

Case Number:	CM15-0074210		
Date Assigned:	04/24/2015	Date of Injury:	09/28/2012
Decision Date:	05/27/2015	UR Denial Date:	03/31/2015
Priority:	Standard	Application Received:	04/18/2015

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 47 year old male, who sustained an industrial injury on 9/28/2012. The mechanism of injury is unknown. The injured worker was diagnosed as having lumbar disc displacement, lumbar degenerative disc disease and spinal stenosis. There is no record of a recent diagnostic study. Treatment to date has included trigger point injections and medication management. In a progress note dated 3/12/2015, the injured worker complains of lumbar spine pain. The treating physician is requesting Orphenadrine/Caffeine, Gabapentin/Pyridoxine and Flurbiprofen/Omeprazole.

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, sixty count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter.

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 <http://www.drugs.com/pro/orphenadrine-extended-release-tablets.html>
<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. Medical records document the long-term use of muscle relaxants. Medical records document the long-term use of NSAIDs. Date of injury was 9/28/12. The primary treating physician's progress report dated 3/12/15 documented subjective complaints of pain to the lumbar spine. The pain level is 6/10. The patient presents with complaints of moderate pain to the lumbar spine. No physical examination was documented. The diagnoses noted were 722.10 and 724.2. 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 the 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). 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. Per ODG, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. No physical examination was documented on the 3/12/15 progress report. MTU S, ACOEM, FDA, and ODG guidelines do not support the request for a compounded product containing Orphenadrine and Caffeine. Therefore, the request for Orphenadrine / Caffeine is not medically necessary.

Gabapentin 250 mg/pyridoxine 10 mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs) Pages 16-22. Gabapentin (Neurontin) Page 18-19. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Vitamin B.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines indicate that Gabapentin (Neurontin) is considered as a treatment for neuropathic pain. A good response to the use of anti-epilepsy drugs (AEDs) 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. 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 AEDs depends on improved outcomes versus tolerability of adverse effects. Official Disability Guidelines (ODG) indicates that Vitamin B is not recommended for the treatment of chronic pain. 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. Date of injury was 9/28/12. The primary treating physician's progress report dated 3/12/15 documented subjective complaints of pain to the lumbar spine. The pain level is 6/10. The patient presents with complaints of moderate pain to the lumbar spine. No physical examination was documented. No physical examination was documented on the 3/12/15 progress report. The diagnoses noted were 722.10 and 724.2. No neuropathic pain was documented. No physical examination was documented on the 3/12/15 progress report. Without a documented physical examination, the request for Gabapentin is not supported. Without documentation of neuropathic pain, the request for Gabapentin is not supported. 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. Gabapentin is a commercially available FDA-approved drug. Per ODG, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. MTUS and ODG guidelines do not support the request for a compounded product containing Gabapentin and Pyridoxine. Therefore, the request for Gabapentin / Pyridoxine is not medically necessary.

Flurb 100 mg/omeprazole 10 mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter.

MAXIMUS guideline: Decision based on MTUS 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. 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. Medical records document the long-term use of NSAIDs. Date of injury was 9/28/12. The primary treating physician's progress report dated 3/12/15 documented subjective complaints of pain to the lumbar spine. The pain level is 6/10. The patient presents with complaints of moderate pain to the lumbar spine. No physical examination was documented.

The diagnoses noted were 722.10 and 724.2. No physical examination was documented on the 3/12/15 progress report. 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 and Omeprazole are a commercially available FDA-approved drugs. Per ODG, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. MTUS and ODG guidelines do not support the request for a compounded product containing Flurbiprofen and Omeprazole. Therefore, the request for Flurbiprofen / Omeprazole is not medically necessary.