

Case Number:	CM15-0087725		
Date Assigned:	05/11/2015	Date of Injury:	12/14/2009
Decision Date:	06/18/2015	UR Denial Date:	04/14/2015
Priority:	Standard	Application Received:	05/07/2015

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: Internal 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 57 year old male, who sustained an industrial injury on 12/14/2009. He reported cumulative trauma to multiple body parts including the back, neck, bilateral lower extremities, right upper extremity, and bilateral wrists/hands, as well as hypertension, diabetes and sleep disturbance. He is status post multiple surgical interventions including left hip, right femur, left shoulder, and bilateral wrists. Diagnoses include Rotator cuff (capsule) sprain, Sprain of lumbar, and Sprain of thoracic. Treatments to date include medication therapy, physical therapy, cortisone injections, and heat/ice contrast therapy. Currently, he complained of pain, stiffness and weakness of the right shoulder, cervical spine and the back. On 1/15/15, the physical examination documented decreased range of motion to the right shoulder. A cortisone injection was administered to the right shoulder on this date. The plan of care included a topical compound Flur/Cyclo/Menth cream 20%/10%/4% #180 grams, Flurbiprofen/omeprazole 100/10mg #60, and orphenadrine 50mg/caffeine 10mg #60.

IMR ISSUES, DECISIONS AND RATIONALES

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

Med Orphenadrine 50mg/caffeine 10mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-49, Chronic Pain Treatment Guidelines Orphenadrine (Norflex) Page 65. Muscle relaxants Page 63-65. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Compound drugs. FDA Prescribing Information Orphenadrine (Norflex) <http://www.drugs.com/monograph/norflex.html>.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) addresses muscle relaxants. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) states that muscle relaxants seem no more effective than NSAIDs for treating patients with musculoskeletal problems. Muscle relaxants may hinder return to function by reducing the patient's motivation or ability to increase activity. Table 3-1 states that muscle relaxants are not recommended. Chronic Pain Medical Treatment Guidelines (Page 63-66) addresses muscle relaxants. Muscle relaxants should be used with caution as a second-line option for short-term treatment. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. According to a review in American Family Physician, muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. Orphenadrine Citrate (Norflex) has been reported in case studies to be abused for euphoria and to have mood elevating effects. FDA Prescribing Information states that Orphenadrine Citrate (Norflex) is indicated for acute musculoskeletal conditions. Orphenadrine has been chronically abused for its euphoric effects. The mood elevating effects may occur at therapeutic doses of Orphenadrine. Official Disability Guidelines (ODG) indicates that compound drugs are not recommended as a first-line therapy. In general, commercially available, FDA-approved drugs should be given an adequate trial. If these are found to be ineffective or are contraindicated in individual patients, compound drugs that use FDA-approved ingredients may be considered. Pharmacy compounding has traditionally involved combining drug ingredients to meet the needs of specific patients for medications that are not otherwise commercially available, and it is undertaken on a patient-by-patient basis for patients who, for example, might be allergic to inactive ingredients in FDA-approved drugs or may need a different dosage strength or route of administration. The issues surrounding compound drugs are due to uncertainties regarding whether the products are medically appropriate. Criteria for compound drugs were presented. Include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs. Is not a copy of a commercially available FDA-approved drug product. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The medical records document the diagnoses of hypertension and diabetes and a history of shoulder, wrist, and hand complaints. Date of injury 12-14-2009. The Official Disability Guidelines (ODG) criteria for compound drugs indicates that the compound drug should not be a copy of a commercially available FDA-approved drug product. Orphenadrine (Norflex) is a commercially available FDA-approved drug. Medical records indicate the long-term use of muscle relaxants for chronic conditions. MTUS and ACOEM guidelines do not recommend the long-term use of muscle relaxants. FDA guidelines state that Orphenadrine (Norflex) is indicated for acute conditions. The long-term use of Norflex for chronic conditions is not supported. The patient has been prescribed NSAIDs. Per MTUS, using muscle relaxants in combination with NSAIDs has no demonstrated benefit. MTUS, ACOEM, and FDA guidelines do not support the use of Orphenadrine (Norflex). Therefore, the request for Orphenadrine / Caffeine is not medically necessary.

