

Case Number:	CM14-0205766		
Date Assigned:	12/17/2014	Date of Injury:	01/29/2013
Decision Date:	02/12/2015	UR Denial Date:	11/26/2014
Priority:	Standard	Application Received:	12/09/2014

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. The expert reviewer is Board Certified in Internal Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 patient is an injured worker with a history of lumbar back complaints, transitional L5-S1, disc collapse and facet disease at L2-L3, low back strain, disc desiccation L3-4, L4-5 and L5-S1. The date of injury was January 29, 2013. The patient was involved in a motor vehicle accident on August 24, 2004. The agree medical examiner comprehensive reexamination report dated July 14, 2014 documented low back complaints. The patient points has complaints in the lumbar spine, bilateral buttocks, and thighs. According to the patient since his last visit on October 8, 2013, he continued to have physical therapy twice a week for the low back, which has helped temporarily. The patient also had shockwave therapy once a week for low back. The patient had acupuncture twice a week for ten visits for the low back, which did not help. Epidural injections for the lumbar spine have been requested. There was no lumbar epidural injection ever done. The patient returns with complaints of pain in the lower back with numbness down to buttocks and thighs. The patient has had physical therapy ongoing twice a week for the low back for approximately one year. The patient indicates that the symptoms in his low back, are the same since the last visit. The patient is currently not working. The patient remains chronically symptomatic. Subjective findings in the clinical exam include limited range of motion, lumbar spine, with tight, hamstrings and limited straight leg raising sitting and supine. There are complaints in the left buttocks and right but Locks. With straight leg raising, there are complaints in the low back. Objectively the patient had an abnormal magnetic resonance imaging of the low back. The patient was taking blood pressure medication and muscle relaxer and pain medication.

IMR ISSUES, DECISIONS AND RATIONALES

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

Synapryn 10mg/1ml #500ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78, 93-94.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol (Ultram); Glucosamine (and Chondroitin Sulfate) Page(s): 93-94, 113, 123; 50. Decision based on Non-MTUS Citation Official Disability (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic) Glucosamine Official Disability Guidelines (ODG) Pain (Chronic) Compound drugs SYNAPRYN <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22416>

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines indicates that Ultram is a centrally acting synthetic opioid analgesic. Ultram is indicated for the management of moderate to moderately severe pain. MTUS Chronic Pain Medical Treatment Guidelines indicates that regarding glucosamine and chondroitin sulfate, controversy on efficacy related to symptomatic improvement continues. Official Disability (ODG) indicates that glucosamine is not recommended for low back pain. Glucosamine is not significantly different from placebo for reducing pain-related disability or improving health-related quality of life in patients with chronic low back pain and degenerative lumbar osteoarthritis, and it should not be recommended for patients with lower back 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. The medical records document low back conditions. Synapryn is a compounding oral suspension containing Tramadol and Glucosamine sulfate. 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. Tramadol is a commercially available FDA-approved drug. Therefore, Synapryn is a copy of the commercially available FDA-approved drug Tramadol. Official Disability (ODG) indicates that glucosamine is not recommended for low back pain. 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 Synapryn 10mg/1ml #500ml is not medically necessary.

Tabradol 1mg/ml #250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 41,64.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, 49, Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril); Muscle relaxants Page(s): 41-42; 63-66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Compound drugs FDA Prescribing Information Flexeril Cyclobenzaprine <http://www.drugs.com/pro/flexeril.html> TABRADOL <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22434>

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, and using them in combination with NSAIDs has no demonstrated benefit. 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 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. Chronic Pain Medical Treatment Guidelines state that Cyclobenzaprine (Flexeril) is an option for a short course of therapy. Treatment should be brief. The addition of Cyclobenzaprine to other agents is not recommended. FDA guidelines state that Cyclobenzaprine is indicated for acute musculoskeletal conditions. Cyclobenzaprine should be used only for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use is not available. Official Disability Guidelines (ODG) indicates that compound drugs are not recommended as a first-line therapy. 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 that the patient's occupational injuries are chronic. MTUS, ACOEM, and FDA guidelines do not support the use of Cyclobenzaprine for chronic conditions. Tabradol is a compounding oral suspension containing Cyclobenzaprine. 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. Cyclobenzaprine is a commercially available FDA-approved drug. Therefore, Tabradol is a copy of the commercially available FDA-approved drug Cyclobenzaprine. The use of Cyclobenzaprine is not supported by MTUS, ACOEM, and FDA guidelines. The request for Tabradol, which is a compounding oral suspension containing Cyclobenzaprine, is not supported by ODG guidelines. Therefore, the request for Tabradol 1mg/ml #250ml is not medically necessary.

Deprizine 15mg/ml #250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation American College of Gastroenterology. Guidelines for Prevention of NSAID-Related Ulcer Complications. Am J Gastroenterol 2009; 104:728 - 738; doi: 10.1038/ajg.2009.115; published online 24 February 2009. Frank L. Lanza , MD, FACG, Francis K.L. Chan, MD, FRCP, FACG, Eamonn M.M. Quigley , MD, FACG and the Practice Parameters Committee of the American College of Gastroenterology. PMID 19240698.
<http://s3.gi.org/physicians/guidelines/NSAIDJournalPublicationFebr>

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address NSAIDs and gastrointestinal risk factors. Proton Pump Inhibitor (PPI), e.g. Omeprazole (Prilosec), is recommended for patients with gastrointestinal risk factors. MTUS does not address Deprizine (Ranitidine). American College of Gastroenterology Guidelines for Prevention of NSAID-Related Ulcer Complications (2009) reported that systematic reviews have shown that H2RA histamine-2-receptor antagonist medications are effective in reducing the risk of NSAID-induced endoscopic gastric ulcers. Official Disability Guidelines (ODG) indicates that compound drugs are not recommended as a first-line therapy. 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 do not present corresponding progress reports from October 2014 regarding the request for Deprizine. Deprizine is a compounding oral suspension containing Ranitidine, which is available over-the-counter. The Official Disability Guidelines (ODG) criteria for compound drugs indicates that the compound drug should include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC over-the-counter drugs. Ranitidine is over-the-counter. Per ODG, the compound drug should not be a copy of a commercially available FDA-approved drug product. Ranitidine is a commercially available FDA-approved drug. Therefore, Deprizine is a copy of the commercially available FDA-approved drug Ranitidine. The request for Deprizine, which is a compounding oral suspension containing Ranitidine, is not supported by ODG guidelines. Therefore, the request for Deprizine 15mg/ml #250ml is not medically necessary.