

Case Number:	CM14-0025119		
Date Assigned:	06/11/2014	Date of Injury:	05/27/2011
Decision Date:	07/15/2014	UR Denial Date:	01/27/2014
Priority:	Standard	Application Received:	02/27/2014

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 Physical Medicine and Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in New York and Texas. 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 69 year old male injured on 5/27/11 while climbing stairs at the plant when he experienced a pop in his left knee. He was able to hold onto the hand rail and did not fall. However, he twisted his low back. Records indicate he was seen by his primary care provider and he was ultimately placed off work on 05/27/11. He is noted to have received physical therapy, acupuncture, and chiropractic treatments. He was recommended to undergo left knee surgery. The clinical records note that on 10/16/13, the injured worker underwent an esophagogastroduodenoscopy with biopsy and colonoscopy. He is noted to have gastroesophageal reflux disease. He subsequently had been diagnosed with right shoulder impingement syndrome, right shoulder labral tear, lumbar spine spondylosis, lumbar sprain/strain, and right knee internal derangement. The most recent clinical note is dated 03/24/14. At this time, the injured worker presents with complaints of bilateral knee pain graded as 7/10 on the visual analog scale. On examination of the knees, the injured worker has tenderness to palpation over the medial knee. Right knee range of motion is 0 to 130. Left knee range of motion is 0 to 130. McMurray's test with internal and external rotation is reported to be positive bilaterally. The record contains a utilization review determination dated 01/27/14 in which requests for 1 bottle of Capsaicin 0.025%, Flurbiprofen 15%, Tramadol 15%, Menthol 2%, and Camphor 2%, 240 grams; 1 bottle of Flurbiprofen 25% and Cyclobenzaprine 0.2%, 240 grams; prescription for 60 tablets of Sentra; and a prescription for 2 bottles of Theramine were non-certified.

IMR ISSUES, DECISIONS AND RATIONALES

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

PRESCRIPTION FOR 1 BOTTLE OF CAPSAICIN 0.025%, FLURBIPROFEN 15%, TRAMADOL 15%, MENTHOL 2%, AND CAMPHOR 2% 240 GRAMS: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chapter 9 Shoulder Complaints, Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Compounded Medications.

Decision rationale: The request for 1 bottle of Capsaicin 0.025%, Flurbiprofen 15%, Tramadol 15%, Menthol 2%, and Camphor 2%, 240 grams is not medically necessary. The submitted clinical records indicate that the injured worker sustained injuries to the knee and low back on 05/27/11. Per California Medical Treatment Utilization Schedule, the Official Disability Guidelines and US FDA do not recommend the use of compounded medications as these medications are noted to be largely experimental in use with few randomized controlled trials to determine efficacy or safety. Further, the FDA requires that all components of a transdermal compounded medication be approved for transdermal use. This compound contains: Flurbiprofen and Tramadol which have not been approved by the FDA for transdermal use. Any compounded product that contains at least one drug (or drug class) that is not recommended and therefore not medically necessary.

PRESCRIPTION FOR 1 BOTTLE OF FLURBIPROFEN 25% AND CYCLOBENZAPRINE 0.2% 240 GRAMS: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints, Chapter 12 Low Back Complaints, Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Compounded Medications.

Decision rationale: The request for 1 bottle of Flurbiprofen 25%, Cyclobenzaprine 0.2%, 240 grams is not supported as medically necessary. The submitted clinical records indicate that the injured worker sustained injuries to the knee and low back on 05/27/11. Per California Medical Treatment Utilization Schedule, the Official Disability Guidelines and US FDA do not recommend the use of compounded medications as these medications are noted to be largely experimental in use with few randomized controlled trials to determine efficacy or safety. Further, the FDA requires that all components of a transdermal compounded medication be approved for transdermal use. This compound contains Flurbiprofen and Cyclobenzaprine which

have not been approved by the FDA for transdermal use. Any compounded product that contains at least one drug (or drug class) that is not recommended and therefore not medically necessary.

PRESCRIPTION FOR 60 TABLETS OF SENTRA: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter and Non-MTUS FDA Website, www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/.

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, Medical Foods.

Decision rationale: The request for 60 tablets of Sentra is not supported as medically necessary. Sentra is classified as a medical food and there is no substantive data to establish the benefit of this supplement. As such, medical necessity is not established.

PRESCRIPTION FOR 2 BOTTLES OF THERAMINE (90 TABLETS): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter and Non-MTUS FDA Website, www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/.

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, Medical Foods.

Decision rationale: The request for 2 bottles of Theramine, 90 tablets is not supported as medically necessary. Theramine is a medical food. The efficacy of this food has not been established through rigorous clinical trials and as such, is not supported as medically necessary.