

<b>Case Number:</b>	CM14-0153752		
<b>Date Assigned:</b>	09/23/2014	<b>Date of Injury:</b>	06/12/1997
<b>Decision Date:</b>	10/24/2014	<b>UR Denial Date:</b>	08/22/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/19/2014

### 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 was injured on 06/12/97. This is a retrospective request for MSContin, Methadone, Zanaflex, Nuvigil, Cymbalta and MSIR. She has diagnoses of postlaminectomy syndrome status post 3-level fusion of the cervical region with neck pain and cervical spondylosis without myelopathy. She also has cervicocranial syndrome and low back pain. She had an epidural spinal cord stimulator implant in 2009. She has been seen approximately monthly by pain management in 2014 and has been taking the same medications for a prolonged period of time. She is opioid dependent. She was evaluated by pain management follow-up on 07/29/14 and had chronic neck pain and upper back pain with bilateral arm pain worse on the right side. She also had headache on the right greater than left side. Her headaches were daily. Her medications were not being approved and she was paying cash for them. Methadone, MSIR and management MSContin 100 to control her pain level. Her pain level averages 5/10. She complained of poor quality sleep. A CT scan of the cervical spine on 06/10/14 revealed she was status post anterior cervical discectomy and fusion at 3 levels. She was status post pain control electrode placement with central stenosis of mild degree from C3-4 through C6-7. She also had right neural foraminal stenosis of mild degree at C3-4. Her current medications included Celecoxib, Methadone, and MSContin. She had ongoing complaints of a baseline neck pain from those sites consistent with cervical spondylosis. She also had cervical facet condition with referred pain and occipital tenderness. There were no neurologic deficits. She was diagnosed with severe myofascial pain and spasm. She also had opioid dependency efficacy but tolerance. She was to continue MSContin and methadone and increase the MSIR. The Lidoderm patches were held. She has had urine drug screens that were reported to be consistent.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**RETRO: MS Contin #90 (Date of Service: 7/29/14): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for Chronic Pain, Page(s): 110.

**Decision rationale:** The history and documentation do not objectively support this retrospective request for the opioid MSContin #90, date of service 7/29/14 with unclear frequency and duration of use. 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 also no indication that periodic monitoring of the claimant's pattern of use and a response to this medication, including assessment of pain relief and functional benefit, has been or will be 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 MSContin is unclear. There is no evidence that a signed pain agreement is on file at the provider's office and 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 ongoing use of MSContin as prescribed on 7/29/14 has not been clearly demonstrated.

**RETRO: Methadone #90 (Date of service: 7/29/14): Upheld**

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

**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 retrospective request for methadone #90, date of service 7/29/14 with unclear frequency and duration of use. The MTUS state "methadone is recommended as a second-line drug for moderate to severe pain if the potential benefit outweighs the risk. The FDA reports that they have received reports of severe morbidity and mortality with this medication. This appears, in part, secondary to the long half-life of the drug (8-59 hours). Pain relief on the other hand only lasts from 4-8 hours.

Methadone should only be prescribed by providers experienced in using it. (Clinical Pharmacology, 2008) Pharmacokinetics: Genetic differences appear to influence how an individual will respond to this medication. Following oral administration, significantly different blood concentrations may be obtained. Vigilance is suggested in treatment initiation, conversion from another opioid to methadone, and when titrating the methadone dose. (Weschules 2008) (Fredheim 2008) Adverse effects: Delayed adverse effects may occur due to methadone accumulation during chronic administration. Systemic toxicity is more likely to occur in patients previously exposed to high doses of opioids. This may be related to tolerance that develops related to the N-methyl-D-aspartate (NMDA) receptor antagonist. Patients may respond to lower doses of methadone than would be expected based on this antagonism. One severe side effect is respiratory depression (which persists longer than the analgesic effect. Precautions are necessary as well for employees in safety sensitive positions, including operation of a motor vehicle." 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 response to this medication, including assessment of pain relief and functional benefit, has been or will be 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. There is no evidence that a signed pain agreement is on file at the provider's office and 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 use of methadone prescribed on 7/29/14 has not been clearly demonstrated.

**RETRO: Zanaflex (Tizanidine) 4mg #60 (Date of service: 7/29/14): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines -- TWC Pain Procedure Summary (last updated 7/10/14)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 97.

