

<b>Case Number:</b>	CM14-0154610		
<b>Date Assigned:</b>	09/24/2014	<b>Date of Injury:</b>	04/21/2005
<b>Decision Date:</b>	10/27/2014	<b>UR Denial Date:</b>	09/08/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/22/2014

### 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 Family Medicine and is licensed to practice in North Carolina. 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 57-year-old with a reported date of injury of 04/21/2005. The patient has the diagnoses of chronic neck pain, status post thoracic spine surgery x2 with chronic pain and status post lumbar surgery with chronic pain. Past treatment modalities have included spinal surgery. Per the most recent progress notes provided for review by the primary treating physician dated 08/18/2014, the patient had complaints of unchanged pain with new swelling in the back. The physical exam noted tenderness in the cervical paraspinal muscles with restricted lumbar range of motion. The treatment plan recommendations included continuation of home exercise medications and pain medications.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Codeine 60 mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of Opioids.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 76-84.

**Decision rationale:** The California chronic pain medical treatment guidelines section on opioids states: On-Going Management. Actions Should Include: (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 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 non-opioid 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. Consider an addiction medicine consult if there is evidence of substance misuse. When to Continue Opioids(a) If the patient has returned to work(b) If the patient has improved functioning and pain(Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004)- Chronic back pain: Appears to be efficacious but limited for short-term pain relief, and long term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. (Martell-Annals, 2007) (Chou, 2007) There are three studies comparing Tramadol to placebo that have reported pain relief, but this increase did not necessarily improve function. (Deshpande, 2007) The long-term use of this medication is not recommended unless certain objective outcome measures have been met as defined above. There is no provided objective outcome measure that shows significant improvement in function while on the medication or a return to work. The patient continues to have unchanged pain despite being on the medication for a prolonged period of time. For these reasons criteria for ongoing and continued use of the medication have not been met. Therefore the request of Codeine 60 mg #120 is not medically necessary and appropriate.

**Gabapentin 800 mg #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines anti-epilepsy drugs (AEDS) Page(s): 16-19.

**Decision rationale:** The California chronic pain medical treatment guideline section on the use of AEDs for chronic pain states: Anti-epilepsy drugs (AEDs) are also referred to as anti-convulsants. Recommended for neuropathic pain (pain due to nerve damage). (Gilron, 2006) (Wolfe, 2004) (Washington, 2005) (ICSI, 2005) (Wiffen-Cochrane, 2005) (Attal, 2006) (Wiffen-Cochrane, 2007) (Gilron, 2007) (ICSI, 2007) (Finnerup, 2007) There is a lack of expert consensus on the treatment of neuropathic pain in general due to heterogeneous etiologies, symptoms, physical signs and mechanisms. Most randomized controlled trials (RCTs) for the use of this class of medication for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy (with diabetic polyneuropathy being the most common example). There are few RCTs directed at central pain and none for painful radiculopathy. (Attal, 2006) Gabapentin (Neurontin, Gabarone, generic available) has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. (Backonja, 2002) (ICSI, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Attal, 2006) This RCT concluded that gabapentin monotherapy appears to be efficacious for the treatment of pain and sleep interference associated with diabetic peripheral neuropathy and exhibits positive effects on mood and quality of life. (Backonja, 1998) It has been given FDA approval for treatment of post-herpetic neuralgia. The number needed to treat (NNT) for overall neuropathic pain is 4. It has a more favorable side-effect profile than Carbamazepine, with a number needed to harm of 2.5. (Wiffen-Cochrane, 2005) (Zaremba, 2006) Gabapentin in combination with morphine has been studied for treatment of diabetic neuropathy and postherpetic neuralgia. When used in combination the maximum tolerated dosage of both drugs was lower than when each was used as a single agent and better analgesia occurred at lower doses of each. (Gilron-NEJM, 2005) Recommendations involving combination therapy require further study. Spinal cord injury: Recommended as a trial for chronic neuropathic pain that is associated with this condition. (Levendoglu, 2004) CRPS: Recommended as a trial. (Serpell, 2002) Fibromyalgia: Recommended as a trial. (Arnold, 2007) Lumbar spinal stenosis: Recommended as a trial, with statistically significant improvement found in walking distance, pain with movement, and sensory deficit found in a pilot study. (Yaksi, 2007) Side-Effect Profile: Gabapentin has a favorable side-effect profile, few clinically significant drug-drug interactions and is generally well tolerated; however, common side effects include dizziness, somnolence, confusion, ataxia, peripheral edema, and dry mouth. (Eisenberg, 2007) (Attal, 2006) Weight gain is also an adverse effect. Dosing Information: Postherpetic neuralgia - Starting regimen of 300 mg once daily on Day 1, then increase to 300 mg twice daily on Day 2; then increase to 300 mg three times daily on Day 3. Dosage may be increased as needed up to a total daily dosage of 1800 mg in three divided doses. Doses above 1800 mg/day have not demonstrated an additional benefit in clinical studies. (Neurontin package insert) Diabetic neuropathy (off-label indication) - Gabapentin dosages range from 900 mg to 3600 mg in three divided doses (Backonja, 2002) (Eisenberg, 2007). Gabapentin is 100% renal excretion. Recommended Trial Period: One recommendation for an adequate trial with gabapentin is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. (Dworkin, 2003) The patient should be asked at each visit as to whether there has been a change in pain or function. Current consensus based treatment algorithms for diabetic neuropathy suggests that if inadequate control of pain is found, a switch to another first-line drug is recommended.

Combination therapy is only recommended if there is no change with first-line therapy, with the recommended change being at least 30%. (TCA, SNRI or AED). (Jensen, 2006) (Eisenberg, 2007) This medication is recommended for a trial period of 3-8 weeks for titration and then 1-2 weeks at maximum dosage. The drug is considered efficacious if there is at least a 30% improvement on the medication. This patient has been on the medication for greater than 10 weeks. The patient continues to have pain which is characterized in the progress notes as unchanged. There is not a documented 30 % improvement in pain while on the medications. For these reasons criteria set forth above for the chronic use of the medication per the California MTUS have not been met. Therefore the request of Gabapentin 800 mg #90 is not medically necessary and appropriate.

