

<b>Case Number:</b>	CM14-0032752		
<b>Date Assigned:</b>	04/18/2014	<b>Date of Injury:</b>	10/12/2012
<b>Decision Date:</b>	07/02/2014	<b>UR Denial Date:</b>	02/06/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/13/2014

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a Physician Reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The Physician Reviewer is Board Certified in Physical Medicine & Rehabilitation, and is licensed to practice in Illinois. 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 Physician 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 injured worker is a 56-year old female who reported a low back injury on 10/12/2012; the mechanism of injury was not provided in the submitted paperwork. Within the submitted documentation the clinical note dated 09/05/2013 noted the injured worker complained of burning left wrist pain that directly affected her activities of daily living. In addition the injured worker reported burning radicular low back pain that travels down to her left leg. The injured worker reported that aspirin alleviated her pain. The request for authorization was not submitted in the paperwork provided.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**SYNAPRIN 10MG/1ML ORAL SUSPENSION 500ML:** 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), PAIN, COMPOUND DRUGS.

**Decision rationale:** The request for Synapryn 10mg/ml oral suspension is not medically necessary. The active ingredient in Synapryn is tramadol. The Official Disability Guidelines

note criteria for a compounded drug includes the medication must 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. The guidelines note it must 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, it must not be a drug that was withdrawn or removed from the market for safety reasons, it should not be a copy of a commercially available FDA-approved drug product, and the medication should 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. Central analgesics drugs such as Tramadol (Ultram) are reported to be effective in managing neuropathic pain. Recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Within the documentation, the injured worker has a complaint of pain, however the report claims aspirin is enough to mitigate the pain. Furthermore, within the documentation it is unclear why an oral suspension would be required as there is a lack of documentation of impairment of the injured worker's ability to swallow. Hence, the request is not medically necessary.

#### **TABRADOL 1MG/ML ORAL SUSPENSION 250ML: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG), PAIN, COMPOUND DRUGS.

**Decision rationale:** The request for Tabradol 1MG/ML oral suspension 250ML is not medically necessary. The active ingredient in Tabradol is cyclobenzaprine. The Official Disability Guidelines note criteria for a compounded drug indicate the medication must 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. The guidelines note it must 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, it must not be a drug that was withdrawn or removed from the market for safety reasons, it should not be a copy of a commercially available FDA-approved drug product, and the medication should 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. Cyclobenzaprine is recommended as an option, using a short course of therapy. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Treatment should be brief. There is also a post-op use. The addition of cyclobenzaprine to other agents is not recommended. Within the documentation the injured worker has a complaint of pain, however the report claims aspirin is enough to mitigate the pain. Furthermore, within the documentation it is unclear why an oral suspension would be required as there is a lack of documentation of impairment of the injured worker's ability to swallow. Hence, the request is not medically necessary.

**DEPRIZINE 15MG/ML ORAL SUSPENSION 250ML: 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), PAIN, COMPOUND DRUGS.

**Decision rationale:** The request for Deprizine 15MG/ML oral suspension 250ML is not medically necessary. The active ingredient in Deprizine is ranitidine. The Official Disability Guidelines note criteria for a compounded drug indicate the medication must 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. The guidelines note it must 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, it must not be a drug that was withdrawn or removed from the market for safety reasons, it should not be a copy of a commercially available FDA-approved drug product, and the medication should 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. Within the documentation, the injured worker had no reported gastric discomfort or gastrointestinal adverse reactions to the aspirin taken. Furthermore, within the documentation, it is unclear why an oral suspension would be required as there is a lack of documentation of impairment of the injured worker's ability to swallow. Hence, the request is not medically necessary.

**DICOPANOL (DIPHENHYDRAMINE) 5MG/ML ORAL SUSPENSION 150ML: 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), PAIN, COMPOUND DRUGS.

**Decision rationale:** The request for Dicopanol 5MG/ML oral suspension 150ML is not medically necessary. The active ingredient in Dicopanol is diphenhydramine. The Official Disability Guidelines note criteria for a compounded drug indicate the medication must 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. The guidelines note it must 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, it must not be a drug that was withdrawn or removed from the market for safety reasons, it should not be a copy of a commercially available FDA-approved drug product, and the medication should 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. Sedating antihistamines have been suggested for sleep aids. Tolerance seems to develop within a few days. Next-day

sedation has been noted as well as impaired psychomotor and cognitive function. This RCT determined that diphenhydramine has been shown to build tolerance against its sedation effectiveness very quickly, with placebo-like results after a third day of use. Within the documentation, the injured worker had no reported episodes of insomnia. Furthermore, within the documentation, it is unclear why an oral suspension would be required as there is a lack of documentation of impairment of the injured worker's ability to swallow. Hence, the request is not medically necessary.

**FANATREX (GABAPENTIN): 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), PAIN, COMPOUND DRUGS.

**Decision rationale:** The request for Fanatrex 15MG/ML oral suspension 250ML is not medically necessary. The active ingredient in Fanatrex is gabapentin. The Official Disability Guidelines note criteria for a compounded drug indicate the medication must 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. The guidelines note it must 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, it must not be a drug that was withdrawn or removed from the market for safety reasons, it should not be a copy of a commercially available FDA-approved drug product, and the medication should 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. Gabapentin is recommended for neuropathic pain. Gabapentin is an anti-epilepsy drug, which has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. Within the documentation, the injured worker has reported neurologic pain; however, the worker's reported pain was mitigated by aspirin. Furthermore, within the documentation, it is unclear why an oral suspension would be required as there is a lack of documentation of impairment of the injured worker's ability to swallow. Hence, the request is not medically necessary.