

Case Number:	CM14-0020940		
Date Assigned:	04/30/2014	Date of Injury:	12/13/2011
Decision Date:	07/11/2014	UR Denial Date:	02/05/2014
Priority:	Standard	Application Received:	02/19/2014

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 Anesthesiology, Pain Medicine and is licensed to practice in Florida. 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 63-year-old female who reported an injury on 12/13/2011. The mechanism of injury was not provided. The injured worker's medication history included Terocin, NAP, Gabacyclotram, Genicin and Somnicin as of 06/2013. The injured worker underwent a urine drug screen on 09/24/2013. The most recent documentation was dated 09/24/2013. The diagnoses included neck sprain/strain, thoracic sprain/strain, and lumbar sprain/strain, as well as lumbar radiculopathy and depression. The treatment plan included a psychological evaluation, acupuncture, and Meloxicam 7.5 mg #60. There was no DWC Form RFA nor PR-2 submitted to support the requested medications. The request as submitted was for a drug screen, Terocin 240 mg, Flurbi (NAP) cream-LA 80 g, Gabacyclotram 180 g, Genicin #90 capsules, and Somnicin #30.

IMR ISSUES, DECISIONS AND RATIONALES

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

DRUG SCREEN: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Page Opioids, Steps To Avoid Misuse/Addiction.

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

Decision rationale: The California MTUS Guidelines indicate that urine drug screens are appropriate for patients who have documentation of addiction abuse or poor pain control. The injured worker had undergone prior urine drug screens. The clinical documentation submitted for review failed to provide a DWC Form RFA or a PR-2 to support the necessity for the drug screen. The request as submitted failed to indicate the quantity of drug screens being requested. Given the above, the request for drug screen is not medically necessary.

TEROCIN 240MG: 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 Salicylate, Topical Analgesic, Topical Capsaicin, Lidocaine Page(s): 105,111,28,112. Decision based on Non-MTUS Citation <http://www.drugs.com/search.php?searchterm=Terocin>.

Decision rationale: California MTUS indicates that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety... are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed...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 Lidocaine/Lidoderm. No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. California MTUS guidelines recommend treatment with topical salicylates. Per Drugs.com, Terocin is a topical analgesic containing capsaicin / Lidocaine / menthol / methyl salicylate. The clinical documentation submitted for review indicated the injured worker had been utilizing the medication for greater than 3 months. There was lack of documentation of efficacy for the requested medication. The request as submitted failed to indicate the frequency and strength of the medication being requested. There was no DWC form RFA nor PR - 2 submitted with the request. There was a lack of documentation indicating the rationale for 2 topical with Lidocaine as an ingredient. Given the above, the request for Terocin 240 mg is not medically necessary.

FLURBI (NAP) CREAM-LA 80GRMS: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, Topical analgesics, Lidocaine, Antidepressants Page(s): 72,111,112,13.

Decision rationale: The California MTUS indicates 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....Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect

over another 2-week period. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration Lidocaine/Lidoderm. No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Per Skolnick, P. (1999) "while local peripheral administration of antidepressants has been demonstrated to produce analgesia in the formalin model of tonic pain; a number of actions, to include inhibition of noradrenaline (NA) and 5-HT reuptake, inhibition of NMDA, nicotinic, histamine, and 5-HT receptors, and block of ion channels and even combinations of these actions, may contribute to the local peripheral efficacy of antidepressant; therefore the contribution of these actions to analgesia by antidepressants, following either systemic or local administration, remains to be determined". The clinical documentation submitted for review failed to provide documentation of exceptional factors to warrant nonadherence to guideline recommendations. The clinical documentation indicated the injured worker had been utilizing the medication since 06/2013. There was lack of documented efficacy for the requested medication. There was a lack of documentation indicating the rationale for 2 topical with Lidocaine as an ingredient. There was lack of documentation of a DWC Form RFA or a PR-2 submitted for the requested medication. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Flurbi (NAP) cream-LA 80 g is not medically necessary.

GABACYCLOTRAM 180 GMS: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Topical Analgesics, Gabapentin, Tramadol Page(s): 41,111,113,82. Decision based on Non-MTUS Citation FDA.gov.

Decision rationale: California MTUS indicates that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety... are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended Gabapentin: Not recommended. There is no peer-reviewed literature to support use. Other anti-epilepsy drugs: There is no evidence for use of any other anti-epilepsy drug as a topical product...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. 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 per CA MTUS guidelines. The clinical documentation submitted for review indicated the injured worker had been utilizing the medication for greater than 3 months. There was lack of documented efficacy for the requested medication. There was lack of documentation of a DWC Form RFA and PR-2 to support the request. The request as

submitted failed to indicate the frequency for the requested medication. Given the above, the request for Gabacyclotram 180 g is not medically necessary.

GENICIN #90 CAPSULES: Upheld

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

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

Decision rationale: The California MTUS Guidelines indicate that glucosamine is recommended as an option given its low risk in patients with moderate arthritis pain, especially for knee osteoarthritis. The clinical documentation submitted for review failed to provide the injured worker had moderate arthritis. The clinical documentation indicated the injured worker had been utilizing the medication for greater than 3 months. There was lack of documentation of the efficacy for the requested medication. There was lack of documentation of a DWC Form RFA or a PR-2 submitted for the requested medication. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Genicin #90 capsules is not medically necessary.

SOMNICIN #30: 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, Insomnia Treatments.

Decision rationale: Somnicin contains melatonin, L-tryptophan, pyridoxine, and magnesium. Per the Official Disability Guidelines, melatonin is recommended in the treatment of sleep disorders. A thorough search of the California MTUS, Official Disability Guidelines, and the National Guideline Clearinghouse failed to reveal guidelines or scientific evidence to L-tryptophan, pyridoxine, or magnesium in the management of insomnia. The clinical documentation submitted for review indicated the injured worker had been utilizing the medication since 06/2013. There was lack of documented efficacy for the requested medication. There was lack of documentation of a DWC Form RFA or a PR-2 submitted for the requested medication. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Somnicin #30 is not medically necessary.