

Case Number:	CM15-0149033		
Date Assigned:	08/12/2015	Date of Injury:	04/05/2007
Decision Date:	09/16/2015	UR Denial Date:	07/07/2015
Priority:	Standard	Application Received:	07/31/2015

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 51 year old female who sustained an industrial injury on 4-5-07. The injured worker was diagnosed as having osteoarthritis and joint pain-leg. Currently, the injured worker reported left knee discomfort. Previous treatments included injection therapy, nonsteroidal anti-inflammatory drugs; status post left knee arthroscopy (11-11-14). Previous diagnostic studies included radiographic studies and a magnetic resonance imaging. Work status was noted as retired. The injured workers pain level was noted as 2 out of 10. Physical examination was not noted. The plan of care was for Orphenadrine 50 milligrams-Caffeine 10 milligrams quantity of 60, KeraTek gel 4 ounces quantity of 1, Gabapentin 250 milligrams-Pyridoxine 10 milligrams quantity of 60, Flurbiprofen-Omeprazole 100-10 milligrams quantity of 60, Flurbiprofen 20%, Cyclobenzapril 10%, Menthol 4% cream, 180 grams quantity of 1, Mometasone 15%-Doxepin 5% 60 mg quantity of 1 and an Interferential unit quantity of 60 days.

IMR ISSUES, DECISIONS AND RATIONALES

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

Orphenadrine 50 mg/ Caffeine 10 mg Qty 60: 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 Muscle Relaxants Page(s): 63-65.

Decision rationale: The request is for Orphenadrine 50 milligrams-Caffeine 10 milligrams quantity of 60. Currently, the injured worker reported left knee discomfort. According to the ODG, Orphenadrine (Norflex) is a muscle relaxant 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. According to CA MTUS guidelines, muscle relaxants are not considered any more effective than nonsteroidal anti-inflammatory drugs (NSAIDs) alone, and are not recommended for the long-term use of chronic pain. The CA MTUS recommends using "muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patient with chronic low back pain. Efficacy appears to diminish over time, and prolonged use of some medication in this class may lead to dependence." Standards of care indicate medications within the drug class of antispasmodic/muscle relaxants are to be utilized for a short course of therapy. Provider documentation does not document rationale for prescribing this compound medication. As such, the request for Orphenadrine-Caffeine 10 is not medically necessary.

KeraTek gel 4 oz, Qty 1: 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, Salicylate Page(s): 111-113, 105. Decision based on Non-MTUS Citation ODG, Pain (chronic), Compound creams; Salicylate topicals, Topical analgesics.

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. Keratek contains menthol and methyl salicylate. The patient has nociceptive pain rather than neuropathic pain. Additionally, the ODG states, "Topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns, a new alert from the FDA warns." As such, the medical necessity for the requested topical analgesic has not been established. The requested topical gel is not medically necessary.

Gabapentin 250 mg/ Pyridoxine 10 mg Qty 60: 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: The request is for Gabapentin 250 milligrams-Pyridoxine 10 milligrams quantity of 60. Currently, the injured worker reported left knee discomfort. CA MTUS Guidelines indicate that topical NSAIDS are indicated for osteoarthritis of the knees, elbow or other joints that are amenable to topical treatments. The guidelines specifically indicate that "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." CA MTUS recommendations state that topical analgesics are largely experimental and primarily recommended for neuropathic pain after trials of antidepressants and anticonvulsants have failed. CA MTUS further states "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." Provider documentation does not show a trial of a first-line therapy as recommended by CA MTUS. As such, the request for Gabapentin 250 milligrams-Pyridoxine 10 milligrams quantity of 60 is not medically necessary.

Flurb/ Omeprazole 100/10 mg Qty 60: 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 NSAIDs Page(s): 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Proton Pump Inhibitor.

Decision rationale: The request is for Flurbiprofen-Omeprazole 100-10 milligrams quantity of 60. Currently, the injured worker reported left knee discomfort. CA MTUS recommends the lowest dose NSAID for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. CA MTUS recommends NSAIDs as a second-line treatment after acetaminophen and as a short term option. CA MTUS recommendations state that long term use of proton pump inhibitors have been shown to increase the risk of hip fractures. Official Disability Guide recommends proton pump inhibitor for patients at risk for gastrointestinal events. "In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all." Provider documentation is without mention of gastrointestinal events, upon physical examination there was documentation of gastrointestinal events, or indication for the prescribing of omeprazole. Additionally, there is no indication as to why these medications were not prescribed separately. As such, the request for Flurbiprofen-Omeprazole is not medically necessary.

Flurb 20%, Cyclo 10%, Menth 4% cream, 180 gm Qty 1: 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, 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. In this case, the topical analgesic compound requested contains: Flurbiprofen 20%, Cyclobenzaprine 10%, and Menthol 4%. Cyclobenzaprine is not FDA approved for use as a topical application. There is no evidence for the use of any muscle relaxant as a topical agent. There are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). The provider documentation does not show a trial of a first-line therapy as recommended by CA MTUS. Medical necessity for the topical analgesic containing, Flurbiprofen, Cyclobenzaprine, and Menthol, has not been established. The requested topical analgesic compound is not medically necessary.

Mometasone 15%/ Doxepin 5% 60 mg Qty 1: 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: The request is for the topical analgesic compound containing Mometasone 15%-Doxepin 5% 60 mg quantity of 1. Currently, the injured worker reported left knee discomfort. CA MTUS recommendations state that topical analgesics are largely experimental and primarily recommended for neuropathic pain after trials of antidepressants and anticonvulsants have failed. CA MTUS further states "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." CA MTUS Guidelines indicate that topical NSAIDs are indicated for osteoarthritis of the knees, elbow or other joints that are amenable to topical treatments. The guidelines specifically indicate that "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." CA MTUS recommendations state that topical analgesics are largely experimental and primarily recommended for neuropathic pain after trials of antidepressants and anticonvulsants have failed. Provider documentation does not show a trial of a first-line therapy as recommended by CA

MTUS. Medical necessity for the topical analgesic containing, Flurbiprofen, Cyclobenzaprine, and Menthol has not been established. The requested topical analgesic compound is not medically necessary.

Interferential unit (days), Qty 60 days: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous electrotherapy; Interferential Current Stimulation (ICS) Page(s): 114-121.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous Electrotherapy Page(s): 118-119.

Decision rationale: The request is for an Interferential unit for 60 days. Currently, the injured worker reported left knee discomfort. CA MTUS recommendations do not recommend Interferential Current Stimulation as an isolated intervention. There is no quality evidence of effectiveness except in conjunction with recommended treatment including return to work, exercise and medications. The randomized control trials that have evaluated the effectiveness of this treatment have included studies for back, jaw, soft tissue shoulder, cervical neck and postoperative knee pain. Although it has been proposed for treatment in general for soft tissue injury or for enhanced wound or fracture healing, there was insufficient literature to support interferential current stimulation for treatment of these conditions. There are no standardized protocols for the use of interferential therapy. The therapy may vary according to the frequency of stimulation, the pulse duration, treatment time and electrode placement technique. Additionally, the body part or parts to which this interferential unit was to have been applied were not specified by the provider and provider documentation does not outline a home exercise program. As such, the request for an Interferential unit quantity of 60 days is not medically necessary.