

Case Number:	CM14-0006954		
Date Assigned:	02/12/2014	Date of Injury:	02/04/2010
Decision Date:	07/14/2014	UR Denial Date:	12/21/2013
Priority:	Standard	Application Received:	01/17/2014

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 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 36-year-old male who has filed a claim for lumbago associated with an industrial injury date of February 04, 2010. Review of progress notes indicates low back pain radiating to the bilateral lower extremities, more on the left, associated with numbness and tingling. Findings include tenderness of the lumbar region, and spasms at the lumbosacral junction. There was slightly decreased sensation at the L4, L5, and S1 dermatomes bilaterally; and decreased motor strength from L2 to S1 myotomes secondary to pain. Treatment to date has included compound medications, TENS, opioids, physical therapy, and chiropractic therapy. Utilization review from December 20, 2013 denied the retrospective requests (date of service 02/16/2012) for Synapryn, Tabradol, and Deprizine as there was no documentation of clinical findings to support these medications; and Dicoprofanol, Fanatrex, and compounded Ketoprofen, as there is no documentation regarding exceptional factors to warrant non-adherence to guideline regulations.

IMR ISSUES, DECISIONS AND RATIONALES

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

SYNAPRYN: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate) Page(s): 113, 50. Decision based on Non-MTUS

Citation Other Medical Treatment Guideline or Medical Evidence: Synapryn
<http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=20039>.

Decision rationale: A search of online resources revealed that Synapryn contains Tramadol hydrochloride 10 mg/mL, in oral suspension with glucosamine - compounding kit. CA MTUS Chronic Pain Medical Treatment Guidelines indicate that Tramadol is an opioid analgesic, not used as first-line therapy. Glucosamine and Chondroitin Sulfate are recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Synapryn has not been found by FDA to be safe and effective, and is not approved by the FDA. Furthermore, there is no clear rationale identifying why a compound/oral suspension is needed for this patient. Therefore, the request for Synapryn was not medically necessary.

TABRADOL: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: 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 any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. 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. In addition, Methylsulfonylmethane (MSM) is not FDA approved. There is no guideline evidence regarding Cyclobenzaprine preparation as an oral suspension. There is no indication regarding this patient's intolerance of taking medications in pill form. Therefore, the request for Tabradol was not medically necessary.

DEPRIZINE: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines nsoids, gi symptoms & cardiovascular risk.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Deprizine <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, and FDA was used instead. Deprizine is ranitidine with other proprietary ingredients in oral suspension. It is used to treat and prevent ulcers in the stomach and intestines. There is no documentation regarding 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 was not medically necessary.

FANATREX: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs), Gabapentin (Neurontin, Gabarone, generic available) Page(s): 18-19.

Decision rationale: Fanatrex is Gabapentin with other proprietary ingredients in oral suspension. CA MTUS Chronic Pain Medical Treatment Guidelines state that Gabapentin is used to treat diabetic painful neuropathy and postherpetic neuralgia. However, there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request for Fanatrex was not medically necessary.

COMPOUNDED KETOPROFEN: 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 Page(s): 111-113.

Decision rationale: As noted on page 111-113 of the 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. There is no discussion concerning the need for variance from the guidelines. Therefore, the request for compounded Ketoprofen was not medically necessary.

DICOPANOL: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Chapter 6, pg. 115.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Dicopanor <http://www.drugs.com/pro/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 was used instead. Dicopanol is Diphenhydramine hydrochloride 5 mg/mL oral suspension. It is used to treat occasional sleeplessness and difficulty falling asleep. There is no documentation regarding sleep issues in this patient. In addition, there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request for Dicopanol was not medically necessary.