MAXIMUS Federal Services

Case Number:	CM15-0111240		
Date Assigned:	06/17/2015	Date of Injury:	10/22/2014
Decision Date:	08/14/2015	UR Denial Date:	05/28/2015
Priority:	Standard	Application Received:	06/09/2015

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 34-year-old female, who sustained an industrial injury on 10/22/2014. She reported injuries to her right wrist, hand and fifth digit due to a box falling onto her hand. Diagnoses have included right wrist sprain/strain, crushing injury of the hand and fingers, finger pain and anxiety disorder. Treatment to date has included physical therapy and medication. According to the progress report dated 3/24/2015, the injured worker complained of burning right wrist, hand and finger pain and muscle spasms. She rated her pain as 7/10. She also complained of weakness, numbness and tingling of the hand and fingers. Exam of the right wrist, hand and fingers revealed weakness at the interossel muscles. There was tenderness to palpation at the PIP joint of the fifth finger. There was also tenderness at the tunnel of Guyon and at the carpal tunnel. Authorization was requested for Ketoprofen/Cyclobenzaprine cream, Synapryn, Tabradol, Deprizine, Dicopanol and Fanatrex.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 20% cream 167 gms/Cyclobenzaprine 5% cream 110 gms: 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, 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. MTUS guidelines state that Ketoprofen, lidocaine, capsaicin and/or muscle relaxants (Cyclobenzaprine in this case) are not recommended for topical applications. Ketoprofen is not currently FDA approved for a topical application, and has an extremely high incidence of photo-contact dermatitis. Medical necessity for the requested topical compounded medication has not been established. Medical necessity for Ketoprofen 20%/ Cyclobenzaprine 5% has not been established. The requested topical analgesic compound is not medically necessary.

Synapryn10 mg/1 ml oral suspension 500 ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation URL [www.dailymed.nim.nih.gov/dailymed/druginfo.cfm?id=20039].

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines OpioidsGlucosamine Page(s): 50, 93-96.

Decision rationale: According to the California MTUS, Synapryn oral suspension (Tramadol hydrochloride with glucosamine) contains 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. There is no evidence that the treating physician has utilized a treatment plan NOT using opioids, or that the patient "has failed a trial of non-opioid analgesics". The MTUS provides support for treating moderate arthritis pain, particularly knee OA, with glucosamine sulphate. Other forms of glucosamine are not supported by good medical evidence. The treating physician in this case has not provided evidence of the form of glucosamine in Synapryn, and that it is the form recommended in the MTUS and supported by the best medical evidence. If there is an indication for glucosamine in this case, it must be given as a single agent apart from other analgesics, particularly analgesics like Tramadol that are habituating. Synapryn is not

medically necessary based on the MTUS, lack of good medical evidence, and lack of a treatment plan for chronic opioid therapy consistent with the MTUS.

Tabradol 1 mg/ml oral suspension 250 ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain chapter - Muscle relaxants.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants Page(s): 42.

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. The MTUS states that treatment with Cyclobenzaprine should be brief, and that the addition of Cyclobenzaprine to other agents is not recommended. In this case, Cyclobenzaprine is added to other agents and the oral suspension form and topical is experimental and unproven. Multiple medications, including a topical muscle relaxant, were prescribed together without adequate trials of each. Per the MTUS, Cyclobenzaprine is not indicated and is not medically necessary.

Deprizine 15 mg/ml oral suspension 250 mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation URL [www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000094] and [www.drugs.com/pro/deprizine.html].

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms Page(s): 69.

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. Evidence-based guidelines and peer-reviewed medical literature do not address the use of medications in oral suspension form. There is no documentation indicating that this patient has any GI symptoms or GI risk factors. Risk factors include, age >65, history of peptic ulcer disease, GI bleeding, concurrent use of aspirin, corticosteroids, and/or anticoagulants or high-dose/multiple NSAIDs. There is no documentation of any reported GI complaints in this case. Based on the available information provided for review, the medical necessity for Deprizine has not been established. The requested medication is not medically necessary.

Dicopanol 5 mg/ml oral suspension 150 ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation URL [www.drugs.com/pro/dicopanol.html] and [www.drugs.com/pro/diphenhydramine.html].

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

Decision rationale: Dicopanol, the oral suspension form of 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. Antihistamines are not indicated for long-term use as tolerance develops quickly. There is no documentation indicating the patient has any history of insomnia. The MTUS does not address the use of hypnotics other than benzodiazepines. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of this in this case. Medical necessity for the requested oral suspension medication has not been established. The requested medication is not medically necessary.

Fanatrex 25 mg/ml oral suspension 420 ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin (Neurontin) Page(s): 18-19. Decision based on Non-MTUS Citation URL [www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000704).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs), Gabapentin (Neurontin) Page(s): 17-19, 49. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Gabapentin (Neurontin).

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. In this case, the patient has neuropathic pain. Gabapentin appears to be medically necessary. However, 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. Medical necessity for the requested medication, Fanatrex 25mg/ml oral suspension, has not been established. The requested oral suspension medication is not medically necessary.