

Case Number:	CM15-0088535		
Date Assigned:	05/12/2015	Date of Injury:	03/27/2012
Decision Date:	06/23/2015	UR Denial Date:	04/02/2015
Priority:	Standard	Application Received:	05/07/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Internal Medicine

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 29 year old male, who sustained an industrial injury on 03/27/2012. He has reported injury to the right wrist and low back. The diagnoses have included right wrist internal derangement; right wrist carpal tunnel syndrome; right wrist pain; low back pain; radiculitis, lower extremity; and rule out lumbar disc displacement herniated nucleus pulposus. Treatment to date has included medications, diagnostics, lumbar epidural steroid injection, and physical therapy. Medications have included Tabradol, Synapryn, Fanatrex, Deprizine, and Dicopanol. A progress note from the treating physician, dated 03/11/2015, documented a follow-up visit with the injured worker. Currently, the injured worker complains of burning right wrist pain and muscles spasms; the pain is constant and rated at 6/10 on the visual analog scale; weakness, numbness, and tingling of the right hand and fingers; constant radicular low back pain and muscle spasms; pain is associated with numbness and tingling of the bilateral lower extremities; low back pain is rated at 6/10; and the medications offer him temporary relief of pain and improve his ability to have restful sleep. Objective findings included tenderness to palpation at the triangular fibrocartilage complex (TFC) and at the scapholunate ligament junction of the right wrist; tenderness at the carpal tunnel; positive Tinel's , Phalen's, and compression testing of the right wrist; tenderness to palpation at the paralumbar muscles and quadratus lumborum of the lumbar spine; and decreased lumbar spine range of motion. The treatment plan has included Dicopanol (diphenhydramine) 5mg/ml 150ml; and Fanatrex (gabapentin) 25mg/ml 420ml.

IMR ISSUES, DECISIONS AND RATIONALES

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

Dicopanol (diphenhydramine) 5mg/ml 150ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Rxlist.com.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Insomnia treatment. Official Disability Guidelines (ODG) Pain (Chronic) Compound drugs. Dicopanol (Diphenhydramine) <http://www.drugs.com/pro/dicopanol.html>.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) does not address Dicopanol (diphenhydramine) for insomnia treatment. Official Disability Guidelines (ODG) guidelines state that over-the-counter sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine). Tolerance seems to develop within a few days. Next-day sedation has been noted as well as impaired psychomotor and cognitive function. Side effects include urinary retention, blurred vision, orthostatic hypotension, dizziness, palpitations, increased liver enzymes, drowsiness, dizziness, grogginess and tiredness. Regarding insomnia treatment, after a few weeks, the recommendation is to discontinue the medication. Patients do better in the long term if medication is stopped after 6 weeks. Dicopanol is Diphenhydramine (Benadryl) compounding oral suspension. Official Disability Guidelines (ODG) indicates that compound drugs are not recommended as a first-line therapy. Criteria for compound drugs were presented. Include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs. Is not a copy of a commercially available FDA-approved drug product. Medical records indicate that Dicopanol, which is a Diphenhydramine (Benadryl) suspension, was requested for the treatment of insomnia. Medical records document the long-term use of Diphenhydramine for sleep complaints. ODG guidelines do not support the use of over-the-counter antihistamines such as Diphenhydramine. The use of Dicopanol (Diphenhydramine) is not supported by ODG guidelines. Therefore, the request for Dicopanol (Diphenhydramine) is not medically necessary.

Fanatrex (gabapentin) 25mg/ml 420ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin (Neurontin).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs), pages 16-22. Gabapentin (Neurontin), page 18-19. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Compound drugs.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines indicate that Gabapentin (Neurontin) is considered as a treatment for neuropathic pain. A good response to the use of antiepilepsy drugs (AEDs) has been defined as a 50% reduction in pain and a moderate response as a 30% reduction. It has been reported that a

30% reduction in pain is clinically important to patients. After initiation of treatment, there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. Official Disability Guidelines (ODG) indicates that compound drugs are not recommended as a first-line therapy. In general, commercially available, FDA-approved drugs should be given an adequate trial. If these are found to be ineffective or are contraindicated in individual patients, compound drugs that use FDA-approved ingredients may be considered. Pharmacy compounding has traditionally involved combining drug ingredients to meet the needs of specific patients for medications that are not otherwise commercially available, and it is undertaken on a patient-by-patient basis for patients who, for example, might be allergic to inactive ingredients in FDA-approved drugs or may need a different dosage strength or route of administration. The issues surrounding compound drugs are due to uncertainties regarding whether the products are medically appropriate. Criteria for compound drugs were presented. Include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs. Is not a copy of a commercially available FDA-approved drug product. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The progress report dated 1/30/15 documented a history of carpal tunnel syndrome and radiculitis. Benefit from medications was not documented. No swallowing disorders were documented that would support the use of an oral suspension. The Official Disability Guidelines (ODG) criteria for compound drugs indicates that the compound drug should not be a copy of a commercially available FDA-approved drug product. Gabapentin is a commercially available FDA-approved drug. Fanatrex is an oral suspension containing Gabapentin, which is a commercially available FDA-approved drug. The request for Fanatrex is not supported by ODG guidelines. Therefore, the request for Fanatrex is not medically necessary.