

<b>Case Number:</b>	CM15-0104885		
<b>Date Assigned:</b>	06/12/2015	<b>Date of Injury:</b>	05/01/2010
<b>Decision Date:</b>	10/15/2015	<b>UR Denial Date:</b>	05/04/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/01/2015

### 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 30 year old male, who sustained an industrial injury on 5/01/2010. He reported a head injury with cognitive deficits, multiple fractures including pelvic, left radius, mandibular and developing chronic pain, sciatica, post traumatic stress, depression with psychosis and severe anxiety. Diagnoses include major depression secondary to heat trauma, pain syndrome, and anxiety. Treatments to date include medication therapy. Currently, he complained of increased anxiety secondary to inability to obtain medications. That anxiety was rated 10/10 with panic attacks occurring at increased frequency. He complained of increased headaches and difficulty sleeping. He demonstrated decreased functioning and following instructions requiring assistance to set up medications. He complained of ongoing brain injury problems with memory, irritability, and sensitivity to light, balance issues and comprehension of both English and Spanish. On 5/18/15, the physical examination documented ongoing cognitive difficulties including forgetfulness, inability to follow medical directions, difficulty with word finding and cannot fill out forms independently. The provider documented that the injured worker required assistance for all executive functioning. The plan of care included a consultation with a learning services program, eight (8) weeks of skilled nursing care, biotype moisturizing spray #1, and biotype mouthwash #1; Lamictal 200mg #30; Lamictal 25mg #60; Abilify 10mg #90; Seroquel 200mg #60, Klonopin 0.5mg #60; and Topamax 100mg #60.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Consultation with Learning Services Program: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) Occupational Medicine Practice Guidelines, Independent Medical Examinations and Consultations Chapter, Page 127.

**Decision rationale:** With regard to the request for specialty consultation, the CA MTUS does not directly address specialty consultation. The ACOEM Practice Guidelines Chapter 7 recommend expert consultation when the plan or course of care may benefit from additional expertise. Thus, the guidelines are relatively permissive in allowing a requesting provider to refer to specialists. Although in this case the injured worker has documentation of brain injury with severe cognitive deficits, the standard of care for the evaluation and management of cognitive deficits is by psychology or speech language pathology. Both of these disciplines can specifically work with the patient in terms of tracking improvement in cognitive domains. There is a lack of specificity with regard to what is entailed in the learning services program requested. Given this, this request is not medically necessary.

### **Skilled nursing (weeks) Quantity: 8: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee Chapter, Skilled Nursing Facility Care.

**Decision rationale:** Regarding the request for skilled nursing facility, California MTUS and ACOEM do not contain criteria for the use of skilled nursing facilities. ODG recommends the use of skilled nursing facilities if the patient has been hospitalized for at least 3 days for major multiple trauma or major surgery and was admitted to the skilled nursing facility within 30 days of discharge, if treatment for the above conditions has caused new functional limitations which preclude management with lower levels of care, and if those functional limitations cause an inability to ambulate more than 50 feet or perform activities of daily living. Additionally, skilled nursing admission would require that the patient needs skilled nursing or skilled rehabilitation services or both on a daily basis at least 5 days per week. The patient needs to benefit from and participate with at least 3 hours per day of physical therapy, occupational therapy, and or speech therapy. Additionally, ODG states that the facility must be a Medicare certified facility, and the treatment is precluded in lower levels of care. In the case of this injured worker, it is not apparent what the rationale for skills nursing for 8 weeks is. A review of the submitted medical record fails to reveal a rationale. The patient is noted to have significant cognitive deficits, mood disorder, and polytrauma. But the patient appears to be outpatient and typically skilled nursing facility services are recommended in the context of post-hospitalization. This request is not medically necessary.

**Biotype Moisturizing Spray Quantity: 1: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS national evidence based citations.

**Decision rationale:** In the case of this request, the California Medical Treatment Utilization Schedule does not contain specific guidelines on this particular request. Therefore, national evidence based guidelines are cited. It is further noted that the Official Disability Guidelines and ACOEM do not have provisions for this request either. In fact, there is a paucity of literature to support this item. Furthermore, in this case, the progress notes do not contain sufficient rationale as to why this request is necessary. Therefore, this request is not medically necessary. It is unclear what specific type of spray the "biotype moisturizing spray" is and why it is necessary. Not medically necessary

**Biotype Mouthwash solution Quantity: 1: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS national evidence based citations.

