

Case Number:	CM15-0165986		
Date Assigned:	09/10/2015	Date of Injury:	01/28/2008
Decision Date:	10/28/2015	UR Denial Date:	08/03/2015
Priority:	Standard	Application Received:	08/24/2015

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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation, Pain Management

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 48 year old female with an industrial injury dated 01-28-2008. A review of the medical records indicates that the injured worker is undergoing treatment for TBI (traumatic brain injury) with frontal lobe syndrome, depression, anxiety, PTSD (post-traumatic stress disorder), panic, basal cell cancer on face status post-surgery, possible osteoarthritis, amenorrhea, and status post recent minor MVA (motor vehicle accident). Treatment consisted of MRI of brain 8-01-2014, prescribed medications, counseling and periodic follow up visits. Medical records (06-02-2015) indicate that the injured worker has post traumatic headaches, but the headaches have not been troubling her. Records also indicate that the injured worker has sensory changes over the face where fractures were sustained. The injured worker is status post bracing of her teeth which corrected the dental malocclusion which followed her industrial injury. Documentation also noted that they injured worker had extensive counseling because of depression, post-traumatic stress disorder, and anxiety caused by her industrial injury. Objective findings (06-02-2015) revealed decreased facial sensation, right central and slight peripheral facial weakness, slightly and diffusely increased muscle tone, muscle spasms along the spine, decreased reflexes and wide based gait. Records (06-02-2015) also indicated that the MMSE (mini mental status exam) score was 22 out of 29 with her declining to do serial sevens, write and draw. The injured worker was noted to be gregarious and impulsive. Magnetic Resonance Imaging (MRI) brain was normal. In a progress report dated 07-21-2015, the injured worker reported improved headaches with Verapamil. Objective findings (07-21-2015) revealed abnormal primary gaze with left 3rd and 6th, right central and slight peripheral facial weakness,

absent jaw jerk reflex, increased muscle tone, slowed "RAMs" on the right, decreased right arm swing, and positive Romberg's sign. The treating physician prescribed Clonidine 1mg, #210 for treatment of PTSD, Complete Metabolic Panel, CBC, Estradiol, LH, Prolactin, Lamotrigine level to check pituitary status and Botox 100 units for headaches, now under review. Utilization Review determination on 08-03-2015, denied the request for Clonidine 1mg, #210, Complete Metabolic Panel, CBC, Estradiol, LH, Prolactin, Lamotrigine level and Botox 100 units.

IMR ISSUES, DECISIONS AND RATIONALES

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

Clonidine 1mg, #210: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Clonidine, Intrathecal. Decision based on Non-MTUS Citation The 2013 Canadian Hypertension Education Program recommendations for blood pressure measurement, diagnosis, assessment of risk, prevention, and treatment of hypertension. (<http://www.guideline.gov/content.aspx?id=46660&search=hypertension>) Uptodate Online, Clonidine.

Decision rationale: Regarding the request for clonidine, Chronic Pain Medical Treatment Guidelines primarily have guidelines of this medication in the context of intrathecal use. Clonidine is a direct acting adrenergic agonist prescribed historically as an antihypertensive agent, but it has found new uses including treatment of some types of neuropathic pain. Further guidelines are found at Uptodate Online, an evidenced-based database. Within the documentation available for review, the requesting physician has indicated that clonidine is being prescribed for the treatment of PTSD. This is off-label use, and it is not apparent what first line agents have been unsuccessfully trialed for this. Given this, the currently requested clonidine is not medically necessary.

Complete Metabolic Panel: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Lab Tests Online, Comprehensive Metabolic Panel (<http://labtestsonline.org/understanding/analytes/cmp/tab/test>).

Decision rationale: With regard to the request for CMP, California MTUS and ODG do not address the issue. A CMP is ordered as a broad screening tool to evaluate organ function and check for conditions such as diabetes, liver disease, and kidney disease. The CMP may also be ordered to monitor known conditions, such as hypertension, and to monitor people taking specific medications for any kidney- or liver-related side effects. Within the documentation

available for review, the provider notes that this is done in the context of check for effects of lamotrigine, which the patient has been taking for some time. This is medically appropriate as lamotrogine has known effects on hepatic enzymes. Thus, this request is medically necessary.

CBC: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Complete Blood Count (<http://labtestsonline.org/understanding/analytes/cbc/tab/test>).

Decision rationale: Regarding the request for CBC, the California MTUS and ODG do not address the issue except in the context of monitoring this lab periodically for patients on long term NSAIDs. Therefore, more thorough guidelines are found in terms of defining the CBC, which consists of measures of hemoglobin, hematocrit, white blood count, and platelets. Within the documentation available for review, the provider notes that this is done in the context of check for effects of lamotrigine, which the patient has been taking for some time. This is medically appropriate as lamotrogine has the potential for blood dys crasias, a very serious potential reaction (although rare). Thus, this request is medically necessary.

Estradiol: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Uptodate Online, Clinical manifestations of hypopituitarism, Hormone Deficiencies.

