

<b>Case Number:</b>	CM14-0193148		
<b>Date Assigned:</b>	11/26/2014	<b>Date of Injury:</b>	08/18/2008
<b>Decision Date:</b>	01/14/2015	<b>UR Denial Date:</b>	11/03/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/18/2014

### 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 Colorado. 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 42 year old female with date of injury to right shoulder 8/18/2008 which developed into cumulative trauma / complex pain syndrome, continues care with the treating physicians. Patient has multiple complaints, lasting several years. Her diagnoses include Cervical displacement, Cervical post-laminectomy syndrome, Neck pain, suboccipital headaches radiating pain to right eye, and right shoulder pain. She is status post Anterior Cervical fusion at C3-C4, C4-C5, and C5-C6, and Right shoulder rotator cuff repair x 2 without relief of symptoms. Patient is maintained on multiple medications and has facet block injection request pending. The patient has comorbid depression and anxiety, also deemed to be work-related, and follows with mental health providers as possible, per the records. The treating physician requests continued renewal of chronic medications Cymbalta, Tizanidine, Topamax, Gabapentin, and Morphine ER, and requests approval for follow up Urine Drug Screening.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective request Cymbalta for 60 mg # 30, DOS 9/18/14: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 14-16 and 43-44.

**Decision rationale:** Per the MTUS Guidelines, antidepressants can be considered first line treatment for neuropathic pain and possible option for treatment for non-neuropathic pain. Tricyclic antidepressants are the recommended first option for treatment of pain with antidepressant and should be used unless ineffective or not tolerated/contraindicated. Pain relief with antidepressants may occur within a few days to 1 week, though any antidepressant effect would take longer to occur. As with other treatments for pain, efficacy should be assessed regularly when using antidepressants. The following aspects associated with pain relief should be addressed: Pain reduction, Improvement in function, Changes in need for other pain medications, Sleep quality and quantity, Psychiatric evaluation, Side effects, especially those that may affect job performance. Long term efficacy of anti-depressants in treatment of pain is not known, and antidepressants in combination with other medications for pain have no quality evidence to support use. While Duloxetine can be used off label for chronic pain and radiculopathy, no high quality evidence supports use of Duloxetine in lumbar radiculopathy treatment. It is recommended as an option in first-line treatment of neuropathic pain. Per the guidelines, 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, and has been found to be effective for treating fibromyalgia in women with and without depression, 60 mg once or twice daily. (Arnold, 2005) Furthermore, improvement in pain symptoms with Cymbalta generally is noted within 1 week of starting the medications. Per the records, the patient of concern has been taking Cymbalta at the current dose for at least 3 months at time of the request for refill approval. No documentation is provided that objectively assesses the functional improvement, side effects, and changes in other medications as relates to the Cymbalta. No pain ratings are documented that verify patient's pain is improving. The most recent full assessment of depression, using multiple scales, in May 2014 reveals patient continues with severe depression, so unclear if the Cymbalta is helping the depression. Patient is taking the Cymbalta, at least in part, for an off label indication with no evidence to support use for radiculopathy, and no documented objective evaluation of its efficacy, so the request to continue Cymbalta is not medically indicated.

**Retrospective request for Topamax 50 mg # 60, DOS 9/18/14: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 16-18 and 21.

**Decision rationale:** Topamax is classified as an Anti-epilepsy drug (AED). AED's have been most studied for treatment of post herpetic neuralgia and diabetic neuropathy. Because neuropathic pain is often multifactorial with variable symptoms and physical findings, there is a lack of agreement among experts on the best treatment. There is also a lack of quality evidence for any specific treatment for neuropathic pain with most randomized control trials addressing the above mentioned post-herpetic neuralgia and other polyneuropathies, and few randomized control trials for central pain, none for treatment of radicular pain. As there is a lack of good evidence / expert agreement, per the guidelines, the choice of a specific agent for treatment of

