

MAXIMUS FEDERAL SERVICES, INC.

Independent Medical Review
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Notice of Independent Medical Review Determination

Dated: 11/7/2013



Employee:	[REDACTED]
Claim Number:	[REDACTED]
Date of UR Decision:	8/5/2013
Date of Injury:	7/30/2008
IMR Application Received:	8/6/2013
MAXIMUS Case Number:	CM13-0007916

- 1) MAXIMUS Federal Services, Inc. has determined the retrospective request for **Terocin pain relief lotion 240gms is not medically necessary and appropriate.**
- 2) MAXIMUS Federal Services, Inc. has determined the retrospective request for **Omeprazole 20mg #120 is not medically necessary and appropriate.**
- 3) MAXIMUS Federal Services, Inc. has determined the retrospective request for **Oxycodone/APAP 10/325mg #120 is not medically necessary and appropriate.**
- 4) MAXIMUS Federal Services, Inc. has determined the retrospective request for **Fentanyl duragesic 75mcg/hr #30 is not medically necessary and appropriate.**

INDEPENDENT MEDICAL REVIEW DECISION AND RATIONALE

An application for Independent Medical Review was filed on 8/6/2013 disputing the Utilization Review Denial dated 8/5/2013. A Notice of Assignment and Request for Information was provided to the above parties on 9/12/2013. 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 retrospective request for **Terocin pain relief lotion 240gms is not medically necessary and appropriate.**
- 2) MAXIMUS Federal Services, Inc. has determined the retrospective request for **Omeprazole 20mg #120 is not medically necessary and appropriate.**
- 3) MAXIMUS Federal Services, Inc. has determined the retrospective request for **Oxycodone/APAP 10/325mg #120 is not medically necessary and appropriate.**
- 4) MAXIMUS Federal Services, Inc. has determined the retrospective request for **Fentanyl duragesic 75mcg/hr #30 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 55-year-old male who reported an injury on 07/30/2008. The documentation submitted for review indicates that the patient has significant injuries to the lumbar spine, with notes indicating the patient underwent an MRI of the lumbar spine demonstrating an L4-5 disc herniation and bilateral L5 nerve impingement. The patient has pain to the low back described as sharp burning pain into the buttocks and complaint of radiating symptoms down the legs bilaterally. The notes indicate that the patient has undergone treatment with activity modification, medications, physical therapy, and lumbar epidural steroid injection. The patient was evaluated on 06/23/2013 with physical examination demonstrating muscle spasms, tenderness to palpation of the lumbar spine, myofascial trigger points and positive straight leg raise bilaterally. Furthermore, there were findings of decreased sensation to the legs bilaterally. The clinical notes submitted for review indicate that the patient was evaluated on 04/24/2013. The notes indicate that the patient had tenderness over the lower lumbar facet joints as well as nonspecific paraspinal tenderness and myofascial trigger points. Treatment plan notes indicated the patient was to continue with the same medication regimen and to continue to try and maximize is neuropathic pain medications as

tolerated to control nerve pain and make any spinal injections work better and last longer in affect. Evaluation of the patient on 06/26/2013 noted essentially no change in the patient's objective clinical findings with notes indicating that despite having undergone a selective epidural steroid injection providing the patient 80% to 90% relief for the proceeding 4 to 7 months, the patient had increase in low back pain bilaterally with sharp burning pain into the buttocks and increasing radiating symptoms down the legs. Treatment plan notes indicate the recommendation for bilateral L5 selective transforaminal epidural steroid injections.

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 retrospective request for Terocin pain relief lotion 240gms:

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, Topical Analgesics, pgs. 111-113, which are part of the California Medical Treatment Utilization Schedule (MTUS).

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines Topical Analgesics and 105, 111-113, which are part of the California Medical Treatment Utilization Schedule (MTUS), and Terocin Topical Pain Relief Lotion – DailyMed dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid..., which is not part of the California Medical Treatment Utilization Schedule (MTUS).

