

## Notice of Independent Medical Review Determination

Dated: 12/13/2013

[REDACTED]

[REDACTED]

Employee:

Claim Number:

Date of UR Decision:

Date of Injury:

IMR Application Received:

MAXIMUS Case Number:

[REDACTED]

7/23/2013

4/23/1999

7/26/2013

CM13-0004691

- 1) MAXIMUS Federal Services, Inc. has determined the request for **Gralise 600mg is not medically necessary and appropriate.**
- 2) MAXIMUS Federal Services, Inc. has determined the request for **Gabapentin 300mg is not medically necessary and appropriate.**
- 3) MAXIMUS Federal Services, Inc. has determined the request for **Oxycontin 10mg is not medically necessary and appropriate.**
- 4) MAXIMUS Federal Services, Inc. has determined the request for **Clonidine 0.1 transdermal patch is not medically necessary and appropriate.**

## INDEPENDENT MEDICAL REVIEW DECISION AND RATIONALE

An application for Independent Medical Review was filed on 7/26/2013 disputing the Utilization Review Denial dated 7/23/2013. A Notice of Assignment and Request for Information was provided to the above parties on 10/21/2013. 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 **Gralise 600mg is not medically necessary and appropriate.**
- 2) MAXIMUS Federal Services, Inc. has determined the request for **Gabapentin 300mg is not medically necessary and appropriate.**
- 3) MAXIMUS Federal Services, Inc. has determined the request for **Oxycontin 10mg is not medically necessary and appropriate.**
- 4) MAXIMUS Federal Services, Inc. has determined the request for **Clonidine 0.1 transdermal patch 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 Physical Medicine and Rehabilitation, 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:**

This patient is a 50-year-old male with a history of chronic low back pain. The clinical notes from 06/27/2013 indicates the patient is prescribed medications of clonidine 0.1 mg, gabapentin 300 mg, Gralise 600 mg, and OxyContin 10 mg. The clinical notes indicate the patient's medications are noted to be helping a small degree. The patient indicates having noticed increased pigmented lesions of the bilateral lower extremities, specifically in the anterior shins that have occurred since trailing Gralise. The patient indicated this also occurred when he trialed Lyrica and the lesions started to fade once he discontinued the medication. The patient also indicated noticing pigmented lesions to his face, specifically at the forehead and the infraorbital/temporal area which the patient attributes to OxyContin. The notes detail the patient's complaint of pain radiating to the bilateral legs in the anteromedial portion of the shins from the lateral to central quadriceps along the L4 distribution with sharp radiating pains, as well as more constant tingling and paresthesia. With regard to the medications, the notes indicate the patient was originally prescribed Gralise on 04/2013 for neuropathic pain with notes indicating the patient is 2 and a half weeks into a 30 days starter pack. The notes indicate the patient (thinks) the medication is helping with some of the pain, but not in the same way that OxyContin did, yet the patient still desires to be off OxyContin.

Furthermore, the notes indicate the patient was not approved to continue with the clonidine patch to mitigate withdrawal symptoms. Assessment plan notes indicate the patient endorses good pain control with his opioids; however, notes indicate the patient desires to be weaned off opioids and to use neuropathic pain medications and maintenance injections instead.

### **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 Records from Claims Administrator
- Medical Treatment Utilization Schedule (MTUS)

### **1) Regarding the request for Gralise 600mg :**

#### 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 MTUS Guidelines regarding anti-epilepsy drugs, which is a part of the MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Gabapentin, pg. 18 and 49, which is a part of the MTUS. and the GRALISE (GABAPENTIN) TABLET, FILM COATED ... - DailyMed [dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=7d12b4e9-ed44](http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=7d12b4e9-ed44), which is not a part of the MTUS.

