MAXIMUS FEDERAL SERVICES, INC.
Independent Medical Review
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MAXIMUS Federal Services

Notice of Independent Medical Review Determination

Dated: 11/4/2013

[redacted]

[redacted]

Employee:	[redacted]
Claim Number:	
Date of UR Decision:	7/22/2013
Date of Injury:	10/15/2012
IMR Application Received:	7/31/2013
MAXIMUS Case Number:	CM13-0004739

1) MAXIMUS Federal Services, Inc. has determined the request for compounded Ketoprofen 20% in PLO gel, 120 grams **is not medically necessary and appropriate.**

2) MAXIMUS Federal Services, Inc. has determined the request for compounded Cyclophene 5% in PLO gel , 120 grams **is not medically necessary and appropriate.**

3) MAXIMUS Federal Services, Inc. has determined the request for Synapryn (10mg/1ml oral suspension 500ml) **is not medically necessary and appropriate.**

4) MAXIMUS Federal Services, Inc. has determined the request for Tabradol 1 mg/ml oral suspension 250 ml **is not medically necessary and appropriate.**

5) MAXIMUS Federal Services, Inc. has determined the request for Deprizine 15 mg/ml oral suspension 250 ml **is not medically necessary and appropriate.**

6) MAXIMUS Federal Services, Inc. has determined the request for Dicopanol (diphenhydramine) 5 mg/ml oral suspension 150 ml **is not medically necessary and appropriate.**

7) MAXIMUS Federal Services, Inc. has determined the request for Fanatrex (gabapentin) 25 mg/ml oral **is not medically necessary and appropriate.**

INDEPENDENT MEDICAL REVIEW DECISION AND RATIONALE

An application for Independent Medical Review was filed on 7/31/2013 disputing the Utilization Review Denial dated 7/22/2013. A Notice of Assignment and Request for Information was provided to the above parties on 8/12/2013. 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 Ketoprofen 20% in PLO gel, 120 grams **is not medically necessary and appropriate.**

2) MAXIMUS Federal Services, Inc. has determined the request for compounded Cyclophene 5% in PLO gel , 120 grams **is not medically necessary and appropriate.**

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7) MAXIMUS Federal Services, Inc. has determined the request for Fanatrex (gabapentin) 25 mg/ml oral **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 Anesthesiology and Pain Management and is licensed to practice in Florida. 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.

Expert Reviewer Case Summary:
The patient is a 45-year-old male who reported an injury on 10/15/2012 when he was reported to have slipped on an oily floor, landing on his buttocks, twisting his back and striking his head on the floor. He was reported to complain of ongoing neck pain and spasms, which he rated at a 6/10 to 7/10. This was aggravated by looking up and looking down and side-to-side as well as by repetitive motion of the head and neck. He was noted to complain of lower back pain and muscle spasms, which he rated at an 8/10 with radiation pain, numbness and tingling to the right thigh. The patient was noted on 01/22/2013 to have intact sensation of the upper extremities in all dermatomes tested and decreased strength of the upper extremities secondary to pain bilaterally.

