

Case Number:	CM14-0009531		
Date Assigned:	02/14/2014	Date of Injury:	02/23/2009
Decision Date:	07/28/2014	UR Denial Date:	12/27/2013
Priority:	Standard	Application Received:	01/23/2014

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 Occupational 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 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:

Patient is a 59-year-old male who has submitted a claim for lumbar disc protrusion associated with an industrial injury date of 02/23/2009. Medical records from 2009 to 2013 were reviewed. Patient complained of low back pain rated 9/10 in severity. Physical examination of the lumbar spine showed tenderness and restricted range of motion. Treatment to date has included lumbar epidural steroid injection, physical therapy, chiropractic care, acupuncture, and medications such as Norco, Relafen, Prilosec, Norflex, Terocin patch, Gabacyclotram, Flurbiprofen cream, Somnicin, and Laxacin. Utilization review from 12/27/2013 denied the request for Prilosec 20mg, #60 because there was no evidence of gastrointestinal risk factor; Relafen 500mg, #60 because long-term use was not recommended; Laxacin #100 because there was no evidence of bowel complaint; Terocin patches 240mg, Gabacyclotram 180 gm., and Flurbo cream 180 gm. because of lack of published studies concerning efficacy and safety of topical products. The request for Norco 325mg, #60 was modified into #30 for weaning purposes because there was no documentation of pain relief. The request for Norflex 100mg, #60 was modified into #30 for weaning purposes because long-term use was not recommended. The request for Somnicin #30 was modified into #15 for weaning purposes since there was no evidence of functional benefit from its use.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 325 mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 91.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78.

Decision rationale: As stated on page 78 of CA MTUS Chronic Pain Medical Treatment Guidelines, there are 4 A's for ongoing monitoring of opioid use: pain relief, side effects, physical and psychosocial functioning and the occurrence of any potentially aberrant drug-related behaviors. The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. In this case, patient has been on opioids since 2010. However, the medical records do not clearly reflect continued analgesia, continued functional benefit, or a lack of adverse side effects. MTUS Guidelines require clear and concise documentation for ongoing management. Therefore, the request for Norco 325 mg #60 is not medically necessary and appropriate.

Prilosec 20 mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI Symptoms, and Cardiovascular Risk Page(s): 68.

Decision rationale: As stated on page 68 of CA MTUS Chronic Pain Medical Treatment Guidelines, clinicians should weigh the indications for Non-Steroid Anti-Inflammatory Drugs (NSAIDs) against both GI and cardiovascular risk factors: age more than 65 years, history of peptic ulcer, GI bleeding or perforation; concurrent use of ASA (Acetylsalicylic Acid), corticosteroids, or anticoagulant; or on high-dose/multiple NSAIDs. Patients with intermediate risk factors should be prescribed proton pump inhibitors (PPI). In this case, patient was prescribed Prilosec for gastritis secondary to intake of chronic medications. However, the only progress report documenting gastrointestinal complaint was dated 2010. The current clinical and functional status of the patient in terms of gastric complaint was not evident on the 2013 medical reports submitted. Monitoring of patient's response to therapy was likewise not evident. The medical necessity was not established due to insufficient information. Therefore, the request for Prilosec 20 mg #60 is not medically necessary and appropriate.

Norflex 100mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxant Page(s): 63.

Decision rationale: According to page 63 of the CA MTUS Chronic Pain Medical Treatment Guidelines, non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. In this case, patient has been on muscle relaxant since 2008. However, long-term use is not recommended as stated by the guidelines above. Moreover, the most recent physical examination failed to provide evidence of muscle spasms. Therefore, the request for Norflex 100mg #60 is not medically necessary and appropriate.

Relafen 500 Mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 46.

Decision rationale: As stated on page 46 of the California MTUS Chronic Pain Medical Treatment guidelines, NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain and that there is no evidence of long-term effectiveness for pain or function. In this case, patient has been on NSAIDs since 2009. However, there is no documentation concerning pain relief and functional improvement derived from its use. Moreover, long-term use is not recommended. Therefore, the request for Relafen 500 Mg #60 is not medically necessary and appropriate.

Terocin Patches 240 mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidocaine patch Page(s): 56-57. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Section, Topical Salicylate.

Decision rationale: Terocin patch contains both lidocaine and menthol. Pages 56 to 57 of CA MTUS Chronic Pain Medical Treatment Guidelines state that topical Lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Regarding the Menthol component, CA MTUS does not cite specific provisions, but the ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns. In this case, the initial date of Terocin patch prescription is unknown due to lack of documentation. There was no evidence that patient initially tried first-line therapy. The most recent progress report likewise failed to provide evidence of neuropathic pain. The medical necessity was not established. Therefore, the request for Terocin Patches 240 mg is not medically necessary and appropriate.

Gabacyclotram 180 gm: Upheld

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

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

Decision rationale: According to CA MTUS Chronic Pain Medical Treatment Guidelines pages 111-113, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Gabapentin is not recommended for use as a topical analgesic. Likewise, cyclobenzaprine has no evidence for use as a topical product. Tramadol is indicated for moderate to severe pain. In this case, initial date of prescription of Gabacyclotram is unknown due to lack of documentation. There is no discussion concerning the need for multiple topical medications in this case. In addition, certain components of this compound are not recommended for topical use. The guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request for Gabacyclotram 180 gm. is not medically necessary and appropriate.

Flurbo cream 180 gm.: Upheld

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

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

Decision rationale: As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. Topical NSAIDs formulation is only supported for diclofenac in the California MTUS. In this case, initial date of prescription of Flurbiprofen cream is unknown due to lack of documentation. There is no discussion concerning the need for multiple topical medications in this case. The requested topical product is likewise not guideline recommended. Therefore, the request for Flurbo cream 180 gm. is not medically necessary and appropriate.

Somnicin #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Treatment of Insomnia.

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

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Official Disability Guidelines (ODG), Pain Section was used instead. Somnicin #30 contains Melatonin, 5-hydroxytryptophan, L-tryptophan, Magnesium, and vitamin B-6. ODG states that medical foods are formulated for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, depression, and sleep disorders. In this case, patient has been on Somnicin since 2009. However, the submitted records failed to include a rationale or laboratory values indicating nutritional deficiency. There is no discussion as to why this medication is being prescribed. A search in the FDA database did not provide any results for Somnicin. The FDA states that specific requirements for the safety or appropriate use of medical foods have not yet been established. Therefore, the request for Somnicin #30 is not medically necessary and appropriate.

Laxacin #100: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation
<http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000100/> stool softeners.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 77.

Decision rationale: As stated on page 77 of the CA MTUS Chronic Pain Medical Treatment Guidelines, prophylactic treatment of constipation should be initiated with opioid treatment. Laxacin is a laxative. In this case, initial date of Laxacin prescription is unknown due to lack of documentation. The request for Norco has been deemed not medically necessary; hence, there is no current indication to provide a prophylactic drug for opioid-induced constipation. The medical necessity was not established. Therefore, the request for Laxacin #100 is not medically necessary and appropriate.