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

Notice of Independent Medical Review Determination

Dated: 12/17/2013

Employee:	
Claim Number:	
Date of UR Decision:	8/7/2013
Date of Injury:	4/24/2013
IMR Application Received:	8/30/2013
MAXIMUS Case Number:	CM13-0018629

1) MAXIMUS Federal Services, Inc. has determined the request for **Ketoprofen 15%/Lidocaine 1%/Capsaicin 0.012%/Tramadol 5% Spray 120ml with two refills is not medically necessary and appropriate.**

2) MAXIMUS Federal Services, Inc. has determined the request for **Flurbiprofen 10%/Cyclobenzaprine 2%/Capsaicin 0.0125%/Lidocaine 1% spray 120ml with two refills is not medically necessary and appropriate.**

INDEPENDENT MEDICAL REVIEW DECISION AND RATIONALE

An application for Independent Medical Review was filed on 8/30/2013 disputing the Utilization Review Denial dated 8/7/2013. A Notice of Assignment and Request for Information was provided to the above parties on 10/11/2013. 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 **Ketoprofen 15%/Lidocaine 1%/Capsaicin 0.012%/Tramadol 5% Spray 120ml with two refills is not medically necessary and appropriate.**

2) MAXIMUS Federal Services, Inc. has determined the request for **Flurbiprofen 10%/Cyclobenzaprine 2%/Capsaicin 0.0125%/Lidocaine 1% spray 120ml with two refills 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 Internal 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 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 64-year-old female who reported an injury on 04/24/2012. Per the documentation submitted for review, this patient reportedly misstepped and fell to the ground, landing on her buttocks and right side. Notes indicate that the patient was transported by ambulance to a hospital emergency room where x-rays were noted to be negative. A follow-up at an industrial clinic resulted in the prescription Norco, Soma, a back brace, and a knee brace. The patient ultimately received 12 sessions of physical therapy and was released to full duties. Permanent and Stationary Report was completed on 06/28/2012, which indicated the patient reached maximum medical improvement and was assessed and permanent and stationary. However, the patient reports continued back pain when bending over or with prolonged standing; however, the knee pain was noted to have resolved. Ultimately, the patient was prescribed medications, to include naproxen 550 mg, cyclobenzaprine 7.5 mg, ondansetron 8 mg, omeprazole 20 mg, and Medrox relief ointment, as well as tramadol 150 mg. The request for authorization 1 month later on 07/31/2013 indicated a pharmacy request for ketoprofen 15%, lidocaine 1%, capsaicin 0.012%, tramadol 5%, and an additional medication of flurbiprofen 10%, cyclobenzaprine 2%, and capsaicin 0.0125%, with lidocaine 1%. Both medications are indicated as a spray at 120 mL

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:

1) **Regarding the request for Ketoprofen 15%/Lidocaine 1%/Capsaicin 0.012%/Tramadol 5% Spray 120ml with two refills:**

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, pages 22, 67-68, Capsaicin, Topical, Topical Analgesics, pages 111-113 and ACOEM guidelines, Chapter 3, pages 47-48, which is are part of the MTUS and the Official Disability Guidelines (ODG), Medications for acute pain, Medications for subacute & chronic pain, NSAIDs specific drug, Pain Chapter, Capsaicin Topical, Topical Analgesics, Topical Analgesics, compounded, which is not a part of MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Topical Analgesics section, page 111-113, which is a part of MTUS and "Effectiveness of topical administration of opioids in palliative care: a systematic review**".** Journal of pain and symptoms, (2009), Elsevie, which is not a part of MTUS.

Rationale for the Decision:
The California MTUS Guidelines indicate topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. 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, therefore, is not recommended. With regard to the ketoprofen, lidocaine, capsaicin, and tramadol spray, ketoprofen is not FDA approved for topical application, as it has an extremely high incidence of photocontact dermatitis. Lidocaine is generally indicated for localized peripheral pain after there has been evidence of a trial of a first line therapy, such as tricyclic or SNRI antidepressants, or an AED, such as gabapentin or Lyrica, and Lidoderm is not commercially approved in a topical formulation other than a transdermal patch for neuropathic pain. Capsaicin is addressed in the guidelines as primarily recommended at a formulation of 0.025% and 0.075% formulation as an option for patients who have not responded or are intolerant to other treatments. Finally, tramadol, which is a synthetic opioid, is not supported by clinical literature, which indicates there is a deficiency of higher quality evidence on the role of topical opioids and that more robust primary studies are required to inform practice recommendations. The medical records submitted for review does not provide documentation to indicate that the employee has been recalcitrant to other treatment options or intolerant to other treatments. **The request for Ketoprofen 15%/Lidocaine 1%/Capsaicin 0.012%/Tramadol 5% Spray 120ml with two refills is not medically necessary and appropriate.**

2) **Regarding the request for Flurbiprofen 10%/Cyclobenzaprine 2%/Capsaicin 0.0125%/Lidocaine 1% spray 120ml with two refills:**

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, pages 22, 67-68, Capsaicin, Topical, Topical Analgesics, pages 111-113 and ACOEM guidelines, Chapter 3, pages 47-48, which is are part of the MTUS and the Official Disability Guidelines (ODG), Medications for acute pain, Medications for subacute & chronic pain, NSAIDs specific drug, Pain Chapter, Capsaicin Topical, Topical Analgesics, Topical Analgesics, compounded, which is not a part of MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Topical Analgesics section, page 111-113, which is a part of MTUS.

Rationale for the Decision:
The California MTUS Guidelines indicate topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety and that they are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. A compounded product that contains at least 1 drug or drug class that is not recommended, therefore, is not recommended. Flurbiprofen is a topical NSAID and non-steroidal anti-inflammatory agents are indicated by the guidelines as effective for short duration of use and indications for use include osteoarthritis and tendonitis in particular, that of the knee or elbow are the joints which are amenable to topical treatment. Cyclobenzaprine is not supported by the guidelines or any other muscle relaxant as a topical product. Also, capsaicin in indicated in a standard formulation of 0.025% and 0.075% as an option for patients who have not responded or are intolerant to other treatments. Lidocaine is indicated for localized peripheral pain after trial of a first line therapy, which includes tricyclic or SNRI antidepressant or an AED, such as gabapentin or Lyrica. Moreover, in the medical records submitted for review it is unclear why the employee requires 2 medications concurrently with the same ingredients of capsaicin and lidocaine. **The request for Flurbiprofen 10%/Cyclobenzaprine 2%/Capsaicin 0.0125%/Lidocaine 1% spray 120ml with two refills 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

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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.