MAXIMUS Federal Services

Case Number:	CM13-0040941		
Date Assigned:	12/20/2013	Date of Injury:	09/06/2007
Decision Date:	02/11/2014	UR Denial Date:	10/18/2013
Priority:	Standard	Application Received:	10/29/2013

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 Pain Management, has a subspecialty in Disability Evaluation 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 claimant is a 50-year-old female with a date of injury of 9/6/2007. The last report by [redacted] was dated 3/25/2013 and it reported persistent neck pain that radiated to upper extremity and was greater on left than right hand with numbness and tingling. The upper extremities were unchanged bilaterally. Examination of the cervical spine revealed paravertebral muscle spasms along upper trapezius muscles greater than the left than right Limited cervical range of motion was noted along with positive axial loading compression test and a positive Spurling's maneuver shoulder was tender and painful with terminal motion, Positive Tinel' s and Phalen's signs present and pain with terminal flexion. No changes were noted in. the upper extremity. Diagnoses included cervical discopathy, left shoulder tendinitis, left shoulder impingement rule out rotator cuff pathology, status post right cubital tunnel release and bilateral carpal tunnel syndrome/double crush syndrome. Patient had responded to acupuncture and conservative treatments. The patient was on modified duty. At issue is the prospective request for Prospective requests submitted regarding 120 F1ur/Cyclo/caps/lid 10%2%0.0125% 1% liquid with 2 refills and 60 Ketop/Lidoc/Cap/Tram 15% 1%0.01215% Iiquid with 2 refills which was denied for lack of medical necessity.â¿¿

IMR ISSUES, DECISIONS AND RATIONALES

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

Prospective request for 60 Ketop/Lidoc/Cap/Tram 15% 1% 0.012/5% liquid with 2 refills:
Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, and National Guidelines Clearinghouse

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): s 111-113.

Decision rationale: According to the MTU Chronic Pain Medical Treatment Guidelines page 111; topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, Î±-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, Î³ agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. MTUS supports Capsaicin, topical, only as an option in patients who have not responded or are intolerant to other treatments. MTUS guidelines only support use of topical/transdermal lidocaine in the patch formulation. MTUS guidelines do not support topical/transdermal use of the NSAID Ketoprofen. MTUS guidelines do not support topical/transdermal use of Tramadol. Regarding topical ketoprofen/lidocaine/capsaicin/tramadol liquid, the guidelines state that any compounded product that contains at least one drug or drug class that is not recommended is not recommended. Ketoprofen is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. Topical lidocaine is recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy. Topical lidocaine, in the formulation of a dermal patch, Lidoderm, has been designated for orphan status by the FDA for neuropathic pain. Topical capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There is no guideline support for the use of topical tramadol, therefore the request for 60 Ketop/Lidoc/Cap/Tram 15% 1% 0.012/5% liquid with 2 refills was not medically necessary.

Prospective request for 120 Flur/Cyclo/caps/lid 10% 2% 0.0125% 1% liquid with 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, and National Guidelines Clearinghouse

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Section Topical Analgesics Page(s): s 111-113.

Decision rationale: Chronic Pain Medical Treatment Guideline, MTUS (Effective July 18, 2009) Topical Analgesics section pages 111-113 of 127 states "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. (Krummel 2000). Cyclobenzaprine is mentioned for use only as an oral agent: page 64 of 127. It is generally not recommended also in accordance with page 113 of the California MTUS Chronic Pain Medical Treatment Guidelines, which does not recommend the use of any muscle relaxants as a topical product. Therefore, the request for topical Ketop/Cyclo 20/20% is not medically necessary.