
Notice of Independent Medical Review Determination

Dated: 11/14/2013

[REDACTED]

[REDACTED]

Employee:	[REDACTED]
Claim Number:	[REDACTED]
Date of UR Decision:	7/8/2013
Date of Injury:	1/17/2013
IMR Application Received:	7/29/2013
MAXIMUS Case Number:	CM13-0004585

- 1) MAXIMUS Federal Services, Inc. has determined the request for **Tabradol 1mg/ml Oral Suspension 250 ml** is not medically necessary and appropriate.
- 2) MAXIMUS Federal Services, Inc. has determined the request for **Cyclophene 5 % in PLO Gel 120g** is not medically necessary and appropriate.
- 3) MAXIMUS Federal Services, Inc. has determined the request for **Ketoprofen 20% in PLO Gel, 120g** is not medically necessary and appropriate.
- 4) MAXIMUS Federal Services, Inc. has determined the request for **Synapryn (10mg/1ml Oral Suspension 500ml)** is not medically necessary and appropriate.
- 5) MAXIMUS Federal Services, Inc. has determined the request for **Deprizine 15mg/ml Oral Suspension 250ml** is not medically necessary and appropriate.
- 6) MAXIMUS Federal Services, Inc. has determined the request for **Dicopanol (diphenhydramine) 5mg/ml Oral Suspension 150ml** is not medically necessary and appropriate.
- 7) MAXIMUS Federal Services, Inc. has determined the request for **Fanatrex (Gabapentin) 25mg/ml Oral Suspension 420ml** is not medically necessary and appropriate.

- 8) MAXIMUS Federal Services, Inc. has determined the request for **chiropractic treatment is not medically necessary and appropriate.**
- 9) MAXIMUS Federal Services, Inc. has determined the request for **physical therapy is not medically necessary and appropriate.**

INDEPENDENT MEDICAL REVIEW DECISION AND RATIONALE

An application for Independent Medical Review was filed on 7/29/2103 disputing the Utilization Review Denial dated 7/8/2013. A Notice of Assignment and Request for Information was provided to the above parties on 8/7/2013. 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 **Tabradol 1mg/ml Oral Suspension 250 ml** is not medically necessary and appropriate.
- 2) MAXIMUS Federal Services, Inc. has determined the request for **Cyclophene 5 % in PLO Gel 120g** is not medically necessary and appropriate.
- 3) MAXIMUS Federal Services, Inc. has determined the request for **Ketoprofen 20% in PLO Gel, 120g** is not medically necessary and appropriate.
- 4) MAXIMUS Federal Services, Inc. has determined the request for **Synapryn (10mg/1ml Oral Suspension 500ml)** is not medically necessary and appropriate.
- 5) MAXIMUS Federal Services, Inc. has determined the request for **Deprizine 15mg/ml Oral Sususpension 250ml** is not medically necessary and appropriate.
- 6) MAXIMUS Federal Services, Inc. has determined the request for **Dicopanl (diphenhydramine) 5mg/ml Oral Suspension 150ml** is not medically necessary and appropriate.
- 7) MAXIMUS Federal Services, Inc. has determined the request for **Fanatrex (Gabapentin) 25mg/ml Oral Suspension 420ml** is not medically necessary and appropriate.
- 8) MAXIMUS Federal Services, Inc. has determined the request for **chiropractic treatment** is not medically necessary and appropriate.
- 9) MAXIMUS Federal Services, Inc. has determined the request for **physical therapy** 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 70-year-old male who reported an injury on 01/17/2013. Notes indicate that the patient was initially injured as a result of lifting a 35 feet length of chain, at which time the patient felt a pulling sensation in the neck, right shoulder, mid back, and low back. Treatment to date has consisted of an unknown number of sessions of chiropractic treatment, providing only temporary partial relief, as well as acupuncture therapy, physical therapy, and pain medications. Notes indicate that the patient utilizes an ambulation-assistive device in the form of a single point cane due to low back pain radiating to the right lower extremity. The patient has currently requested for additional medications and further chiropractic treatment and physical therapy treatment.

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 Tabradol 1mg/ml Oral Suspension 250 ml :

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

The Claims Administrator did not cite any evidence based criteria for its decision.

The Expert Reviewer found the Chronic Pain Medical Treatment Guidelines, Cyclobenzaprine, pages 41-42, which is part of the MTUS, and DailyMed dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=5d19ef8b-eef3, Tabradol, which is not part of the MTUS.

