

Case Number:	CM13-0072043		
Date Assigned:	01/08/2014	Date of Injury:	03/09/2011
Decision Date:	06/13/2014	UR Denial Date:	12/19/2013
Priority:	Standard	Application Received:	12/30/2013

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 Illinois. 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 42-year-old female who reported an injury on 03/09/2011. The mechanism of injury was the injured worker turned her head to the left and felt a sudden pop in her shoulder and had an immediate onset of pain in the left shoulder. Prior treatment includes physical therapy, medications, and injections. The medication history included flurbiprofen 15%, cyclobenzaprine 10%, 240 mg of tramadol 8%, gabapentin 10%, and menthol 2%, camphor 2%, and capsaicin 0.5%, as well as tramadol, acetaminophen, cyclobenzaprine hydrochloride, Medrox patches, and Ativan as of 04/2013. The injured worker underwent a previous urine drug screen on 04/03/2013 which was noted to be consistent with prescribed medications. The documentation of 11/27/2013 revealed the injured worker had complaints of constant neck pain radiating to the left upper extremity. The injured worker noted no side effects with oral or topical medications and pain without medications was a 9/10 and with medications was a 2 to 3/10. It was indicated topicals decreased pain and increased sleep. The diagnoses included neck sprain/strain, cervical disc protrusion, status post left shoulder surgery 07/12/2012, and right carpal tunnel syndrome. The treatment plan included omeprazole 10 mg #90 to be taken as directed for the treatment of gastrointestinal irritation, Terocin pain patch box #2 to be taken as directed for the treatment of minor aches and muscle pains, Ativan 1 mg #60, Norco 10/325 #30, Robaxin 750 mg #60, theramine #60, Trepadone #120, Sentra AM #60, Sentra PM #60, GABAdone #60 to be taken as directed, and Terocin 240 mL, Flurbi (NAP) cream- LA, gabacyclotram, Genicin #90 capsules, and Somnicin #30 capsules for the treatment of insomnia, anxiety, and muscle relaxation.

IMR ISSUES, DECISIONS AND RATIONALES

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

60 THERAMINE (THROUGH [REDACTED]) BETWEEN 12/16/2013 AND 1/30/2014: 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), Pain (Chronic).

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, Theramine.

Decision rationale: The Official Disability Guidelines do not recommend theramine. The duration of use could not be established through supplied documentation. As such, there could be no indication of the efficacy for the requested medication. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. The request as submitted failed to indicate the frequency. Given the above, the requested theramine (through [REDACTED]) between 12/16/2013 and 01/30/2014 is not medically necessary or appropriate.

120 TREPADONE (THROUGH [REDACTED]) BETWEEN 12/16/2013 AND 1/30/2014: 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), Pain (Chronic).

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, Trepadone and Medical Foods.

Decision rationale: The Official Disability Guidelines state indicate that Trepadone is a medical food that contains L arginine, L glutamine, choline bitartrate, L- serine and GABA. They further indicate that GABA is recommended for the treatment of epilepsy, spasticity and tardive dyskinesia. There is no indication for L serine, L arginine or choline. The duration of use and efficacy for the requested medication could not be established. The frequency was not submitted with the request. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. Given the above, the request for 120 Trepadone (through [REDACTED]) between 12/16/2013 and 01/30/2014 is not medically necessary or appropriate.

60 SENTRA AM (THROUGH [REDACTED]) BETWEEN 12/16/2013 AND 1/30/2014: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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, Medical Foods and <http://www.marvistahealthcenter.com/medicalfoods/SentraAMProductMonograph.pdf>.

Decision rationale: The Official Disability Guidelines state indicate that choline has no medical need except for the cases of long term parenteral nutrition or for individuals with choline deficiencies secondary to liver deficiency. Glutamic acid is used for the treatment of hypochlohydria and achlorhydria. It is used for digestive disorders and complementary medicine. Per marvistahealthcenter.com, Sentra AM is a patented blend of choline bitartrate and glutamate, acetyl L Carnitine, glutamate, and coco powder, grape seed extract, Hawthorne berry, cocoa powder, and ginkgo biloba per Marvistahealthcenter.com. There was no documented rationale for the use of this medication. The duration of use and efficacy of the medication could not be established through the supplied documentation. The request as submitted failed to indicate the frequency for the given medication. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. Given the above, the request for 60 Sentra AM (through [REDACTED]) between 12/16/2013 and 01/30/2014 is not medically necessary or appropriate.

ONE (1) DRUG SCREEN BETWEEN 12/16/2013 AND 1/30/2014: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines (Substance abuse(tolerance, dependence, addiction). Decision based on Non-MTUS Citation University of Michigan Health System Guidelines for Clinical Care: Managing Chronic Non-terminal Pain, Including Prescribing Controlled Substances, page 33.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines On-going Management, Page(s): 78.

