

Case Number:	CM15-0202850		
Date Assigned:	10/19/2015	Date of Injury:	09/19/2012
Decision Date:	12/07/2015	UR Denial Date:	09/21/2015
Priority:	Standard	Application Received:	10/15/2015

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: Physical Medicine & Rehabilitation, Pain Management

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 43 year old male, who sustained an industrial injury on 9-19-2012. Medical records indicate the worker is undergoing treatment for headaches, low back pain and lumbar radiculopathy. A recent progress report dated 8-12-2015, reported the injured worker complained of headaches and low back pain rated 7-8 out of 10. The injured worker reported the medications offer temporary relief and allow him to restful sleep. Physical examination revealed lumbar paraspinal and lumbosacral sacral junction tenderness to palpation and positive straight leg raise test bilaterally. Treatment to date has included physical therapy and medication management. The physician is requesting Compound cream Ketoprofen 20%cream, 167 grams, Cyclobenzaprine 5% cream, 110 grams, Synapryn 10mg-1ml oral suspension 500ml, Medication-Tabradol 1mg-ml oral suspension 250ml, Deprizine 15mg-ml oral suspension 250ml and Medication-Dicopanl 5mg-ml oral suspension 150ml-Fanatrex 20mg-ml oral suspension 420ml. On 9-22-2015, the Utilization Review noncertified the request for Compound cream Ketoprofen 20%cream, 167 grams, Cyclobenzaprine 5% cream, 110 grams, Synapryn 10mg-1ml oral suspension 500ml, Medication-Tabradol 1mg-ml oral suspension 250ml, Deprizine 15mg-ml oral suspension 250ml and Medication-Dicopanl 5mg-ml oral suspension 150ml-Fanatrex 20mg-ml oral suspension 420ml.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 20% cream 167 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril), Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: Regarding the request for topical Ketoprofen, guidelines state that topical NSAIDs are recommended for short-term use. Oral NSAIDs contain significantly more guideline support, provided there are no contraindications to the use of oral NSAIDs. Ketoprofen is not FDA approved for a topical application. Within the documentation available for review, there's no indication that the patient has obtained any specific analgesic effect (in terms of percent reduction in pain, or reduced NRS) or specific objective functional improvement from the use of topical Ketoprofen. Additionally, there is no documentation that the patient would be unable to tolerate oral NSAIDs, which would be preferred, or that the topical Ketoprofen is for short term use, as recommended by guidelines. Additionally, Ketoprofen is not FDA approved for a topical application. In the absence of clarity regarding those issues, the currently requested topical Ketoprofen is not medically necessary.

Cyclobenzaprine 5% cream 110 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: Regarding the request for topical cyclobenzaprine, Chronic Pain Medical Treatment Guidelines state that topical muscle relaxants are not recommended. They go on to state that there is no evidence for the use of any muscle relaxants as a topical product. Therefore, in the absence of guideline support for topical muscle relaxants, the currently requested cyclobenzaprine powder is not medically necessary.

Synapryn 10mg/1ml oral suspension 500ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids (Classification).

Decision rationale: Regarding the request for Synapryn, this compound is noted to contain tramadol and glucosamine. With regard to opioids such as tramadol, California MTUS Chronic Pain Medical Treatment Guidelines state that, due to high abuse potential, close follow-up is

recommended with documentation of analgesic effect, objective functional improvement, side effects, and discussion regarding any aberrant use. Guidelines go on to recommend discontinuing opioids if there is no documentation of improved function and pain. With regard to glucosamine, it is recommended as an option in patients with moderate arthritis pain, especially for knee osteoarthritis. Within the documentation available for review, there is no indication that the medication is improving the patient's pain (in terms of percent reduction in pain or reduced NRS), no discussion regarding aberrant use, no documentation of knee osteoarthritis, and no clear rationale for the use of this oral suspension compounded kit rather than the FDA-approved oral tablet forms. In the absence of such documentation, the currently requested Synapryn is not medically necessary.

Tabradol 1mg/1ml oral suspension 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids (Classification).

Decision rationale: Regarding the request for Tabradol, Tabradol contains cyclobenzaprine hydrochloride 1 mg/mL, in oral suspension with MSM - compounding kit. Regarding cyclobenzaprine, Chronic Pain Medical Treatment Guidelines support the use of non-sedating muscle relaxants to be used with caution as a 2nd line option for the short-term treatment of acute exacerbations of pain. Guidelines go on to state that cyclobenzaprine specifically is recommended for a short course of therapy. Within the documentation available for review, there is no identification of a specific analgesic benefit or objective functional improvement as a result of the cyclobenzaprine. Additionally, it does not appear that this medication is being prescribed for the short-term treatment of an acute exacerbation, as recommended by guidelines. Finally, there is no clear rationale for the use of this oral suspension compounded kit rather than the FDA-approved oral tablet forms. In the absence of such documentation, the currently requested Tabradol is not medically necessary.

Deprizine 15mg/ml oral suspension 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Proton Pump Inhibitors (PPIs).

Decision rationale: Regarding the request for Deprizine, Deprizine contains active and inactive bulk materials to compound a ranitidine hydrochloride oral suspension. California MTUS states that proton pump inhibitors are appropriate for the treatment of dyspepsia secondary to NSAID therapy or for patients at risk for gastrointestinal events with NSAID use. Within the documentation available for review, there is no indication that the patient has complaints of

dyspepsia secondary to NSAID use, a risk for gastrointestinal events with NSAID use, or another indication for this medication. Finally, there is no clear rationale for the use of this oral suspension compounded kit rather than the FDA-approved oral tablet forms. In light of the above issues, the currently requested Deprizine is not medically necessary.

Dicopanол 5mg/ml oral suspension 150ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Insomnia treatment and Other Medical Treatment Guidelines
<http://www.drugs.com/pro/dicopanол.html>.

Decision rationale: Regarding the request for Dicopanол, Dicopanол contains active and inactive bulk materials to compound a diphenhydramine hydrochloride oral suspension. California MTUS guidelines are silent. ODG states 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. They go on to state the failure of sleep disturbances to resolve in 7 to 10 days, may indicate a psychiatric or medical illness. Within the documentation available for review, there are no subjective complaints of insomnia, no discussion regarding how frequently the insomnia complaints occur or how long they have been occurring, no statement indicating what behavioral treatments have been attempted for the condition of insomnia, and no statement indicating how the patient has responded to treatment with Dicopanол. Furthermore, there is no indication that Dicopanол is being used for short term use as recommended by guidelines. Finally, there is no clear rationale for the use of this oral suspension compounded kit rather than the FDA-approved oral tablet forms. In the absence of such documentation, the currently requested Dicopanол is not medically necessary.

Fanatrex 20mg/ml oral suspension 420ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs).

Decision rationale: Regarding the requested for Fanatrex, Fanatrex contains active and inactive bulk materials to prepare 420 mL of a gabapentin oral suspension containing 25 mg/mL gabapentin. Chronic Pain Medical Treatment Guidelines state that antiepilepsy drugs are recommended for neuropathic pain. They go on to state that a good outcome is defined as 50% reduction in pain and a moderate response is defined as 30% reduction in pain. Guidelines go on to state that 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. Within the documentation available for review, there is no identification of any specific analgesic benefit (in terms of percent reduction in pain or reduction of NRS), and no documentation of specific objective functional improvement. Additionally, there is no discussion regarding side effects from this medication. Finally, there is no clear rationale for the use of this oral suspension compounded kit rather than the FDA-approved oral tablet forms. In the absence of such documentation, the currently requested Fanatrex is not medically necessary.