

<b>Case Number:</b>	CM13-0012725		
<b>Date Assigned:</b>	06/06/2014	<b>Date of Injury:</b>	01/20/2000
<b>Decision Date:</b>	08/11/2014	<b>UR Denial Date:</b>	08/09/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/16/2013

### 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 Neurology, has a subspecialty in Neuromuscular Medicine and is licensed to practice in New Jersey. 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 patient is a 54-year-old woman who sustained a work related injury on January 20, 2000. Subsequently, she developed back and knee pain. According to the progress report dated on August 9, 2013, the patient reported continuous. The patient was taking Lexapro, Phenergan, Soma, Neurontin, Xanax, Norco and Lunesta since July 9, 2013. Her physical examination demonstrated lumbar pain with reduced range of motion and no focal neurological signs. The provider requested authorization for the following medications.

### IMR ISSUES, DECISIONS AND RATIONALES

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

#### **1 PRESCRIPTION OF SOMA 350 MG #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines CARISOPRODOL (SOMA (R)); MUSCLE RELAXANTS (FOR PAIN); WEANING.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines SOMA Page(s): 29.

**Decision rationale:** According to MTUS guidelines, non sedating muscle relaxants is recommended with caution as a second line option for short term treatment of acute exacerbations in patients with chronic lumbosacral pain. Efficacy appears to diminish over time and prolonged use may cause dependence. According to the provided file, the patient was

prescribed Soma for several months without clear evidence of spasm or efficacy on exacerbation of back pain. There is no documentation of functional improvement or reduction of pain severity. There is no justification for prolonged use of Soma. The request for Soma 350mg, 1 Table po qhs prn #30 is not medically necessary.

### **3 PRESCRIPTIONS OF PRILOSEC #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI SYMPTOMS & CARDIOVASCULAR RISK.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI SYMPTOMS & CARDIOVASCULAR RISK Page(s): 68.

**Decision rationale:** According to MTUS guidelines, Omeprazole is indicated when NSAID are used in patients with intermediate or high risk for gastrointestinal events. The risk for gastrointestinal events are: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. There is no documentation that the patient is taking NSAID or has GI issue that requires the use of Prilosec. There is no documentation in the patient's chart supporting that she is at intermediate or high risk for developing gastrointestinal events. Therefore, Prilosec 20mg#60 prescription is not medically necessary.

### **1 PRESCRIPTION OF PRILOSEC DR (DELAYED RELEASE) 20 MG #180: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI SYMPTOMS & CARDIOVASCULAR RISK.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms & cardiovascular risk Page(s): 68.

**Decision rationale:** According to MTUS guidelines, Omeprazole is indicated when NSAID are used in patients with intermediate or high risk for gastrointestinal events. The risk for gastrointestinal events are: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. There is no documentation that the patient is taking NSAID or has GI issue that requires the use of Prilosec. There is no documentation in the patient's chart supporting that she is at intermediate or high risk for developing gastrointestinal events. Therefore, Prilosec 20mg#60 prescription is not medically necessary.

### **1 URINE DRUG SCREEN: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS, STEPS TO AVOID MISUSE/ADDICTION.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS, STEPS TO AVOID MISUSE/ADDICTION Page(s): 77-78; 94.

**Decision rationale:** According to MTUS guidelines, urine toxicology screens are indicated to avoid misuse/addiction. (j) Consider the use of a urine drug screen to assess for the use or the presence of illegal drugs. There is no evidence that the patient have aberrant behavior or urine drug screen. There is no clear evidence of abuse, or addiction from previous urine testing. There is no documentation that the patient has a history of use of illicit drugs. Therefore, the request for Urine drug screen is not medically necessary.

**1 PRESCRIPTION OF LEXAPRO 20 MG #30 WITH 5 REFILLS:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines ANTIDEPRESSANTS FOR CHRONIC PAIN.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Lexapro, <http://www.worklossdatainstitute.verioiponly.com/odgtwc/stress.htm>.

**Decision rationale:** According to ODG guidelines, Lexapro is recommended as a first-line treatment option for major depressive disorder. There is no documentation that the patient suffered major depression. There is no evidence that the patient failed or did not tolerate tricyclic antidepressants which are considered the first line option for treating chronic pain. Therefore, Lexapro is not medically necessary.

**1 PRESCRIPTION OF LUNESTA 3 MG #30:** 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) Non-Benzodiazepine sedative-hypnotics (Benzodiazepine-receptor agonists (<http://worklossdatainstitute.verioiponly.com/odgtwc/pain.htm>)).

