

<b>Case Number:</b>	CM15-0234160		
<b>Date Assigned:</b>	12/09/2015	<b>Date of Injury:</b>	05/11/2006
<b>Decision Date:</b>	01/22/2016	<b>UR Denial Date:</b>	11/19/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/30/2015

### 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: Colorado

Certification(s)/Specialty: Family Practice

### 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 injured worker is a (n) 63 year old female, who sustained an industrial injury on 5-11-06. The injured worker was diagnosed as having lumbar degenerative disc disease, lumbar radiculitis, cervical degenerative disc disease and cervical radiculitis. Subjective findings (4-21-15, 5-20-15, 7-21-15 and 9-21-15) indicated pain in her neck radiating to the upper extremity and low back pain. She rates her pain 7-9 out of 10 without medications and 3-6 out of 10 with medications. Objective findings (3-24-15, 7-21-15 and 9-21-15) revealed a positive Spurling's maneuver, tenderness over the bilateral C5-C6 and C6-C7 paraspinals and decreased cervical range of motion. Examination of the lumbar spine shows a positive straight leg raise test and tenderness over the lumbar paraspinals. The treating physician noted that the injured worker's PHQ-9 score was decreasing from 18 to 13. Current medications include Norco (since at least 1-27-15), Cymbalta (since at least 1-27-15), Flexeril (since at least 1-27-15), Prilosec, Naprosyn, Wellbutrin and Protonix. Treatment to date has included psychotherapy and a TENS unit. The Utilization Review dated 11-19-15, non-certified the request for Cyclobenzaprine 7.5mg #60 and modified the request for Hydrocodone-Acetaminophen 10-325mg #60 to Hydrocodone-Acetaminophen 10-325mg #30 and Duloxetine 60mg #30 to Duloxetine 60mg #15.

### IMR ISSUES, DECISIONS AND RATIONALES

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

### **Cyclobenzaprine 7.5mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril), Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril), Muscle relaxants (for pain).

**Decision rationale:** Per the Guidelines, Cyclobenzaprine, and other antispasmodics are recommended for musculoskeletal pain associated with spasm, but only for a short course. It has been shown to help more than placebo with back pain and fibromyalgia, but has several side effects that limit its use. Furthermore, Cyclobenzaprine works best in the first 4 days of use, so short courses recommended, no more than 2-3 weeks. No quality consistent evidence exists to support chronic use of Cyclobenzaprine. Common side effects of Cyclobenzaprine include: anticholinergic effects (drowsiness, urinary retention and dry mouth). Sedative effects may limit use. Headache has been noted. This medication should be avoided in patients with arrhythmias, heart block, heart failure and recent myocardial infarction. Side effects limit use in the elderly. (See, 2008) (Toth, 2004) The records supplied indicate patient of concern has been taking Cyclobenzaprine greater than 2-3 weeks, with no change in pain over time. As there is no support, per the guidelines, for long-term use, the request for Cyclobenzaprine is not medically necessary.

### **Hydrocodone/Acetaminophen 10/325mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids (Classification).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use, Opioids for chronic pain, Opioids, dealing with misuse & addiction, Opioids, steps to avoid misuse/addiction.

**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 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 4 A'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 substances 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, it is documented that patient's pain is improved with medication regimen, which includes Norco. (Pain rating 4/10 with medications and 7/10 without medications at recent visit) Function was discussed at multiple visits, but only walking/standing changes were documented, and no clinically validated tool for assessment of function was documented. Urine drug screen in last 6 months was consistent with medications. Side effects and aberrant behaviors were denied per patient, though no details on the discussion were provided. Though patient does have the majority of the 4A's documented, he does not have documentation of objective assessment of / improvement in function, so the request for Norco is not medically necessary.

**Duloxetine HCL 60mg #30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antidepressants for chronic pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antidepressants for chronic pain, Duloxetine (Cymbalta).

**Decision rationale:** Per the MTUS Guidelines, antidepressants can be considered first line treatment for neuropathic pain and as 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. Duloxetine can be used off label for chronic pain and radiculopathy. 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 Duloxetine generally is noted within 1 week of starting the medications. Per the records, the patient of concern has been taking Duloxetine for over 6 months at time of the request for refill approval. The treating physician indicated in March 2015 that patient's depression improved initially with Duloxetine, but that improvement did not last. Duloxetine was continued despite that observation. Patient is also taking Wellbutrin, so if depression is improved recently, it may be due to the Wellbutrin, which should not be taken in conjunction with Duloxetine. Pain ratings did not improve after initiation of Duloxetine, and patient was unable to tolerate increased doses of Duloxetine to the recommended dosages for pain relief. There is also no documentation that patient ever tried tricyclic anti-depressants for her pain and depression, so Cymbalta would not be considered appropriate without documentation of previous trials. Given that patient has no documentation of lasting pain relief or depression improvement with Duloxetine, and given lack of evidence of trial / failure of tricyclic antidepressant, the request for Duloxetine is not medically necessary.