

Case Number:	CM15-0119658		
Date Assigned:	06/30/2015	Date of Injury:	06/12/2013
Decision Date:	09/22/2015	UR Denial Date:	06/15/2015
Priority:	Standard	Application Received:	06/22/2015

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: Texas, Illinois

Certification(s)/Specialty: Preventive Medicine, Occupational 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 40-year-old female who sustained industrial injuries on 6/12/2013 resulting in multiple symptoms including pain in the lower back; neck; bilateral shoulder and upper arm; and, her left knee and leg. The injured worker was diagnosed with cervical spine sprain/strain, bilateral shoulder sprain/strain, lumbar disc displacement, and left knee internal derangement. Treatment has included physical therapy, acupuncture, chiropractic treatment for which effectiveness is not documented, and oral and transdermal medications, which the injured worker reports provide temporary pain relief and improvement in her ability to sleep. She continues to report pain at multiple sites, which she says, reduces her ability to perform activities of daily living. The treating physician's plan of care includes Synapryn, Tabradol, Deprizine, Dicopanor, and Fenatrex. She is presently working.

IMR ISSUES, DECISIONS AND RATIONALES

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

Synapryn 10 mg/1 ml oral suspension, 500 ml , 1 tsp (5 ml) 3 times daily: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate).

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) Compound drugs.

Decision rationale: The injured worker sustained a work related injury on 6/12/2013. The medical records provided indicate the diagnosis of cervical spine sprain/strain, bilateral shoulder sprain/strain, lumbar disc displacement, and left knee internal derangement. Treatment has included physical therapy, acupuncture, chiropractic treatment for which effectiveness is not documented, and oral and transdermal medications, which the injured worker reports provide temporary pain relief and improvement in her ability to sleep. The medical records provided for review do not indicate a medical necessity for Synapryn 10 mg/1 ml oral suspension, 500 ml, 1 tsp (5 ml) 3 times daily. Synapryn oral suspension is a compounded drug containing the active and inactive agents as follows: Tramadol hydrochloride; purified water, glycerin, cherry flavor xanthan gum, sodium citrate, citric acid, potassium sorbate, sodium benzoate. The MTUS is silent on Compounded products, but the Official Disability Guidelines criteria for compounded products is as follows: (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. Therefore, the requested treatment is not medically necessary due to presence of non- recommended agents.

Tabradol 1 mg/ml oral suspension, 250 ml , 1 tsp (5 ml) 2-3 times daily: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain).

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) Compound drugs and Other Medical Treatment Guidelines
<http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22434>.

Decision rationale: The injured worker sustained a work related injury on 6/12/2013. The medical records provided indicate the diagnosis of cervical spine sprain/strain, bilateral shoulder sprain/strain, lumbar disc displacement, and left knee internal derangement. Treatment has included physical therapy, acupuncture, chiropractic treatment for which effectiveness is not documented, and oral and transdermal medications, which the injured worker reports provide temporary pain relief and improvement in her ability to sleep. The medical records provided for

review do not indicate a medical necessity for Tabradol 1 mg/ml oral suspension, 250 ml, 1 tsp (5 ml) 2-3 times daily. Tabradol oral suspension is a compounded drug containing the active and inactive agents as follows: Cyclobenzaprine; purified water, glycerin, cherry flavor, xanthan gum, sodium citrate, citric acid, potassium sorbate, sodium benzoate. The MTUS is silent on Compounded products, but the Official Disability Guidelines criteria for compounded products is as follows: (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. Therefore, the requested treatment is not medically necessary due to presence of non-recommended agents.

Deprizine 15 mg/ml oral suspension, 250 ml, 2 tsp (10 ml) 1 time daily: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk.

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) Compound drugs and Other Medical Treatment Guidelines <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22536>.

