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| <b>Case Number:</b>   | CM14-0170825 |                              |            |
| <b>Date Assigned:</b> | 10/23/2014   | <b>Date of Injury:</b>       | 12/13/1990 |
| <b>Decision Date:</b> | 11/21/2014   | <b>UR Denial Date:</b>       | 09/16/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 10/15/2014 |

### 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 Psychiatry & Neurology, Addiction Medicine, has a subspecialty in Geriatric Psychiatry and is licensed to practice in California. 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:

Records reviewed include 178 pages of medical and administrative records. The injured worker is a 60-year old female whose date of injury is 12/13/1990. There is no description of said injury other than that it was orthopedic and psychiatric in nature. From what I could discern from records provided, her Workers Comp diagnoses are fibromyalgia, major depressive disorder, and migraine headaches. There is a psychiatric AME of 04/2008 by [REDACTED]. The patient developed chronic depression as far back as 1990 with her fibromyalgia. At the time of this exam she also suffered from irritable bowel, cognitive problems, and substantial fatigue. She was on Wellbutrin 450mg per day, among other medications, and was in counseling, which she uses primarily for ventilation. She was stable on medications, and the point was made that as she was relatively stable it is not a reason to stop treatment, that is the precise reason that the person is stable-that would be the equivalent of cutting off antihypertensive medication to a hypertensive patient because the blood pressure is "normal". There is a progress note from [REDACTED] of 11/21/13 indicating that the patient had improved compared to the last appointment and is willing to follow the same regimen until remission is achieved. Increase in Cymbalta 60mg BID and Savella 50mg BID helped. She felt too sleepy, cut the Cymbalta back to zero. She started her left over Wellbutrin without consulting her clinician. She was restarted on Wellbutrin SR 150mg BID after she had been taking it for 4 weeks, and restarted on Ativan 1mg at HS prn. The patient said that Wellbutrin and Ativan work, sleep and appetite are okay and she said she can drive. She does not participate in social activities due to pain. At that time she was not taking Buspar. Another progress note of 01/09/14 shows that the patient was taking the following medications: Lisinopril, Zocor, Oxycontin ER 60mg BID prn, Wellbutrin SR 150mg BID, Lunesta 6mg at HS, Lyrica 75mg

BID. The patient's PCP had started her on diazepam for tinnitus, she indicated that her anxiety had improved. She wanted to increase the Wellbutrin to 450mg, her clinician agreed. Mood was predominantly anxious with congruent affect. Buspar and Ativan were discontinued. There are UR reports that refer to office visits and physician letters however the actual documentation was not provided as such I am unable to review them.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Sonata (Zaleplon) 10 mg, 1-2 at bedtime:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/sonata.html>

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress, Insomnia Treatment

**Decision rationale:** Per ODG, short term use of up to 5 weeks is indicated. As such, this request is noncertified. MTUS does not reference Zaleplon (Sonata). Per ODG, Non-Benzodiazepine sedative-hypnotics (Benzodiazepine-receptor agonists): First-line medications for insomnia. Although direct comparisons between benzodiazepines and the non-benzodiazepine sedative-hypnotics have not been studied, it appears that the non-benzodiazepines have similar efficacy to the benzodiazepines with fewer side effects and short duration of action. . Zaleplon (Sonata) reduces sleep latency. Because of its short half-life (one hour), may be readministered upon nocturnal waking provided it is administered at least 4 hours before wake time. This medication has a rapid onset of action. Short-term use (7-10 days) is indicated with a controlled trial showing effectiveness for up to 5 weeks. Sonata (Zaleplon) 10 mg, 1-2 at bedtime is not medically necessary.

**Wellbutrin (Bupropion) SR 150 mg:** 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) Mental Illness & Stress, Bupropion (Wellbutrin)

**Decision rationale:** The most recent documentation provided from a clinician was dated 01/09/2014, the rest consisted of UR reports. This indicated that the patient's mood was predominantly anxious, and she had requested that the provider increase the Wellbutrin to 450mg. There was no documentation as to why that request was made by the patient or why it was agreed to by the provider. Although the patient does have a longstanding history of depression dating back to around 1990, there is no current record to show the patient's status on the current dose of Wellbutrin. As such, this request is noncertified. MTUS does not reference

Wellbutrin related to major depressive disorder. Per ODG, bupropion is recommended as a first-line treatment option for major depressive disorder. See Antidepressants for treatment of MDD (major depressive disorder). FDA has concluded that the generic drug Budeprion XL (bupropion hydrochloride) cannot be considered therapeutically equivalent to the brand-name product Wellbutrin.

**Neurontin (Gabapentin) 100 mg, 1-3X and 2 at bedtime:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy Drugs (AEDS).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Specific Antiepilepsy Drugs Page(s): 18 of 127.

