

<b>Case Number:</b>	CM13-0060395		
<b>Date Assigned:</b>	12/30/2013	<b>Date of Injury:</b>	04/25/2000
<b>Decision Date:</b>	06/24/2014	<b>UR Denial Date:</b>	11/15/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/03/2013

### 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 Physical Medicine and Rehabilitation and Pain Medicine and is licensed to practice in Texas and Oklahoma. 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 injured worker is a 55-year-old female with a reported date of injury on 04/25/2000. The mechanism of injury was not submitted within the medical records. Her diagnoses included lumbar radiculopathy, cervical radiculopathy, myalgia/myositis, fibromyalgia, chronic pain, and status post spinal cord stimulation explant. Her previous treatments were reported to include aqua therapy and medications. The progress note date 12/17/2013 listed her medications as Tramadol orally and topically, Neurontin, Cymbalta, and Trepadone for fibromyalgia from the rheumatologist. The pain specialist listed the medication as Vitamin D, Tizanidine, Pantoprazole, Senokot-S, Neurontin, Norco, Naprosyn, and Butrans. The request of authorization form was not submitted within the medical records. The request is for a retrospective Sentraflox AM #80 dated 11/09/2012, and retrospective Trepadone #180 dated 11/09/2012 for fibromyalgia.

### IMR ISSUES, DECISIONS AND RATIONALES

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

#### **RETROSPECTIVE REQUEST FOR SENTRAFLOX AM, #180 DOS :11/9/12: 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) Pain, Antidepressant for Chronic pain.

**Decision rationale:** The injured worker has been prescribed Trepadone for fibromyalgia since 05/2013. The Official Disability Guidelines indicate that Trepadone is a proprietary blend of L-arginine, L-glutamine, choline bitartrate, L-serine, and gamma-aminobutyric acid. Trepadone is intended for the use in the management of joint disorders associated with pain and inflammation. The guideline's criteria for the use of a medical food is the product must be a food for oral or tube feeding, the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements, and the product must be used under medical supervision. According to the guidelines, L-arginine is not indicated for pain or inflammation, instead it is indicated to detoxify urine. The guidelines also state that L-glutamine is used generally for digestive disorders and complementary medicine. The guidelines also state that choline has no known medical need except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. The guidelines also state that L-serine has no indication for use of this supplement. The guidelines also state that gamma aminobutyric acid is indicated for epilepsy, spasticity, and tardive dyskinesia. There is no high quality peer-reviewed literature that suggests gamma is indicated for the treatment of insomnia. Trepadone does not meet the guideline's labeled use for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. The ingredients of this medical food are not indicated for the use of fibromyalgia. Therefore, the request is not medically necessary.

**RETROSPECTIVE REQUEST FOR TREPADONE #180 DOS:11/9/12:** 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) Pain, Medical Foods

**Decision rationale:** The injured worker has been prescribed this medication since at least 05/2013 for fibromyalgia. The Official Disability Guidelines recommend antidepressants as a first-line option for neuropathic pain, and as a possibility for non-neuropathic pain. Tricyclics are generally considered a first-line agent unless they are ineffective poorly tolerated, or contraindicated. The guidelines state that an assessment of treatment with efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medications, sleep quality and duration, and psychological assessment. The guidelines state that there is more information needed regarding the use of selective serotonin reuptake inhibitors (SSRIs) in the treatment of fibromyalgia, therefore, tricyclics may be used for that treatment. The documentation provided reports that the injured worker's pain level is unchanged with an average pain level of 7/10 with medications, and 9/10 without medications. The documentation submitted reports activities of daily living limitations in regards to activity, ambulation, and sleep. The documentation also reports continued total body pain, chronic fatigue, and problems sleeping. Therefore, due to the lack of efficacy regarding pain and sleep quality and duration, as well as guidelines recommending tricyclics due to needing more information regarding the role of SSRIs in fibromyalgia, the request is not medically necessary.