neuropathic pain and the decision to continue treatment with a specific anti-epileptic drug are generally determined by efficacy of the medication and any adverse reactions experienced. When using anti-epileptic drugs for treatment of neuropathic pain, the guidelines define a "good" response to the use of AEDs...as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent (2) combination therapy if treatment with a single drug agent fails. (Eisenberg, 2007) (Jensen, 2006) Per the guidelines, patient pain levels and functional improvement while taking medications should be documented at follow up appointments. For Topamax specifically, the evidence that it is beneficial for treatment of neuropathic pain is variable, and Topamax is only recommended when other AED's fail to resolve pain. For the patient of concern, the records are unclear as to exactly why patient takes the Topamax. (headaches, radicular symptoms, combination) Regardless, the records do not show any assessment of pain or function improvement that would suggest a "good" or "moderate" response to AED. Also, patient is taking another AED, and there is no documentation that response is better with the 2 agents than with a single agent. Given lack of documentation that confirms efficacy of Topamax, the request for Topamax is not medically indicated.

#### **Retrospective request for Morphine ER 15 mg # 120, DOS 9/18/14: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 74-75, 79-80, 85, 88-89.

**Decision rationale:** The Guidelines establish criteria for use of opioids, including long term use (6 months or more). When managing patients using long term opioids, the following should be addressed: Re-assess the diagnosis and review previous treatments and whether or not they were helpful. When re-assessing, pain levels and improvement in function should be documented. Pain levels should be documented every visit. Function should be evaluated every 6 months using a validated clinical tool. Adverse effects, including hyperalgesia, should also be addressed each visit. Patient's motivation and attitudes about pain / work / interpersonal relationships can be examined to determine if patient requires psychological evaluation as well. Aberrant / addictive behavior should be addressed if present. Do not decrease dose if effective. Medication for breakthrough pain may be helpful in limiting overall medication. Follow up evaluations are recommended every 1-6 months. To summarize the above, the 4A's of Drug Monitoring (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking Behaviors) have been established. 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) Several circumstances need to be considered when determining to discontinue opioids: 1) Verify patient has not had failure to improve because of inappropriate dosing or under-dosing of opioids 2) Consider possible reasons for immediate discontinuation including diversion, prescription forgery, illicit drug use, suicide attempt, arrest related to opioids, and aggressive or threatening behavior in clinic. Weaning from the medication over 30 day period, under direct medical supervision, is recommended unless a reason for immediate

discontinuation exists. If a medication contract is in place, some physicians will allow one infraction without immediate discontinuation, but the contract and clinic policy should be reviewed with patient and consequences of further violations made clear to patient.3) Consider discontinuation if there has been no improvement in overall function, or a decrease in function.4) Patient has evidence of unacceptable side effects.5) Patient's pain has resolved.6) Patient exhibits "serious non-adherence," Per the Guidelines, Chelminski defines "serious substance misuse" or non-adherence as meeting any of the following criteria: (a) cocaine or amphetamines on urine toxicology screen (positive cannabinoid was not considered serious substance abuse); (b) procurement of opioids from more than one provider on a regular basis; (c) diversion of opioids; (d) urine toxicology screen negative for prescribed drugs on at least two occasions (an indicator of possible diversion); & (e) urine toxicology screen positive on at least two occasions for opioids not routinely prescribed. (Chelminski, 2005)7) Patient requests discontinuing opioids.8) Consider verifying that patient is in consultation with physician specializing in addiction to consider detoxification if patient continues to violate the medication contract or shows other signs of abuse / addiction. 9) Document the basis for decision to discontinue opioids. Likewise, when making the decision to continue opioids long term, consider the following: Has patient returned to work? Has patient had improved function and decreased pain with the opioids? For the patient of concern, there are consistent urine drug screens and reference is made to a pain agreement in place. However, there is little objective evidence of pain improvement (Rare pain rating documented is still quite high 8/10) and no functional improvement documented using a valid clinical tool for objective information. Without documentation of patient's pain and function improvement, the monitoring for chronic opioid use does not meet the requirements of the guidelines. The request for Morphine is not medically necessary.