**Decision rationale:** In the case of this request, the California Medical Treatment Utilization Schedule does not contain specific guidelines on this particular request. Therefore, national evidence based guidelines are cited. It is further noted that the Official Disability Guidelines and ACOEM do not have provisions for this request either. In fact, there is a paucity of literature to support this item. Furthermore, in this case, the progress notes do not contain sufficient rationale as to why this request is necessary. Therefore, this request is not medically necessary. It is unclear what specific type of mouthwash solution the "biotype mouthwash" is and why it is necessary. Not medically necessary

**Lamictal 200mg Quantity: 30: Overturned**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs). Decision based on Non-MTUS Citation Uptodate Online, Lamictal.

**Decision rationale:** The CPMTG states the following: "Lamotrigine (Lamictal, generic available) has been proven to be moderately effective for treatment of trigeminal neuralgia, HIV, and central post-stroke pain; (Backonja, 2002) (Namaka, 2004) (Maizels, 2005) (ICSI, 2005) (Dworkin, 2003) (Wiffen-Cochrane, 2007). It has not been shown to be effective for diabetic neuropathy. Dosing Information:(off-label indication) Begin with 25 mg daily; then titrate up by 25 mg to 50 mg every 1-2 weeks up to 400 mg/day; titration must occur slowly and tapering should occur upon discontinuation. (ICSI, 2007)" However, in this case, it should be noted that the Lamictal is primarily recommended for a mood disorder. Lamictal can be utilized for mood disorders and is FDA approved for the treatment of bipolar disorder. This worker is noted to have severe cognitive and mood disorders, and is followed by psychiatry. The psychiatrist has diagnosed major depression secondary to head trauma and has been following the dosing of Lamictal. Given the need for pharmacologic intervention for mood disorder, the off-label use of Lamictal is appropriate in brain injured populations. This request is medically necessary.

**Lamictal 25mg Quantity: 60: Overturned**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs). Decision based on Non-MTUS Citation Uptodate Online, Lamictal.

**Decision rationale:** The CPMTG states the following: "Lamotrigine (Lamictal, generic available) has been proven to be moderately effective for treatment of trigeminal neuralgia, HIV, and central post-stroke pain; (Backonja, 2002) (Namaka, 2004) (Maizels, 2005) (ICSI, 2005) (Dworkin, 2003) (Wiffen-Cochrane, 2007). It has not been shown to be effective for diabetic neuropathy... Dosing Information:(off-label indication) Begin with 25 mg daily; then titrate up by 25 mg to 50 mg every 1-2 weeks up to 400 mg/day; titration must occur slowly and tapering should occur upon discontinuation. (ICSI, 2007)" However, in this case, it should be noted that the Lamictal is primarily recommended for a mood disorder. Lamictal can be utilized for mood disorders and is FDA approved for the treatment of bipolar disorder. This worker is noted to have severe cognitive and mood disorders, and is followed by psychiatry. The psychiatrist has diagnosed major depression secondary to head trauma and has been following the dosing of Lamictal. Given the need for pharmacologic intervention for mood disorder, the off-label use of Lamictal is appropriate in brain injured populations. This request is medically necessary.

**Abilify 10mg Quantity: 90: Overturned**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**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 and Stress Chapter, Aripiprazole Uptodate Online, Abilify Entry.

**Decision rationale:** Regarding the request for Abilify, California MTUS guidelines do not contain criteria for the use of Abilify. ODG states Abilify is not recommended as a first-line treatment. Abilify (aripiprazole) is an antipsychotic medication. Antipsychotics are the first-line psychiatric treatment for psychotic disorders such as schizophrenia. It is also FDA approved as an adjunctive medication for the treatment of depression. For this latter indication, it should be noted that the FDA approval for this follows the time in which the latest ODG were authored. Within the information made available for review, a diagnosis of traumatic brain injury with psychotic depression is noted. The patient is followed by a psychiatrist and a note from 4/2015 indicates that the patient has a GAF score of 50. The patient continues with mood disorder and it is appropriate to utilize Abilify as an adjunctive medication in the management of depression. Given this, the currently requested Abilify is medically necessary.

