

**MAXIMUS FEDERAL SERVICES, INC.**

Independent Medical Review  
P.O. Box 138009  
Sacramento, CA 95813-8009  
(855) 865-8873 Fax: (916) 605-4270



**Notice of Independent Medical Review Determination**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

- 1) MAXIMUS Federal Services, Inc. has determined the request for compounded Cyclophene 5 percent PLO gel 120 grams #1 **is not medically necessary and appropriate.**
- 2) MAXIMUS Federal Services, Inc. has determined the request for Synapryn 10mg/1ml oral suspension 500ml #1 **is not medically necessary and appropriate.**
- 3) MAXIMUS Federal Services, Inc. has determined the request for Tabradol 1mg/ml oral suspension 250ml #1 **is not medically necessary and appropriate.**
- 4) MAXIMUS Federal Services, Inc. has determined the request for compounded Ketoprofen 20 percent in PLO gel 120 grams #1 **is not medically necessary and appropriate.**

## INDEPENDENT MEDICAL REVIEW DECISION AND RATIONALE

An application for Independent Medical Review was filed on 5/31/2013 disputing the Utilization Review Denial dated 5/16/2013. A Notice of Assignment and Request for Information was provided to the above parties on 6/3/2013. 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 compounded Cyclophene 5 percent PLO gel 120 grams #1 **is not medically necessary and appropriate.**
- 2) MAXIMUS Federal Services, Inc. has determined the request for Synapryn 10mg/1ml oral suspension 500ml #1 **is not medically necessary and appropriate.**
- 3) MAXIMUS Federal Services, Inc. has determined the request for Tabradol 1mg/ml oral suspension 250ml #1 **is not medically necessary and appropriate.**
- 4) MAXIMUS Federal Services, Inc. has determined the request for compounded Ketoprofen 20 percent in PLO gel 120 grams #1 **is not medically necessary and appropriate.**

### **Medical Qualifications of the Professional 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, has a subspecialty in Pain 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 professional 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.

## Case Summary:

Disclaimer: The following case summary was taken directly from the utilization review denial/modification dated May 16, 2013

Clinical summary: According to initial comprehensive examination dated 4/19/2013 by [REDACTED] MD, the patient came in for evaluation due to complaint of upper back pain with burning, radicular, upper back pain radiating towards the neck. The pain was described as constant, moderate to severe. The pain was aggravated by prolonged positioning including sitting, standing, walking, and bending. Low back pain showed pain was associated with numbness and tingling, as well as radiates into the left buttock and down the left leg to the left foot. Upon examination, Palpable tenderness with spasms was noted over the bilateral thoracic paraspinals, over the spinous process T1 to T12, the rhomboids and the distal trapezius muscles. The patient was able to heel-toe walk, however with pain in the low back. The patient ambulated with the use of a cane. There is tenderness to palpation over the paraspinal muscles, quadratus lumborum, with a trigger point on the left. Palpable tenderness was also noted at the lumbosacral junction, the Posterior superior iliac Spine, as well as at the left sciatic notch. There are noticeable spasms as well as listing to the left. Neurologic exam showed slightly decreased sensation at L4, L5 and S1 dermatome. There was positive Lasague, Tripod sign and Flip test noted.

Date of injury: 03/07/13

Diagnoses: 724.2724.4847.2

Requester name: [REDACTED]

Phone #: [REDACTED]

Mechanism of injury: The patient was carrying several board and tripped over resulting to lower back.

Current medications: The patient received prescription of Compounded Ketoprofen 20 percent, Synapryn 10mg/1ml and Tabradol 1 mg/ml on office visit dated 4/19/2013.

Surgeries: The patient had appendectomy dated 2001, gallbladder stone removal 2010 and ovarian removal

Diagnostic imaging and other therapies: The patient has had PT visits (frequency and date unspecified)

Reason given for request: Not documented in the clinical records submitted with this request

## 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 for Independent Medical Review (received 5/31/13)
- Utilization Review Determination (dated 5/16/13)
- Requested Medical Records were not supplied for this review
- Official Disability Guidelines (ODG), (updated 5/14/13), Pain Chapter, Cyclobenzaprine
- Official Disability Guidelines (ODG), (updated 5/14/13), Pain Chapter, Tramadol
- Official Disability Guidelines (ODG), (updated 5/14/13), Pain Chapter, Ketoprofen, topical
- Official Disability Guidelines (ODG), (updated 5/14/13), Pain Chapter, Compound Drugs