Deep tendon reflexes were 2+ and symmetrical in the upper extremities. The patient was noted to have 2+ tenderness to palpation at the suboccipital muscles, scalenes and over the sternocleidomastoid muscles. The patient was noted to have decreased range of motion of the cervical spine in all planes except for left lateral flexion. The patient was reported to have a positive cervical distraction test on examination. Examination of the low back noted that the patient was able to heel and toe walk, but it caused lower back pain. He was able to squat to approximately 20% of normal due to pain in his back. There was tenderness to palpation over the bilateral PSIS and bilateral lumbar paraspinal muscle guarding with tenderness to palpation over the spinous process from L3-5. The patient was noted to have decreased range of motion in flexion, extension and left and right lateral flexion of the lumbar spine with a positive straight leg raise at 50 degrees on the left and a positive Braggard's on the left. He was noted to have slightly decreased sensation to pinprick and light touch over the L3 and L4 dermatomes in the right lower extremity and decreased strength of the bilateral lower extremities secondary to pain. Deep tendon reflexes were 1+ at the right lower extremity and 2+ at the left lower extremity. An MRI of the cervical spine performed on 06/29/2013 and read by Dr. [redacted] reported an impression of degenerative disc disease and small disc protrusions at C3-4, C4-5, C5-6 and C6-7 with right uncovertebral arthrosis producing right neural foraminal stenosis at C4-5, C5-6 and C6-7. An MRI of the lumbar spine, performed on 06/29/2013 and read by Dr. [redacted], reported degenerative disc disease at L5-S1 with a 2.6 mm diffuse disc bulge and facet osteoarthrosis. The clinical note dated 06/20/2013, signed by Dr. [redacted], reported that the patient continued to complain of headaches rated at a 6/10 to 7/10; dull, aching neck pain rated at a 7/10 to 8/10; and sharp stabbing low back pain rated at a 6/10 to 7/10. He reported that his medications did offer him temporary relief with pain and improved his ability for restful sleep. The patient was noted to deny any problems with medications, and the pain was also alleviated by activity restrictions. The patient was noted to continue to have tenderness over the suboccipital scalene sternocleidomastoid muscles, decreased range of motion with a positive distraction test and a negative foraminal compression test. Sensation was intact, but strength was decreased. An examination of the lumbar spine reported that the patient was able to heel and toe walk with pain and was only able to squat to 10% of normal. He had tenderness over the bilateral PSIS and bilateral lumbar paraspinal muscles. Guarding was noted at L3-S1. The patient had decreased range of motion, a positive straight leg on the right at 50 degrees, a positive Bragard's test on the right and a positive flip test. He had slightly decreased sensation in the right lower extremity, and motor strength was decreased.

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** compounded Ketoprofen 20% in PLO gel, 120 grams **:**

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, pg. 111-113, which is part of the MTUS.

The Expert Reviewer based his/her decision on Chronic Pain Medical Treatment Guidelines, Topical Analgesics, pg. 111-112, which is part of the MTUS.

Rationale for the Decision:
The employee has been prescribed ketoprofen gel. The California MTUS guidelines do not recommend the use of ketoprofen for topical application because it has not been approved by the FDA. The guidelines further note there is little evidence for the utilization of topical NSAIDs for the treatment of osteoarthritis of the spine, hip or shoulder and no evidence to support its use for neuropathic pain. Ketoprofen is noted to have an extremely high incidence of photocontact dermatitis. There was no specific clinical rationale from the provider to warrant this medication. **The requested compounded Ketoprofen 20% in PLO gel at 120 gm is not medically necessary nor appropriate.**

2) **Regarding the request for** compounded Cyclophene 5% in PLO gel , 120 grams **:**

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, pg. 111-113, which is part of the MTUS.

The Expert Reviewer based his/her decision on Chronic Pain Medical Treatment Guidelines, Topical Analgesics, pg. 111-11, which is part of the MTUS.

Rationale for the Decision:
The records provided for review note complaints of ongoing headaches, neck pain and low back pain. The records indicate the employee experiences radiation of pain to the right anterior thigh, decreased range of motion of the cervical and lumbar spines with decreased strength of the bilateral upper and lower extremities secondary to pain. Cyclophene gel 5% contains cyclobenzaprine. The California MTUS Guidelines do not recommend the use of cyclobenzaprine noting there is no evidence to support the use of topical muscle relaxants. **The request for compounded Cyclophene 5% in PLO gel at 120 gm is not medically necessary nor appropriate.**

3) **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 provide any evidence-based guidelines for its decision.

The Expert Reviewer based his/her decision on the Chrinic Pain Medical Treatment Guidelines, Opioid, Criteria for use, pg 78, which is part of the MTUS.

Rationale for the Decision:
Synapryn (oral suspension) contains tramadol. The California MTUS guidelines state that there should be ongoing review and documentation of pain relief, functional status, appropriate medication use and side effects for patients taking narcotic analgesics. The guidelines note that the pain assessment should include current pain, pain over the period since the last assessment, average pain, intensity of pain after taking the opioid, how long it takes for pain relief and how long the pain relief lasts. Satisfactory treatment may be indicated by the patient's decreased pain, increased level of function or improved quality of life. A review of the records provided note the employee to have decreased range of motion of the lumbar and cervical spine. The records note radiation of pain to the right anterior thigh, decreased strength of the bilateral upper and lower extremities secondary to pain, and decreased sensation in the right lower extremity in the L3 and L4 distributions. However, the records do not indicate that the employee has had a pain assessment to access the effects of this medication. In addition, there records do not indicate why the employee is unable to take oral capsules or tablets requiring the use of a compounded oral suspension. **The request for Synapryn (10mg/1ml oral suspension 500 ml) is not medically necessary or appropriate.**

4) **Regarding the request for** Tabradol 1 mg/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 provide any evidence-based guidelines for its decision.

