

Case Number:	CM13-0034289		
Date Assigned:	12/06/2013	Date of Injury:	12/03/2012
Decision Date:	01/14/2014	UR Denial Date:	09/25/2013
Priority:	Standard	Application Received:	10/11/2013

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 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. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

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

The patient is a 26 year old female who reported injury on 12/03/2012. The mechanism of injury was stated to be a slip and fall. The patient had complaints of low back pain and was taking oxycodone. The patient had decreased range of motion in the thoracolumbar region and had decreased lower extremity motor strength. The diagnosis was noted to include L4-L5 extended disc protrusion and Left L4 radiculopathy per (EMG) Electromyography. The treatment plan included Medrox patches applied as directed, one month supply, Theramine #60, 2 bottles for month - two capsules, twice to thrice daily, BCKL Baclofen 2% - Cyclobenzaprine 2% - Ketoprofen 15% - Lidocaine 5% QTY. 24gm and BCKKL Baclofen 2% - Cyclobenzaprine 2% - Ketoprofen 15% - Ketamine 10%- Lidocaine 5 % QTY. 24 gm.

IMR ISSUES, DECISIONS AND RATIONALES

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

The request for Medox patches applied as directed, one month supply: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Salicylate, Topical Analgesics, Capsaicin, and Medrox online package insert. Page(s): 10.

Decision rationale: CA MTUS does not specifically address Medrox, however, the CA MTUS states that topical analgesics are "Largely experimental in use with few randomized control trials to determine efficacy or safety....Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended....Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments....There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy." Additionally it indicates that Topical Salicylates are approved for chronic pain. According to the Medrox package insert, Medrox is a topical analgesic containing Menthol 5.00% and 0.0375% Capsaicin and it is indicated for the "temporary relief of minor aches and muscle pains associated with arthritis, simple backache, strains, muscle soreness, and stiffness." The patient was noted to have pain, a 4/10. The patient's active range of motion was noted to be limited due to pain. The Kemp's test was positive bilaterally and the straight leg raise test in the supine position was positive on the left at 60 degrees. The clinical information submitted for review failed to provide exceptional factors to warrant non-adherence to guideline recommendations. Capsaicin is not approved and Medrox is being used for chronic pain, by the foregoing guidelines, the request for Medrox is not medically necessary.

The request for Theramine #60, 2 bottles for month - two capsules, twice to thrice daily:
Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)..

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Theramine, Online Version..

Decision rationale: California MTUS does not address Theramine, a medical food. Per Official Disability Guidelines Theramine is not recommended. The patient was noted to have pain, a 4/10. The patient's active range of motion was noted to be limited due to pain. The Kemp's test was positive bilaterally and the straight leg raise test in the supine position was positive on the left at 60 degrees. The clinical information failed to provide a rationale for the use of this product and failed to provide exceptional factors to warrant non-adherence to guideline recommendations. As such the request for Theramine #60, 2 bottles for month - two capsules, twice to thrice daily is not medically necessary.

The request for BCKL Baclofen 2% - Cyclobenzaprine 2% - Ketoprofen 15% - Lidocaine 5% QTY. 24gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Topical Analgesics, Ketoprofen, Lidocaine, and Baclofen, Page(s): 41,111,112,11.

Decision rationale: California MTUS indicates "Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety....Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended... There is no peer-reviewed literature to support the use of topical Baclofen...do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product... The addition of cyclobenzaprine to other agents is not recommended...Regarding the use of Ketoprofen: This agent is not currently FDA approved for a topical application...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 patient was noted to have pain, a 4/10. The patient's active range of motion was noted to be limited due to pain. The Kemp's test was positive bilaterally and the straight leg raise test in the supine position was positive on the left at 60 degrees. The clinical documentation submitted for review failed to provide exceptional factors to warrant non-adherence to guidelines recommendations. As such the request for BCKL Baclofen 2% - Cyclobenzaprine 2% - Ketoprofen 15% - Lidocaine 5% QTY. 24gm is not medically necessary.

The request for BCKKL Baclofen 2% - Cyclobenzaprine 2% - Ketoprofen 15% - Ketamine 10% - Lidocaine 5% QTY. 24gm: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation the National Library of Medicine.

MAXIMUS guideline: Decision based on MTUS ACOEM,Chronic Pain Treatment Guidelines Cyclobenzaprine, Topical analgesics, Lidocaine, Ketamine, and Baclofen, Page(s): 41,111,113,1.

Decision rationale: California MTUS indicates "Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety....Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended... There is no peer-reviewed literature to support the use of topical baclofen...do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product...The addition of cyclobenzaprine to other agents is not recommended...Regarding the use of Ketoprofen: This agent is not currently FDA approved for a topical application... topical Ketamine which is under study and is only recommended in treatment of neuropathic pain which is refractory to all primary and secondary treatment...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 patient was noted to have pain, a 4/10. The patient's active range of motion was noted to be limited due to pain. The Kemp's test was positive bilaterally and the straight leg raise test in the supine position was positive on the left at 60 degrees. The clinical documentation submitted for review failed to provide exceptional factors to warrant non-adherence to guidelines recommendations. As such the request for BCKKL Baclofen 2% - Cyclobenzaprine 2% - Ketoprofen 15% - Ketamine 10%- Lidocaine 5 % QTY. 24 gm is not medically necessary.