

<b>Case Number:</b>	CM14-0101128		
<b>Date Assigned:</b>	08/08/2014	<b>Date of Injury:</b>	05/10/2005
<b>Decision Date:</b>	09/25/2014	<b>UR Denial Date:</b>	05/26/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/30/2014

### 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 Internal Medicine 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:

The patient is an injured worker with post-traumatic headaches, right knee sprain, and carpal tunnel syndrome. The date of injury was 05-10-2005. The progress report dated 05-05-2014 documented a history of post concussive syndrome. Subjective complaints were of headaches two to three times per week which are moderately severe. Typically they are bifrontal and throbbing. She is using Depakote 500 mg BID in addition to Cymbalta 60mg per day. She takes Lyrica and Motrin. Allergies were Dilantin (critical), sulfa based (critical), and codeine (critical). Past medical history included hypercholesterolemia, stomach ulcers, broken bones, knee arthritis, seizures, head injury, migraines, cancer, immune system disorder, thyroid disease. Past surgical history included double bunionectomy, carpal tunnel release, left hand trigger, right knee meniscus. Medications were Cymbalta 60 mg, Tramadol-Acetaminophen 37.5-325 mg, Cymbalta 60 mg, Divalproex 250 mg, Ranitidine 150 mg, Ibuprofen 800 mg, Lyrica 300 mg, Furosemide 20 mg, Levothyroxine 100 mcg, and Liothyronine 5 mcg. Vital signs were blood pressure 120/82, pulse 72, and height 66 inches, weight 145 pounds. The patient was well-nourished and appropriately groomed with normal musculoskeletal development and no obvious deformities. The patient was oriented to time, place, person with mood appropriate. Gait and station was normal. Romberg is negative with normal heel-to-toe gait and normal rapid alternating movements. Sensation is normal to light touch in all four extremities. She is left handed. Clinically she is alert with fluent speech and no papilledema. Her visual fields, pupils and extraocular movements are normal. There is no weakness or sensory loss and gait and station are normal. She has good mobility in her neck with no spasm. Her blood pressure is 120/82, pulse 72, and respirations regular. Diagnosis was post-concussion syndrome. Treatment plan was to continue medications. She was to continue on the above regime which keeps her functional. Neck exercises were discussed. She does appear permanent and stationary. Recheck appointment

will be in three months. Primary treating physician's progress report dated 3/18/14 documented subjective complaints of right knee pain, upper and lower extremity problems, occasional spasms in the thumb and index fingers of both hands lately, with respect to her right knee. She wears the orthosis which prevents hyperextension and allows her to take walks. Past medical history included migraine headaches and hypothyroidism autoimmune. Past surgical history included carpal tunnel release, DeQuervain's disease, trigger finger release, right knee 2012, and lumbar epidurals. Exam showed patient to be in no obvious discomfort at rest. She moves about reasonably well. Wrist and hand exam is not significantly changed. Right knee has a trace of effusion. There is minimal medial joint line tenderness. Mild crepitation noted on ranging. Diagnoses were status post sprain right knee with residual pain and mild instability, chondromalacia involving medial and patellofemoral compartments, tendinitis and carpal tunnel syndrome of wrists and hands with repetitive strain syndrome, knee pain, tibial plateau chondromalacia, and carpal tunnel syndrome. Treatment plan included a neoprene knee sleeve and magnesium supplementation for the hand cramps. The progress report dated 2/4/14 documented headaches occurring two times per week which are generalized more through the occipital region and can be throbbing. Depakote and Cymbalta afford moderate relief. The patient has a diagnosis of post-traumatic headaches. Utilization review determination date was 5/26/14.

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

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

**Cymbalta 50mg:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain Page(s): 13-16. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence FDA Prescribing Information Cymbalta [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2010/022516lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022516lbl.pdf).

**Decision rationale:** The request is for Cymbalta 50 mg. Medical records document that the patient has been prescribed Cymbalta 60 mg - not 50 mg. The FDA Prescribing Information documents that Cymbalta is supplied as 20 mg, 30 mg, and 60 mg capsules. Cymbalta is not supplied as a 50 mg capsule. Therefore, the request for Cymbalta 50 mg cannot be endorsed, because Cymbalta is not available as a 50 mg capsule. Therefore, the request for Cymbalta 50 mg is not medically necessary.

**Tramadol-Acetaminophen 37.5- 325mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of Opioids.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol (Ultram) Page(s): 93-94, 113, 123.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address Ultram (Tramadol). Tramadol is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. Tramadol is not classified as a controlled substance by the DEA. Tramadol is indicated for the management of moderate to moderately severe pain. Tramadol may increase the risk of seizure. Medical records document that the patient has a history of seizures. Therefore, Tramadol is not recommended in this patient with seizure disorder. Therefore, Tramadol-Acetaminophen 37.5-325 mg is not recommended. Therefore, the request for Tramadol-Acetaminophen 37.5-325mg is not medically necessary.

**Cymbalta 60mg:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain Page(s): 13-16. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence FDA Prescribing Information Cymbalta [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2010/022516lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022516lbl.pdf).