Rationale for the Decision:

Chronic Pain Medical Treatment Guidelines indicate that salicylate topicals are recommended as significantly better than placebo in chronic pain. Furthermore, guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine 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 one drug or drug class that is not recommended is not recommended. Clinical literature indicates that Terocin topical pain relief lotion has active ingredients consisting of methyl salicylate 25%, capsaicin 0.025%, menthol 10%, and lidocaine 2.5%. The Guidelines do not address menthol. Capsaicin is recommended in a formulation of 0.025% for the treatment of osteoarthritis. Furthermore, lidocaine is recommended for use as a first line therapy for treatment if there is evidence of trial of a first line therapy to include tricyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica. Topical lidocaine, in the formulation of a dermal patch has been designated for orphan status by

the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine, whether creams, lotions or gels, are indicated for neuropathic pain. The documentation submitted for review indicates that the employee has neuropathic pain for which the employee is currently receiving conservative therapies to include epidural steroid injections. Furthermore, there is indication in the notes that the employee is receiving treatment for sciatica. The current formulation of lidocaine at 2.5% is not indicated for the treatment of neuropathic pain in a non-patch variety. The guideline criteria have not been met. **The retrospective request for Terocin pain relief lotion 240gms is not medically necessary and appropriate.**

2) Regarding the retrospective request for Omeprazole 20mg #120:

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, NSAIDs (non-steroidal anti-inflammatory drugs), pgs. 67-68, which are part of the California Medical Treatment Utilization Schedule (MTUS).

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, NSAIDs, pg. 68, which is part of the California Medical Treatment Utilization Schedule (MTUS).

Rationale for the Decision:

Proton pump inhibitors such as omeprazole are indicated by the Chronic Pain Medical Treatment Guidelines for patients at intermediate risk for gastrointestinal events. The documentation submitted for review indicates that the employee is currently prescribed omeprazole 20 mg; however, there is a lack of documentation indicating current GI symptoms of the employee. Furthermore, there is a lack of documentation indicating a gastrointestinal history to include GI bleeding, ulcers or gastroesophageal reflux disease. The guideline criteria have not been met. **The retrospective request for Omeprazole 20mg #120 is not medically necessary and appropriate.**

3) Regarding the retrospective request for Oxycodone/APAP 10/325mg #120:

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, Opioids, criteria for use of Opioids, pgs. 76-80 and 91-94, which are part of the California Medical Treatment Utilization Schedule (MTUS).

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Opioids, pgs. 78, 92, which are part of the California Medical Treatment Utilization Schedule (MTUS).

Rationale for the Decision:

Chronic Pain Medical Treatment Guidelines indicate Oxycodone is for the treatment of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. The guidelines further indicate the recommendation for the “4 A’s” for ongoing monitoring of patients on opioid analgesics, indication for monitoring of analgesia, activities of daily living, adverse side effects, and aberrant drug related behaviors. The documentation submitted for review indicates that the employee has a current regimen of medications to include oxycodone. However, there is a lack of documentation of analgesic effect of the medication, proven that the employee’s abilities to undertake activities of daily living, or documentation indicating adverse side effects of the medication and drug related behaviors have been addressed. The guideline criteria have not been met. **The retrospective request for Oxycodone/APAP 10/325mg #120 is not medically necessary and appropriate.**

4) Regarding the retrospective request for Fentanyl duragesic 75mcg/hr #30:
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, Opioids, criteria for use of Opioids, pgs. 76-80 and 91-94, which are part of the California Medical Treatment Utilization Schedule (MTUS).

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Opioids, pgs. 78, 92, which are part of the California Medical Treatment Utilization Schedule (MTUS).

Rationale for the Decision:

Chronic Pain Medical Treatment Guidelines indicate that Fentanyl transdermal is indicated for the management of persistent chronic pain which is moderate to severe requiring continuous, around-the-clock opioid therapy. However, while the guidelines further recommend the monitoring of patients on opioids of the “4 A’s” for analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors. Medical records submitted and reviewed lack documentation indicating the necessity for 2 concurrent around-the-clock opioid analgesics. Furthermore, there is a lack of documentation indicating functional response of the employee to fentanyl patches, and there is no indication that the employee has had a decrease in pain, increase in ability to undertake activities of daily living, or to indicate that adverse side effects or drug related behaviors have been addressed with the employee. The guideline criteria have not been met. **The retrospective request for Fentanyl duragesic 75mcg/hr #30 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

/ldh

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.