**Seroquel 200mg Quantity: 60:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter & Mental Illness and Stress Chapter, Atypical Anti-Psychotic Topic and Other Medical Treatment Guidelines Uptodate Online, Seroquel Entry.

**Decision rationale:** The California Medical Treatment Utilization Schedule does not specifically address anti-psychotic medication. The ODG Mental Illness and Stress Chapter states the following regarding atypical anti-psychotics: "Not recommended as a first-line treatment. There is insufficient evidence to recommend atypical antipsychotics (eg, quetiapine, risperidone) for conditions covered in ODG. See PTSD pharmacotherapy. Adding an atypical antipsychotic to an antidepressant provides limited improvement in depressive symptoms in adults, new research suggests. The meta-analysis also shows that the benefits of antipsychotics in terms of quality of life and improved functioning are small to nonexistent, and there is abundant evidence of potential treatment-related harm. The authors said that it is not certain that these drugs have a favorable benefit-to-risk profile. Clinicians should be very careful in using these medications. (Spielmans, 2013) The American Psychiatric Association (APA) has released a list of specific uses of common antipsychotic medications that are potentially unnecessary and sometimes harmful. Antipsychotic drugs should not be first-line treatment to treat behavioral problems. Antipsychotics should be far down on the list of medications that should be used for insomnia, yet there are many prescribers using quetiapine (Seroquel), for instance, as a first line for sleep, and there is no good evidence to support this. Antipsychotic drugs should not be first-line treatment for dementia, because there is no evidence that antipsychotics treat dementia. (APA, 2013) Antipsychotic drugs are commonly prescribed off-label for a number of disorders outside of their FDA-approved indications, schizophrenia and bipolar disorder. In a new study funded by the National Institute of Mental Health, four of the antipsychotics most commonly prescribed off label for use in patients over 40 were found to lack both safety and effectiveness. The four atypical antipsychotics were aripiprazole (Abilify), olanzapine (Zyprexa), quetiapine (Seroquel), and risperidone (Risperdal). The authors concluded that off-label use of these drugs

in people over 40 should be short-term, and undertaken with caution. (Jin, 2013)"In the case of this injured worker, there is documentation of psychotic depression and the patient is followed by psychiatry. Seroquel is FDA approved for the treatment of schizophrenia and bipolar disorder, but can be utilized to manage psychosis symptoms or as adjunctive therapy in severe depression. The patient does have documentation of this depression in a progress note from April 2015. There is a statement that the patient was very depressed at lower dosages of this medication. Given this, this request is medically necessary as it appears to help mood and social functioning.

**Klonopin 0.5mg Quantity: 60: Overturned**

**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): Benzodiazepines.

**Decision rationale:** Regarding the request for Klonopin (clonazepam), Chronic Pain Medical Treatment Guidelines state the benzodiazepines are not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Within the documentation available for review, there is documentation of improvement in panic attacks with the use of Klonopin. It should be noted that the CA MTUS recommend against long-term use. However, in this case, the worker is being optimized on preventative anxiety medications and continues to have episodes of breakthrough anxiety, especially when exposed to claustrophobic environments, therefore it reasonable to continue this prn benzodiazepine is medically necessary

**Topamax 100mg Quantity: 60: 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): Anti-epilepsy drugs (AEDs).

**Decision rationale:** Regarding request for topiramate (Topamax), Chronic Pain Medical Treatment Guidelines state that anti-epilepsy drugs are recommended for neuropathic pain. They go on to state that a good outcome is defined as 50% reduction in pain and a moderate response is defined as 30% reduction in pain. Guidelines go on to state that after initiation of treatment, there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. Within the documentation available for review, there is no identification of any specific analgesic benefit (in terms of percent reduction in pain or reduction of NRS), and no documentation of specific objective functional improvement. Although there is documentation that this medication is utilized for pain and migraines, these specific details of efficacy are not noted in the submitted records. In the absence of such documentation, the currently requested topiramate (Topamax) is not medically necessary.