

Case Number:	CM15-0143971		
Date Assigned:	08/04/2015	Date of Injury:	09/06/2011
Decision Date:	09/23/2015	UR Denial Date:	07/02/2015
Priority:	Standard	Application Received:	07/24/2015

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 42 year old male, who sustained an industrial injury on 9-6-2011. Diagnoses include lumbar spine herniated nucleus pulposus and lumbar radiculopathy. Treatments to date include medications, physical therapy, and chiropractic therapy. Currently, he complained of low back pain associated with numbness, tingling and weakness. On 6-15-15, the physical examination documented lumbar tenderness with muscle spasms noted. The appeal requested authorization for Dicopanol 5mg-ML, 150ML, Deprizine 5mg-ML, Fanatrex 25mg-ML 500ML, from Dates of Service including June 15, 2015, January 26, 2015, December 14, 2014, and September 2014; and Synapryn 10mg-ML 500ML, Tabradol 1mg-ML 250ML from dates of services including June 15, 2015, January 26, 2015, December 14, 2014, and September 2014.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retro: Dicopanol 5mg/ml 150ml #1 DOS 06/15/2015, 1/26/2015, 12/29/2014, 09/29/2014:
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 (online version).

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 9-6-2011. The medical records provided indicate the diagnosis of Diagnoses include lumbar spine herniated nucleus pulposus and lumbar radiculopathy. Treatments to date include medications, physical therapy, and chiropractic therapy. The medical records provided for review do not indicate a medical necessity for Retro: Dicopanor 5mg/ml 150ml #1 DOS 06/15/2015, 1/26/2015, 12/29/2014, 09/29/2014. Dicopanor oral suspension is a compound drug with active agent diphenhydramine hydrochlorid; and inactive agents, water, glycerin, xylitol, monoammonium glycyrrhizinate, pineapple flavor, xanthan gum, stevia powder, orange flavor, citric acid, sodium citrate, melatonin, potassium sorbate, sodium benzoate. The MTUS is silent on Compound medications, but the Official Disability Guidelines states does not recommend compound drugs as first-line. The Official Disability Guidelines criteria for the use of compound drugs 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. The recommended treatment is not medically necessary due to the presence of non-recommended agents.

Retro: Deprizine 5mg/ml 250ml #1 DOS 06/15/2015, 1/26/2015, 12/29/2014, 09/29/2014:
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 (online version).

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 9-6-2011. The medical records provided indicate the diagnosis of Diagnoses include lumbar spine herniated nucleus pulposus and lumbar radiculopathy. Treatments to date include medications, physical therapy, and chiropractic therapy. The medical records provided for review do not indicate a medical necessity for Retro: Deprizine 5mg/ml 250ml #1 DOS 06/15/2015, 1/26/2015, 12/29/2014, 09/29/2014. Deprizine suspension is a compounded drug with the active agent Ranitidine, and inactive agents 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 Compound medications, but the Official Disability Guidelines states does not recommend compound drugs as first-line. The Official Disability Guidelines criteria for the use of compound drugs 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. The recommended treatment is not medically necessary due to the presence of non-recommended agents.

Retro: Fanatrex 25mg/ml 420ml #1 DOS 06/15/2015, 1/26/2015, 12/29/2014, 09/29/2014:
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 (online version).

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 9-6-2011. The medical records provided indicate the diagnosis of Diagnoses include lumbar spine herniated nucleus pulposus and lumbar radiculopathy. Treatments to date include medications, physical therapy, and chiropractic therapy. The medical records provided for review do not indicate a medical necessity for Retro: Fanatrex 25mg/ml 420ml #1 DOS 06/15/2015, 1/26/2015, 12/29/2014, and 09/29/2014. Fanatrex suspension is a compounded drug with the active agent Gabapentin; and inactive agents, 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 Compound medications, but the

Official Disability Guidelines states does not recommend compound drugs as first-line. The Official Disability Guidelines criteria for the use of compound drugs 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. The recommended treatment is not medically necessary due to the presence of non-recommended agents.

Retro: Synyprin 10mg/1ml 500ml #1 DOS 06/15/2015, 1/26/2015, 12/29/2014, 09/29/2014:
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 (online version).

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 9-6-2011. The medical records provided indicate the diagnosis of Diagnoses include lumbar spine herniated nucleus pulposus and lumbar radiculopathy. Treatments to date include medications, physical therapy, and chiropractic therapy. The medical records provided for review do not indicate a medical necessity for Retro: Synyprin 10mg/1ml 500ml #1 DOS 06/15/2015, 1/26/2015, 12/29/2014, 09/29/2014. Synyprin is a compounded drug containing tramadol hydrochloride, as an active agent, and the inactive agents, water, glycerin, cherry flavor xanthan gum, sodium citrate, citric acid, potassium sorbate, sodium benzoate. The MTUS is silent on Compound medications, but the Official Disability Guidelines states does not recommend compound drugs as first-line. The Official Disability Guidelines criteria for the use of compound drugs 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. The recommended treatment is not medically necessary due to the presence of non-recommended agents.

Retro: Trabradol 1mg/ml 250ml #1 DOS 06/15/2015, 1/26/2015, 12/29/2014, 09/29/2014:
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 (online version).

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 9-6-2011. The medical records provided indicate the diagnosis of Diagnoses include lumbar spine herniated nucleus pulposus and lumbar radiculopathy. Treatments to date include medications, physical therapy, and chiropractic therapy. The medical records provided for review do not indicate a medical necessity for Trabradol 1mg/ml 250ml #1 DOS 06/15/2015, 1/26/2015, 12/29/2014, 09/29/2014. Tabradol suspension is a compounded drug containing Cyclobenzaprine, Methylsulfonylmethane and other proprietary agents. The MTUS is silent on Compound medications, but the Official Disability Guidelines states does not recommend compound drugs as first-line. The Official Disability Guidelines' criteria for the use of compound drugs 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. The recommended treatment is not medically necessary due to the presence of non-recommended agents.