MAXIMUS Federal Services

Case Number:	CM15-0127409		
Date Assigned:	07/20/2015	Date of Injury:	09/15/2010
Decision Date:	10/06/2015	UR Denial Date:	06/29/2015
Priority:	Standard	Application Received:	07/01/2015

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: Emergency Medicine

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 31 year old female, who sustained an industrial injury on 9-15-2010. She reported feeling a snapping sensation and pain to the right wrist and right hand. Diagnoses have included right shoulder joint derangement unspecified, bilateral shoulder pain and status post right carpal tunnel release with residual pain. Treatment to date has included physical therapy, chiropractic treatment, acupuncture and medication. According to the progress report dated 6-8-2015, the injured worker complained of sharp, bilateral shoulder pain, radiating down the arm to the fingers, associated with muscle spasms. She rated the pain as seven out of ten. She stated that she continued to feel pain at the right wrist and thumb rated six out of ten. She was status post right carpal tunnel release. She stated that medications offered her temporary relief of pain and improved her ability to have restful sleep. Exam of the bilateral shoulders revealed tenderness to palpation. There was palpable tenderness over the carpal bones of the right wrist. Authorization was requested for Ketoprofen cream, Cyclobenzaprine cream, Synapryn, Tabradol, Deprizine, Dicopanol, Fanatrex and a urinalysis toxicology evaluation.

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 Medical Treatment 2009.

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

Decision rationale: The request is for ketoprofen 20%, which is a topical compound applied to the skin. Topical analgesics are recommended as an option in specific situations. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. According to the MTUS guidelines, ketoprofen is currently not FDA approved for topical use. Therefore, the request is not medically necessary.

Cyclobenzaprine 5% cream 110gm: 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): Topical Analgesics.

Decision rationale: The request is for cyclobenzaprine 5%, which is a topical compound applied to the skin. Topical analgesics are recommended as an option in specific situations. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. There is no evidence for use of any other muscle relaxant as a topical product. Therefore, the request 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 Medical Treatment 2009, Section(s): Opioids, criteria for use.

Decision rationale: The request is for Synapryn, also known as tramadol, a synthetic opioid. The chronic use of opioids requires the ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity

of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug- taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. The MTUS guidelines support the chronic use of opioids if the injured worker has returned to work and there is a clear overall improvement in pain and function. The treating physician should consider consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psychiatric consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. Opioids appear to be efficacious for the treatment of low back pain, but limited for short-term pain relief, and long- term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time- limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. In regards to the injured worker, there is no clear documentation to support the use of an oral compounded suspension rather than a pill or capsule. Therefore, the request as written is not medically necessary.

Tabradol 1mg/ml oral suspension 250ml: Upheld

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

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

Decision rationale: The request is for tabradol, also known as cyclobenzaprine, which is an antispasmodic used to decrease muscle spasm in conditions such as low back pain, although it appears that these medications are often used for the treatment of musculoskeletal conditions whether spasm is present or not. The mechanism of action for most of these agents is not known. Non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most low back pain cases, they show no benefit beyond non-steroidal anti-inflammatory drugs in pain and overall improvement. Also there is no additional benefit shown in combination with non-steroidal anti-inflammatory drugs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. Cyclobenzaprine is not recommended to be used for longer than 2-3 weeks. The request as written is not supported by the MTUS guidelines and therefore 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: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: The request is for deprizine, also known as ranitidine, an H2 blocker used to treat disorders of the stomach and esophagus. The MTUS guidelines support the use of a proton pump inhibitor in the following circumstances at increased risk for gastrointestinal side effects: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID. Without any risk factors for gastrointestinal disease, there is no clear indication to utilize a proton pump inhibitor in the treatment of an injured worker. The documentation provided does not support the ongoing use of NSAIDs, nor does it suggest that the injured worker is at increased risk for gastrointestinal disease. The request as written is not supported by the MTUS and is therefore 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 Official Disability Guidelines (ODG) Pain Chapter, Insomnia treatment.

Decision rationale: The request is for dicopanol, a liquid formulation of diphenhydramine, and antihistamine used for the treatment of allergy. It also has sedative properties and has been used as a sleep aid. The MTUS guideline does not clearly address the use of diphenhydramine. Side effects include prolonged sedation as well as impaired psychomotor and cognitive function. The documentation provided supplies unclear necessity, and furthermore does not clearly demonstrate a need for an oral suspension compounded kit over the FDA-approved oral capsule. Therefore, the request is not medically necessary.

Fanatrex 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 Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs).

Decision rationale: The request is for fanatrex, an oral suspension of gabapentin, which is an anti-epilepsy drug used for the treatment of neuropathic pain. It has predominantly been shown

to be effective for treatment of painful diabetic neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. It has also shown benefit in other conditions, including lumbar stenosis, chronic regional pain syndrome and fibromyalgia. A "good" response to the use of anti-epilepsy drugs has been defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent; or (2) combination therapy if treatment with a single drug agent fails. 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 anti-epilepsy drugs depends on improved outcomes versus tolerability of adverse effects. A recent review has indicated that there is insufficient evidence to recommend for or against antiepileptic drugs for axial low back pain. The documentation provided does not clearly justify ongoing use, not does it clearly demonstrate why an oral compounded suspension is necessary over the FDA-approved tablet. The request is not medically necessary.

UA toxicology evaluation: 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 rationale: The request is for a urine toxicology evaluation. The MTUS guidelines support the use of urine drug screen to assess for the use or the presence of illegal drugs as a part of the criteria of use for opioid therapy for chronic pain. There is no documentation of erratic behavior that would raise suspicion for misuse or abuse of controlled substances. Furthermore, ongoing use of opioids has not been recommended at this time. Therefore, the need for a urine toxicology evaluation is unclear and not medically necessary.