

<b>Case Number:</b>	CM15-0171239		
<b>Date Assigned:</b>	09/21/2015	<b>Date of Injury:</b>	11/29/2012
<b>Decision Date:</b>	11/10/2015	<b>UR Denial Date:</b>	08/18/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/31/2015

### 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: California

Certification(s)/Specialty: Emergency 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 60 year old male, who sustained an industrial injury on 11-29-2012. A review of the medical records indicates that the injured worker (IW) is undergoing treatment for high blood pressure, cervical spine pain, strain and radiculopathy, thoracic spine pain and strain, lumbar spine pain and strain, headaches, bilateral shoulder pain, bilateral elbow pain, bilateral wrist pain, bilateral hand pain, abdominal pain, right rib strain or sprain, bilateral knee pain, and bilateral ankle pain. Medical records ( 05-11-2015 to 08-12-2015) indicate ongoing constant moderate to severe headaches (rated 6-7 out of 10); constant moderate to severe radiating neck pain and muscle spasms (rated 8 out of 10); constant moderate to severe bilateral shoulder pain (rated 6-8 out of 10); constant moderate bilateral elbow pain radiating to both hands with weakness, numbness and tingling (rated 4-6 out of 10), constant moderate to severe bilateral wrist and hand pain with muscle spasms (rated 4-8 out of 10); sharp throbbing abdominal pain which is aggravated with any increased of the intra-abdominal pressure; sharp stabbing right rib pain (rated 6-7 out of 10); constant moderate to severe mid back pain with spasms (rated 6-7 out of 10); constant moderate to severe low back pain and spasms radiating into the bilateral lower extremities (rated 8 out of 10), constant moderate to severe bilateral knee pain and spasms (rated 6-8 out of 10); and constant moderate to severe bilateral ankle pain and muscle spasms (rated 4-6 out of 10). The IW reports that the pain persists, but the medications provide temporary relief of pain and improve his ability to sleep. Per the treating physician's progress report (PR), the IW has not returned to work. The physical exams, dated 07-15-2015 and 08-12-2015, revealed no changes in physical exam findings. Relevant treatments have included extracorporeal shockwave

therapy, chiropractic treatments, acupuncture, physical therapy (PT), heat and cold therapy, electrical stimulation, work restrictions, and medications (Synapryn, Tabradol, Deprizine, Dicopanol, and Fanatrex for several months). The request for authorization (08-12-2015) shows that the following medications were requested: Synapryn, Tabradol, Deprizine, Dicopanol, and Fanatrex. The original utilization review (08-18-2015) denied the request for: (1) Synapryn based on the absence of documented rationale as to why the IW requires a compounded oral suspension form of Tabradol and glucosamine over the more commonly used oral tablet or capsule form; (2) Tabradol based on the lack of documented efficacy with prior use and a rationale as to why the IW requires a compounded oral suspension form of Tabradol and glucosamine over the more commonly used oral tablet or capsule form; (3) Deprizine based on the absence of documented evidence of gastrointestinal (GI) issues or complaints, or objective findings supportive of complaints; (4) Dicopanol based on the absence of documented sleep difficulties, comprehensive sleep history, or objective findings supportive of complaints; and (5) Fanatrex based on the absence of a documented rationale as to why the IW requires a compounded oral suspension form of Tabradol and glucosamine over the more commonly used oral tablet or capsule form.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Synapryn:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain.

**Decision rationale:** Tramadol is a pain medication in the category of a centrally acting analgesic. They exhibit opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Centrally acting drugs are reported to be effective in managing neuropathic type pain although it is not recommended as first line therapy. The side effect profile is similar to opioids. For chronic back pain, it appears to be efficacious for short term pain relief, but long term (>16 weeks) results are limited. It also did not appear to improve function. The use of tramadol for osteoarthritis is indicated for short term use only (<3 months) with poor long-term benefit. In this case, the patient does not meet the qualifying criteria. This is secondary to the duration of use, with this medication being indicated on a short-term basis only. As such, the request is not medically necessary.

**Tabradol:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**Decision rationale:** The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) Due to inadequate documentation of a recent acute exacerbation and poor effectiveness for chronic long-term use, the request is not medically necessary.

**Dezprizine:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consultation.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)/Compounded drugs.

**Decision rationale:** The request is for the use of a compounded medication. The official disability guidelines state the following regarding this topic: 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. Criteria for Compound

drugs: (1) 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. (2) Include only bulk ingredients that are components of FDA-approved drugs that have been made in an FDA-registered facility and have an NDC code. (3) Is not a drug that was withdrawn or removed from the market for safety reasons. (4) Is not a copy of a commercially available FDA-approved drug product. (5) Include only drug substances that have been supported as safe and effective for the prescribed indication by the FDA-approval process and/or by adequate medical and scientific evidence in the medical literature. This would allow off-label usage when supported by medical evidence. See specific entries for each ingredient in ODG for the medical and scientific evidence. (6) Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. See also Topical analgesics, compounded. (Wynn, 2011) As stated above the use of this medication is not indicated. This is secondary to no documentation which states that there has been a failure of first-line FDA approved drug therapy or any explanation as to why this compounded formula is superior in efficacy. As such, the request is not medically necessary.

**Dicoprofanol:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness and Stress/Diphenhydramine (Benadryl).

**Decision rationale:** The request is for the use of Diphenhydramine which is in the category of an antihistamine. The MTUS guidelines are silent regarding this topic. The ODG states the following regarding its use: Not recommended. See Insomnia treatment, where sedating antihistamines are not recommended for long-term insomnia treatment. The AGS updated Beers criteria for inappropriate medication use includes diphenhydramine. (AGS, 2012) Anticholinergic drugs, including diphenhydramine, may increase the risk for dementia by 50% in older adults. There is an obvious dose-response relationship between anticholinergic drug use and risk of developing dementia, but chronic use, even at low doses, would be in the highest risk category. While there is awareness that these drugs may cause short-term drowsiness or confusion, which is included in the prescribing information, there is no mention of long-term effects on cognition, and generally awareness of this issue is very low, and both the public and doctors need to be encouraged to use alternative treatments where possible. (Gray, 2015) As stated above, the use of this medication is not indicated for use in this patient for insomnia. There is inadequate documentation of the reasoning for its use for other indications. As such, the request is not medically necessary.

**Fanatrex:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)/Compounded drugs.

**Decision rationale:** The request is for the use of a compounded medication. The official disability guidelines state the following regarding this topic: 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. Criteria for Compound drugs: (1) 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. (2) Include only bulk ingredients that are components of FDA-approved drugs that have been made in an FDA-registered facility and have an NDC code. (3) Is not a drug that was withdrawn or removed from the market for safety reasons. (4) Is not a copy of a commercially available FDA-approved drug product. (5) Include only drug substances that have been supported as safe and effective for the prescribed indication by the FDA-approval process and/or by adequate medical and scientific evidence in the medical literature. This would allow off-label usage when supported by medical evidence. See specific entries for each ingredient in ODG for the medical and scientific evidence. (6) Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. See also Topical analgesics, compounded. (Wynn, 2011) As stated above the use of this medication is not indicated. This is secondary to no documentation which states that there has been a failure of first-line FDA approved drug therapy or any explanation as to why this compounded formula is superior in efficacy. As such, the request is not medically necessary.