MAXIMUS Federal Services

Case Number:	CM14-0134595		
Date Assigned:	08/27/2014	Date of Injury:	11/26/2008
Decision Date:	10/16/2014	UR Denial Date:	07/29/2014
Priority:	Standard	Application Received:	08/21/2014

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert 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 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 injured worker is a 62-year-old male who reported an injury on 11/26/2008, due to an unknown mechanism. Diagnoses were hypertension with left ventricular diastolic rhythm, hyperlipidemia, gastroesophageal reflux disease secondary to NSAIDS, sleep disturbance, obstructive sleep apnea, status post H. pylori treatment, status post lumbar surgery, sexual dysfunction, psychiatric diagnosis, dizziness. Physical examination on 06/27/2014 revealed the injured worker had ongoing nausea every morning secondary to anxiety. There were reports of occasional gastroesophageal reflux symptoms and left sided headaches (about once a week). The injured worker stated his blood pressure was okay at home. Blood pressure average was 120/70 mm/Hemoglobin. Examination revealed a nontender abdomen without muscle guarding. No cyanosis, clubbing, or edema of the extremities. Medications were lisinopril, Prilosec, Gaviscon, Colace, simvastatin, aspirin (ASA), flurbiprofen, gabapentin. Treatment plan was to take medications as directed. The rationale and request were not submitted for review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol ER 150mg 1 tablet daily #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol, Ongoing Management, Page(s): 82,93,94,113, 78.

Decision rationale: The decision for tramadol ER 150 mg 1 tablet daily quantity 30 is not medically necessary. The California Medical Treatment Utilization Schedule states central analgesic drugs such as tramadol (Ultram) are reported to be effective in managing neuropathic pain, and it is not recommended as a first line oral analgesic. The medical guidelines recommend that there should be documentation of the 4 A's for ongoing monitoring, including analgesia, activities of daily living, adverse side effects, and aberrant drug taking behavior. The 4 A's for ongoing monitoring were not reported. Functional improvement from taking this medication was not reported. The clinical information submitted for review does not provide evidence to justify continued use. Therefore, this request is not medically necessary.

TGHot (Tramadol 8%, Gabapentin 10%, Menthol 2%, Camphor 2 %, Capsaicin 0.05%) 180gram jar: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol, Gabapentin, Topical Capsaicin, Topical Analgesics, , Topical Salicylates Page(s): 82,.

Decision rationale: The decision for TGHot (tramadol 8%, gabapentin 10%, menthol 2%, camphor 2%, capsaicin 0.05%) 180 g jar is not medically necessary. The California Medical Treatment Utilization Schedule indicates that topical analgesics are largely experimental and used 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, is not recommended. Topical salicylates are recommended. A thorough search of FDA.gov did not indicate there was a formulation of topical tramadol that had been FDA approved. The approved form of tramadol is for oral consumption, which is not recommended as a first line therapy. Gabapentin is not recommended. There is no peer reviewed literature to support use. Capsaicin is 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. The medical guidelines do not support the use of compounded topical analgesics. The medical guidelines do not support the use of gabapentin as a topical analgesic. This request does not indicate a frequency for the medication. There were no other significant factors provided to justify the use outside of current guidelines. Therefore, this request is not medically necessary.

FlurFlex (Flurbiprofen 10%, Cyclobenzaprine 10%) 180 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Topical Analgesics, Flurbiprofen, Page(s): page 41,page 111,page 72.

Decision rationale: The decision for FlurFlex (Flurbiprofen 10%, cyclobenzaprine 10%) 180 g is not medically necessary. The California Medical Treatment Utilization Schedule Guidelines indicate topical analgesics are largely experimental and used 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, is not recommended. The guidelines do not recommend the topical use of cyclobenzaprine as a topical muscle relaxant, 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. The FDA approved routes of administration of Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. The medical guidelines do not support the use of cyclobenzaprine and Flurbiprofen as a topical analgesic. There were no significant factors provided to justify the use outside of current guidelines. Therefore, this request is not medically necessary.

Relafen 750mg 1 tablet twice a day: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, specific drug list & adverse effects Page(s): 70-73.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, Page(s): 67.

Decision rationale: The decision for Relafen 750 mg 1 tablet twice a day is not medically necessary. The California Medical Treatment Utilization Schedule Guidelines indicate that NSAIDS are recommended for short term symptomatic relief of low back pain. It is generally recommended that the lowest effective dose be used for all NSAIDS for the shortest duration of time consistent with the individual patient treatment goals. There should be documentation of objection functional improvement and an objective decrease in pain. There were no reports of objective functional improvement and objective decrease in pain for the injured worker on this medication. The clinical information submitted for review does not provide evidence to justify continued use. Therefore, this request is not medically necessary.