

Case Number:	CM14-0156799		
Date Assigned:	09/26/2014	Date of Injury:	06/27/2012
Decision Date:	11/07/2014	UR Denial Date:	08/29/2014
Priority:	Standard	Application Received:	09/24/2014

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, has a subspecialty in Pain 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:

The patient is a 41 year old male who sustained an industrial injury on 6/27/2012. He slipped and fell down stairs, injuring his back. The prior peer review on 8/29/2014 modified the request for Norco 10/325 #120 to allow #120 with no refills, modified to allow Cyclobenzaprine 10mg #60 with no refills, certified Gabapentin 600mg #60, and non-certified Flurbi (NAP) cream 180gm, Terocin 120mg, Gabacyclotram 180mg, Genicin #90 and Somnicin #30. The lumbar MRI study on 4/2/2013 reveals: 1. Diffuse circumferential disc bulge at L3-4, 1mm. 2. Broad-based central disc protrusion at L4-5, 3-4mm, with mild to moderate central spinal canal stenosis and moderate narrowing of the caudal margin of the neural foramen bilaterally. There is no significant facet arthropathy. 3. There is a 1-2mm disc bulge at L5-S1. The 4/4/2013 EMG/NCV study of the lower extremities revealed mildly abnormal EMG involving the L4-5 and to some degree L5, greater on the left; mildly abnormal NCV involving the left posterior tibial nerve, this may correlate with the EMG, that of an L5-S1 nerve root involvement. According to the secondary treating physician's PR-2 dated 7/16/2014, the patient complains of constant low back pain radiating to the left lower extremity with numbness and tingling, rated 7/10. He denies any side effects to oral/topical medications. He denies any GI symptoms with use of medications. On examination, lumbar ROM is 35 degrees flexion, 10 degrees extension, 15 degrees side flexion, positive SLR bilaterally, decreased sensation in right S1 and left L5-S1. Diagnosis is lumbar radiculopathy. Treatment plan is to provide Norco, Omeprazole, Gabapentin, Terocin patch, Methoderm gel, Calypso cream, Theramine, Trepadone, Sentra AM, Sentra PM, and Gabadone. He will be also sent from pharmacy Terocin, Flurbi (NAP) cream, Gabacyclotram, Genicin, and Somnicin. A vitamin B12 injection was administered intramuscularly to the gluteus muscle. Work status is per PTP. According to the secondary treating physician's PR-2 dated 8/13/2014, the patient complains of constant low back pain radiating to the left lower extremity with

numbness and tingling, rated 7/10. On examination, lumbar ROM is 30 degrees flexion, 10 degrees extension and side flexion. There are no other objective exam findings provided. Diagnosis is lumbar radiculopathy. Treatment plan is to provide Omeprazole, Gabapentin, Terocin patch, Methoderm gel, Calypso cream, Theramine, Trepadone, Sentra AM, and Sentra PM. He will be also sent from pharmacy Terocin, flurbi (NAP) cream, Gabacyclotram, Genicin, and Somnicin. A vitamin B12 injection was administered intramuscularly to the gluteus muscle. Work status is per PTP. An operative report dated 8/22/2014 documents the patient underwent L4-5 PLIF.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 10/325mg #120: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Guidelines Opioids, Page(s): page(s) 75-94.

Decision rationale: According to the CA MTUS guidelines, Norco is indicated for moderate to moderately severe pain. It is classified as a short-acting opioid, which are seen as an effective method in controlling chronic pain. They are often used for intermittent or breakthrough pain. These agents are often combined with other analgesics such as acetaminophen and aspirin. The guidelines state opioids may be continued: (a) If the patient has returned to work and (b) If the patient has improved functioning and pain. The medical records do not support that the requirements for continued opioid therapy have been met. However, it is noted that the patient subsequently underwent L4-5 fusion on 8/22/2014. Although functional improvement with Norco is not been clearly demonstrated within the records, the patient indicates pain reduction with Norco and denies any side effects. The medical necessity of Norco has been established. The request is certified.