Decision rationale: With regard to the request for an estradiol level test, the CA MTUS, ACOEM, and ODG do not address this issue. Alternate guidelines from Uptodate Online are cited, which state: "In women, hypogonadism means ovarian hypofunction, which results in decreased estradiol secretion. The clinical consequences of estradiol deficiency in women with secondary hypogonadism are similar to those seen in women with primary hypogonadism (primary ovarian insufficiency [premature ovarian failure]). Findings in premenopausal women include irregular periods or amenorrhea, anovulatory infertility, vaginal atrophy, and hot flashes. No physical findings of hypogonadism are detectable initially, but after several years, breast tissue decreases and bone mineral density (BMD) declines." A review of the submitted documentation in this case indicates that the request for this lab test is because of concern for amenorrhea and early menopause in this patient. The patient has a history of traumatic brain injury, which can result in selective or pan-hypopituitarism. Therefore, a work-up of causes for amenorrhea is appropriate and is justified as industrially related. This request is medically necessary.

LH: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Uptodate Online, Clinical manifestations of hypopituitarism, Hormone Deficiencies.

Decision rationale: With regard to the request for a Lutenizing Hormone serum blood test, the CA MTUS, ACOEM, and ODG do not address this issue. Alternate guidelines from Uptodate Online are cited, which state: "Deficient secretion of the gonadotropins follicle-stimulating hormone (FSH) and luteinizing hormone (LH) results in hypogonadotropic hypogonadism (secondary hypogonadism) in both women and men." A review of the submitted documentation in this case indicates that the request for this lab test is because of concern for amenorrhea and early menopause in this patient. The patient has a history of traumatic brain injury, which can result in selective or pan-hypopituitarism. Therefore, a work-up of causes for amenorrhea is appropriate and is justified as industrially related. In fact, because the requesting provider may not have the necessary expertise in hormonal work-ups possible endocrine consultation is appropriate. This request is medically necessary.

Prolactin: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Uptodate Online, Clinical manifestations of hypopituitarism, Hormone Deficiencies Mukherjee A, Murray RD, Columb B, et al. Acquired prolactin deficiency indicates severe hypopituitarism in patients with disease of the hypothalamic-pituitary axis. Clin Endocrinol (Oxf) 2003; 59:743.

Decision rationale: With regard to the request for a prolactin serum blood test, the CA MTUS, ACOEM, and ODG do not address this issue. Alternate guidelines from Uptodate Online are cited, which state: "The only known clinical manifestation of prolactin deficiency is the inability to lactate after delivery. Isolated prolactin deficiency is rare; most patients with acquired prolactin deficiency have evidence of other pituitary hormone deficiencies." In fact, an article by Mukherjee A et al indicates that acquire prolactin deficiency may be an indicator of severe hypopituitarism. A review of the submitted documentation in this case indicates that the request for this prolactin lab test is because of concern for amenorrhea and early menopause in this patient. The patient has a history of traumatic brain injury, which can result in selective or pan-hypopituitarism. Therefore, a work-up of causes for amenorrhea is appropriate and is justified as industrially related. This request is medically necessary.

Lamotrigine level: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Uptodate Online, Lamotrigine Hirsch LJ et al. Correlating lamotrigine serum concentrations with tolerability in patients with epilepsy. Neurology. 2004 Sep 28; 63 (6): 1022-6.

Decision rationale: With regard to the request for a lamotrigine level serum test, the CA MTUS, ACOEM, and ODG are silent regarding this. Instead, an evidence based database in Uptodate Online is cited, as well as a scholarly article. Lamotrigine levels are appropriate for monitoring, although there is some controversy as to when these levels need to be drawn. Hirsch LJ et al states: "There is a correlation between LTG serum level and tolerability, independent of the use of other AEDs. Adverse effects requiring a dose change are uncommon with the most frequently encountered LTG concentrations (<10 microg/mL) and occur in only 7.4% of patients at levels obtained during the majority of clinical trials (<5 microg/mL). An initial target range of 1.5 to 10 microg/mL is suggested, though higher levels, up to >20 microg/mL, are often tolerated and can lead to additional efficacy in refractory patients." In the case of this injured worker, a progress note from 7/25/15 indicates that the requesting provider is concerned for lamotrigine side effects. The provider has identified that the patient has been having unusual symptoms including amenorrhea. It should be noted that lamotrigine has not been associated with menstrual dysfunction, unlike another AED carbamazepine. However, given the literature does not establish consensus on when to draw lamotrigine levels, it is appropriate to monitor this as suggested by the scholarly article cited above. This request is medically necessary.

Botox 100 units: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Botulinum toxin (Botox Myobloc). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Head Chapter, Botox.

Decision rationale: Regarding the request for botulinum toxin, Chronic Pain Medical Treatment Guidelines state that botulinum toxin has mixed evidence for migraine headache. However, since these guidelines were released, Botox is now FDA approved for chronic migraines since additional supportive studies have been carried out. The ODG recommends botulinum for prevention of headache in patients with chronic migraine. ODG states that to treat chronic migraine, botulinum toxin A is given approximately every 12 weeks as multiple injections around the head and neck to try to dull future headache symptoms. It has not been shown to work for the treatment of episodic migraine headaches that occur 14 days or fewer per month, or for other forms of headache. ODG recommends continuation of Botox for migraine headache prophylaxis if the frequency of headaches was reduced by at least 7 days per month (when compared to pre-treatment average); or duration was reduced by at least 100 hours per month (compared to pre-treatment). Within the documentation available for review, there is no

clear documentation that the patient experiences 15 or greater headache days per month, or clear description of the current frequency and duration of the headaches. There is a distinction between classic/common migraine and chronic migraine, which involves more headache days per month. Although the patient does have migraine and takes verapamil for prophylaxis, given the lack of documentation in the associated note dated 6/2/15, the current request is not medically necessary.