Decision rationale: The California MTUS Guidelines indicate that urine drug screens are appropriate when there are documented issues of abuse, addiction, or poor pain control. The clinical documentation submitted for review indicated the injured worker had an appropriate urine drug screen on 04/13/2013. There is lack of documentation indicating the injured worker had issues of abuse, addiction, or poor pain control. Given the above, the request for 1 urine drug screen between 12/16/2013 and 01/30/2014 not medically necessary.

90 OMEPRAZOLE 20MG (THROUGH [REDACTED]) BETWEEN 12/16/2013 AND 1/30/2014: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risks..

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 69.

Decision rationale: The California MTUS Guidelines recommend PPIs for the treatment of dyspepsia secondary to NSAID therapy. The clinical documentation submitted for review indicated the medication was to be taken as directed for the treatment of gastrointestinal irritation. However, there is lack of documentation of the efficacy for the requested medication. The duration of use could not be established. The request as submitted failed to indicate the frequency for the requested medication. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. Given the above, the request for 90 omeprazole 20 mg (through [REDACTED]) between 12/16/2013 and 01/30/2014 is not medically necessary.

60 ATAVAN 1MG(THROUGH [REDACTED] BETWEEN 12/16/2013 AND 1/30/2014: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines, Page(s): 24.

Decision rationale: The California MTUS Guidelines indicate that benzodiazepines are not recommended as treatment for patients with chronic pain for longer than 3 weeks due a high risk of psychological and physiological dependence. The clinical documentation submitted for review indicated the injured worker had been utilizing the medication since 04/2013. There is lack of documentation of the efficacy for the requested medication. There is lack of documentation of objective functional improvement. Therefore, the continued use would not be supported. The request as submitted failed to indicate the frequency for the requested medication. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. Given the above, the request for 60 Ativan 1 mg (through [REDACTED] [REDACTED] between 12/16/2013 and 01/30/2014 is not medically necessary.

30 NORCO10/325MG (THROUGH [REDACTED] BETWEEN 12/16/2013 AND 1/30/2014: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, Ongoing Management, Page(s): 60, 78.

Decision rationale: The California MTUS Guidelines recommend opiates for the treatment of chronic pain. There should be evidence of objective functional improvement, an objective decrease in pain, and documentation the injured worker is being monitored for aberrant drug behavior and side effects. The clinical documentation submitted for review indicated the injured

worker had an objective decrease in pain and that the injured worker was being monitored for aberrant drug behavior and side effects. The injured worker was noted to be utilizing this classification of medications since early 2013. There was a lack of documentation of objective functional benefit that was received from the medication. The request as submitted failed to indicate the frequency for the requested medication. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. Given the above, the requested Norco 10/325 mg (through [REDACTED]) between 12/16/2013 and 01/30/2014 is not medically necessary.

60 ROBAXIN 750MG (THROUGH [REDACTED]) BETWEEN 12/16/2013 AND 1/30/2014: Upheld

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

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

Decision rationale: The California MTUS Guidelines recommend muscle relaxants as a second line option for the short term treatment of acute low back pain. Their use is recommended for less than 3 weeks. There should be documentation of objective functional improvement. The clinical documentation submitted for review indicated the injured worker had been utilizing the medication since 04/2013. There was a lack of documentation of objective functional improvement. The request would not be supported. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for 60 Robaxin 750 mg (through [REDACTED]) between 12/16/2013 and 01/30/2014 is not medically necessary.

60 SENTRA PM (THROUGH [REDACTED]) BETWEEN 12/16/2013 AND 1/30/2014: 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), Pain Chapter.

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, Sentra PM.

Decision rationale: The Official Disability Guidelines indicate that Sentra PM includes the ingredients of choline, glutamic acid, and 5-hydroxytryptophan. Per the Official Disability Guidelines, the indications for choline include no medical need for choline supplementation. The glutamic acid is utilized for the treatment of hypochlohydria and achlorhydria. It is used for digestive disorders and complementary medicine. The use of 5-hydroxytryptophan has been found to be possibly effective in the treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. It has been found to be effective for depression. The clinical documentation

submitted for review failed to provide a documented rationale for the use of the medication. The duration of use could not be established through supplied documentation. The request as submitted failed to indicate the frequency for the requested medication. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. Given the above, the request for 60 Sentra PM (through [REDACTED]) between 12/16/2013 and 01/30/2014 is not medically necessary.

60 GABADONE (THROUGH [REDACTED] BETWEEN 12/16/2013 AND 1/30/2014: 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), Pain (Chronic).

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, Gabadone.