The Expert Reviewer based his/her decision on Chronic Pain Medical Treatment Guidelines, Muscle relaxants (for pain), pg. 63-64, which is part of the MTUS.

Rationale for the Decision:
The records indicate the employee has been prescribed Tabradol oral suspension which contains cyclobenzaprine. The California MTUS guidelines recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. The guidelines further note that cyclobenzaprine is not recommended to be used longer than 2-3 weeks. The records indicate the employee has been taking Tabradol suspension since March 2013 on a routine basis, but there is no documentation indication of an acute exacerbation of low back pain. In addition, there is no indication as why the employee is unable to take a pill or capsule orally, and as such, the need for a compounded suspension is not established. **The request for Tabradol 1mg/ml oral suspension 250ml is not medically necessary or appropriate.**

5) **Regarding the request for** Deprizine 15 mg/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 based its decision on the American College of Occupational and Environmental Medicine (ACOEM) Occupational Practice Guidelines, 2nd Edition, 2004, Non-steriodal Anti-inflammatory Drugs (NSAIDs) and Acetaminophen Prevention of Adverse Gastrointestinal (GI) Effects, which is part of the MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, NSAIDs, GI symptoms & cardiovascular risk, pg. 68-69, which is part of the MTUS.

Rationale for the Decision:
The patient is reported to have been prescribed Deprizine suspension which contrains ranitidine, H2 blocker. CA MTUS does not specifically address H2 blockers; however, the California MTUS guidelines recommend the use of proton pump inhibitors for patients taking NSAIDs and who are at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID. MedlinePluse states that ranitidine is used to treat ulcers; gastroesophageal reflux disease (GERD), and injury of the food pipe (esophagus). The records indicate the employee is utilizing a NSAID for pain, and is not reported to have a history of gastrointestinal upset, peptic ulcers, GI bleeding or perforation, the request Deprizine suspension does not meet guideline recommendations. In addition, there is no indication as why the employee is unable to take a pill or capsule orally, and as such, the need for a compounded suspension is not established.. **The request for Deprizine 15mg/ml oral suspension 150 ml is not medically necessary or appropriate.**

6) **Regarding the request for** Dicopanol (diphenhydramine) 5 mg/ml oral suspension 150 ml **:**

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 Work Loss Data Institute, ODG Treatment in Workers Compensation, 5th Edition, 2007 or current year, Mental Illness & Stress. Diphenhydramine (Benedryl), which is not a 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 Official Disability Guidelines (ODG), Pain (Chronic) Chapter, Online Version. Insomnia treatment, a Medical Treatment Guideline (MTG).

Rationale for the Decision:
The records indicate the employee to have difficulty sleeping due to pain. The California MTUS guidelines do not address the use of medications for the treatment of insomnia. The Official Disability Guidelines state that sedating antihistamines have been suggested for sleep aids, but tolerance seems to develop within a few days. The guidelines further state next day sedation has also been noted as well as impaired psychomotor and cognitive functions. A review of the records provided indicate the employee has been taking Dicopanol on a long-term ongoing basis, which is not in accordance with guideline recommendations. In addition, there is no indication as to why the employee cannot take an oral tablet and pill and requires an oral suspension. As such, the requested Dicopanol oral suspension does not meet guideline recommendations. **The request for Dicopanol (diphenhydramine) 5 mg/mL oral suspension 150 mL is not medically necessary nor appropriate.**

7) **Regarding the request for** Fanatrex (gabapentin) 25 mg/ml oral **:**

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 7/18/2009 pr. 18-19, 49, 113, which is part of the MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Antiepilepsy drugs (AEDs), pg. 16 -18, which is a part of the MTUS.

Rationale for the Decision:
The California MTUS Guidelines recommend the use of gabapentin for the treatment of diabetic painful neuropathy and postherpetic neuralgia and as a first-line treatment for neuropathic pain. The medical records indicate the employeehas neuropathic pain and may benefit from the use of gabapentin. However, there was no indication as to why the employee requires an oral suspension and cannot take pills or capsules by mouth to alleviate pain. **The request for Fanatrex (gabapentin) 25 mg/mL oral is not medically necessary nor 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
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.