses have included thoracic/lumbosacral radiculopathy, post laminectomy syndrome and cervicgia. The patient's surgical history includes treatment with a laminectomy. The patient has also had epidural injections. Per the doctor's note dated 12/4/14 patient had complaints of neck, low back and right leg pain at 5-9/10. Physical examination revealed she was using walker, neck and back pain and tenderness over SI joint bilaterally. The MRI of the lumbar spine revealed s/p laminectomy, spinal canal stenosis, and MRI of the cervical spine revealed s/p discectomy and fusion and foraminal stenosis. The patient has chronic pain and the patient's medical condition can have intermittent exacerbations. Having Nucynta available for use during sudden unexpected exacerbations of pain is medically appropriate and necessary. This request for Nucynta IR 75 mg, 120 count, provided on December 4, 2014, with one refill dispensed on December 31 is deemed as medically appropriate and necessary.

**Vimovo 500/20 mg, sixty count, provided on December 4, 2014, with one refill dispensed on December 31, 2014: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (Non-Steroidal Anti-Inflammatory Drugs), GI (Gastrointestin.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications NSAIDs, GI symptoms & cardiovascular risk Page(s): 22, 68-69. Decision based on Non-MTUS Citation Pain (updated 11/21/14) Vimovo (esomeprazole magnesium/ naproxen )

**Decision rationale:** The medication Vimovo contains Naproxen and Esomeprazole Magnesium. CA MTUS does not address this request. Per the ODG guidelines cited below, not recommended as a first-line therapy, a trial of omeprazole and naproxen or similar combination is recommended before Vimovo therapy. Per the CA MTUS NSAIDs guidelines cited below, regarding use of proton pump inhibitors with NSAIDs, the MTUS Chronic Pain Guidelines recommend PPIs in Patients at intermediate risk for gastrointestinal events, Patients at high risk for gastrointestinal events, Treatment of dyspepsia secondary to NSAID therapy. Per the cited guidelines, patient is considered at high risk for gastrointestinal events with the use of NSAIDS when- (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or anticoagulant; or (4) high dose/multiple NSAID (e.g.,

NSAID + low-dose ASA). A rationale for combining Naproxen and a proton pump inhibitor, in the same tablet is not specified in the records provided. The response to the individual medicines is not specified in the records provided. In addition, the records provided do not specify the duration of the NSAID therapy. The records provided do not specify any objective evidence of GI disorders, GI bleeding or peptic ulcer. The medical necessity of the request for Vimovo 500/20 mg is not fully established in this patient.

**Fentora 400 mcg/tablet, 28 count, provided on December 4, 2014, with one refill dispensed on December 31, 2014: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Section Page(s): 47, 78, and 93.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use, Therapeutic Trial of Opioids Page(s): 76-80.

**Decision rationale:** According to CA MTUS guidelines cited below, 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. The records provided do not specify that patient has set goals regarding the use of opioid analgesic. A treatment failure with non-opioid analgesics is not specified in the records provided. Other criteria for ongoing management of opioids are: The lowest possible dose should be prescribed to improve pain and function. Continuing review of the overall situation with regard to non-opioid means of pain control. Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Consider the use of a urine drug screen to assess for the use or the presence of illegal drugs. The records provided do not provide a documentation of response in regards to pain control and functional improvement to opioid analgesic for this patient. The continued review of overall situation with regard to non-opioid means of pain control is not documented in the records provided. As recommended by MTUS a documentation of pain relief, functional status, appropriate medication use, and side effects should be maintained for ongoing management of opioid analgesic, these are not specified in the records provided. MTUS guidelines also recommend urine drug screen to assess for the use or the presence of illegal drugs in patients using opioids for long term. Whether improvement in pain translated into objective functional improvement including ability to work is not specified in the records provided. With this, it is deemed that, this patient does not meet criteria for ongoing continued use of opioids analgesic. The medical necessity of Fentora 400 mcg/tablet, 28 count, provided on December 4, 2014, with one refill dispensed on December is not established for this patient.

**Urine drug screen, provided on December 4, 2014: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Drug Testing Section Page(s): 43.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Drug Testing Page(s): 43.

**Decision rationale:** Per the CA MTUS guideline cited above, drug testing is recommended as an option, using a urine drug screen to assess for the use or the presence of illegal drugs. Per the guideline cited below, drug testing is the test should be used in conjunction with other clinical information when decisions are to be made to continue, adjust or discontinue treatment. Frequency of urine drug testing should be based on documented evidence of risk stratification including use of a testing instrument. Patients at moderate risk for addiction/aberrant behavior are recommended for point-of-contact screening 2 to 3 times a year with confirmatory testing for inappropriate or unexplained results. As per records provided medication lists includes Fentanyl patch, Fentora, Nucynta, Lyrica, Cymbalta, Celebrex, naprelan and Rozerem It is medically appropriate and necessary to perform a urine drug screen to monitor the use of any controlled substances in patients with chronic pain. It is possible that the patient is taking controlled substances prescribed by another medical facility or from other sources like - a stock of old medicines prescribed to him earlier or from illegal sources. The presence of such controlled substances would significantly change the management approach. The request for Urine drug screen, provided on December 4, 2014 is medically appropriate and necessary in this patient.

**Bilateral sacroiliac joint block injection:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Web Edition, Hip and Pelvis Chapter, Sacroiliac Joint Blocks Section

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Hip and Pelvis chapter, Sacroiliac joint injections (SJI )

**Decision rationale:** California Medical Treatment Utilization Schedule (MTUS), does not address SI joint injection under fluoroscopy. Therefore ODG used. As per ODG, SI joint injection under fluoroscopy recommended as an option if failed at least 4-6 weeks of aggressive conservative therapy. Patient has received an unspecified number of PT visits for this injury. Any conservative therapy notes were not specified in the records provided. A response to recent rehabilitation efforts including physical therapy and chiropractic sessions was not specified in the records provided. Evidence of lack of response to conservative treatment including exercises, physical methods, NSAIDs and muscle relaxants was not specified in the records provided. A detailed examination of the SI joint was not specified in the records provided. The medical necessity of the request for bilateral sacroiliac joint block injection is not fully established in this patient.