Decision rationale: The Official Disability Guidelines do not recommend Gabadone. It is intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep, and reducing snoring in patients who are experiencing anxiety related to sleep disorders. The clinical documentation submitted for review failed to indicate the duration of use. The request as submitted failed to indicate the frequency for the requested medication. Additionally, there was lack of documented rationale for the use of the requested medication. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. Given the above, the request for 60 Gabadone (through [REDACTED]) between 12/16/2013 and 01/30/2014 is not medically necessary.

TWO (2) BOXES OF TEROGIN PATCHES (THROUGH [REDACTED] BETWEEN 12/16/2013 AND 1/30/2014: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidocaine Topical, Capsaicin Topical, Slicylate Topicals..

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Salicylates, Topical Analgesics, Lidocaine Page(s): 105, 111, 112. Decision based on Non-MTUS Citation <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=100ceb76-8ebe-437b-a8de-37cc76ece9bb>

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; 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

dailymed.nlm.nih.gov, Terocin patches are topical Lidocaine and Menthol. It was indicated the topicals decreased pain and increased sleep. However, there was a lack of documentation of the objective efficacy of the medication. There was lack of documentation indicating a necessity for 2 topical formulations that including lidocaine. There was a lack of documentation indicating the necessity for 2 forms of Terocin. The request as submitted failed to indicate the frequency for the requested medication. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. Given the above the request for 2 boxes of Terocin patches (through [REDACTED]) between 12/16/2013 and 01/30/2014 are not medically necessary.

ONE (1) PRESCRIPTION OF FLURBI (NAP) CREAM-LA 180GM (THROUGH [REDACTED]) BETWEEN 12/16/2013 AND 1/30/2014: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidocaine Topical, Capsaicin Topical, Slicylate Topicals..

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, Topical Analgesics, Lidocaine, Antidepressants Page(s): 72, 111, 112, 13. Decision based on Non-MTUS Citation Skolnick P (1999) Antidepressants for the new millennium. Eur J Pharmacol 375:31-40.

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 indicate the injured worker had a trial and failure of antidepressants and anticonvulsants. There is lack of documentation of exceptional factors to warrant nonadherence to FDA and California MTUS Guidelines. The clinical documentation indicated the injured worker had been utilizing the medication since 04/2013. The request as submitted failed to indicate the frequency for the requested medication. It was indicated the topicals decreased pain and increased sleep. However, there was a lack of documentation of the objective efficacy of the medication. Given the above, the request for 1 prescription of Flurbi

(NAP) cream-la 180 gm (through [REDACTED]) between 12/16/2013 and 01/30/2014 is not medically necessary.

ONE (1) PRESCRIPTION OF GABACYCLOTRAM 180GMS BETWEEN 12/16/2013 AND 1/30/2014: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidocaine Topical, Capsaicin Topical, Slicylate Topicals..

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: The California MTUS states 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 California MTUS guidelines. The clinical documentation submitted for review failed to indicate the injured worker had a trial and failure of antidepressants and anticonvulsants and failed to indicate documentation of exceptional factors to warrant nonadherence to guideline recommendations and FDA recommendations. The clinical documentation submitted indicated the injured worker had been utilizing the medication since 04/2013. It was indicated the injured worker's pain was decreased and the injured worker had increased sleep. The objective functional benefit was not provided. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for 1 prescription of Gabacyclotram 180 gm between 12/16/2013 and 01/30/2014 is not medically necessary.

ONE (1) PRESCRIPTION OF TEROGIN 240ML (THROUGH [REDACTED]) BETWEEN 12/16/2013 AND 1/30/2014: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidocaine Topical, Capsaicin Topical, Slicylate Topicals..

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Salicylate, Topical Analgesics, Topical Capsaicin, Lidocaine, Page(s): 105, 111, 28, 112. Decision based on Non-MTUS Citation <http://www.drugs.com/search.php?searchterm=Terogin>

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 since 04/2013. There is lack of documentation of objective functional benefit that was received. There is lack of documentation that the injured worker had a trial and failure of antidepressants and anticonvulsants. The request as submitted failed to indicate the frequency for the requested medication. There is lack of documentation indicating exceptional factors to warrant nonadherence to California MTUS Guidelines and FDA guidelines. Additionally, there was lack of documentation indicating a necessity for both a topical cream and a topical lotion. Given the above, the request for 1 prescription of Terocin 240 mL (through [REDACTED]) between 12/16/2013 and 01/30/2014 is not medically necessary.

30 SOMNICIN (THROUGH [REDACTED]) BETWEEN 12/16/2013 AND 1/30/2014: 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), Head.

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 failed to provide the duration of use. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for 30 Somnicin (through [REDACTED]) between 12/16/2013 and 01/30/2014 is not medically necessary.