

**MAXIMUS FEDERAL SERVICES, INC.**

Independent Medical Review

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**Notice of Independent Medical Review Determination**

Dated: **12/12/2013**

[REDACTED]

[REDACTED]

Employee:	[REDACTED]
Claim Number:	[REDACTED]
Date of UR Decision:	8/13/2013
Date of Injury:	10/9/2007
IMR Application Received:	9/4/2013
MAXIMUS Case Number:	CM13-0019907

- 1) MAXIMUS Federal Services, Inc. has determined the request for **Theramine one capsule two times a day, #90 times two is not medically necessary and appropriate.**

## INDEPENDENT MEDICAL REVIEW DECISION AND RATIONALE

An application for Independent Medical Review was filed on 9/4/2013 disputing the Utilization Review Denial dated 8/13/2013. A Notice of Assignment and Request for Information was provided to the above parties on 10/11/2013. A decision has been made for each of the treatment and/or services that were in dispute:

- 1) MAXIMUS Federal Services, Inc. has determined the request for **Theramine one capsule two times a day, #90 times two is not medically necessary and appropriate.**

### **Medical Qualifications of the Expert Reviewer:**

The independent Medical Doctor who made the decision has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Internal Medicine and Cardiology, has a subspecialty in Cardiovascular Disease 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 treatments and/or services at issue.

### **Expert Reviewer Case Summary:**

The patient is a 53-year-old female who was reported to have been injured on 10/09/2007. Mechanism of injury was not stated. The patient was noted to have undergone a right elbow tendon lengthening with reattachment of the flexor pronator mass and ulnar nerve transposition on 06/02/2009. A clinical note dated 03/26/2013 reported the patient's chief complaint was cervicalgia, right arm pain, and RSD improving. She was noted to have completed 12 sessions of physical therapy and her RSD is noted to have improved dramatically. She was noted to continue on gabapentin twice a day and occasionally takes 3 times a day. On physical exam, she was noted to have moderate decreases of range of motion of the cervical spine with pain. She had pain and tenderness over the medial epicondyle with direct palpation and examination of her right hand noted less pain and the examiner was able to grasp, grip, and move her hand around much more easily. She reported some numbness, mostly in the 3<sup>rd</sup> finger, sometimes in the 2<sup>nd</sup> finger, and sometimes in the 4<sup>th</sup> finger. On 05/21/2013, the patient's right upper extremity pain was noted to continue to improve. She reported to have completed her remaining physical therapy. She reported some medial elbow pain and numbness in the tip of her 3<sup>rd</sup> finger. On examination of her hand, the examiner was able to grasp and grip and move her hand around much more easily but she continued to report some numbness in the 3<sup>rd</sup> finger and sometimes in the 2<sup>nd</sup> and 4<sup>th</sup> fingers of the hand. On 06/26/2013, the patient was reported to have made improvements in regards to her right sided neck pain, shoulder pain, and hand pain. Her primary concern on that date was her ongoing pain in the elbow which was at the lateral aspect and medial aspect along the ulnar nerve. She also reported pain and numbness radiating down the ulnar distribution into the 4<sup>th</sup> and 5<sup>th</sup> fingers. An MRI of the right elbow performed on 06/24/2010 demonstrated mild increased size but normal size morphology of the transposed ulnar nerve and expected postsurgical changes in the common flexor tendon and cubital retinaculum. There was mild tendinosis of the common extensor tendon. The patient was noted to continue to have mild deficits in

range of motion of the cervical spine with minimal amount of pain at all endpoints. She had slight tenderness to direct palpation at the right elbow over the medial epicondyle and with resisted wrist flexion she had slight pain at the medial epicondyle. She had very positive Tinel's at the cubital tunnel and decreased sensation along the ulnar distribution. In addition, the patient had pain with direct palpation of the lateral epicondyle. With resisted wrist extension, she had pain at the lateral epicondyle. A clinical note dated 07/25/2013, signed by Dr. [REDACTED] reported the patient was doing very well, making improvements with each visit, with regards to her right sided neck pain and her arm and hand pain. However, the patient was currently experiencing a flare up of her right elbow and forearm pain. The notes stated that when the patient tried to use her arm, her forearm began to shake and quiver. She was noted to continue to have positive findings on physical exam. Furthermore, the patient was noted to have completed 2 of 12 authorized sessions at that time. She was instructed to take her gabapentin 300 mg 3 times a day rather than once to twice a day.