**1) Regarding the request for compounded Cyclophene 5 percent PLO gel 120 grams #1:**

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

The Claims Administrator based its decision on the Official Disability Guidelines (ODG), (updated 5/14/13), Pain Chapter, Cyclobenzaprine, a nationally-recognized medical treatment guideline (MTG), which is not a part of the Medical Treatment Utilization Schedule (MTUS). The provider did not dispute the guidelines used by the Claims Administrator. The Expert Reviewer found the Chronic Pain Medical Treatment Guidelines (May, 2009), Part 2, Pain Interventions and Treatments of the MTUS, pg 111-113, were applicable and relevant to the issue at dispute.

Rationale for the Decision:

On 3/7/13 the employee tripped when carrying several boards and injured the lower back. On 4/19/13 a comprehensive examination revealed a burning, radicular, upper back pain radiating towards the neck. Pain was aggravated by prolonged sitting, standing, walking or bending. Numbness and tingling were present with pain radiating into the left buttock and down the left leg. The employee walked with the use of a cane. There was decreased sensation at L4, L5 and S1 dermatome and Lasegue, Tripod sign and Flip tests were positive. A request for compounded Cyclophene 5 percent PLO gel 120 grams #1, Synapryn 10mg/ml oral suspension 500ml #1, Tabradol 1mg/ml oral suspension 250ml #1, compounded Ketoprofen 20 percent in PLO gel 120 grams #1 was submitted but there was no reason supplied for this request.

Medical records were not supplied for this review and there were no reports from the treating physician clarifying or disputing the Utilization Review (UR) determination. It appeared that the UR Physician requested information as to what medications make up "compounded Cyclophene 5%", but this was not supplied. An internet search by the Expert Reviewer did not provide any insight.

The Expert Reviewer was not able to verify if a component of the compound "cyclophene" is cyclobenzaprine, a muscle relaxant. MTUS states there is no evidence supporting use of muscle relaxants as a topical product. If "Cyclophene" contains a muscle relaxant, it would not be recommended.

Regardless of whether "cyclophene" contains a muscle relaxant, the MTUS states, "topical analgesics are recommended when trials of anticonvulsants and antidepressants have failed". According to the UR letter, the employee's injury date was 3/7/13, but the first doctor's report was on 4/17/13, and Dr. [REDACTED] initial evaluation was on 4/19/13. Given these dates the employee could not have had an adequate trial of antidepressants or anticonvulsants in two days. MTUS states that with antidepressants, analgesic effect "occurs within a few days to a week". The employee would need to be on these for at least a week to consider it a failure. The employee does not meet the MTUS requirement for topical

analgesics. The request for compounded Cyclophene 5 percent PLO gel 120 grams #1 **is not medically necessary and appropriate.**

**2) Regarding the request for Synapryn 10mg/ml oral suspension 500ml #1:**

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

The Claims Administrator based its decision on the Official Disability Guidelines (ODG), (updated 5/14/13), Pain Chapter, Tramadol, a nationally-recognized medical treatment guideline (MTG) which is not a part of the Medical Treatment Utilization Schedule (MTUS). The provider did not dispute the guidelines used by the Claims Administrator. The Expert Reviewer found the Chronic Pain Medical Treatment Guidelines (May, 2009), Part 2, Pain Interventions and Treatments of the MTUS, pg 111-113, were applicable and relevant to the issue at dispute.

Rationale for the Decision:

On 3/7/13 the employee tripped when carrying several boards and injured the lower back. On 4/19/13 a comprehensive examination revealed burning, radicular and upper back pain radiating towards the neck. Pain was aggravated by prolonged sitting, standing, walking or bending. Numbness and tingling were present with pain radiating into the left buttock and down the left leg. The employee walked with the use of a cane. There was decreased sensation at L4, L5 and S1 dermatome and Lasegue, Tripod sign and Flip tests were positive. A request for compounded Cyclophene 5 percent PLO gel 120 grams #1, Synapryn 10mg/ml oral suspension 500ml #1, Tabradol 1mg/ml oral suspension 250ml #1, compounded Ketoprofen 20 percent in PLO gel 120 grams #1 was submitted but there was no reason supplied for this request.

