MAXIMUS Federal Services

Case Number:	CM14-0021452		
Date Assigned:	05/12/2014	Date of Injury:	01/16/2013
Decision Date:	07/25/2014	UR Denial Date:	01/14/2014
Priority:	Standard	Application Received:	02/20/2014

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. The expert reviewer is Board Certified in Anesthesiology, has a subspecialty in Pain Medicine and is licensed to practice in California. 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/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 patient is a 47-year-old female with a 1/16/13 date of injury, when she was walking in grass, tripped over a water hose, and fell; injuring her neck, buttocks, hips, and pelvis. Diagnosis includes cervical spine pain, cervical radiculopathy, and low back pain. Treatment rendered has included medications. A progress note dated 12/9/13 described ongoing neck, left shoulder, and low back pain that increases with cold weather. Medications provide temporary relief. Clinically there was tenderness at the left occiput with trigger points in the paracervical muscles and mild stiffness. There is reduced range of motion, positive distraction and compression testing, tenderness at the rhomboid, supraspinatus, trapezius, lavator scapula muscle groups. There is positive impingement, Hawkins, and speed testing. In the lumbar spine, there was positive provocative testing including tripod, Flip, and Laseques testing. Treatment plan discussed medications and suspension. 3/19/14 psychological assessment described a diagnostic impression that included Axis I: Episode of mental/clinical disorder; pain disorder; adjustment disorder. Axis II: Personality disorder. Axis III: Physical disorders and conditions are as diagnosed by appropriate examining specialist. Axis IV: This area of psychosocial stressors was moderate. GAF was 65. Biofeedback therapy and cognitive behavioral therapy were recommended. 5/8/14 letter of medical necessity described requested medications in oral suspension, their components, and use.

IMR ISSUES, DECISIONS AND RATIONALES

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

Synapryn 10mg/1ml susp, 500 ml #1: 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 Other Medical Treatment Guideline or Medical Evidence:http://www.drugsdb.eu/drug.php?d=Synapryn&m=Fusion%20Pharmaceuticals%20Llc&id=7bdbe51a-e381-4d83-ba8e-a7562ced650f.xml.

Decision rationale: Medical necessity for the requested Synapryn is not established. Synapryn contains tramadol hydrochloride 10 mg/mL, in oral suspension with glucosamine - compounding kit. This drug has not been found by FDA to be safe and effective, and the FDA has not approved this labeling. Furthermore, there is no clear rationale identifying why a compound/oral suspension (as opposed to the evidence based guidelines supported and FDA approved non-compounded medication) is needed for this patient. This request is not medically necessary.

Tabradol 1mg/ml susp. 250ml #1: 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 Other Medical Treatment Guideline or Medical Evidence:http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22434 (Cyclobenzaprine hydrochloride 1 mg/mL, in oral suspension with MSM - compounding kit).

Decision rationale: Medical necessity for the requested Tabradol is not established. Tabradol contains Cyclobenzaprine hydrochloride with MSM oral suspension, however CA MTUS Chronic Pain Medical Treatment Guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Tabradol contains Methylsulfonylmethane (MSM), which is not FDA approved. This request is not medically necessary.

Deprizine 15mg/ml oral suspension 250ml #1: 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 Other Medical Treatment Guideline or Medical Evidence:Deprizine http://www.drugs.com/pro/deprizine.html(Ranitidine hydrochloride 16.8 mg/mL [15 mg/mL ranitidine], in oral suspension compounding kit).

Decision rationale: Medical necessity for the requested Deprizine is not established. Deprizine contains Ranitidine with other proprietary ingredients in an oral suspension. There is no report of GI disorders such as peptic ulcer disease that would indicate a need for a H2 blocker. In addition,

there is no rationale provided for the medical necessity of an oral suspension. This request is not medically necessary.

Dicopanol (diphenhydramine) 5mg/ml oral suspension 500ml #1: 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 Other Medical Treatment Guideline or Medical Evidence:Dicopanolhttp://www.drugs.com/cdi/diphenhydramine.htmlDicopanol (diphenhydramine hydrochloride 5 mg/mL, in oral suspension - compounding kit).

Decision rationale: Medical necessity for the requested dicopanol is not established. Dicopanol contains Diphenhydramine hydrochloride in oral suspension. There are no clinical findings such as insomnia that would support the use of an antihistamine. In addition, there is no rationale provided for the medical necessity of an oral suspension. This request is not medically necessary.

Fanatrex (gabapentin) 25mg/ml oral suspension 420 ml #1: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 18-19.

Decision rationale: Medical necessity for the requested Fanatrex is not established. Fanatrex contians Gabapentin in an oral suspension. The patient has cervical and lumbar pain, due to a slip and fall. However, there is no rationale provided for the medical necessity of an oral suspension. This request is not medically necessary.