Omeprazole 20mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): pages 68-69..

Decision rationale: The guidelines state PPIs such as Omeprazole may be indicated for patients at risk for gastrointestinal events, which are: 1) age over 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). However, none of these criteria apply to this patient. The medical records do not establish any of these potential significant risk factors apply to this patient. The ODG states PPIs are highly effective for their approved

indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. The medical records do not include supportive correlating subjective/objective findings that would establish Omeprazole is medically indicated. The patient does not describe any GI issues. The medical necessity of Omeprazole has not been established. The request is non-certified.

Terocin 140ml (Capsaicin 0.025% Methyl Salicylate 25%, Menthol 10%, Lidocaine 2.5%): 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): , page(s) 111-113..

Decision rationale: According to the CA MTUS guidelines, Lidocaine is recommended for neuropathic pain, 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. The patient is currently on Gabapentin. Furthermore, Capsaicin is appropriate and medically necessary for patients that are intolerant to first-line therapies, which is not the case for this patient. The guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The medical records do not establish this compounded topical product is appropriate or medically indicated. The medical necessity of Terocin is not established. The request is non-certified.

Flurbi (NAP) Cream LA 180 grams (Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 4%): 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): , page(s) 111-113..

Decision rationale: According to the CA MTUS guidelines, topical analgesics are an option with specific indications, many agents are compounded as mono-therapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). 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. There is not evidence-based support for topical Amitriptyline. According to the guidelines, topical application of an NSAID, such as flurbiprofen, may be indicated for short duration use, for osteoarthritis of joints that are amenable to topical treatment. However, there is little evidence to utilize topical NSAIDs for treatment of the spine. Furthermore, topical lidocaine is only recommended as an option for neuropathic pain having failed first-line

therapies, however this patient has not failed gabapentin. The patient tolerates oral medications, which are considered standard care. Furthermore, objective benefit from use of topical analgesics has not been established in this case. The request for Flurbi (NAP) cream is not medically necessary. The request is non-certified.

Gabaclotram 180 grams (Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%):
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): , page(s) 111-113..

Decision rationale: According to CA MTUS guidelines, Gabapentin is not recommended in topical formulations. There is no support to use gabapentin in a topical form. There is no peer-reviewed literature to support use. Cyclobenzaprine is a central muscle relaxant which is also not recommended as there is no evidence of using any other muscle relaxant as a topical product. There is no evidence-based support for use of gabapentin, tramadol or cyclobenzaprine as topicals. The guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore this topical compound is not medically necessary according to the guidelines. The request is non-certified.

Genicin (Glucosamine Sodium 500 mg) #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate) Page(s): 50.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Guidelines Glucosamine (and Chondroitin Sulfate), Page(s): page(s) 50.

Decision rationale: According to the CA MTUS guidelines, glucosamine is recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. The medical records document the patient diagnosed with lumbar radiculopathy. The medical records do not establish the existence of moderate OA pain. Based on the CA MTUS guidelines and criteria as well as the clinical documentation stated above, the request is not medically necessary. The request is non-certified.

Somnicin #30 (Melatonin 2mg-51 ITP 50mg-L tryptophan 100mg-Pyridoxine 10mg-Magnesium 50mg): Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.prlog.org/11964811-hootan-melamed-pharmd-and-los-angeles-based-pharmaceutical-company-alexso-inc-make-announcement.html>

Decision rationale: According to the manufacturer, this product contains Melatonin, 5-HTP, L-tryptophan, Vitamin B6 and Magnesium, that "aims to cure certain conditions like insomnia, anxiety and depression." This product is not recognized by the FDA. The medical records do not establish the patient has a medical condition that necessitates this product as treatment. In reference to the Official Disability Guidelines, Somnicin is not recommended as it does not meet the criteria set by the guidelines. The medical records do not establish this patient has a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. The medical records do not establish this product is labeled as intended for the specific dietary management of a disorder, disease or condition for which a distinctive nutritional requirement exists, and has been established by a medical evaluation. The medical necessity of Somnicin is not established. The request is non-certified.