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| Case Number: | CM14-0095907 | | |
| Date Assigned: | 08/08/2014 | Date of Injury: | 06/28/2012 |
| Decision Date: | 05/22/2015 | UR Denial Date: | 06/05/2014 |
| Priority: | Standard | Application Received: | 06/24/2014 |

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. 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 (IW) is a 49-year-old male who sustained an industrial injury on 06/28/2012. Diagnoses include bilateral knee meniscus derangement, synovial cyst of popliteal space-left knee, effusion and subluxation of the bilateral knees and bilateral post-traumatic osteoarthritis of the knee. Treatment to date has included medications, acupuncture, physical therapy, aqua therapy, weight loss treatment and surgery. Diagnostics performed to date included x-rays, electrodiagnostic studies and MRIs. According to the progress notes dated 4/10/14, the IW reported bilateral knee pain and muscle spasms with associated weakness, swelling, numbness, tingling and pain radiating to the feet. A request was made for compounded Ketoprofen 20% in Pluronic Lecithin Organogel (PLO) gel, Compounded Cyclophene 5% in PLO gel, Synapryn oral suspension, Tabradol oral suspension, Deprizine oral suspension, Dicopanol oral suspension and Fanatrex oral suspension for pain management while awaiting evaluation by an orthopedic surgeon.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compounded Ketoprofen 20% in Pluronic Lecithin Organogel (PLO) gel, 120grams:
 Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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 is Ketoprofen 20% PLO gel. 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 medication has not been established. The requested topical gel is not medically necessary.

Compounded Cyclophene 5% in Pluronic Lecithin Oranogel (PLO) gel, 120 grams: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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. In this case, the requested topical agent is a muscle relaxant, Cyclobenzaprine 5% PLO gel. Cyclobenzaprine is not FDA approved for use as a topical application. Medical necessity for the requested topical analgesic has not been established. The requested topical gel is not medically necessary.

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

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids 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 250 ml: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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 no muscle spasms documented on physical exam. 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 cite any medical evidence for its decision.

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

Decision rationale: Deprizine (Ranitidine) oral suspension is a histamine blocker and antacid used to treat peptic ulcers, gastritis and gastroesophageal 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 (Ranitidine) 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 cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate website (www.uptodate.com).

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 5mg/ml, 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(Gabapentin) 25mg/ml oral suspension 420ml: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Gabapentin.

Decision rationale: According to the CA MTUS (2009) 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.