#### Rationale for the Decision:

California MTUS/ACOEM Guidelines do not specifically address Gralise. Official Disability Guidelines do not specifically address Gralise. Clinical literature indicates Gralise is a prescription medication to treat pain from damaged nerves following the healing of shingles. Gralise is not interchangeable with other gabapentin products. Gralise contains gabapentin which has been used for years to treat postherpetic neuralgia and neuropathic pain. The documentation submitted for review indicates the employee was started on a trial of Gralise with notes indicating the employee has not yet reached the 1800 mg dosage before acquiring hyperpigmented lesions to the bilateral shins. The notes indicated the employee was recommended to stop the use of Gralise. Given the employee's reaction to the medication and that the treating physician suggests the discontinuation of the medication, there is no clear clinical rationale to support prescription for Gralise 600 mg. Given the above, **the request for Gralise 600mg is not medically necessary and appropriate.**

## 2) Regarding the request for Gabapentin 300mg :

### 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 MTUS Guidelines regarding anti-epilepsy drugs, which is a part of the MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Gabapentin, pg. 18 and 49, which is a part of the MTUS.

### Rationale for the Decision:

California MTUS Guidelines indicate gabapentin has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. Gabapentin is an antiepilepsy drug considered as a first-line treatment. A review of the records indicates the employee is currently prescribed gabapentin 300 mg. Furthermore, the notes indicate in the employee's history and physical that the employee has complaints of pain radiating to the bilateral legs and to the anteromedial portion of the shins from the lateral to central quadriceps along the L4 distribution with notice of increased constant tingling and paresthesias. However, the documentation submitted for review on physical examination of the employee fails to indicate significant neuropathology to support the subjective complaints of the employee. **The request for gabapentin 300 mg is not medically necessary and appropriate.**

## 3) Regarding the request for Oxycontin 10mg :

### 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 MTUS guidelines regarding opioids for chronic pain, which is a part of the MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Opioids, specific drug list, pg. 78, ongoing management, and pg. 92, Oxycodone, which is a part of the MTUS.

### Rationale for the Decision:

California MTUS Guidelines indicate OxyContin is a controlled release formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. Furthermore, guidelines indicate recommendation for the "4 As" for ongoing monitoring of patients on opioid analgesics with the 4 domains having been proposed as the most relevant for ongoing monitoring of chronic patients. These include consideration for analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors. A review of the records indicates a general statement that the employee endorses good pain control with use of opioids.

However, the notes also indicate the employee wishes to be weaned completely from opioids and be maintained on neuropathic pain medications and maintenance injections. Furthermore, the clinical notes fail to indicate pain scales and improvement in activities of daily living with the use of OxyContin. **The request for OxyContin 10 mg is not medically necessary and appropriate.**

**4) Regarding the request for Clonidine 0.1 transdermal patch :**

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 Drugs.com regarding Clonidine, which is not a part of the MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, CRPS treatment (complex regional pain syndrome), Clonidine Intrathecal, pg. 34-35 and pg. 41, which is a part of the MTUS.

Rationale for the Decision:

California MTUS Guidelines indicate clonidine is thought to act synergistically with opioids. Most studies on the use of this drug intrathecally for chronic non-malignant pain are limited to case reports. Clonidine is a direct-acting, adrenergic agonist historically prescribed as an antihypertensive agent, but has also found new uses including treatment of some types of neuropathic pain. A review of the records details the request for clonidine 0.1 transdermal patch. Guidelines further recommend that clonidine has been given transdermally and epidurally for treatment of CRPS. The documentation submitted for review indicates the employee is currently attempting to wean off OxyContin and that based on difficulties with authorization and timely receipt of OxyContin, the employee has gone into withdrawal syndrome expressing irritability, anxiety, general unease, and malaise which are likely related to opioid withdrawal. However, guidelines do not detail a direct recommendation for the use of clonidine patches for the purposes of managing withdrawal symptoms. Furthermore, there is no indication the employee is currently diagnosed with CRPS to justify the use of clonidine 0.1% transdermal patch. **The request for clonidine 0.1% transdermal patch 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  
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Oakland, CA 94612

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