
Notice of Independent Medical Review Determination

Dated: 12/17/2013

[REDACTED]

[REDACTED]

Employee: [REDACTED]
Claim Number: [REDACTED]
Date of UR Decision: 8/21/2013
Date of Injury: 3/1/2013
IMR Application Received: 8/30/2013
MAXIMUS Case Number: CM13-0018646

- 1) MAXIMUS Federal Services, Inc. has determined the request for **Synapryn 10mg/1ml (in ml) a quantity of 500 is not medically necessary and appropriate.**
- 2) MAXIMUS Federal Services, Inc. has determined the request for **Trabado1 1mg/ml (in mL) a quantity of 250 is not medically necessary and appropriate.**
- 3) MAXIMUS Federal Services, Inc. has determined the request for **Compounded Ketoprofen 20% 120 grams is not medically necessary and appropriate.**
- 4) MAXIMUS Federal Services, Inc. has determined the request for **Compounded Cyclophene 5% 120 grams is not medically necessary and appropriate.**
- 5) MAXIMUS Federal Services, Inc. has determined the request for **Deprizine 15mg/ml 250 ml is not medically necessary and appropriate.**
- 6) MAXIMUS Federal Services, Inc. has determined the request for **Dicopanol 5mg 150ml is not medically necessary and appropriate.**

INDEPENDENT MEDICAL REVIEW DECISION AND RATIONALE

An application for Independent Medical Review was filed on 8/30/2013 disputing the Utilization Review Denial dated 8/21/2013. 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 **Synapryn 10mg/1ml (in ml) a quantity of 500 is not medically necessary and appropriate.**
- 2) MAXIMUS Federal Services, Inc. has determined the request for **Trabadol 1mg/ml (in mL) a quantity of 250 is not medically necessary and appropriate.**
- 3) MAXIMUS Federal Services, Inc. has determined the request for **Compounded Ketoprofen 20% 120 grams is not medically necessary and appropriate.**
- 4) MAXIMUS Federal Services, Inc. has determined the request for **Compounded Cyclophene 5% 120 grams is not medically necessary and appropriate.**
- 5) MAXIMUS Federal Services, Inc. has determined the request for **Deprizine 15mg/ml 250 ml is not medically necessary and appropriate.**
- 6) MAXIMUS Federal Services, Inc. has determined the request for **Dicopanol 5mg 150ml 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 Family Practice and is licensed to practice in Texas. 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 47-year-old female who reported an injury on 03/01/2013 with the mechanism of injury being the patient was involved in a motorcycle vehicle accident and was rear-ended. The patient was noted to have decreased sensation bilaterally and 4/5 motor strength bilaterally. The patient was noted to have tenderness in the occiputs and subacromial space, the paracervical, the trapezius, and the levator scapula muscles. The patient indicated she had temporary relief of pain and improved ability to have restful sleep. The patient's diagnoses were noted to include cervical spine pain, cervical radiculopathy, lumbar spine pain, and lumbar radiculopathy. The requested treatment to include Synapryn 10 mg per 1 mL, Tabradol 1 mg/mL, compounded ketoprofen 20%, compounded Cyclophene 5%, Deprizine 15 mg/mL, and Dicopanol 5 mg.

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:



1) Regarding the request for Synapryn 10mg/1ml (in ml) a quantity of 500:

The Medical Treatment Guidelines Relied Upon by the Expert Reviewer to Make His/Her Decision

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

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Tramadol, page 113, On-Going Monitoring page 78, which is part of MTUS.

Rationale for the Decision:

MTUS Guidelines recommend documentation of an employee's pain relief, side effects, physical and psychosocial functioning and the occurrence of any potentially aberrant or non-adherent drug-related behaviors for continuation of medications. Synapryn per the submitted Letter of Medical Necessity contains tramadol and glucosamine. The clinical documentation submitted for review indicated the employee had persistent symptoms, and the employee indicated that the medications were noted to offer the employee temporary relief and the pain level was noted to be 8/10 and it was noted the medications improved the employee's ability to have restful sleep and it was noted the employee denied problems with medications. The clinical documentation submitted for review failed to provide that the employee had trialed other first line oral analgesics and failed to provide documentation of the required 4 domains to support ongoing use of opioids. **The request for Synapryn 10 mg/1 mL (in mL) a quantity of 500 is not medically necessary and appropriate.**

2) Regarding the request for Trabadol 1mg/ml (in mL) a quantity of 250:

The Medical Treatment Guidelines Relied Upon by the Expert Reviewer to Make His/Her Decision

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

The Expert Reviewer based his/her decision on Chronic Pain Medical Treatment Guidelines, Cyclobenzaprine, page 41, which is part of MTUS.

