

Case Number:	CM15-0096052		
Date Assigned:	05/26/2015	Date of Injury:	08/24/2008
Decision Date:	06/30/2015	UR Denial Date:	05/08/2015
Priority:	Standard	Application Received:	05/19/2015

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: New York
 Certification(s)/Specialty: Anesthesiology

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 35-year-old female, who sustained an industrial injury on 8/24/08. She reported pain in neck and upper back. The injured worker was diagnosed as having cervical spine sprain/strain, cervical radiculopathy and bilateral shoulder sprain/strain. Treatment to date has included physical therapy, oral medications, topical medications and home exercise program. Currently, the injured worker complains of burning radicular neck pain described as constant and moderate to severe rated 6/10 and associated with numbness and tingling of bilateral upper extremities and burning bilateral shoulder pain rated 6-7/10 described as constant and moderate to severe. She notes the medications offer her temporary relief of pain and improve her ability to have restful sleep. Physical exam noted tenderness to palpation at the sub occipital region and over both scalene and trapezius muscles with diminished range of motion and tenderness at the delto-pectoral groove and at insertion of supraspinatus muscle of bilateral shoulders with no restrictions in range of motion. A request for authorization was submitted for Ketoprofen cream, Cyclobenzaprine cream, Synapryn oral suspension, Tabradol oral suspension, Deprizine oral suspension, Dicopanol oral suspension, Fanatrex oral suspension and Terocin patches.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 20% cream 167gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

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

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. The requested topical analgesic compound for this patient contains Ketoprofen 20%. Ketoprofen is not currently FDA approved for a topical application, and has an extremely high incidence of photocontact dermatitis. Medical necessity for the requested topical compounded medication has not been established. The requested topical analgesic compound is not medically necessary.

Cyclobenzaprine 5% cream 110gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

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

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. The requested topical analgesic compound for this patient contains Cyclobenzaprine. Cyclobenzaprine is not FDA approved for use as a topical application. There is no evidence for the use of any muscle relaxant as a topical agent. In addition, there is no documentation of intolerance to other previous oral medications. The medical necessity of the requested compounded medication has not been established. The requested topical analgesic compound is not medically necessary.

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

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for the treatment of chronic pain Page(s): 93-96.

Decision rationale: According to the California MTUS, Synapryn oral suspension (Tramadol hydrochloride) is a synthetic opioid, which affects the central nervous system and is indicated for the treatment of moderate to severe pain. Per CA MTUS Guidelines, certain criteria need to be followed, including an ongoing review and documentation of pain relief and functional status, appropriate medication use, and side effects. Pain assessment should include current pain: last reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid, and the duration of pain relief. According to the medical records, there has been no documentation of the medication's analgesic effectiveness or functional improvement, and no clear documentation that the patient has responded to ongoing opioid therapy. An oral suspension is a suspension consisting of undissolved particles of one or more medicinal agents mixed with a liquid vehicle for oral administration. Evidence-based guidelines and peer-reviewed medical literature do not address the use of medications in oral suspension form. Oral suspensions of medications are generally for use in patients for whom taking the pill/tablet form of the medication is either impractical or unsafe. In this case, there is no documentation in the medical records of any conditions that would preclude the use of medications in their pill/tablet form. Medical necessity for the requested Synapryn 10mg/1 ml Oral Suspension has not been established. Of note, discontinuation of an opioid analgesic requires a taper to avoid withdrawal symptoms. The requested medication is not medically necessary.

Tabradol 1mg/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 Official Disability Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63.

Decision rationale: According to the reviewed literature, Tabradol (Cyclobenzaprine) oral suspension is not recommended for the long-term treatment of chronic pain. This medication has its greatest effect in the first four days of treatment. According to CA MTUS Guidelines, muscle relaxants are not considered any more effective than non-steroidal anti-inflammatory medications alone. In this case, there are muscle spasms documented on physical exam but is no documentation of functional improvement from any previous use of this medication. Tabradol oral suspension is a suspension consisting of undissolved particles of one or more medicinal agents mixed with a liquid vehicle for oral administration. Evidence-based guidelines and peer-reviewed medical literature do not address the use of medications in oral suspension form. Oral suspensions of medications are generally for use in patients for whom taking the pill/tablet form of the medication is either impractical or unsafe. In this case, there is no documentation in the medical records of any conditions that would preclude the use of medications in their pill/tablet form. Based on the currently available information, the medical necessity for Tabradol 1mg/ml Oral Suspension has not been established. The requested medication is not medically necessary.

Deprizine 15mg/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 Official Disability Guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Ranitidine.

Decision rationale: Deprizine (Ranitidine) oral suspension is a histamine blocker and antacid used to treat peptic ulcers, gastritis and gastro-esophageal reflux (GERD). Ranitidine works by blocking the effects of histamine on the receptor site known as H2. Proton Pump Inhibitors (PPI's) are prescribed to prevent and treat ulcers in the duodenum (where most ulcers develop) and the stomach. Deprizine oral suspension is a suspension consisting of undissolved particles of one or more medicinal agents mixed with a liquid vehicle for oral administration. Evidence-based guidelines and peer-reviewed medical literature do not address the use of medications in oral suspension form. Oral suspensions of medications are generally for use in patients for whom taking the pill/tablet form of the medication is either impractical or unsafe. In this case, there is no documentation in the medical records of any conditions that would preclude the use of medications in their pill/tablet form. Medical necessity of the Deprizine oral suspension has not been established. The requested medication is not medically necessary.

Dicopanol 5mg/ml oral suspension 150ml: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate.

Decision rationale: Diphenhydramine is an antihistamine that is used for the temporary relief of seasonal and perennial allergy symptoms. The medication is sedating and has been used for short-term treatment of insomnia. There is no documentation indicating the patient has any history of insomnia. Dicopanol, the oral suspension form of Diphenhydramine, is generally for use in patients for whom taking the pill/tablet form of the medication is either impractical or unsafe. In this case, there is no documentation in the medical records of any conditions that would preclude the use of medications in their pill/tablet form. Medical necessity for the requested oral suspension medication is not established. The requested medication is not medically necessary.

Fanatrex 25mg/ml oral suspension 420ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drugs (AEDs) Page(s): 17-19.

Decision rationale: According to the CA MTUS and ODG, Fanatrex Oral Suspension (Gabapentin) is an anti-epilepsy drug, which has been considered a first-line treatment for neuropathic pain. Oral suspensions of medications are generally for use in patients for whom taking the pill/tablet form of the medication is either impractical or unsafe. In this case, there is no documentation in the medical records of any conditions that would preclude the use of medications in their pill/tablet form. Medical necessity for the requested medication, Fanatrex

25mg/ml oral suspension, has not been established. The requested medication is not medically necessary.

Terocine patches: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

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

Decision rationale: According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, local anesthetics or antidepressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, there is no documentation provided necessitating Terocin. This medication contains methyl salicylate, capsaicin, menthol, and lidocaine. MTUS states that capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There is no documentation of intolerance to other previous oral medications. Medical necessity for the requested topical medication has not been established. The requested treatment is not medically necessary.