Rationale for the Decision:

Clinical literature indicates that Tabradol is an oral suspension of Cyclobenzaprine. The Chronic Pain guidelines indicate that Cyclobenzaprine is recommended as an option using a short course of therapy and that, based on the indication that the effect of the medication is greatest in the first 4 days of treatment, shorter courses of therapy are better. There was a lack of clear clinical rationale indicating the necessity for a suspension version of Cyclobenzaprine versus an oral tablet, in the submitted records for review. There is no indication that the employee has difficulty with swallowing medications in a pill form. Additionally, there is a lack of documentation in the recent clinical notes submitted for review to support evidence of muscle spasms requiring the necessity for the use of a muscle relaxant, such as Cyclobenzaprine. **The request for Tabradol 1mg/ml Oral Suspension 250ml is not medically necessary and appropriate.**

2) Regarding the request for Cyclophene 5 % in PLO Gel 120g :

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

The Claims Administrator did not cite any evidence based criteria for its decision.

The Expert Reviewer found the Chronic Pain Medical Treatment Guidelines, Topical Analgesics, pages 111-113, which is part of the MTUS, and Pharmacy RxUSA, rxusa.com/cgi-bin2/db/db.cgi?name2=cyclobenzaprine, which is not part of the MTUS.

Rationale for the Decision:

The Chronic Pain guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine their efficacy or safety and they are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug or drug class that is not recommended, likewise, is not recommended. The guidelines further indicate that Baclofen and other muscle relaxants are not recommended for use in a topical formulation as there is no evidence for use of any other muscle relaxants as a topical product. The submitted medical records lack a clear rationale for the indication for both an oral administration and topical application concurrently of cyclobenzaprine. **The request for Cyclophene 5% in PLO Gel 120g is not medically necessary and appropriate.**

3) Regarding the request for Ketoprofen 20% in PLO Gel, 120g :

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, page 111-112, which is part of the MTUS.

The Expert Reviewer found the Chronic Pain Medical Treatment Guidelines, Topical Analgesics, page 111-113, which is part of the MTUS.

Rationale for the Decision:

The Chronic Pain guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine their efficacy or safety and they are primarily recommended for neuropathic pain when trials of other antidepressants or anticonvulsants have failed. Any compounded product that contains at least 1 drug or drug class that is not recommended, likewise, is not recommended. The current request for Ketoprofen 20% in PLO Gel, 120g is not supported, given that Ketoprofen is not FDA approved for use as a topical ointment. It has an extremely high incidence of photocontact dermatitis and topical treatment can result in blood concentrations in systemic effect comparable to those taken from oral forms, and caution should be used for patients at risk, including those with renal failure. **The request for Ketoprofen 20% in PLO Gel 120mg is not medically necessary and appropriate.**

4) Regarding the request for Synapryn (10mg/1ml Oral Suspension 500ml) :

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

The Claims Administrator did not cite any evidence based criteria for its decision.

The Expert Reviewer found the Chronic Pain Medical Treatment Guidelines, Tramadol, page 93-94, which is part of the MTUS, and DailyMed at dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid, Synapryn, which is not part of the MTUS.

Rationale for the Decision:

Clinical literature indicates that Synapryn is an oral suspension of tramadol hydrochloride with inclusion of glucosamine. The Chronic Pain guidelines indicate that tramadol is a synthetic opioid affecting the central nervous system. Glucosamine is recommended as an option given its low risk in patients with moderate arthritic pain, especially for knee osteoarthritis. There is a lack of documentation submitted for review indicating that the employee has difficulty with intake of medications in pill form, such that necessity of an oral suspension is required. Furthermore, there is no demonstrated efficacy of an oral suspension versus pill form medication. Additionally, the Chronic Pain guidelines detail the recommendation for the 4 A's for ongoing monitoring of patients on opioid medications. These 4 domains include monitoring for analgesia, adverse side effects, activities of daily living, and adverse drug related behaviors. Moreover, there is a lack of documentation indicating any significant demonstrated efficacy with the use of Synapryn in decreasing the employee's pain levels, improving the employee's ability to undertake activities of daily living, or demonstrating any significant functional improvement of the employee overall. **The request for Synapryn (10mg/ml Oral Suspension 500ml) not medically necessary and appropriate.**

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

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 www.ncbi.nlm.nih.gov/pubmed/2712050 Title: Concentration uniformity of extemporaneously prepared ranitidine suspension Abstract, which is not part of the MTUS.

The Expert Reviewer found [Deprizine Official FDA information, side effects and uses. - Drugs.com](http://www.drugs.com), www.drugs.com > [Drugs A to Z](#) > [De](#), which is not part of the MTUS.

Rationale for the Decision:

Clinical literature indicates that Deprizine is ranitidine hydrochloride in an oral suspension which is a histamine H2 receptor antagonist which inhibits stomach acid production. There is no clear clinical indication in the documentation submitted for review of GI symptoms of the employee. Furthermore, there is no clinical indication that the employee is prescribed these medications on a prophylactic basis. Furthermore, there is a lack of documentation indicating the necessity for an oral suspension versus pill form medication. **The request for Deprizine 15mg/ml Oral Suspension 250ml is not medically necessary and appropriate.**

6) Regarding the request for Dicopanol (diphenhydramine) 5mg/ml Oral Suspension 150ml :

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

The Claims Administrator did not cite any evidence based criteria for its decision.

