MAXIMUS Federal Services

Case Number:	CM15-0200814		
Date Assigned:	10/15/2015	Date of Injury:	03/07/2013
Decision Date:	12/04/2015	UR Denial Date:	09/30/2015
Priority:	Standard	Application Received:	10/13/2015

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 45 year old male, who sustained an industrial injury on 3-07-2013. The injured worker was diagnosed as having low back pain, lumbar spine herniated nucleus pulposus, and lower extremity radiculitis. Treatment to date has included diagnostics, physical therapy, acupuncture, extracorporeal shockwave therapy, and medications. Currently (9-10-2015), the injured worker complains of "burning, radicular lower back pain and muscle spasms", rated 4 out of 10 (4-5 out of 10 on 8-14-2015), described as "constant, moderate to severe". He also complained of left leg weakness. He reported that medications offered temporary relief of pain and improved the ability to have restful sleep and denied any problems with the medications. Function with activities of daily living was not specified. Exam of the lumbar spine noted tenderness to palpation over the lower lumbar spine with paravertebral spasms, along with sciatic notch tenderness. Range of motion in the lumbar spine was decreased and straight leg raise was positive on the left. Motor was 4 of 4 in the lower extremities and sensation was slightly decreased at the L5 and S1 dermatomes bilaterally. The use of Synapryn, Tabradol and Fanatrex was noted since at least 12-2014. His work status remained total temporary disability. The treatment plan included Fanatrex 25mg-ml 420ml, Tabradol 1mg-ml 250ml, and Synapryn 10mg-ml 500ml, modified by Utilization Review on 9-30-2015 to Fanatrex 25mg-ml 210ml (weaning), Synapryn 10mg-ml 250ml (weaning), and Tabradol 1mg-ml 125ml (weaning).

IMR ISSUES, DECISIONS AND RATIONALES

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

Synapryn 10mg/1ml, 500ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Low Back Complaints 2004, Section(s): Summary. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Compound drugs and Other Medical Treatment Guidelines http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22416.

Decision rationale: The injured worker sustained a work related injury on 3-07-2013. The injured worker was diagnosed as having low back pain, lumbar spine herniated nucleus pulposus, and lower extremity radiculitis. Treatment to date has included diagnostics, physical therapy, acupuncture, extracorporeal shockwave therapy, and medications. The medical records provided for review do not indicate a medical necessity for Synapryn 10mg/1ml, 500ml. Synapryn is a compound drug containing tramadol hydrochloride as the active agent, and several other agents, including purified water, glycerin, cherry flavor xanthan gum, sodium citrate, citric acid, potassium sorbate, sodium benzoate. The MTUS is silent on compound drugs, but the Official Disability Guidelines does not recommend the use of compound drugs as first line agents. Also, the Official Disability Guidelines states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The records indicate the injured worker has been using this opioid containing drug for several years. The compound drug contains several agents that are not recommended, thereby making the requested treatment not medically necessary. MTUS does not recommend the use of opioids for more than two weeks for the treatment of low back pain.

Tabradol 1mg/ml, 250ml: 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): Muscle relaxants (for pain). Decision based on Non-MTUS Citation http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22434.

Decision rationale: The injured worker sustained a work related injury on 3-07-2013. The injured worker was diagnosed as having low back pain, lumbar spine herniated nucleus pulposus, and lower extremity radiculitis. Treatment to date has included diagnostics, physical therapy, acupuncture, extracorporeal shockwave therapy, and medications. The medical records provided for review do not indicate a medical necessity for Tabradol 1mg/ml, 250ml Tabradol is a compound drug containing cyclobenzaprine as the active agent, and several other agents, including purified water, glycerin, cherry flavor, xanthan gum, sodium citrate, citric acid, potassium sorbate, sodium benzoate). The MTUS is silent on compound drugs, but the Official Disability Guidelines does not recommend the use of compound drugs as first line agents. Also,

the Official Disability Guidelines states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The records indicate the injured worker has been using this muscle relaxant drug for several years. The compound drug contains several agents that are not recommended, thereby making the requested treatment not medically necessary. MTUS does not recommend the use of cyclobenzaprine for more than 2-3 weeks.

Fanatrex 25mg/ml, 420ml: 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 http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=24354.

Decision rationale: The injured worker sustained a work related injury on 3-07-2013. The injured worker was diagnosed as having low back pain, lumbar spine herniated nucleus pulposus, and lower extremity radiculitis. Treatment to date has included diagnostics, physical therapy, acupuncture, extracorporeal shockwave therapy, and medications. The medical records provided for review do not indicate a medical necessity for Fanatrex 25mg/ml, 420ml. Fanatrex 25mg/ml, 420ml is a compound drug containing gabapentin as the active agent, and several other agents, including 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 drugs, but the Official Disability Guidelines does not recommend the use of compound drugs as first line agents. Also, the Official Disability Guidelines states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The records indicate the injured worker has been using this muscle relaxant drug for several years. The compound drug contains several agents that are not recommended, thereby making the requested treatment not medically necessary.