**Decision rationale:** The history and documentation do not objectively support the retrospective request for Zanaflex (Tizanidine) 4 mg #60, unknown frequency and duration, date of service 7/29/14. The MTUS state regarding "muscle relaxants (for pain): Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. (Homik, 2004) Sedation is the most commonly reported adverse effect of muscle relaxant medications. These

drugs should be used with caution in patients driving motor vehicles or operating heavy machinery." MTUS state "relief of pain with the use of medications is generally temporary and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain, the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication to be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medication should show effects within 1 to 3 days ... A record of pain and function with the medication should be recorded. (Mens 2005) The medical documentation provided does not establish the need for long-term/chronic usage of Tizanidine which MTUS guidelines advise against. Additionally, the medical records provided do not provide objective findings of acute spasms or a diagnosis of acute spasm that is resolved by the use of this medication. In this case, the claimant's pattern of use of her multiple medications, including trials of first line drugs such as acetaminophen and anti-inflammatories and her response to them, including relief of symptoms and documentation of functional improvement, have not been described. As such, this request for Zanaflex (Tizanidine) 4 mg #60, date of service 7/29/14 was not medically necessary.

**RETRO: Nuvigil 150mg #30 (Date of service: 7/29/14): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Gold Standard

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

**Decision rationale:** The history and documentation do not objectively support the retrospective request for Nuvigil 150 mg #30, frequency and duration unknown, date of service 7/29/14. The ODG formulary states that Nuvigil is "not recommended. It is not recommended solely to counteract sedation effects of narcotics. Armodafinil is used to treat excessive sleepiness caused by narcolepsy or shift work sleep disorder. It is very similar to Modafinil. Studies have not demonstrated any difference in efficacy and safety between Armodafinil and Modafinil. (Tembe, 2011) For more information see also Modafinil (Provigil), where it is not recommended solely to counteract sedation effects of narcotics until after first considering reducing excessive narcotic prescribing, and it is noted that there should be heightened awareness for potential abuse of and dependence on this drug. Recently Cephalon produced a campaign advertising Nuvigil's ability to help shift workers stay alert on the job without impeding their ability to sleep during the day. The FDA is conducting an investigation into the possibility that this advertising or promotional information may have violated current regulations." In this case, the indication for the use of Nuvigil has not been stated and none can be ascertained from the records. The medical necessity of the use of Nuvigil 150 mg prescribed on 7/29/14 has not been clearly demonstrated.

**RETRO: Cymbalta (Duloxetine) 60mg #30 (Date of service: 7/29/14): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Duloxetine, Page(s): 77.

**Decision rationale:** The history and documentation do not objectively support the retrospective request for Cymbalta (duloxetine) 60 mg #30, frequency and duration unknown, date of service 7/29/14. The MTUS state "duloxetine (Cymbalta) is recommended as an option in first-line treatment option in neuropathic pain. Duloxetine (Cymbalta) is a norepinephrine and serotonin reuptake inhibitor antidepressant (SNRIs). It has FDA approval for treatment of depression, generalized anxiety disorder, and for the treatment of pain related to diabetic neuropathy, with effect found to be significant by the end of week 1 (effect measured as a 30% reduction in baseline pain)." In this case, there is no evidence of depression for which this medication has been prescribed and no diagnosis of neuropathic pain including diabetic neuropathy. There is no documented evidence of clinical or functional improvement from the use of this medication. The indication for its use has not been stated and none can be ascertained from the records. The medical necessity of the use of duloxetine 60 mg has not been clearly demonstrated.

**RETRO: MS IR 30mg (Date of service: 7/29/14): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for Chronic Pain, Page(s): , page 110.

**Decision rationale:** The history and documentation do not objectively support this retrospective request for the opioid MS IR 30 mg, date of service 7/29/14 with unclear frequency and duration of use. 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 also no indication that periodic monitoring of the claimant's pattern of use and a response to this medication, including assessment of pain relief and functional benefit, has been or will be 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 MS IR is unclear. There is no evidence that a signed pain agreement is on file at the provider's office and 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

ongoing use of MS IR as prescribed on 7/29/14 has not been clearly demonstrated therefore, this request is not medically necessary.