

Case Number:	CM14-0194705		
Date Assigned:	12/02/2014	Date of Injury:	08/01/2012
Decision Date:	01/14/2015	UR Denial Date:	10/31/2014
Priority:	Standard	Application Received:	11/20/2014

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 Occupational 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:

According to the records made available for review, this is a 45-year-old female with a 08/01/2012 date of injury. At the time of request for authorization (10/10/14), for Tabradol 1mg/ml 250ml #1, Deprizine 15mg/ml #1, Synapryn 10mg/1ml 500ml #1, and Dicopanol (diphenhydramine) 5mg/ml #1; there is documentation subjective of (moderate to severe neck pain radiating to the bilateral upper extremities with numbness and tingling, bilateral shoulder pain, mid back pain with muscle spasms, and low back pain) and objective of (decreased range of motion of the cervical spine, positive foraminal compression test and Spurling's test, tenderness to palpation over the cervical, thoracic, and lumbar spine, decreased range of motion of the bilateral shoulders and lumbar spine) findings and current diagnoses (cervical spine sprain/strain, bilateral shoulder sprain a/strain, thoracic spine pain, and lumbar spine sprain/strain), and treatment to date (physical therapy, chiropractic treatments, and medications (including ongoing treatment with Ibuprofen).

IMR ISSUES, DECISIONS AND RATIONALES

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

Tabradol 1mg/ml 250ml, quantity 1:

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscles Relaxants.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Co-pack drugs Other Medical Treatment Guideline or Medical Evidence:
<http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22434>

Decision rationale: Medical treatment guidelines identify Tabradol as cyclobenzaprine hydrochloride, in oral suspension with MSM - compounding kit. The MTUS does not address the issue. ODG identifies that co-packs are convenience packaging of a medical food product and a generic drug into a single package that requires a prescription. While the generic drug is FDA-approved, the co-pack of a medical food and FDA-approved drug is not unless the manufacturer obtains FDA approval for the product as a new drug. There are no high quality medical studies to evaluate co-packs on patient outcomes. Therefore, based on guidelines and a review of the evidence, the request for Tabradol 1mg/ml 250ml #1 is not medically necessary.

Deprizine 250ml, quantity #1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Co-pack drugs

Decision rationale: Medical treatment guideline identifies Deprizine as ranitidine hydrochloride in oral suspension kit. The MTUS does not address the issue. ODG identifies that co-packs are convenience packaging of a medical food product and a generic drug into a single package that requires a prescription. While the generic drug is FDA-approved, the co-pack of a medical food and FDA-approved drug is not unless the manufacturer obtains FDA approval for the product as a new drug. There are no high quality medical studies to evaluate co-packs on patient outcomes. Therefore, based on guidelines and a review of the evidence, the request for Deprizine 15mg/ml 250ml #1 is not medically necessary.

Synapryn 500ml, quantity 1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Co-pack drugs

Decision rationale: Medical treatment guidelines identify Synapryn as tramadol hydrochloride, in oral suspension with glucosamine-compounding kit. The MTUS does not address the issue. ODG identifies that co-packs are convenience packaging of a medical food product and a generic drug into a single package that requires a prescription. While the generic drug is FDA-approved, the co-pack of a medical food and FDA-approved drug is not unless the manufacturer obtains

FDA approval for the product as a new drug. There are no high quality medical studies to evaluate co-packs on patient outcomes. Therefore, based on guidelines and a review of the evidence, the request for Synapryn 10mg/1ml 500ml #1 is not medically necessary.

Dicopanol (diphenhydramine) 5mg/ml 150ml, quantity 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 Official Disability Guidelines (ODG), Pain Chapter, Co-pack drugs

Decision rationale: Medical treatment guideline identifies Dicopanol as diphenhydramine hydrochloride in oral suspension kit. The MTUS does not address the issue. ODG identifies that co-packs are convenience packaging of a medical food product and a generic drug into a single package that requires a prescription. While the generic drug is FDA-approved, the co-pack of a medical food and FDA-approved drug is not unless the manufacturer obtains FDA approval for the product as a new drug. There are no high quality medical studies to evaluate co-packs on patient outcomes. Therefore, based on guidelines and a review of the evidence, the request for Dicopanol (diphenhydramine) 5mg/ml 150ml #1 is not medically necessary.