**Decision rationale:** The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines state that antidepressants for chronic pain are recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. Duloxetine (Cymbalta) is FDA-approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. Duloxetine is used off-label for neuropathic pain and radiculopathy. Duloxetine is recommended as a first-line option for diabetic neuropathy. FDA Prescribing Information documents that Cymbalta is indicated for major depressive disorder, generalized anxiety disorder, diabetic peripheral neuropathic pain, fibromyalgia, and chronic musculoskeletal pain. Medical records document the medical history and diagnoses of post-traumatic headaches, right knee sprain, carpal tunnel syndrome, post-concussion syndrome, knee arthritis, head injury, migraine headaches, bunionectomy, carpal tunnel release surgery, left hand trigger release surgery, right knee meniscus surgery, lumbar epidural injections, sprain right knee with residual pain and mild instability, chondromalacia involving medial and patellofemoral compartments, tendinitis and carpal tunnel syndrome of wrists and hands with repetitive strain syndrome, knee pain, tibial plateau chondromalacia, and carpal tunnel syndrome. The patient reported benefit from Cymbalta. Medical records document that the patient has chronic musculoskeletal pain, which is an FDA indication for Cymbalta. Medical records document neuropathic pain. MTUS and FDA guidelines support the prescription Cymbalta 60 mg. Therefore, the request for Cymbalta 60 mg is medically necessary.

**Divalproex Sodium 250mg:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy (AEDs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDS) Page(s): 16-20. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence FDA Prescribing Information Divalproex (Depakote) <http://www.drugs.com/cdi/divalproex-delayed-release-tablets.html>.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines state that antiepilepsy drugs (AEDs) may be used for neuropathic pain. FDA Prescribing Information documents that Divalproex (Depakote) is an antiepilepsy drug (AED) that is indicated for therapy in the treatment of seizures and epilepsy. Depakote is indicated for prophylaxis of migraine headaches. Withdrawal of antiepilepsy drugs is associated with increased seizure frequency. Medical records document that the patient has a history of seizures and migraine headaches. Divalproex is an antiepileptic drug that is indicated for seizures and migraine headaches. Withdrawal of antiepilepsy drugs is associated with increased seizure frequency. Medical records document the medical history and diagnoses of post-traumatic headaches, right knee sprain, carpal tunnel syndrome, post-concussion syndrome, knee arthritis, head injury, migraine headaches, bunionectomy, carpal tunnel release surgery, left hand trigger release surgery, right knee meniscus surgery, lumbar epidural injections, sprain right knee with residual pain and mild instability, chondromalacia involving medial and patellofemoral compartments, tendinitis and carpal tunnel syndrome of wrists and hands with repetitive strain syndrome, knee pain, tibial plateau chondromalacia, and carpal tunnel syndrome. Medical records document that the patient has chronic musculoskeletal pain and neuropathic pain. The patient reported benefit from Depakote. The patient has a history of seizures. Depakote is an antiepileptic drug. Withdrawal of antiepilepsy drugs is associated with increased seizure frequency, according to FDA guidelines. Therefore, the maintenance of Divalproex (Depakote) is medically necessary. Therefore, the request for Divalproex Sodium 250 mg is medically necessary.

**Ranitidine HCL 150mg:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: FDA Prescribing Information Zantac (Ranitidine) [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2005/018703s065,019675s031,020251s016lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/018703s065,019675s031,020251s016lbl.pdf).

**Decision rationale:** The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address NSAIDs and gastrointestinal risk factors. Proton Pump Inhibitor (PPI), e.g. Omeprazole (Prilosec), is recommended for patients with gastrointestinal risk factors. MTUS does not address Ranitidine (Zantac). FDA Prescribing Information documents that Zantac is indicated for treatment of gastric ulcer and maintenance therapy for gastric ulcer. The progress report dated 05-05-2014 documented medical history stomach ulcers. Medications include Ranitidine (Zantac) and Ibuprofen 800 mg. Ibuprofen, which is an NSAID, is a gastrointestinal risk factor. The patient has a history of gastric ulcer. FDA Prescribing

Information documents that Zantac (Ranitidine) is indicated for treatment of gastric ulcer and maintenance therapy for gastric ulcer. Therefore, Ranitidine is medically necessary. Therefore, the request for Ranitidine HCL 150mg is medically necessary.

**Ibuprofen 800mg:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAID ( non-steroidal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints, Chapter 11 Forearm, Wrist, and Hand Complaints, Chapter 12 Low Back Complaints, Chapter 13 Knee Complaints, Chapter 14 Ankle and Foot Complaints Page(s): 181,271,308,338,376. Decision based on Non-MTUS Citation FDA Prescribing Information Ibuprofen<http://www.drugs.com/pro/ibuprofen.html>.