**Decision rationale:** Lunesta is a nonbenzodiazepine hypnotic agent that is a pyrrolopyrazine derivative of the Cyclopyrrolone class. According to MTUS guidelines, tricyclic antidepressants are recommended as a first line option in neuropathic pain, especially if pain is accompanied by insomnia, anxiety or depression. According to ODG guidelines, <Non-Benzodiazepine sedative-hypnotics (Benzodiazepine-receptor agonists): First-line medications for insomnia. This class of medications includes Zolpidem (Ambien and Ambien CR), Zaleplon (Sonata), and Eszopicolone (Lunesta). Benzodiazepine-receptor agonists work by selectively binding to type-1 benzodiazepine receptors in the CNS. All of the benzodiazepine-receptor agonists are schedule

IV controlled substances, which means they have potential for abuse and dependency>. In this patient, there is no clear documentation of insomnia that justifies the long term use of Lunesta. There is no documentation of sleep study that better characterize the patient insomnia. There is no periodic objective documentation of the effect of previous use of Lunesta on the sleep quality and the patient functionality. Lunesta could be used as an option to treat insomnia after failure of first line medications and non pharmacologic therapies; however it should not be used for a long-term without periodic evaluation of its need. Therefore, the prescription of Lunesta is not medically necessary.

### **1 PRESCRIPTION OF NEURONTIN 600 MG #180 WITH 5 REFILLS: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NEURONTIN (R) (GABAPENTIN).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines GABAPENTIN Page(s): 49.

**Decision rationale:** According to MTUS, Neurontin has been shown to be effective for the treatment of diabetic painful neuropathy and post herpetic neuralgia and has been considered to be first line treatment for neuropathic pain. However there is a limited research to support its use for foot pain. There is no documentation that the patient developed neuropathic pain and there is no clear rationale for using Neurontin. There is no objective documentation of pain and functional improvement with previous use of Neurontin. Based on the above, the prescription of Neurontin is not medically necessary.

### **1 PRESCRIPTION OF NORCO 10/325 MG #200 WITH 2 REFILLS: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines HYDROCODONE/ACETAMINOPHEN (NORCO).

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

**Decision rationale:** According to MTUS guidelines, Norco (Hydrocodone/Acetaminophen) is a synthetic opioid indicated for the pain management but not recommended as a first line oral analgesic. In addition and according to MTUS guidelines, ongoing use of opioids should follow specific rules: According to MTUS guidelines, Norco (Hydrocodone/Acetaminophen) is a synthetic opioid indicated for the pain management but not recommended as a first line oral analgesic. In addition and according to MTUS guidelines, ongoing use of opioids should follow specific rules: (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 non adherent) 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. There is no clear evidence of objective and recent functional and pain improvement with previous use of opioids (Norco). There no clear documentation of the efficacy/safety of previous use of Norco. The patient was using Duragesic with Norco and completed a weaning process from Duragesic. Her clinical condition requires a weaning from Norco. There is no clear justification for the need to continue the use of Norco. Therefore, the prescription of Norco 10/325 mg #200 with 2 refills is not medically necessary.

### **1 PRESCRIPTION OF PHENERGAN 25 MG #50 WITH 3 REFILLS: 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).

**Decision rationale:** Antiemetics (for opioid nausea) Not recommended for nausea and vomiting secondary to chronic opioid use. Recommended for acute use as noted below per FDA-approved indications. Nausea and vomiting is common with use of opioids. These side effects tend to diminish over days to weeks of continued exposure. Studies of opioid adverse effects including nausea and vomiting are limited to short-term duration (less than four weeks) and have limited application to long-term use. If nausea and vomiting remains prolonged, other etiologies of these symptoms should be evaluated for. The differential diagnosis includes gastroparesis (primarily due to diabetes). Current research for treatment of nausea and vomiting as related to opioid use primarily addresses the use of antiemetics in patients with cancer pain or those utilizing opioids for acute/postoperative therapy. Recommendations based on these studies cannot be extrapolated to chronic non-malignant pain patients. There is no high-quality literature to support any one treatment for opioid-induced nausea in chronic non-malignant pain patients. (Moore 2005) Promethazine (Phenergan): This drug is a phenothiazine. It is recommended as a sedative and antiemetic in pre-operative and post-operative situations. Multiple central nervous system effects are noted with use including somnolence, confusion and sedation. Tardive dyskinesia is also associated with use. This is characterized by involuntary movements of the tongue, mouth, jaw, and/or face. Choreoathetoid movements of the extremities can also occur. Development appears to be associated with prolonged treatment and in some cases can be irreversible. Anticholinergic effects can occur (dry mouth, dry eyes, urinary retention and ileus). There is no documentation that the patient developed nausea a vomiting secondary to opioid use and ODG guidelines do not recommend the use of Phenergan secondary to nausea and vomiting induced by opioids. Therefore, the use of Phenergan is not medically necessary.