

Case Number:	CM14-0023502		
Date Assigned:	05/14/2014	Date of Injury:	09/10/2013
Decision Date:	07/11/2014	UR Denial Date:	02/04/2014
Priority:	Standard	Application Received:	02/24/2014

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 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:

This 44 year-old male sustained an injury on 9/10/13 while employed by the [REDACTED]. The request under consideration include Baclofen/ Flurbiprofen/ Acetyl-Carnitine 7/ 60/ 125 MG three times a day #90 and Tramadol/ L Carnitine 40 /125 MG three times a day #90. A report of 1/22/14 from the chiropractic provider noted patient with constant severe neck pain with stiffness and weakness; low back pain with stiffness and heaviness; left knee pain; and left shoulder pain with stiffness, weakness, and numbness. An exam of the cervical spine showed no bruising, swelling or lesion; lumbar spine with no bruising, swelling, atrophy, or lesion. Diagnoses included cervical radiculopathy/sprain and strain; left shoulder sprain/strain; right shoulder impingement syndrome; lumbar radiculopathy/ sprain/ strain; thoracic sprain/strain; sleep disturbances. The treatment plan included compounded medications of Tramadol/L-Carnitine and Baclofen/Flurbiprofen/Acetyl-carnitine. Other medications currently prescribed include Tramadol 15%, Capsaicin 0.0375%, Diclofenac 20%, Cartivisc, Gabapentin 10%, Lidocaine 10%, Tramadol 10%, Ketoprofen 10%, Camphor 2% and Menthol 2% besides the above prescription. A request for the above compounded medications were non-certified on 2/4/14 citing guidelines criteria and lack of medical necessity.

IMR ISSUES, DECISIONS AND RATIONALES

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

BACLOFEN/FLURBIPROFEN/ACETYL-CARNITINE 7/60/125 MG THREE TIMES A DAY #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 64. Decision based on Non-MTUS Citation ODG Pain, Compound Drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants and Anti-inflammatory Drugs Page(s): 22,64-65.

Decision rationale: The efficacy in clinical trials for compound medication treatment modality has been inconsistent and most studies are small and of short duration. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety for the use of these compounded medications for treatment of chronic low back pain. There is little to no research to support the use of many of these agents and any compounded product that contains at least one drug or drug class (as in this case for Baclofen and Flurbiprofen) that is not recommended is not recommended. The patient is also taking concurrent Diclofenac in addition to the now prescribed compounded Flurbiprofen. It is not clear why the provider is prescribing two NSAIDs concurrently. Submitted reports have not demonstrated any change in symptom complaints, functional improvement, improved self-management of pain, or decrease in medical utilization for this injury. The patient has not shown any clinical improvement with treatment of compounded medication already rendered. There was no report of acute flare-up or new injuries to establish medical necessity for the compound medication outside the recommendations of the Guidelines nor is there any clinical presentation documented to support its continued use. The Baclofen/Flurbiprofen/Acetyl-Carnitine 7/60/125 MG three times a day #90 is not medically necessary and appropriate.

TRAMADOL/L CARNITINE 40/125 MG THREE TIMES A DAY #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 93. Decision based on Non-MTUS Citation ODG Pain, Compound Drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, on-going management Page(s): 74-96.

Decision rationale: The efficacy in clinical trials for compound medication treatment modality has been inconsistent and most studies are small and of short duration. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety for the use of these compounded medications for treatment of chronic low back pain. There is little to no research to support the use of many of these agents and any compounded product that contains at least one drug or drug class (as in this case for Tramadol) that is not recommended is not recommended. The patient is also taking concurrent topical Tramadol in addition to the now prescribed compounded Tramadol/ L. Carnitine. It is not clear why the provider is prescribing the same opioid concurrently in two different formulations. Submitted reports have not demonstrated any change in symptom complaints, functional improvement, improved self-management of pain, or decrease in medical utilization for this injury. The patient has not shown any clinical improvement with treatment of compounded opioid medication already rendered. There was no report of acute flare-up or new injuries to establish medical necessity for the compound medication outside the recommendations of the Guidelines nor is there any clinical presentation documented to support its continued use. The

Tramadol/L Carnitine 40/125 MG three times a day #90 is not medically necessary and appropriate.