

Case Number:	CM15-0091811		
Date Assigned:	05/18/2015	Date of Injury:	03/01/2013
Decision Date:	09/22/2015	UR Denial Date:	04/20/2015
Priority:	Standard	Application Received:	05/12/2015

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: Preventive Medicine, Occupational 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 47 year old female, who sustained an industrial injury on 3-01-2013. The injured worker was diagnosed as having status post left knee revision surgery 1-08-2015, chronic myoligamentous sprain-strain in the lumbar spine, superimposed on degenerative disc disease, status post left knee arthroscopy with residuals and diffuse tricompartmental degenerative joint disease, compensatory sprain-strain with aggravation of tricompartmental osteoarthritis of the right knee, right knee osteoarthritis with joint space narrowing, herniated nucleus pulposus at L4-5 and L5-S1 with bilateral lower extremity radicular complaints, and left knee post-operative changes. Treatment to date has included diagnostics, left knee surgery, acupuncture, and medications. On 4-14-2015, the injured worker complains of low back pain, rated 6-8 out of 10, with radiation to the bilateral lower extremities, with associated numbness, tingling, and weakness. She also reported right knee pain, rated 5 out of 10. Current medications included Norco, Omeprazole, Ultram, and Colace. She also reported anxiety, depression, stress, and insomnia. Urine toxicology (4-14-2015) was positive for Norhydrocodone. On 3-26-2015, she reported left knee pain, rated 7 out of 10. X-rays showed no increase of osteoarthritis. She was prescribed Orphenadrine-Caffeine, Gabapentin-Pyridoxine, Omeprazole-Flurbiprofen, Flurbiprofen-Cyclo-Menthol cream, KeraTek gel, and Diclofenac-Lidocaine.

IMR ISSUES, DECISIONS AND RATIONALES

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

Orphenadrine 50mg/Caffeine 10mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Non-sedating muscle relaxants.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain) Section, Weaning of Medications Section Page(s): 63-65 and 124.

Decision rationale: Non-sedating muscle relaxants (for pain) are recommended by the MTUS Guidelines with caution for short periods for treatment of acute exacerbations of chronic low back pain, but not for chronic or extended use. In most low back pain cases, they show no benefit beyond NSAIDs in pain and overall improvement. Norflex is similar to diphenhydramine, but has greater anticholinergic effects. The mode of action is not clearly understood. Effects are thought to be secondary to analgesic and anticholinergic properties. In this case, Orphenadrine is being used in a chronic nature which is not supported by the established guidelines. The request for Orphenadrine 50mg/Caffeine 10mg #60 is determined to not be medically necessary.

Flurb/Omeprazole 100/10mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Section, NSAIDs, GI Symptoms & Cardiovascular Risk Section Page(s): 67-71.

Decision rationale: The use of NSAIDs is recommended by the MTUS Guidelines with precautions. NSAIDs are recommended to be used secondary to Acetaminophen and at the lowest dose possible for the shortest period in the treatment of acute pain or acute exacerbation of chronic pain as there are risks associated with NSAIDs and the use of NSAIDs may inhibit the healing process. Proton pump inhibitors, such as Prilosec are recommended by the MTUS Guidelines when using NSAIDs if there is a risk for gastrointestinal events. There is no indication that the injured worker has had a gastrointestinal event or is at increased risk of a gastrointestinal event, which may necessitate the use of Prilosec when using NSAIDs. The injured worker has chronic injuries with no change in pain level and no acute injuries reported and there is no evidence of a trial with acetaminophen. Additionally, there is no quantity information included with this request for medication. The request for Flurb/Omeprazole 100/10mg is determined to not be medically necessary.

Flurb 20%/Cyclo 10%/Menth Cream 4%: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Section, Topical Analgesics Section Page(s): 67-73 and 111-113.

Decision rationale: The MTUS Guidelines recommend the use of topical analgesics as an option for the treatment of chronic pain, however, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. Topical NSAIDs have been shown to be superior to placebo for 4-12 weeks for osteoarthritis of the knee. The injured worker's pain is not described as pain from osteoarthritis. Topical Flurbiprofen is not an FDA approved formulation. The MTUS Guidelines state that there is no evidence for use of muscle relaxants, such as Cyclobenzaprine, as a topical product. Menthol is not addressed by the MTUS Guidelines or the ODG, but it is often included in formulations of anesthetic agents. It induces tingling and cooling sensations when applied topically. Menthol induces analgesia through calcium channel-blocking actions, as well as binding to kappa-opioid receptors. Menthol is also an effective topical permeation enhancer for water-soluble drugs. There are reports of negative effects from high doses of menthol such as 40% preparations. As at least one of the medications in the requested compounded medication is not recommended by the established guidelines, the request for Flurb 20%/Cyclo 10%/Menth Cream 4% is determined to not be medically necessary.

Gabapentin/Pyridoxine 250mg/10mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy Drugs (AEDs) Section Page(s): 16-21. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Vitamin B6 (pyridoxine) Section.

Decision rationale: Gabapentin/Pyridoxine is a combination drug of Gabapentin and Vitamin B6. The MTUS Guidelines recommend the use of anti-epilepsy drugs for neuropathic pain. Most randomized controlled trials for the use of anti-epilepsy drugs for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy, with polyneuropathy being the most common example. There are few RCTs directed at central pain, and none for painful radiculopathy. 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 to this magnitude may be the trigger for switching to a different first line agent, or combination therapy if treatment with a single drug 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. Gabapentin has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first line treatment for neuropathic pain. Per the ODG Pyridoxine is not recommended. Vitamin B6 (pyridoxine) is often used in CTS when it is perceived to be deficient, but this practice is not consistently supported by the medical evidence. Vitamin B6 does not significantly improve overall symptoms. There is limited evidence that vitamin B6 improves finger swelling and movement discomfort with 12 weeks of treatment. Limited evidence suggests that vitamin B6 does not improve symptoms, nocturnal discomfort, hand co-ordination, Phalen's sign and Tinel's sign in the short-term. In this case, the injured worker is noted to have neuropathic pain which would

warrant the use of Gabapentin. However, it is unclear why a combination of Gabapentin and Vitamin B6 is requested. There is no rationale for this in the available documentation. The request for Gabapentin/Pyridoxine 250mg/10mg is determined to not be medically necessary.

Kera Tek Gel: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics.

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

Decision rationale: Per manufacturer information, Kera Tek gel is a compounded topical analgesic containing the active ingredients Menthol, and Methyl Salicylate 28%. The MTUS Guidelines recommend the use of topical analgesics as an option for the treatment of chronic pain, however, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. Methyl Salicylate topical is recommended by the MTUS Guidelines, as it is significantly better than placebo in chronic pain. Menthol is not addressed by the MTUS Guidelines, but it is often included in formulations of anesthetic agents. It induces tingling and cooling sensations when applied topically. Menthol induces analgesia through calcium channel-blocking actions, as well as binding to kappa-opioid receptors. Menthol is also an effective topical permeation enhancer for water-soluble drugs. There are reports of negative effects from high doses of menthol such as 40% preparations. While this medication is supported by the established guidelines, there is no quantity information included with this request; therefore, the request for Kera Tek Gel is determined to not be medically necessary.