Rationale for the Decision:

Guidelines recommend cyclobenzaprine for the management of back pain. However, it recommends a short, brief treatment. The clinical documentation submitted for review indicated the employee had subjective and objective findings with muscle spasms to support the need for a muscle relaxant and it failed to provide the duration that the employee had been on the medication as it was recommended for short term use. Additionally, it failed to provide the medication's efficacy and the medication Cyclophene was noted to contain cyclobenzaprine and there was a lack of documentation supported the necessity for 2 forms of the same medication. **The request for Tabradol 1 mg/mL (in mL) a quantity of 250 is not medically necessary and appropriate.**

3) Regarding the request for Compounded Ketoprofen 20% 120 grams:

The Medical Treatment Guidelines Relied Upon by the Expert Reviewer to Make His/Her Decision

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

The Expert Reviewer based his/her decision on Chronic Pain Medical Treatment Guidelines, page 112, Topical Analgesics, which is part of MTUS.

Rationale for the Decision:

MTUS guidelines do not approve ketoprofen as it is not currently FDA approved for topical application. It was noted the employee had subjective complaints of pain and objective findings of tenderness, however, the clinical documentation submitted for review failed to provide exceptional factors to warrant non-adherence to guideline recommendations. **The request for compounded ketoprofen 20% 120 grams is not medically necessary and appropriate.**

4) Regarding the request for Compounded Cyclophene 5% 120 grams:

The Medical Treatment Guidelines Relied Upon by the Expert Reviewer to Make His/Her Decision

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

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Topical Analgesics, page 113, which is part of MTUS.

Rationale for the Decision:

MTUS Guidelines do not recommend the topical use of Cyclobenzaprine for a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. The clinical documentation submitted for review indicated the employee had subjective and objective findings of tenderness in the cervical spine and lumbar spine and per the letter of medical necessity, this medication was a compounded product with cyclobenzaprine. The clinical documentation submitted for review failed to provide the necessity for 2 forms of the same medication and it failed to provide exceptional factors to warrant non-adherence to guideline recommendations. **The request for compounded Cyclophene 5% 120 grams is not medically necessary and appropriate.**

5) Regarding the request for Deprizine 15mg/ml 250 ml:

The Medical Treatment Guidelines Relied Upon by the Expert Reviewer to Make His/Her Decision

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

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, NSAID Therapy, page 68, which is part of MTUS.

Rationale for the Decision:

MTUS Guidelines recommend proton pump inhibitors for treatment of dyspepsia secondary to NSAID therapy. The clinical documentation submitted for review indicated the medication Deprizine was noted to include ranitidine which is can be used for the treatment of dyspepsia. However, the clinical documentation submitted for review failed to provide the efficacy of the medication and failed to provide the necessity for the treated medication as there was lack of documentation of signs and symptoms of dyspepsia. **The request for Deprizine 15 mg/mL 250 mL is not medically necessary and appropriate.**

6) Regarding the request for Dicopanol 5mg 150ml:

The Medical Treatment Guidelines Relied Upon by the Expert Reviewer to Make His/Her Decision

The Claims Administrator based its decision on the www.nlm.nih.gov, which is not 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 <http://www.drugs.com/search.php?searchterm=Dicopanol>, which is not part of the MTUS.

Rationale for the Decision:

According to Drugs.com, Dicopanol is diphenhydramine hydrochloride and it was noted this drug has not been found by the FDA to be safe and effective and the labeling was not approved by the FDA. The clinical documentation submitted for review failed to provide exceptional factors to warrant non-adherence to FDA regulations. **The request for Dicopanol 5 mg 150 mL 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, 18th 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.