Decision rationale: The injured worker sustained a work related injury on 6/12/2013. The medical records provided indicate the diagnosis of cervical spine sprain/strain, bilateral shoulder sprain/strain, lumbar disc displacement, and left knee internal derangement. Treatment has included physical therapy, acupuncture, chiropractic treatment for which effectiveness is not documented, and oral and transdermal medications, which the injured worker reports provide temporary pain relief and improvement in her ability to sleep. The medical records provided for review do not indicate a medical necessity for Deprizine 15 mg/ml oral suspension, 250 ml, 2 tsp (10 ml) 1 time daily. Deprizine oral suspension is a compounded drug containing active and inactive agents including ranitidine, water, glycerin, L-glutamine, xylitol, monoammonium glycyrrhizinate, pineapple flavor, xanthan gum, stevia powder, orange flavor, sodium citrate, citric acid, potassium sorbate, sodium benzoate. The MTUS is silent on Compounded products, but the Official Disability Guidelines criteria for compounded products is as follows: (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. Therefore, the requested treatment is not medically necessary due to presence of non-recommended agents.

Dicopanol (diphenhydramine) 5 mg/ml oral suspension, 150 ml , 1 ml by mouth at bedtime:
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 - Insomnia treatment.

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) Compound drugs and Other Medical Treatment Guidelines
<http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=76c12e0d-735b-44d1-aa82-73e3f3a09d1b>.

Decision rationale: The injured worker sustained a work related injury on 6/12/2013. The medical records provided indicate the diagnosis of cervical spine sprain/strain, bilateral shoulder sprain/strain, lumbar disc displacement, and left knee internal derangement. Treatment has included physical therapy, acupuncture, chiropractic treatment for which effectiveness is not documented, and oral and transdermal medications, which the injured worker reports provide temporary pain relief and improvement in her ability to sleep. The medical records provided for review do not indicate a medical necessity for Dicopanol (diphenhydramine) 5 mg/ml oral suspension, 150 ml, and 1 ml by mouth at bedtime. Dicopanol (diphenhydramine) is a compounded drug containing the active and inactive agents as follows: Water ; Glycerin; Xylitol; Glycyrrhizin ammoniated; Pineapple ; Xanthan Gum; Stevia Leaf; Orange; Citric acid; Sodium Citrate; Melatonin; Potassium Sorbate ; and Sodium Benzoate. The MTUS is silent on Compounded products, but the Official Disability Guidelines criteria for compounded products is as follows: (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. Therefore, the requested treatment is not medically necessary due to presence of non-recommended agents.

Fanatrex (Gabapentin) 25 mg/ml oral suspension, 420 ml , 1 tsp (5 ml) 3 times daily: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti epilepsy drugs (AEDs).

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)Compound drugs and Other Medical Treatment Guidelines
<http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=24354>.

Decision rationale: The injured worker sustained a work related injury on 6/12/2013. The medical records provided indicate the diagnosis of cervical spine sprain/strain, bilateral shoulder sprain/strain, lumbar disc displacement, and left knee internal derangement. Treatment has included physical therapy, acupuncture, chiropractic treatment for which effectiveness is not documented, and oral and transdermal medications, which the injured worker reports provide temporary pain relief and improvement in her ability to sleep. The medical records provided for review do not indicate a medical necessity for Fanatrex (Gabapentin) 25 mg/ml oral suspension, 420 ml, 1 tsp (5 ml) 3 times daily . Fanatrex is a compounded drug containing the active and inactive agents as follows: Gabapentin, USP 420 mL oral suspension vehicle (water, banana flavor, N-acetyl-D-glucosamine, strawberry flavor, marshmallow flavor, glycerin, stevia powder, acesulfame potassium, xanthan gum, monoammonium glycyrrhizinate, sodium saccharin, sodium benzoate, potassium sorbate, dibasic sodium phosphate). The MTUS is silent on Compounded products, but the Official Disability Guidelines criteria for compounded products is as follows: (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. Therefore, the requested treatment is not medically necessary due to presence of non-recommended agents.