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| Case Number: | CM13-0001804 | | |
| Date Assigned: | 11/01/2013 | Date of Injury: | 04/23/2013 |
| Decision Date: | 02/19/2014 | UR Denial Date: | 07/01/2013 |
| Priority: | Standard | Application Received: | 07/17/2013 |

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Family Practice and is licensed to practice in Texas. 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 physician 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 28-year-old male who reported an injury on 04/23/2013. The patient is diagnosed with crushing injury of the ankle and foot. The patient's latest physical examination was documented on 10/22/2013 by [REDACTED]. The patient demonstrated normal ankle range of motion with intact deep tendon reflexes, sensation, and motor strength. Treatment recommendations included continuation of current therapy with custom orthotics and return to full duty as of 10/22/2013. A Letter of Medical Necessity was submitted by [REDACTED] on 06/21/2013 for continuation of current medication, including ketoprofen, Cyclophene, Dicopanol, Deprizine, Fanatrex, and Tabradol.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compounded Ketoprofen 20% in PLO gel 120gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112-113.

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

Decision rationale: California MTUS Guidelines state topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. They are

primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The only FDA-approved topical NSAID is diclofenac, which is indicated for the relief of osteoarthritis pain. As per the clinical notes submitted, the patient does not maintain a diagnosis of osteoarthritis or neuropathic pain. There is no documentation of a significant neurological deficit on physical examination. There is also no evidence of a failure to respond to first-line oral medication prior to initiation of a topical analgesic. Based on the clinical information received, the request is non-certified.

Synapryn (10mg/ml) oral suspension, 500ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.drugsdb/drug-Synapryn.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 74-82.

Decision rationale: California MTUS Guidelines state a therapeutic trial of opioids should not be employed until the patient has failed a trial of nonopioid analgesics. Baseline pain and functional assessments should be made. Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects should occur. As per the clinical notes submitted, there is no documentation of a failure to respond to nonopioid analgesics prior to initiation of an opioid medication. Additionally, there is no indication that the patient is unable to safely swallow pills or capsules. Based on the clinical information received, the request is non-certified.

Abradol 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 dailymed.nlm.nih.gov/dailymed/archives/fdaDruginfo

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 63-66.

Decision rationale: California MTUS Guidelines state muscle relaxants are recommended as non-sedating second-line options for short-term treatment of acute exacerbations in patients with chronic low back pain. Efficacy appears to diminish over time, and prolonged use may lead to dependence. Cyclobenzaprine should not be used for longer than 2 to 3 weeks. As per the clinical notes submitted, there is no indication of palpable muscle spasm, spasticity, or muscle tension on physical examination. There is also no indication that this patient cannot safely swallow pills or capsules. Based on the clinical information received, the request is non-certified.

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 www.drugs.com/pro/deprizine.html

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68-69.

Decision rationale: California MTUS Guidelines state proton pump inhibitors are recommended for patients with intermediate or high risk for gastrointestinal events. Patients with no risk factor and no cardiovascular disease do not require the use of a proton pump inhibitor, even in addition to a nonselective NSAID. As per the clinical notes submitted, there is no indication of cardiovascular disease or increased risk factors for gastrointestinal events. There is also no indication that this patient cannot safely swallow pills or capsules. Based on the clinical information received, the request is non-certified.

Dicopanol (diphenhydramine) 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 www.drugs.com/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) Chronic Pain Chapter, Insomnia Treatment.

Decision rationale: The Official Disability Guidelines state diphenhydramine is a sedating antihistamine, often utilized as an over-the-counter medication for insomnia treatment. As per the clinical notes submitted, there is no indication of chronic insomnia or a chronic condition where an antihistamine is necessary. There is also no indication that this patient cannot safely swallow pills or capsules. Based on the clinical information received, the request is non-certified

Fanatrex (gabapentin) 25mg/ml oral suspension, 420ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 18-19.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16-18.

Decision rationale: California MTUS Guidelines state anti-epilepsy drugs are recommended for neuropathic pain. Gabapentin is recommended for treatment of diabetic painful neuropathy and postherpetic neuralgia, and has also been considered first-line treatment for neuropathic pain. As per the clinical notes submitted, there is no documentation of neuropathic pain upon physical examination. The patient's current physical examination on 10/22/2013, as well as a previous examination on 09/30/2013, indicated normal sensation, normal motor strength, and normal deep tendon reflexes with normal range of motion. There is also no indication that this patient is unable to safely swallow pills or capsules. Based on the clinical information received, the request is non-certified.

Compounded Cyclophene 5% in PLO gel, 120gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112-113.

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

Decision rationale: California MTUS Guidelines state topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. As per the clinical notes submitted, there is no documentation of neuropathic pain upon physical examination. There is also no evidence that this patient has failed to respond to first-line oral medication prior to initiation of a topical analgesic. Based on the clinical information received, the request is non-certified.