

Case Number:	CM13-0039420		
Date Assigned:	03/26/2014	Date of Injury:	07/19/2009
Decision Date:	07/23/2014	UR Denial Date:	10/07/2013
Priority:	Standard	Application Received:	10/28/2013

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 Occupational Medicine, 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 patient is a 67-year-old male who has filed a claim for lumbago and lumbar radiculopathy associated with an industrial injury date of July 19, 2009. Review of progress notes indicates low back pain radiating into the buttock and bottom of the right foot, associated with numbness and tingling of the bilateral lower extremities, more on the right. Patient also complains of burning right hip pain with muscle spasms, pain in the head, bilateral shoulder pain traveling to the middle of the neck, constant neck pain, and decreased quality. Patient reports that the medications offer temporary relief of pain and improve the ability to have restful sleep. Findings include tenderness over the cervical and lumbar regions, and positive lumbar facet test bilaterally. Regarding the right hip, there was tenderness over the right trochanter and slightly decreased range of motion. Patient ambulates with a cane. Treatment to date has included topical compounded medications, Synapryn, Tabradol, Deprizine, Dicopanol, Fanatrex, physical therapy, and acupuncture. Utilization review from October 07, 2013 denied the requests for compounded ketoprofen and compounded cyclophene as these medications are not recommended for topical application; and for Synapryn, Tabradol, Deprizine, Dicopanol, and Fanatrex as there is no indication of failure of use of oral tablets.

IMR ISSUES, DECISIONS AND RATIONALES

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

COMPOUND KETOPROFEN 20% IN PLO GEL: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: As noted on pages 111-113 of the CA MTUS Chronic Pain Medical Treatment Guidelines, many agents are compounded as monotherapy or in combination for pain control. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Ketoprofen is not currently FDA-approved for topical application. It has an extremely high incidence of photocontact dermatitis. Patient has been on this medication since at least March 2013. There is no documentation regarding intolerance to or failure of first-line pain medications. There is no discussion concerning the need for variance from the guidelines. Therefore, the request for compounded ketoprofen 20% in PLO gel 120g was not medically necessary.

COMPOUND CYCLOPHENE 5% IN PLO GEL: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: Cyclophene contains cyclobenzaprine hydrochloride and other proprietary ingredients. As noted on pages 111-113 of the CA MTUS Chronic Pain Medical Treatment Guidelines, ketoprofen, lidocaine (in creams, lotion or gels), capsaicin in a 0.0375% formulation, baclofen and other muscle relaxants, and gabapentin and other antiepilepsy drugs are not recommended for topical applications. Patient has been on this medication since at least March 2013. There is no documentation regarding intolerance to or failure of first-line pain medications. There is no discussion concerning the need for variance from the guidelines. Therefore, the request for compounded cyclophene 5% gel was not medically necessary.

SYNAPRYN 10MG/1ML ORAL SUSPENSION 500ML: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Synapryn
<http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=20039>.

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, FDA was used instead. A search of online resources revealed that Synapryn contains tramadol hydrochloride 10 mg/mL, in oral suspension with glucosamine - compounding

kit. Additionally, this drug has not been found by FDA to be safe and effective, and is not approved by the FDA. Patient has been on this medication since at least March 2013. There is no documentation regarding intolerance to or failure of first-line pain medications. Furthermore, there is no clear rationale identifying why a compound/oral suspension (as opposed to the evidence based guidelines supported and FDA approved non-compounded medication) is needed for this patient. Therefore, the request for Synapryn 10mg/1ml suspension 500ml was not medically necessary.

TABRADOL 1MG/ML ORAL SUSPENSION 250ML: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Page(s): 41-42. Decision based on Non-MTUS Citation Tabradol <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22434>.

Decision rationale: Tabradol is cyclobenzaprine hydrochloride with MSM in oral suspension. CA MTUS Chronic Pain Medical Treatment Guidelines state that cyclobenzaprine is a skeletal muscle relaxant and a CNS depressant that is recommended as a short-course therapy. The effect is greatest in the first 4 days of treatment. Patient has been on this medication since at least March 2013. There is no documentation regarding intolerance to cyclobenzaprine in tablet form. In addition, Methylsulfonylmethane (MSM) is not FDA approved, and this medication is not recommended for long-term use. There is no discussion concerning the need for variance from the guidelines. Therefore, the request for tabradol 1mg/ml oral suspension 250ml was not medically necessary.

DEPRIZINE 5MG/ML ORAL SUSPENSION 250ML: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Depirizine <http://www.drugs.com/pro/deprizine.html>.

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, FDA was used instead. According to FDA, Deprizine is ranitidine with other proprietary ingredients in oral suspension. It is used to treat and prevent ulcers in the stomach and intestines. Patient has been on this medication since at least March 2013. There is no documentation regarding upper GI symptoms in this patient. In addition, there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request for Deprizine 15mg/ml oral suspension 250ml was not medically necessary.

DICOPANOL 5MG/ML ORAL SUSPENSION 150ML: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Dicopanol <http://www.drugs.com/cdi/diphenhydramine.html>.

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, FDA was used instead. Dicopanol is diphenhydramine hydrochloride 5 mg/mL oral suspension. It is used to treat occasional sleeplessness and difficulty falling asleep. Patient has been on this medication since at least March 2013. Although this patient reports issues with sleep, there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request for Dicopanol 5mg/ml oral suspension 150ml was not medically necessary.

FANATREX 25MG/ML ORAL SUSPENSION 420ML: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs) Page(s): 16-18.

Decision rationale: Fanatrex is gabapentin with other proprietary ingredients in oral suspension. Gabapentin is used to treat diabetic painful neuropathy and postherpetic neuralgia. Patient has been on this medication since at least March 2013. However, there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request for Fanatrex (gabapentin) 25mg/ml oral suspension 420ml was not medically necessary.