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

Independent Medical Review Final Determination Letter

[redacted]

Dated: 12/18/2013

Employee:	[redacted]
Claim Number:	[redacted]
Date of UR Decision:	7/3/2013
Date of Injury:	3/8/2006
IMR Application Received:	8/1/2013
MAXIMUS Case Number:	CM13-0006179

DEAR [redacted]

MAXIMUS Federal Services has completed the Independent Medical Review ("IMR") of the above workers' compensation case. This letter provides you with the IMR Final Determination and explains how the determination was made.

Final Determination: UPHOLD. This means we decided that none of the disputed items/services are medically necessary and appropriate. A detailed explanation of the decision for each of the disputed items/services is provided later in this letter.

The determination of MAXIMUS Federal Services and its physician reviewer is deemed to be the Final Determination of the Administrative Director of the Division of Workers' Compensation. This determination is binding on all parties.

In certain limited circumstances, you can appeal the Final Determination. Appeals must be filed with the Workers' Compensation Appeals Board within 30 days from the date of this letter. For more information on appealing the final determination, please see California Labor Code Section 4610.6(h).

Sincerely,

Paul Manchester, MD, MPH
Medical Director

cc: Department of Industrial Relations, [redacted]

/jr

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Internal Medicine and Cardiology, has a subspecialty in cardiovascular disease 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 physician 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 disputed items/services.

DOCUMENTS REVIEWED

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 the Claims Administrator
- Medical Treatment Utilization Schedule (MTUS)

CLINICAL CASE SUMMARY

The physician reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This patient reported an injury on 03/08/2006. The documentation submitted for review indicates the patient was evaluated on 06/17/2013 with complaints of pain to both the cervical and lumbar spine with extension into the respected extremities and with notes indicating the patient was being treated conservatively and that the patient had benefited from the use of appropriate pharmacological agents. The notes indicated also the patient's symptomatology of the bilateral shoulders had not changed significantly. The patient complained of headaches that were migrainous in nature associated with periods of increased pain in the cervical spine. The patient further indicated that her headaches caused nausea which was not alleviated by Prilosec. Physical examination of the cervical spine was noted to be unchanged with tenderness to palpation of the cervical paravertebral muscles and upper trapezius muscles with spasms. Pain was noted on range of motion. Examination of bilateral shoulders was again unchanged with tenderness at the subacromial space and anteriorly as well as positive impingement sign and pain with terminal motion. In the lumbar spine, physical examination was unchanged with tenderness at the lumbar paravertebral muscles as well as with spasm and pain at terminal motion. Seated nerve root test was noted to be positive. Treatment plan notes indicate that the patient underwent 2 injections, with 1 for the administration of a Vitamin B12 complex and the second an injection of Toradol mixed with 1 cc of Marcaine. Furthermore, a recommendation was made for electrodiagnostic studies of the bilateral upper and lower extremities as well as for medications which included Naproxen sodium 550 mg, omeprazole 20 mg, ondansetron 8 mg, cyclobenzaprine 7.5 mg, and tramadol hydrochloride extended release capsules 150 mg as well as Medrox relief ointment. Also, a national pharmacy information sheet dated 06/17/2013 indicates the patient is to receive Ketoprofen 15%, Lidocaine 1%, capsaicin 0.012%, and Tramadol 5% and a topical analgesic cream as well as flurbiprofen 10%, cyclobenzaprine 1%, capsaicin 0.125%, and Lidocaine 1% and a topical formulation at 120 ml. Furthermore, it appears from the documentation submitted for review that these medications are indicated as transdermal applications.

IMR DECISION(S) AND RATIONALE(S)

The Final Determination was based on decisions for the disputed items/services set forth below:

1. Error! Reference source not found. is not medically necessary and appropriate.

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

The Physician Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Topical Analgesics Section, pages 111-113, which is part of the MTUS.

The Physician Reviewer's decision rationale:
California MTUS Guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine their efficacy or safety and 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 is not recommended. Topical analgesics work locally underneath the skin where they are applied and these do not include transdermal analgesics which are systemic agents entering the body through a transdermal means. Furthermore, guidelines indicate that use of nonsteroidal anti-inflammatory agents may be for the treatment of osteoarthritis and tendonitis, in particular that of the knee or elbow or other joints which are amenable to topical application; however, they are recommended for short-term use. There is little evidence to support utilization of topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. With regards to Ketoprofen, the guidelines indicate that it is a non FDA approved agent which is noted to have an extremely high incidence of photo contact dermatitis when used in topical application. Capsaicin is indicated as an option in patients who have not responded or are intolerant to other treatments. Lidocaine is recommended for localized peripheral pain after there has been evidence of a trial of first line therapy which included tricyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica. Finally, there is a lack of documentation indicating or addressing the use of tramadol in a topical formulation. However, recent clinical documentation indicates that there is deficiency of high quality evidence in the role of topical opioids and that more robust primary studies are required to inform practice recommendations. **The request for Error! Reference source not found. is not medically necessary and appropriate.**

2. Error! Reference source not found. is not medically necessary and appropriate.

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

The Physician Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Topical Analgesics Section, pages 111-113, which is part of the MTUS.

The Physician Reviewer's decision rationale:
California MTUS Guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine their efficacy or safety and 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 is not recommended. The current request for consideration is for a topical compounded medication with ingredients to include flurbiprofen 10%, cyclobenzaprine 2%, capsaicin 0.0125% and lidocaine 1% and a liquid, for what appears to be transdermal application. The California MTUS Guidelines support the use of lidocaine in a transdermal

formulation as a treatment for localized peripheral pain and with designation for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulations of lidocaine whether creams, lotions or gels are indicated for neuropathic pain and non dermal patch formulations are generally indicated as local anesthetics and antipruritics. Capsaicin is indicated in a standard formulation of 0/025% and 0.075% formulation for those patients who have not responded or are intolerant to other treatments. Nonsteroidal anti-inflammatory agents are indicated for a short-term use of 4 to 12 weeks, particularly for use in treating osteoarthritis and tendonitis of the knee and elbow or other joints which are amenable to topical application. However, there is little indication to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Cyclobenzaprine is not recommended by the guidelines as there is no peer reviewed literature to support its use. Given that the current requested medication contains a medication which is not recommended, the current request for Flur/cyclo/caps/lido is not supported. Also, there is a lack of clear clinical rationale as to why 2 separate medications with similar ingredients are required by the patient in liquid form, primarily including lidocaine and capsaicin. **The request for Error! Reference source not found. is not medically necessary and appropriate.**

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.

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