Med Flurbiprofen/Omeprazole 100/10mg #60 with Pentravan Plus: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Compound drugs.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines addresses NSAIDs (non-steroidal anti-inflammatory drugs). All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Use of NSAIDs may compromise renal function. FDA package inserts for NSAIDs recommend periodic lab monitoring of a CBC complete blood count and chemistry profile including liver and renal function tests. Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. All NSAIDs have the potential to raise blood pressure in susceptible patients. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) indicates that nonsteroidal anti-inflammatory drugs (NSAID) can cause gastrointestinal irritation or ulceration or, less commonly, renal or allergic problems. Studies have shown that when NSAIDs are used for more than a few weeks, they can retard or impair bone, muscle, and connective tissue healing and perhaps cause hypertension. Therefore, they should be used only acutely. Official Disability Guidelines (ODG) indicates that compound drugs are not recommended as a first-line therapy. In general, commercially available, FDA-approved drugs should be given an adequate trial. If these are found to be ineffective or are contraindicated in individual patients, compound drugs that use FDA-approved ingredients may be considered. Pharmacy compounding has traditionally involved combining drug ingredients to meet the needs of specific patients for medications that are not otherwise commercially available, and it is undertaken on a patient-by-patient basis for patients who, for example, might be allergic to inactive ingredients in FDA-approved drugs or may need a different dosage strength or route of administration. The issues surrounding compound drugs are due to uncertainties regarding whether the products are medically appropriate. Criteria for compound drugs were presented. Include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs. Is not a copy of a commercially available FDA-approved drug product. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Medical records document the long-term use of NSAIDs. Per MTUS, it is generally recommended that the lowest dose be used for NSAIDs for the shortest duration of time. The medical records document the diagnoses of hypertension and diabetes and a history of shoulder, wrist, and hand complaints. Date of injury 12-14-2009. Per MTUS, NSAIDs are associated with the risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. Long-term NSAID use is not recommended by MTUS. The use of the NSAID Flurbiprofen is not supported by MTUS guidelines. The Official Disability Guidelines (ODG) criteria for compound drugs indicates that the compound drug should not be a copy of a commercially available FDA-approved drug product. Flurbiprofen is a commercially available FDA-approved drug. Omeprazole is a commercially available FDA-approved drug. Omeprazole is over the counter. Per ODG, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request for compounded Flurbiprofen / Omeprazole is not medically necessary.

Med Flurb/Cyclo/Menth Cream 20%/10%/4% #180 gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page 111-113. NSAIDs (non-steroidal anti-inflammatory drugs) Page 67-73.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. There is no evidence for use of a muscle relaxant as a topical product. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The efficacy in clinical trials of topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be either not superior to placebo after two weeks, or with a diminishing effect after two weeks. For osteoarthritis of the knee, topical NSAID effect appeared to diminish over time. There are no long-term studies of their effectiveness or safety for chronic musculoskeletal pain. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain as there is no evidence to support use. MTUS Chronic Pain Medical Treatment Guidelines addresses NSAIDs (non-steroidal anti-inflammatory drugs). All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Use of NSAIDs may compromise renal function. FDA package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile including liver and renal function tests. Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. Medical records document the long-term use of NSAIDs. Per MTUS, it is generally recommended that the lowest dose be used for NSAIDs for the shortest duration of time. The medical records document the diagnoses of hypertension and diabetes and a history of shoulder, wrist, and hand complaints. Date of injury 12-14-2009. Per MTUS, NSAIDs are associated with the risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. Long-term NSAID use is not recommended by MTUS. The use of the NSAID Flurbiprofen is not supported by MTUS guidelines. MTUS Chronic Pain Medical Treatment Guidelines do not support the use of topical products containing the muscle relaxant Cyclobenzaprine. Per MTUS, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. MTUS does not support the use of a topical analgesic containing the muscle relaxant Cyclobenzaprine. Therefore, the request for topical compound cream containing Cyclobenzaprine is not supported by MTUS guidelines. Per MTUS, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request for topical Flurbiprofen / Cyclobenzaprine / Menthol is not medically necessary.