

Case Number:	CM14-0122505		
Date Assigned:	08/08/2014	Date of Injury:	04/02/2012
Decision Date:	09/12/2014	UR Denial Date:	07/15/2014
Priority:	Standard	Application Received:	08/04/2014

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 Florida. 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 injured worker is a 31-year-old female who reported an injury on 04/02/2012. The mechanism of injury was not provided. On 03/06/2014 the injured worker presented with headaches, neck, mid back pain, low back pain, stress, anxiety and depression. On examination of the cervical spine there was tenderness to the suboccipital, scalene and sternocleidomastoid muscles, and decreased range of motion. There was a positive cervical distraction and maximal foraminal compression. There was decreased sensation over the C5 to T1 and decreased myotomes in C5, C6, C7, C8 and T1. Examination of the thoracic spine revealed tenderness to the spinous processes T3 to T8 and thoracic spinal muscle guarding, decreased range of motions and a positive Kemp's sign. Examination of the lumbar spine noted decreased range of motion, negative straight leg raise and intact sensation. The diagnoses were headaches, sprain of ligaments of the cervical spine, pain in the thoracic spine, sprain of the ligaments of the thoracic spine, low back, sprain of the ligaments of the lumbar spine, anxiety disorder, unspecified mood disorder and acute stress reaction. A current medication list was not provided. The provider recommended Synapryn and Tabradol. The provider's rationale was not provided. The Request for Authorization form was not included in the medical documents for review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Synapryn 10mg/ml 3 times daily: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Sulfate, Ongoing management, Tramadol Page(s): 50,78, 82.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Pain, Compound Drug.

Decision rationale: The request for Synapryn 10 mg/mL 3 times daily is not medically necessary. The Official Disability Guidelines state compound medications should include at least 1 drug substance or active ingredient that is the sole active ingredient in an FDA approved prescription drug, not including OTC drugs. The guidelines note compounded medications should 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, and should not include a drug that was withdrawn or removed from the market for safety reasons, and is not a copy or a commercially available FDA approved drug. The guidelines note the medication should include only drug substances that have been supported as safe and effective for prescribed indication by the FDA approval process and/or by adequate medical and scientific evidence in the medical literature. The documentation lacked evidence of this medication providing desired effects for the injured worker. There were lack of adequate and complete pain assessments within the documentation. It was unclear why the injured worker would require compounded oral suspension medications, as opposed to noncompounded traditional oral medications. It did not appear the injured worker had significant difficulties taking traditional tablet medications, which would indicate the injured worker's need for compounded oral suspension medications. As such, the request is not medically necessary.

Tabradol 1mg/ml 2-3 times daily: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41,64.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Pain, Compound Drug.

Decision rationale: The request for Tabradol 1 mg/mL 2 to 3 times daily is not medically necessary. The Official Disability Guidelines state compound medications should include at least 1 drug substance or active ingredient that is the sole active ingredient in an FDA approved prescription drug, not including OTC drugs. The guidelines note compounded medications should 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, and should not include a drug that was withdrawn or removed from the market for safety reasons, and is not a copy or a commercially available FDA approved drug. The guidelines note the medication should include only drug substances that have been supported as safe and effective for prescribed indication by the FDA approval process and/or by adequate medical and scientific evidence in the medical literature. The documentation lacked evidence of this medication providing desired effects for the injured worker. There were lack of adequate and complete pain assessments within the documentation. It was unclear why the injured worker would require compounded oral suspension medications, as opposed to noncompounded traditional oral medications. It did not

appear the injured worker had significant difficulties taking traditional tablet medications, which would indicate the injured worker's need for compounded oral suspension medications. As such, the request is not medically necessary.