The Expert Reviewer found Drugs.com at www.drugs.com › Drugs A to Z › Di, Dicopanol, Official FDA information, side effects and uses, which is not part of the MTUS.

Rationale for the Decision:

Clinical literature indicates that Dicopanol is diphenhydramine in an oral suspension and that diphenhydramine is an antihistamine with sedative properties which is not recommended for long term use for insomnia treatment. The documentation submitted for review fails to indicate a clear clinical rationale for the necessity of prescribed diphenhydramine. Furthermore, the documentation submitted for review fails to indicate a necessity for oral suspension medication versus pill form medications for the employee. There is no indication in the clinical notes of sleep complaints of the employee or allergic signs or symptoms necessitating the prescription of Dicopanol. **The request for Dicopanol (diphenhydramine) 5mg/ml Oral Suspension 150 ml is not medically necessary and appropriate.**

7) Regarding the request for Fanatrex (Gabapentin) 25mg/ml Oral Suspension 420ml :

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 www.ncbi.nlm.nih.gov/pubmed/10207927 Title: Development of two stable oral suspensions for gabapentin, which is not part of the MTUS.

The Expert Reviewer found the Chronic Pain Medical Treatment Guidelines, Specific Anti-Epilepsy Drugs, pages 16-19, which is part of the MTUS, and Drugs.com at www.drugs.com › Drugs by Condition › Epilepsy, Fanatrex Official FDA information, side effects and uses, which is not part of the MTUS.

Rationale for the Decision:

Clinical literature indicates that Fanatrex is Gabapentin in an oral suspension form. The California MTUS/ACOEM Guidelines indicate that Gabapentin is an anti-epileptic medication which is recommended for the treatment of diabetic painful neuropathy and postherpetic neuralgia, with consideration as a first line treatment for neuropathic pain. The documentation submitted for review indicates the employee has pain to the low back, right shoulder and neck, as well as thoracic spine. However, an AME conducted on 07/08/2013, while indicating decreased range of motion of the cervical, thoracic, and lumbar spine, failed to indicate a significant neural pathology on physical exam to support the recommendation for the employee to be treated with Gabapentin. Furthermore, there is a lack of documentation indicating a clinical rationale for the prescription of oral suspension of the medication versus a pill form treatment. There is no indication that the employee has difficulty swallowing medications in pill form.

The request for Fanatrex (Gabapentin) 25mg/ml Oral Suspension 420ml is not medically necessary and appropriate.

8) Regarding the request for chiropractic treatment :

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, Manual Therapy, pages 58-59, which is part of the MTUS.

The Expert based his/her decision on the Chronic Pain Medical Treatment Guidelines, Manual therapy & manipulation, pages 58-59, which is part of the MTUS.

Rationale for the Decision:

The Chronic Pain guidelines indicate that manual therapy and manipulation is recommended for chronic pain if it is caused by musculoskeletal conditions. The medical records submitted for review indicate that the employee has decreased range of motion of the cervical, thoracic, and lumbar spine, as well as in the right shoulder with pain and tenderness on palpation, and decreased range of motion of both the cervical and thoracic spine. Furthermore, there is indication of paraspinal musculature tenderness in the cervical spine as well as lumbar spine. Clinical records indicate that the employee has attended an unknown previous number of sessions of chiropractic and physical therapy as well as acupuncture therapy. However, the request for continued chiropractic treatment is not supported, given that the number of prior sessions attended is unknown and the employee's functional response to the prior sessions attended is unknown. **The request for chiropractic treatment is not medically necessary and appropriate**

9) Regarding the request for physical therapy :

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, Physical Medicine, page 99, which is part of the MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Physical Medicine, pages 98-99, which is part of the MTUS.

Rationale for the Decision:

The Chronic Pain guidelines indicate that physical therapy is recommended and based on the philosophy that therapeutic exercise and/or activity is beneficial for restoring flexibility, strength, endurance, function, range of motion, and that it can alleviate discomfort. Treatment for myalgia and myositis is recommended at 9 visits to 10 visits over 8 weeks, and a recommendation is provided for the maximum of 8 visits to 10 visits over 4 weeks for treatment of neuralgia, neuritis, and radiculitis. The documentation submitted for review indicates that the employee has attended prior sessions of physical therapy, chiropractic therapy and acupuncture therapy. The records indicate that the employee received temporary partial relief from these treatments. However, there is a lack of documentation indicating quantified ranges of motion of the lumbar spine, manual muscle testing, or progression of the employee's stated goals in physical therapy sessions attended previously to warrant continued treatment. Additionally, further clarification is required on the number of sessions attended thus far to support the recommendation for continued therapy. Also, there is a lack of documentation indicating exceptional factors for treatment outside the recommendation of the guidelines versus a home exercise program. **The request for physical therapy 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

/bh

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.