**Retrospective request for Tizanidine 4 mg # 60, DOS 9/18/14: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Muscle Relaxants

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 63 and 66.

**Decision rationale:** Per the Guidelines, Tizanidine, a centrally acting muscle relaxant approved for use to treat spasticity, is recommended for musculoskeletal pain associated with spasm, but only for a short course. It has been shown to help low back pain in several studies and to help myofascial pain in one study. The antispasmodic / anti-spasticity drugs have diminishing effects over time, so are not recommended for long term use. No quality consistent evidence exists to support chronic use of Tizanidine. The records supplied for the patient of concern indicate patient has been taking Tizanidine greater than 3 months. Even if patient only takes the Tizanidine intermittently, its effectiveness diminishes so quickly, that its use after 3 months would yield little benefit relative to the risks of side effects, based on the evidence. As there is no support, per the guidelines, for long term use, the request for continued Tizanidine is not medically indicated.

**Retrospective request for Gabapentin 600 mg # 180, DOS 10/16/14: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 16-19.

**Decision rationale:** Per the guidelines, Gabapentin, an anti-epileptic drug, is recommended for treatment of neuropathic pain, as is the class of anti-epilepsy drugs (AED's). These drugs have been most studied for treatment of post herpetic neuralgia and diabetic neuropathy. Because neuropathic pain is often multifactorial with variable symptoms and physical findings, there is a lack of agreement among experts on the best treatment. There is also a lack of quality evidence for any specific treatment for neuropathic pain with most randomized control trials addressing the above mentioned post-herpetic neuralgia and other polyneuropathies, and few randomized control trials for central pain, none for treatment of radicular pain. As there is a lack of good evidence / expert agreement, per the guidelines, the choice of a specific agent for treatment of neuropathic pain and the decision to continue treatment with a specific anti-epileptic drug are generally determined by efficacy of the medication and any adverse reactions experienced. When using anti-epileptic drugs for treatment of neuropathic pain, the guidelines define a "good" response to the use of AEDs...as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent (2) combination therapy if treatment with a single drug agent fails. (Eisenberg, 2007) (Jensen, 2006) Per the guidelines, patient pain levels and functional improvement while taking medications should be documented at follow up appointments. Gabapentin specifically has good evidence to support its use, first-line, in neuropathic pain. (Backonja, 2002) (ICSI, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Attal, 2006) It is FDA-approved for use in post-herpetic neuralgia. In addition to use in neuropathic pain, Gabapentin has evidence to support its use in spinal stenosis, fibromyalgia, spinal cord injury, and some evidence to support its use in post-operative pain to decrease anxiety and need for opioids. Per the records for the patient of concern, there is no documentation that patient has had a "good" or "moderate" response to the Gabapentin. The patient has not had objective quantifiable documentation of functional improvement with the Gabapentin. As patient has not achieved recommended level of pain relief and function improvement with Gabapentin, the Gabapentin is not medically necessary.

**Retrospective request for Urine Drug Screening, DOS 10/16/14: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Urine Drug Testing (UDT)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 78-79 and 85.

**Decision rationale:** Per the Guidelines, opioid use should be monitored, and there are tools recommended for that, including the 4 A's for Ongoing Monitoring: Analgesia, Adverse effects,

Activities of Daily Living, and Aberrant behaviors. Urine drug screens negative for the substances prescribed would be indicators of possible aberrant behavior including noncompliance and diversion. Within the Guidelines, Chelminski includes "urine toxicology screen negative for prescribed drugs on at least two occasions (an indicator of possible diversion)" as one of the criteria defining serious substance misuse / non-adherence. Furthermore, evidence of serious non-adherence warrants immediate discontinuation of opioids. For the patient of concern, there is no clear documentation that patient has achieved pain relief or objective functional improvement with opioids. Therefore, Urine drug screening would not be medically necessary.