

Case Number:	CM14-0056380		
Date Assigned:	08/06/2014	Date of Injury:	03/21/2008
Decision Date:	09/23/2014	UR Denial Date:	03/25/2014
Priority:	Standard	Application Received:	04/25/2014

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 & 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 52-year-old female who reported injury on 03/31/2008. The injured worker was noted to be utilizing the requested topical compounds since at least 12/2013. The prior therapies included acupuncture, myofascial release and therapy. The injured worker was noted to be undergoing urine drug screens. The mechanism of injury was not provided. The surgical history was not provided. The diagnostic studies were not provided. The documentation of 03/05/2014 revealed the injured worker had complaints of neck pain. The injured worker had pain radiating from the bilateral shoulders to the bilateral hands. The injured worker had numbness in the bilateral arms and bilateral hands. The injured worker had weakness in the right leg, left ankle and left foot. The note was of poor fax quality and difficult to read. The rest of the physical examination was illegible. There was no request for authorization submitted for review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol HCL ER 150 MG #45: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines for Chronic pain, ongoing management, opioid dosing Page(s): 60; 78; 86.

Decision rationale: The California MTUS Guidelines recommend opioids for the treatment of chronic pain. There should be documentation of objective functional improvement, and 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 failed to provide documentation of the above criteria. The request as submitted failed to indicate the frequency for the requested medication. The duration of use could not be established. Additionally, this request was being concurrently reviewed with a topical form of tramadol. There was a lack of documentation indicating a necessity for both a topical and oral form of tramadol. Given the above, the request for Tramadol Hydrochloride ER 150 mg #45 is not medically necessary.

Cyclobenzaprine HCL 7.5 mg #90: 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 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 pain. The recommendation is for usage of not more than 3 weeks. There should be documentation of objective functional improvement. The clinical documentation submitted for review failed to provide documentation of the duration of use. The request as submitted failed to indicate the frequency for the requested medication. The medication was being concurrently reviewed for a topical and oral form of the medication. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. Given the above, the request for Cyclobenzaprine Hydrochloride 7.5 mg #90 is not medically necessary.

Pantoprazole Sodium 20mg #60: Upheld

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

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 for dyspepsia secondary to NSAID therapy. The duration of use could not be established. The request as submitted failed to indicate the frequency for the medication. There was a lack of documentation of efficacy for the requested medication. Given the above, the request for Pantoprazole Sodium 20 mg #60 is not medically necessary.

Naproxen Sodium 550mg #90: 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): 67.

Decision rationale: The California MTUS Guidelines recommend NSAIDs for the short-term treatment of acute low back pain. There should be documentation of objective functional improvement and an objective decrease in pain. The clinical documentation submitted for review failed to provide documentation of the above criteria. The duration of use could not be established. There was a lack of documentation indicating a necessity for an oral form and 2 topical forms of NSAIDs. This request was concurrently being reviewed with a flector patch and a compounded medication including an NSAID. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Naproxen Sodium 550 mg #90 is not medically necessary.

Flector I 3% Patch #90: 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, Topical NSAIDS Page(s): 111; 112.

Decision rationale: The California MTUS guidelines indicates that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety topical analgesics 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. The guidelines also indicate that 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. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use. The clinical documentation submitted for review failed to provide documentation of a trial and failure of antidepressants and anticonvulsants. The duration of use for topicals was at least since 12/2013. There was a lack of documentation indicating a necessity for both an oral and 2 topical forms of the medication. The duration of use could not be established through the supplied documentation. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Flector 3% Patch #90 is not medically necessary.

Compound Gabapentin 10% Dextromethorphan 10% Amitriptyline 10% 210 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 Topical Analgesics, Antidepressants, Topical Antiepileptic Medications, does not address topical dextromethorphan Page(s): 111; 13; 113. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Skolnick P (1999) Antidepressants for the new millennium. Eur J Pharmacol 375:31-40.<http://www.drugs.com/dextromethorphan.html>.

Decision rationale: The California MTUS guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled 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. Peer reviewed literature states that 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. Topical Gabapentin is not recommended as there is no peer reviewed literature to support its use. Per Drugs.com, "Dextromethorphan is a cough suppressant. It affects the signals in the brain that trigger cough reflex. " The clinical documentation submitted for review failed to indicate the injured worker had a trial and failure of antidepressants and anticonvulsants. There was a lack of documentation indicating a rationale for dextromethorphan in the compound. The request as submitted failed to indicate the frequency for the requested medication. The duration of use was since at least 12/2013. There was a lack of documentation of objective functional improvement and an objective decrease in pain. Given the above, the request for Compound Gabapentin 10%, Dextromethorphan 10% and amitriptyline 10% 210 grams is not medically necessary.

Compound Flurbiprofen 20% Tramadol 20% Cyclobenzaprine 4% 210 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 Flurbiprofen, Topical analgesics Cyclobenzaprine, Tramadol Page(s): 72; 111; 41; 82. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: FDA.gov.

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. Any compounded product that contains at least one drug (or drug class) that is not

recommended is not recommended. 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. Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. 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... 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...the guidelines 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. There was a lack of documentation indicating a necessity for 2 topical forms of NSAIDs as well as an oral form of an NSAID. There was a lack of documentation indicating a necessity for an oral and topical form of tramadol and an oral and topical form of cyclobenzaprine. There was a lack of documentation indicating the injured worker had a trial and failure of antidepressants and anticonvulsants. The duration of use was since at least 12/2013. There was a lack of documentation of objective functional benefit and an objective decrease in pain. 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 for the requested medication. Given the above, the request for Compound Flurbiprofen 20%, Tramadol 20%, Cyclobenzaprine 4% 210 grams is not medically necessary.