#### **Documents Reviewed for Determination:**

The following relevant documents received from the interested parties and the documents provided with the application were reviewed and considered. These documents included:

- Application of Independent Medical Review
- Utilization Review Determination
- Medical Treatment Utilization Schedule (MTUS)
- Medical Records from:
  - Claims Administrator
  - Employee/Employee Representative
  - Provider

#### **1) Regarding the request for Theramine one capsule two times a day, #90 times two:**

##### Section of the Medical Treatment Utilization Schedule Relied Upon by the Expert Reviewer to Make His/Her Decision

The Claims Administrator based its decision on the Chronic Pain Medical Treatment Guidelines, Section Antiepilepsy drugs and Theramine, which is part of MTUS.

The Expert Reviewer found that no section of the MTUS was applicable. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Expert Reviewer based his/her decision on the Official Disability Guidelines (ODG), Pain (Chronic), section Medical food: Theramine, which is not part of MTUS.

##### Rationale for the Decision:

The employee reported an injury on 10/09/2007. The employee was noted to have undergone a right elbow tendon lengthening, with reattachment of the flexor pronator mass and ulnar nerve transposition on 06/02/2009. The employee was noted to have developed a chronic regional pain syndrome of the right hand. According to the clinical documentation submitted for review, the treatments

included physical therapy, nonsteroidal anti-inflammatories, splinting, and hand therapy. The employee showed improvement of the symptoms in the right hand. On 07/2013, the employee was noted to have a flare up of the right elbow and forearm pain. The clinical documentation also noted that the employee have completed 2 of 12 authorized sessions of physical therapy. On physical exam, the employee had a positive Tinel's at the cubital tunnel, decreased sensation along the ulnar nerve distribution, and positive pain with resisted wrist flexion bilateral epicondyle. The employee has been prescribed Theramine. The Official Disability Guidelines (ODG) indicate that Theramine is not recommended as it contains gamma-aminobutyric acid (GABA), choline bitartrate, L-arginine, and L-serine. The guidelines indicate there is no high quality peer reviewed literature that suggest that GABA or L-arginine is effective for treatment of chronic pain. In addition, there is no known medical need for choline supplementation or L-serine. As such, the request for Theramine does not meet guidelines' recommendations. Also, there are no high quality studies to support the use of the ingredients in Theramine. **The request for Theramine one capsule two times a day, #90 times two is not medically necessary and appropriate.**

**Effect of the Decision:**

The determination of MAXIMUS Federal Services and its physician reviewer is deemed to be the final determination of the Administrative Director, Division of Workers' Compensation. With respect to the medical necessity of the treatment in dispute, this determination is binding on all parties.

In accordance with California Labor Code Section 4610.6(h), a determination of the administrative director may be reviewed only if a verified appeal is filed with the appeals board for hearing and served on all interested parties within 30 days of the date of mailing of the determination to the employee or the employer. The determination of the administrative director shall be presumed to be correct and shall be set aside only upon proof by clear and convincing evidence of one or more of the grounds for appeal listed in Labor Code Section 4610.6(h)(1) through (5).

Sincerely,

Paul Manchester, MD, MPH  
Medical Director

cc: Department of Industrial Relations  
Division of Workers' Compensation  
1515 Clay Street, 18<sup>th</sup> Floor  
Oakland, CA 94612

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Disclaimer: MAXIMUS is providing an independent review service under contract with the California Department of Industrial Relations. MAXIMUS is not engaged in the practice of law or medicine. Decisions about the use or nonuse of health care services and treatments are the sole responsibility of the patient and the patient's physician. MAXIMUS is not liable for any consequences arising from these decisions.