

Case Number:	CM14-0185404		
Date Assigned:	11/13/2014	Date of Injury:	07/02/2013
Decision Date:	12/19/2014	UR Denial Date:	10/08/2014
Priority:	Standard	Application Received:	11/06/2014

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 Orthopedic Surgery 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 64-year-old male with a 7/2/13 date of injury. At the time (9/11/14) of request for authorization for Cyclobenzaprine 5 percent cream, 100 g, apply three times per day for muscle spasms, Synapryn 10 mg /1 ml oral suspension, 500 ml, 1 tsp three times per day as directed for pain, Tabradol 1mg/ml oral suspension 250 ml, 1 tsp 2-3 times per day for muscle spasms, and Ketoprofen 20 percent cream 165 g, apply three times per day for inflammation, there is documentation of subjective (right knee residual pain following right knee meniscus repair surgery) and objective (decreased right knee flexion, decreased sensation at the L4, L5, and S1 dermatomes in the right lower extremity, and 4/5 motor strength in the right lower extremity) findings, current diagnoses (status post right knee meniscus repair with residual pain), and treatment to date (right knee surgery and physical modalities).

IMR ISSUES, DECISIONS AND RATIONALES

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

Cyclobenzaprine 5 percent cream, 100 g, apply three times per day for muscle spasms:
Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 113.

Decision rationale: MTUS Chronic Pain Medical Treatment Guidelines identifies that there is no evidence for use of any muscle relaxant as a topical product. Therefore, based on guidelines and a review of the evidence, the request for Cyclobenzaprine 5 percent cream, 100 g, apply three times per day for muscle spasms is not medically necessary.

Synapryn 10 mg/1 ml oral suspension, 500 ml, 1 tsp three times per day as directed for pain: Upheld

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

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://www.drugs.com/cons/fusepaq-synapryn.html>

Decision rationale: Medical Treatment Guidelines identify Synapryn as Tramadol hydrochloride, in oral suspension with glucosamine-compounding kit. 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 10 mg/1 ml oral suspension, 500 ml, 1 tsp three times per day as directed for pain is not medically necessary.

Tabradol 1mg/ml oral suspension 250 ml, 1 tsp 2-3 times per day for muscle spasms: Upheld

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

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. 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 oral suspension 250 ml, 1 tsp 2-3 times per day for muscle spasms is not medically necessary.

Ketoprofen 20 percent cream 165 g, apply three times per day for inflammation: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112.

Decision rationale: MTUS Chronic Pain Medical Treatment Guidelines identifies that Ketoprofen is not currently FDA approved for a topical application. Therefore, based on guidelines and a review of the evidence, the request for Ketoprofen 20 percent cream 165 g, apply three times per day for inflammation is not medically necessary.