

<b>Case Number:</b>	CM14-0026585		
<b>Date Assigned:</b>	03/05/2014	<b>Date of Injury:</b>	01/27/2000
<b>Decision Date:</b>	09/10/2014	<b>UR Denial Date:</b>	02/18/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/04/2014

### 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 Anesthesiology, has a subspecialty in Pain Medicine and is licensed to practice in Massachusetts. 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:

According to documents available for review, the patient is a 48 year old female. The date of injury is January 27, 2000. The patient sustained injuries to her cervical spine upper strategies and shoulders. The mechanism of injury is not described in the documents available for review. The patient carries a diagnosis of displacement of cervical disc, brachial neuritis were ridiculous it is, lesion of owner nerve, osteoarthritis, rotator cuff syndrome, medial epicondylitis and reflex sympathetic dystrophy of the upper extremity, myalgia and myositis, cervical spondylosis, displacement of lumbar intravertebral disk, lumbosacracl neuritis. The patient is being treated with a multimodal pain medication regimen consisting of Medrol, Percocet, OxyContin, Topamax, Valium, DLC cream, Zofran, Restoril. Request for Medrol, Percocet, OxyContin, Topamax, Valium, DLC cream, Zofran, Restoril was denied.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**MEDROL DOSE PACK #1:** 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).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic), Corticosteroids.

**Decision rationale:** According to the ODG, Medrol is recommended in limited circumstances as for acute radicular pain. 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. According to the documents available for review, there is no discussion of the criteria for use as outlined above. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

**PERCOCET 10/325MG #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS Page(s): 76-80.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, On-Going Management Page(s): 74-97.

**Decision rationale:** According to the MTUS Chronic Pain Medical Treatment Guidelines section on Opioids, On-Going Management, p 74-97, (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. 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. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control.(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).(g) Continuing review of overall situation with regard to nonopioid means of pain control. (h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually

required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Additionally, the MTUS states that continued use of opioids requires (a) the patient has returned to work, (b) the patient has improved functioning and pain. The MTUS guidelines recommend that dosing not exceed 120 mg oral morphine equivalents per day, and for patients taking more than one opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose. In general, the total daily dose of opioid should not exceed 120 mg oral morphine equivalents. Rarely, and only after pain management consultation, should the total daily dose of opioid be increased above 120 mg oral morphine equivalents. There is no current documentation of baseline pain, pain score with use of opioids, functional improvement on current regimen, side effects. Additionally, according to the documents available for review, there is no evidence of a pain consultation despite the fact that the patient is been maintained on opiates for greater than three months and is on a dose that exceeds 120 mg of morphine equivalents per day. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

**OXYCONTIN 20MG #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS Page(s): 76-80.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, On-Going Management Page(s): 74-97.

**Decision rationale:** According to the MTUS Chronic Pain Medical Treatment Guidelines section on Opioids, On-Going Management, p 74-97, (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. 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. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control.(f) Documentation of misuse of medications (doctor-

shopping, uncontrolled drug escalation, drug diversion).(g) Continuing review of overall situation with regard to nonopioid means of pain control. (h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Additionally, the MTUS states that continued use of opioids requires (a) the patient has returned to work, (b) the patient has improved functioning and pain. The MTUS guidelines recommend that dosing not exceed 120 mg oral morphine equivalents per day, and for patients taking more than one opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose. In general, the total daily dose of opioid should not exceed 120 mg oral morphine equivalents. Rarely, and only after pain management consultation, should the total daily dose of opioid be increased above 120 mg oral morphine equivalents. There is no current documentation of baseline pain, pain score with use of opioids, functional improvement on current regimen, side effects. Additionally, according to the documents available for review, there is no evidence of a pain consultation despite the fact that the patient is been maintained on opiates for greater than three months and is on a dose that exceeds 120 mg of morphine equivalents per day. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

**TOPAMAX 100MG #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines ANTI-EPILEPSY DRUGS (AEDs) Page(s): 16.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Anti-epilepsy drugs (AEDs), Topiramate, p21.

**Decision rationale:** MTUS, Chronic Pain Medical Treatment Guidelines, Anti-epilepsy drugs (AEDs), Topiramate, p21 has been shown to have variable efficacy, with failure to demonstrate efficacy in neuropathic pain of "central" etiology. It is still considered for use for neuropathic pain when other anticonvulsants fail. Topiramate has recently been investigated as an adjunct treatment for obesity, but the side effect profile limits its use in this regard. (Rosenstock, 2007). According to the documents available for review, indication of the patient has tried other anticonvulsants for her neuropathic pain. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

**ZOFRAN 4MG #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 (ODG).

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

**Decision rationale:** According to the ODG, Ondansetron (Zofran): It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use. Acute use is FDA-approved for gastroenteritis. According to the documents available for review, the patient has none of the FDA approved indications for the use of this medication. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

**VALIUM 10MG #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

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

**Decision rationale:** According to the ODG, Valium is not recommended for long-term use because long-term efficacy is unproven and there is a risk of psychological and physical dependence or frank addiction. Most guidelines limit use to 4 weeks. Benzodiazepines are a major cause of overdose, particularly as they act synergistically with other drugs such as opioids (mixed overdoses are often a cause of fatalities). Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly (3-14 day). Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. Tolerance to lethal effects does not occur and a maintenance dose may approach a lethal dose as the therapeutic index increases. The best prevention for substance use disorders due to benzodiazepines is careful prescribing. (Baillargeon, 2003) (Ashton, 2005) (Dickinson, 2009) (Lader, 2009) Adults who use hypnotics, including benzodiazepines such as Temazepam, have a greater than 3-fold increased risk for early death, according to results of a large matched cohort survival analysis. The risks associated with hypnotics outweigh any benefits of hypnotics, according to the authors. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

**DLC CREAM 60 GRAMS:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 113.

**Decision rationale:** According to the MTUS, there is little to no research to support the use of topical compounded creams. It also contains menthol, a non-recommended topical agent. Any compounded product that contains at least one drug (or drug class) that is not recommended is

not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Topical analgesics are largely experimental and there are a few randomized controlled trials to determine efficacy or safety. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

**RESTORIL 15MG #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 (ODG).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) < Pain (Chronic), Benzodiazepines.

**Decision rationale:** According to the ODG, Temazepam is not recommended for long-term use because long-term efficacy is unproven and there is a risk of psychological and physical dependence or frank addiction. Most guidelines limit use to 4 weeks. Benzodiazepines are a major cause of overdose, particularly as they act synergistically with other drugs such as opioids (mixed overdoses are often a cause of fatalities). Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly (3-14 day). Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. Tolerance to lethal effects does not occur and a maintenance dose may approach a lethal dose as the therapeutic index increases. The best prevention for substance use disorders due to benzodiazepines is careful prescribing. (Baillargeon, 2003) (Ashton, 2005) (Dickinson, 2009) (Lader, 2009) Adults who use hypnotics, including benzodiazepines such as Temazepam, have a greater than 3-fold increased risk for early death, according to results of a large matched cohort survival analysis. The risks associated with hypnotics outweigh any benefits of hypnotics, according to the authors. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.