**Decision rationale:** The most recent documentation provided from a clinician was dated 01/09/2014, the rest consisted of UR reports. The patient suffers from fibromyalgia. Neurontin is recommended for neuropathic pain. There is no description of her pain symptomatology, no pain rating provided, no description of medication efficacy, and no current records. As such this request is noncertified. MTUS: Gabapentin (Neurontin, Gaborone, 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. 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. 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. 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. 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. 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. Therefore, Neurontin (Gabapentin) 100 mg, 1-3X and 2 at bedtime is not medically necessary.

**Naratriptan 2.5 mg:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/naratriptan.html>

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Webmd.com

**Decision rationale:** The most recent documentation provided from a clinician was dated 01/09/2014, the rest consisted of UR reports. The patient suffers from migraines. Naratriptan is indicated for the diagnosis of migraine headaches, however there is no current documentation to support the need for this medication. There is no description of headache symptomatology, prior treatment provided and efficacy, or functional improvement. As such this request is noncertified. Neither MTUS nor ODG reference Naratriptan. Per webmd.com Naratriptan is used to treat migraines. It is used to relieve headaches, pain and other symptoms of migraines, including sensitivity to light/sound, nausea, and vomiting. It does not prevent future migraines or reduce how often a migraine may occur. Naratriptan belongs to a group of drugs called triptans. It affects serotonin that constricts blood vessels in the brain. It may also block other pain pathways in the brain. Therefore, Naratriptan 2.5 mg is not medically necessary.

**Oxycodone 20 mg, 1-6X:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria or use of Opioids Page(s): 78-82 of 127.

**Decision rationale:** The patient suffers from fibromyalgia. There is no specific description of her pain symptomatology described which would include nature, location, and intensity. There is no evidence of objective functional improvement, and no evidence of efficacy of other medications tried. There is no documentation of any urine drug screening, risk assessments, or attempts at weaning and tapering per MTUS guidelines. No VAS scores were provided before and after medication administration. As such this request is noncertified. Per MTUS: 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 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.(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 poorpain control.(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drugescalation, drug diversion).(g) Continuing review of overall situation with regard to nonopioid means of paincontrol.(h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioidsare 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. Therefore, Oxycodone 20 mg, 1-6X is not medically necessary.

**Buspar (Buspirone) 15 mg, 1-3 X: 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), Treatment in Workers Compensation (TWC), Pain Procedure Summary, last updated 07/10/2014

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Anti-anxiety Medications in Chronic Pain

**Decision rationale:** The UR of 09/15/14 allowed for Buspar 15mg #60 as partial certification in order to allow downward titration and complete discontinuation of medication should no further records is provided. SSRI's are considered first line agents in the treatment of anxiety, which would also have the added benefit of treating this patient's depression. In addition, per ODG below efficacy of Buspirone is decreased in recent prior benzodiazepine use, which applies in this patient's use of Ativan and Valium. As no records have been provided, this request is noncertified. MTUS does not address Buspar (Buspirone). ODG recommends diagnosing and controlling anxiety as an important part of chronic pain treatment, including treatment with anxiety medications based on specific DSM-IV diagnosis as described below. Definition of anxiety disorders: Anxiety disorders for this entry include (1) generalized anxiety disorder (GAD); (2) panic disorder (PD); (3) post-traumatic stress disorder (PTSD); (4) social anxiety disorder (SAD); & (5) obsessive-compulsive disorder (OCD). Many antidepressants, in particular the Selective Serotonin Reuptake Inhibitors (SSRIs) are considered first-line agents in the treatment of most forms of anxiety. They also have the advantage of treating comorbid depression. Selective Norepinephrine Reuptake Inhibitors (SNRIs), in particular Effexor (venlafaxine) have also been proven to be effective in the treatment of many anxiety disorders. Benzodiazepines are often used to treat anxiety disorders; however, many guidelines discourage the long-term use of benzodiazepines due to sedation effects and potential for abuse and psychological dependence. Long-term use is often associated with withdrawal symptoms. Some other drug classes used to treat anxiety are antihistamines (e.g. hydroxyzine), 5HT1 agonist (e.g. Buspirone), and some anti-epilepsy drugs. (c) 5-HT1A Agonist: Buspirone (Buspar, generic available): also approved for short-term relief of anxiety symptoms. Efficacy is decreased in patients with recent prior benzodiazepine use. Buspar (Buspirone) 15 mg, 1-3 X is not medically necessary.

**Docusate 100 mg, 2-3 X:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consult, Docusate

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Drugs.com

**Decision rationale:** The most recent documentation provided from a clinician was dated 01/09/2014; the rest consisted of UR reports. Ducosate is a stool softener used to treat or prevent constipation or to prevent fecal impaction. The patient has a diagnosis of irritable bowel syndrome; however it is well known that a prominent side effect of opioid pain medications (e.g. oxycodone) is constipation. However, there is no recent documentation showing that this is the case in this patient. As such this request is noncertified. Neither MTUS nor ODG reference Ducosate. Per Drugs.com, Ducosate is a stool softener. It works by helping fat and water into the stool mass to soften the stool. It is used for relieving occasional constipation and preventing dry, hard stools. Docusate 100 mg, 2-3 X is not medically necessary.