Synapryn is reported to be an oral suspension of Tramadol. MTUS specifically states, "Tramadol (Ultram®) is not recommended as a first-line oral analgesic". The physician prescribed the oral solution of Tramadol on the initial visit. This appears to be used as a first-line oral analgesic. The request for Synapryn 10mg/1ml oral suspension 500ml #1 **is not medically necessary and appropriate.**

**3) Regarding the request for Tabradol 1mg/ml oral suspension 250ml #1:**

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

The Claims Administrator based its decision on the Official Disability Guidelines (ODG), (updated 5/14/13), Pain Chapter, Cyclobenzaprine, a nationally-recognized medical treatment guideline (MTG) which is not a part of the Medical Treatment Utilization Schedule (MTUS). The provider did not dispute the guidelines used by the Claims Administrator. The Expert Reviewer found the

Chronic Pain Medical Treatment Guidelines (May, 2009), Part 2, Pain Interventions and Treatments of the MTUS, pg 111-113, were applicable and relevant to the issue at dispute.

Rationale for the Decision:

On 3/7/13 the employee tripped when carrying several boards and injured the lower back. On 4/19/13 a comprehensive examination revealed burning, radicular and upper back pain radiating towards the neck. Pain was aggravated by prolonged sitting, standing, walking or bending. Numbness and tingling were present with pain radiating into the left buttock and down the left leg. The employee walked with the use of a cane. There was decreased sensation at L4, L5 and S1 dermatome and Lasegue, Tripod sign and Flip tests were positive. A request for compounded Cyclophene 5 percent PLO gel 120 grams #1, Synapryn 10mg/ml oral suspension 500ml #1, Tabradol 1mg/ml oral suspension 250ml #1, compounded Ketoprofen 20 percent in PLO gel 120 grams #1 was submitted but there was no reason supplied for this request.

Tabradol is Cyclobenzaprine in oral suspension. Physical examination on 4/19/13 reported muscle spasms. MTUS recommends a short course of therapy (the greatest effect appears to be in the first four days of treatment) but does not recommend use longer than 2-3 weeks, for muscle spasms. The request did not include the dosing information; therefore, it is not clear if the prescription would exceed the three weeks. MTUS recommends dosing of "5 mg three times a day [which] can be increased to 10 mg three times a day". Additionally, there was no explanation as to why the tablet form was not attempted. MTUS defines "medical necessity" as "treatment that is reasonably required to cure or relieve"... From the available information, the oral suspension of cyclobenzaprine is not reasonably required, as the tablet form is available and more commonly used. The request for Tabradol 1mg/ml oral suspension 250ml #1 **is not medically necessary and appropriate.**

**4) Regarding the request for compounded Ketoprofen 20 percent in PLO gel 120 grams #1:**

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

The Claims Administrator based its decision on the Official Disability Guidelines (ODG), (updated 5/14/13), Pain Chapter, Ketoprofen - topical, a nationally-recognized medical treatment guideline (MTG) which is not a part of the Medical Treatment Utilization Schedule (MTUS). The provider did not dispute the guidelines used by the Claims Administrator. The Expert Reviewer found the Chronic Pain Medical Treatment Guidelines (May, 2009), Part 2, Pain Interventions and Treatments of the MTUS, pg 111-113, were applicable and relevant to the issue at dispute.

Rationale for the Decision:

On 3/7/13 the employee tripped when carrying several boards and injured the lower back. On 4/19/13 a comprehensive examination revealed burning, radicular and upper back pain radiating towards the neck. Pain was aggravated by prolonged sitting, standing, walking or bending. Numbness and tingling were present with pain radiating into the left buttock and down the left leg. The employee walked with the use of a cane. There was decreased sensation at L4, L5 and S1 dermatome and Lasegue, Tripod sign and Flip tests were positive. A request for compounded Cyclophene 5 percent PLO gel 120 grams #1, Synapryn 10mg/ml oral suspension 500ml #1, Tabradol 1mg/ml oral suspension 250ml #1, compounded Ketoprofen 20 percent in PLO gel 120 grams #1 was submitted but there was no reason supplied for this request.

MTUS specifically recommends against the use of topical Ketoprofen stating, "Ketoprofen is not currently FDA approved for topical application". The request for compounded Ketoprofen 20 percent in PLO gel 120 grams #1 **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;

Richard C. Weiss, MD, MPH, MMM, PMP  
Medical Director

cc: Department of Industrial Relations  
Division of Workers' Compensation  
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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.