**Decision rationale:** The Medical Treatment Utilization Schedule (MTUS) addresses NSAIDs. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) states that NSAIDs are recommended for knee, neck, back, and wrist conditions (pages 181, 271, 308, 338, 376). FDA Prescribing Information documents that Ibuprofen is indicated for relief of mild to moderate pain. Medical records document the medical history and diagnoses of post-traumatic headaches, right knee sprain, carpal tunnel syndrome, post-concussion syndrome, knee arthritis, head injury, migraine headaches, bunionectomy, carpal tunnel release surgery, left hand trigger release surgery, right knee meniscus surgery, lumbar epidural injections, sprain right knee with residual pain and mild instability, chondromalacia involving medial and patellofemoral compartments, tendinitis and carpal tunnel syndrome of wrists and hands with repetitive strain syndrome, knee pain, tibial plateau chondromalacia, and carpal tunnel syndrome. ACOEM guidelines support the use of Ibuprofen (NSAID) for the patient's conditions. Therefore, the request for Ibuprofen 800mg is medically necessary.

**Lyrica 300mg:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDS) Pregabalin (Lyrica) Page(s): 16-20, 19-20. Decision based on Non-MTUS Citation FDA Prescribing Information Lyrica<http://www.drugs.com/pro/lyrica.html>.

**Decision rationale:** The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines state that antiepilepsy drugs (AEDs) may be used for neuropathic pain. FDA Prescribing Information documents that the withdrawal of Lyrica, which is an antiepileptic drug, is associated with the potential of increased seizure frequency. Medical records document that the patient has a history of seizures. Lyrica is an antiepileptic drug. Withdrawal of Lyrica has the potential of increased seizure frequency. Medical records document the medical history and diagnoses of post-traumatic headaches, right knee sprain, carpal tunnel syndrome, post-concussion syndrome, knee arthritis, head injury, migraine

headaches, bunionectomy, carpal tunnel release surgery, left hand trigger release surgery, right knee meniscus surgery, lumbar epidural injections, sprain right knee with residual pain and mild instability, chondromalacia involving medial and patellofemoral compartments, tendinitis and carpal tunnel syndrome of wrists and hands with repetitive strain syndrome, knee pain, tibial plateau chondromalacia, and carpal tunnel syndrome. Medical records document that the patient has chronic musculoskeletal pain and neuropathic pain. The patient has a history of seizures. Lyrica is an antiepileptic drug. Withdrawal of Lyrica has the potential of increased seizure frequency, according to FDA guidelines. Therefore, the maintenance of Lyrica is medically necessary. Therefore, the request for Lyrica 300 mg is medically necessary.

**Furosemide 20mg:** 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.

**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: FDA Prescribing Information Furosemide <http://www.drugs.com/pro/furosemide.html>.

**Decision rationale:** The Medical Treatment Utilization Schedule (MTUS) does not address Furosemide. FDA Prescribing Information documents that Furosemide is indicated for the treatment of hypertension and edema associated with congestive heart failure, cirrhosis of the liver and renal disease. Laboratory tests, serum electrolytes, potassium, and creatine should be determined frequently during the first few months of Furosemide therapy and periodically thereafter. The medical records do not document any of the FDA indications for Furosemide. Medical records do not present laboratory tests, as recommended by FDA guidelines. Therefore, the request for Furosemide is not supported. Therefore, the request for Furosemide 20 mg is not medically necessary.

**Levothyroxine Sodium 100mg:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MD Consult, Levothyroxine.

**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: FDA Prescribing Information Levothyroxine <http://www.drugs.com/pro/levothyroxine.html>.

**Decision rationale:** The Medical Treatment Utilization Schedule (MTUS) does not address Levothyroxine. FDA Prescribing Information for Levothyroxine recommends periodic laboratory tests. The diagnosis of hypothyroidism is confirmed by measuring TSH levels and measurement of free T4. The adequacy of therapy is determined by periodic assessment of appropriate laboratory tests and clinical evaluation. It is recommended that a physical examination and a serum TSH measurement be performed at least annually in patients receiving Levothyroxine. Medical records do not present laboratory tests, as recommended by FDA

guidelines for Levothyroxine. Medical records document a history of hypothyroidism. But no TSH measurements were documented to assess the adequacy of therapy. Therefore the prescription for Levothyroxine cannot be endorsed without recent laboratory tests, per FDA guidelines. Therefore, the request for Levothyroxine Sodium 100mg is not medically necessary.

**Liothyronine Sodium 5mcg:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MD Consult Drugs Monograph: Liothyronine, Hormone and Hormone Modifiers, Thyroid Agents.

**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: FDA Prescribing Information Liothyronine <http://www.drugs.com/pro/liothyronine.html>.

**Decision rationale:** The Medical Treatment Utilization Schedule (MTUS) does not address Liothyronine. FDA Prescribing Information for Liothyronine recommends periodic laboratory tests. Treatment of patients with thyroid hormones requires the periodic assessment of thyroid status by means of appropriate laboratory tests besides the full clinical evaluation. Serum T3 and TSH levels should be monitored to assess dosage adequacy and biologic effectiveness. Medical records do not present laboratory tests, as recommended by FDA guidelines for Liothyronine. Medical records document a history of hypothyroidism. But no serum T3 and TSH levels were documented to assess the adequacy of therapy. Therefore the prescription for Liothyronine cannot be endorsed without recent laboratory tests, per FDA guidelines. Therefore, the request for Liothyronine Sodium 5 mcg is not medically necessary.