

<b>Case Number:</b>	CM14-0114499		
<b>Date Assigned:</b>	09/22/2014	<b>Date of Injury:</b>	12/02/1996
<b>Decision Date:</b>	10/21/2014	<b>UR Denial Date:</b>	06/27/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/22/2014

### 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 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 the documents available for review, the patient is an injured female worker. The date of injury is December 2, 1996. The patient sustained an injury to the lumbar spine and bilateral legs. The specific mechanism of injury was not elaborated on in the notes available for review. The patient subsequently underwent lumbar spine surgery. Her current diagnosis is post laminectomy syndrome. The patient currently complains of pain in the low back and bilateral legs worse with movement. The patient is maintained on the multimodal pain medication regimen including, hydrocodone, OxyContin, Dulcolax, lidocaine, baclofen, gabapentin. A request for hydrocodone, OxyContin, Dulcolax, lidocaine, baclofen, gabapentin was denied.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Hydrocodone/APAP 10/325mg, #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids - (Washington, 2002) (Warfield, 2004).

**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. There is no current documentation of baseline pain, pain score with use of opioids, functional improvement on current regimen, side effects or review of potentially aberrant drug taking behaviors as outlined in the MTUS and required for ongoing treatment. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

**Oxycontin 20mg, #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids. Decision based on Non-MTUS Citation Agency Medical Director's Group (AMDG) Guidelines from Washington State/Opioid dosing calculator

**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. There is no current documentation of baseline pain, pain score with use of opioids, functional improvement on current regimen, side effects or review of potentially aberrant drug taking behaviors as outlined in the MTUS and required for ongoing treatment. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

**Bisacodyl/Dulcolax 5mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Therapeutic trial of Opioids.

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

**Decision rationale:** According to the MTUS bowel prophylaxis is recommended for chronic opioid therapy. However based on the documents available for review, chronic opioid therapy is not indicated in this patient. Therefore at this time the requirements for treatment have not been met, and medical necessity has not been established.

**Lidocaine 5%:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics (Namaka, 2004) (Colombo, 2006).

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

**Decision rationale:** According to the MTUS, there is little to no research to support the use of topical compounded creams. 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.

**Baclofen 10mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (Chou, 2007) (Van Tulder, 1998).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Baclofen Page(s): 64.

**Decision rationale:** According to the MTUS, Baclofen is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Baclofen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain (trigeminal neuralgia, non- FDA approved) (ICSI, 2007). According to the documents available for review, patient has none of the MTUS / FDA recommended 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.

**Celebrex 200mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) (Chen, 2008) (Lai).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Celebrex, Page(s): 70.

**Decision rationale:** According to the MTUS, Celebrex is approved for the relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. COX-2 inhibitors (e.g., Celebrex) may be considered if the patient has a risk of GI complications, but not for the majority of patients. According to the documents available for review, the patient has none of the aforementioned MTUS 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.

**Gabapentin 300mg, #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs) (Gilron, 2006) (Wolfe, 2004).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 18.

**Decision rationale:** 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 (randomized controlled trials) 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. (Wiffen2-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. Mechanism of action: This medication appears to be effective in reducing abnormal hypersensitivity (allodynia and hyperalgesia), to have anti-anxiety effects, and may be beneficial as a sleep aid. (Arnold, 2007) Specific pain states: There is limited evidence to show that this medication is effective for postoperative pain, where there is fairly good evidence that the use of gabapentin and gabapentin-like compounds results in decreased opioid consumption. This beneficial effect, which may be related to an anti-anxiety effect, is accompanied by increased sedation and dizziness. (Peng, 2007) (Buvanendran, 2007) (Menigaux, 2005) (Pandey, 2005) 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 300mg 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 has 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% renally excreted. 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. According to the documents available for review, the patient has none of the aforementioned MTUS 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.