

Case Number:	CM13-0026526		
Date Assigned:	11/22/2013	Date of Injury:	03/01/2008
Decision Date:	02/11/2014	UR Denial Date:	08/16/2013
Priority:	Standard	Application Received:	09/19/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician 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 physician 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 58-year-old male who reported injuries on 03/01/2008 through 03/01/2009. The patient was noted to have subjective complaints of neck pain radiating to the upper extremities, constant low back pain radiating to the lower extremities, and frequent bilateral shoulder pain with numbness and tingling as well as frequent knee pain with numbness and tingling. The mechanism of injury was not provided. The patient's diagnoses were noted to include neck sprain/strain, cervical disc protrusion, brachial neuritis or radiculitis, lumbar sprain/strain, disc protrusion, radiculopathy, bilateral shoulder sprain/strain, and bilateral knee sprain/strain. The submitted request was made for retrospective as well as current medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective Cyclobenzaprine 7.5mg, #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants for chronic pain -Cyclobenzaprine (Flexeril) Page.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41, 64.

Decision rationale: CA MTUS states that Cyclobenzaprine (Flexeril®) is recommended for a short course of therapy. Flexeril is more effective than placebo in the management of back pain;

however, the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. This medication is not recommended to be used for longer than 2-3 weeks. The addition of cyclobenzaprine to other agents is not recommended. The clinical documentation submitted for review indicated the patient was taking cyclobenzaprine for the treatment of muscle spasms and cramping. There was a lack of documentation indicating the patient had muscle spasms on the day of exam. Additionally, there was a lack of documentation indicating the efficacy of the medication as well as the necessity for long-term use. Given the above, the request for retrospective Cyclobenzaprine 7.5mg, #60 is not medically necessary.

Alprazolam 1mg, #60: Upheld

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

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

Decision rationale: California MTUS guidelines do not recommend Benzodiazepines for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks and the guidelines indicate that chronic benzodiazepines are the treatment of choice in very few conditions. The clinical documentation submitted for review indicated the patient was taking the medication for anxiety. However, there was a lack of documentation of the efficacy of the medication being requested. Additionally, there was a lack of documentation indicating the necessity for long-term use and the necessity for 60 tablets. Given the above, the request for Alprazolam 1mg, #60 is not medically necessary.

Retrospective Gabapentin/L Carnitine 250/125mg, no amount or frequency: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin (Neurontin) Page(s): 18. Decision based on Non-MTUS Citation ODG, Pain Chapter, Medical foods and Compound drugs

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 16. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Compounded Drugs; and the following website:
<http://www.webmd.com/vitamins-supplements/ingredientmono-1026-L-CARNITINE.aspx?activeIngredientId=1026&activeIngredientName=L-CARNITINE>

Decision rationale: California MTUS Guidelines indicate gabapentin is recommended for neuropathic pain; however, as this medication was noted to be compounded, it is not recommended as a first line therapy for most patients but is recommended as an option after a trial of a first line FDA approved drug if the compound drug uses FDA approved ingredients that are recommended in ODG. The clinical documentation indicated the medication was gabapentin and L-carnitine. L carnitine is noted per WebMD.com to be used in people with muscle disorders associated with certain AIDS medications, and chronic fatigue syndrome. There is a

lack of documentation indicating the rationale for the use of the medication and efficacy including functional benefit. The request as submitted failed to include a quantity. Given the above, the request for retrospective Gabapentin/L Carnitine 250/125mg, no amount or frequency is non-certified

Retrospective Flurbiprofen 15%/Cyclobenzaprine 10%, #240: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, Topical analgesics, Cyclobenzaprine Page(s): 41, 72, 111.

Decision rationale: Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. The CA 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 ... California MTUS 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." The clinical documentation submitted for review indicated the medication would be used for the treatment of pain and inflammation. However, this request was concurrently submitted with a request for cyclobenzaprine. There is a lack of documentation indicating the necessity for 2 forms of the same medication and Flurbiprofen is not recommended for topical use. Given the above, the request for retrospective Flurbiprofen 15%/Cyclobenzaprine 10%, #240 is not medically necessary.

Retrospective Tramadol 8%/Gabapentin 10%/Menthol 2%/Camphor 2%/Capsaicin 0.5%, #240: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol, Topical Salicylates, Topical Analgesics, Gabapentin, Capsaicin Page(s): 82, 105, 111,.

Decision rationale: The California MTUS states, "Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. ... Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. ... Topical Salicylates are 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. ... Gabapentin: Not recommended. There is no peer-reviewed literature to support use ... Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. ... There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. California MTUS guidelines recommend Topical Salicylates." The clinical documentation submitted for review indicated the patient's medications were concurrently being reviewed for gabapentin. There is a lack of documentation indicating the necessity for 2 forms of the same medication. Additionally, tramadol and gabapentin are not recommended for topical formulations. Given the above, and that several of the ingredients are not recommended, the request for retrospective Tramadol 8%/Gabapentin 10%/Menthol 2%/Camphor 2%/Capsaicin 0.5%, #240 is not medically necessary.