

<b>Case Number:</b>	CM14-0158298		
<b>Date Assigned:</b>	10/01/2014	<b>Date of Injury:</b>	03/22/2006
<b>Decision Date:</b>	10/31/2014	<b>UR Denial Date:</b>	08/21/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/26/2014

### 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 New York. 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 a 53-year-old male with a date of injury of 03/22/2006. He had treatment with physical therapy, chiropractic therapy, medications, and L4-L5, L5-S1 surgery. A CAT scan of the lumbar spine on 12/02/2009 revealed post-operative changes. He has been treated with Synapryn since at least 03/2013. His back pain is 4- 5/10. On 07/22/2014, his back pain was again 4-5/10. Straight leg raising was positive. He had decreased lumbar range of motion.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Synapryn (Tramadol &Glucosamine) 10mg/1MI Oral Suspension 500MI:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Chronic Pain, Compound Drugs

**Decision rationale:** Except for compound topical analgesics, MTUS is silent about compound drugs. The request is for an oral compound drug. ODG 2014 under Chronic Pain notes 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. (Wynn, 2011) See specific entries for each ingredient. See also Topical analgesics, compounded. 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. Unlike commercially available drugs, these products are not approved by the FDA but rather are regulated by the state pharmacy board and state law governing the practice of pharmacy. The FDA does not regulate pharmacy-compounded products in recognition of the important public health function performed by traditional compounding. Recently, some pharmacies have been making and marketing stock compound drugs for the WC patient population. Among the FDA "Red Flags" for Enforcement Action on Compounded Drugs is: "Compounding drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to amounts compounded after receiving valid prescriptions." (FDA, 2011) Compound topical analgesics may provide relief by acting locally over the painful site with lower risk of systemic adverse effects on the gastrointestinal system and drug interactions than oral NSAIDs. The issues surrounding compound drugs are due to uncertainties regarding whether the products are medically appropriate and whether payments are reasonable, with the latter issue possibly also involving who dispenses the drug. Medical necessity should be based on the patient's needs combined with the medical and scientific evidence presented in ODG. ODG does not address pricing and fee schedules, but in general, there should be consistency within a pharmacy fee schedule for products containing the same active ingredients, so that there is not an inappropriate incentive to use compounding. (Wynn, 2011) See also Co-pack drugs; Medical foods; Physician-dispensed drugs; Repackaged drugs; & Topical analgesics, compounded. For this patient there is no documentation that he failed a trial of Tramadol or Glucosamine. There is no documentation provided to substantiate the medical necessity for using compound drugs for this patient.