

Case Number:	CM15-0024635		
Date Assigned:	02/17/2015	Date of Injury:	11/17/2005
Decision Date:	03/30/2015	UR Denial Date:	01/14/2015
Priority:	Standard	Application Received:	02/09/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
 State(s) of Licensure: California
 Certification(s)/Specialty: Emergency Medicine

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, who sustained an industrial injury on November 17, 2005. He has reported an injury to his right hip and back. The diagnoses have included right knee internal derangement, a history of right knee anterior cruciate ligament tear, and right knee advanced/end-stage osteoarthritis. Treatment to date has included x-rays, MRI, electrodiagnostic studies, urine drug testing, physical therapy, acupuncture, and medications that included a muscle relaxant, a non-steroidal anti-inflammatory, a topical non-steroidal anti-inflammatory/muscle relaxant, and a topical compounded medication. On December 10, 2014, the treating physician noted pain of the right knee. The pain was rated 4/10, which was improved from since the prior visit when it was 6/10. The physical exam revealed grade 2 tenderness to palpation of the right knee, decreased from grade 3 on the last visit. The range of motion was decreased, and the anterior drawer and McMurray's test were positive. The injured worker walked with a cane. Urine Drug Screen collected on 12/10/14 was appropriate. On February 9, 2015, the injured worker submitted an application for IMR for review of requests for 1 prescription for Fluriflex 180gm, apply a thin layer to the affected area two times a day; 1 prescription for TGHOT 180gm, apply a thin layer to the affected area two times a day; Extracorporeal Shock Wave Therapy (ECSWT) to the right knee once a week for 4 weeks; and a urine toxicology. The Fluriflex was non-certified based on lack of evidence that the patient has been refractory to or intolerant of standard oral medications. Fluriflex contains Flurbiprofen and cyclobenzaprine. Topical non-steroidal anti-inflammatory drugs are only recommended for the acute phase of treatment and only in joints amenable to topical treatment, which does not include

the spine, hip, or shoulder. The only (Food and Drug Administration) approved topical non-steroidal anti-inflammatory drug currently is diclofenac. Topical muscle relaxants are not recommended by the guidelines. The TGHOT (Tramadol/Gabapentin, Menthol/Camphor/Capsaicin) was non-certified based on when any compounded product contains at least one drug that is not recommended the entire compounded cream is not recommended. Gabapentin is not recommended for use as a topical product. Topical menthol is available over the counter and does not need to be combined with these other agents. There was no of evidence that the patient has been refractory to or intolerant of standard oral medications. Topical capsaicin is only recommended as an option in patients who have not responded to other treatments. The Extracorporeal Shock Wave Therapy was non-certified based on lack of support in the medical literature for the use of extracorporeal shock wave therapy for this patient's diagnoses. The urine toxicology was non-certified based on lack of documentation of any indicators for a potential abuse/adverse behavior, or prior inconsistent urine drug screen results to support the request, and the lack of evidence of opioids and/or controlled substances being prescribed for this patient that would require monitoring. The California Medical Treatment Utilization Schedule (MTUS): Chronic Pain Medical Treatment Guidelines, ACOEM (American College of Occupational and Environmental Medicine) Guidelines and the Official Disability Guidelines (ODG) were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Fluriflex 180gm, apply a thin layer to the affected areas two times per day (prescribed 12/10/14): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: Fluriflex is a non-FDA compounded product containing Flurbiprofen and Flexeril. As per MTUS guidelines "Any compound product that contains a drug or drug class that is not recommended is not recommended." 1) Flurbiprofen: Topical NSAIDs are shown to be superior to placebo. It should not be used long term. It may be useful. Flurbiprofen is not FDA approved for topical application. There is no justification by the provider as to why the patient requires a non-FDA approved compounded NSAID when there are multiple other approved products including over the counter medications on the market. Flurbiprofen is not medically necessary. 2) Cyclobenzaprine is not FDA approved for topical use. It is not recommended. There is no evidence for efficacy as a topical product. This non-evidence based compounded product is not medically necessary.

TG HOT 180mg, apply a thin layer to the affected areas 2 times per day (prescribed 12/10/14): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: TGHOT is a non-FDA approved compounded product containing Tramadol, Gabapentin and Capsaicin. As per MTUS guidelines "Any compound product that contains a drug or drug class that is not recommended is not recommended." 1)Tramadol: As per MTUS Chronic pain guidelines, topical Tramadol is not an FDA approved application. It is a compounded off-label product. As per MTUS guidelines, only FDA approved products are recommended. Topical Tramadol has no good evidence for efficacy or safety. Topical compound tramadol is not medically necessary. 2)Gabapentin: As per MTUS guidelines, it is not recommended with no evidence to support its use as a topical product. 3)Capsaicin: Data shows efficacy in muscular skeletal pain and may be considered if conventional therapy is ineffective. There is no documentation of treatment failure or a successful trial of capsaicin. It is not recommended. 4)Menthol/Camphor: There is no data on Menthol in the MTUS. Since multiple substances are not recommended; TGHOT is not medically necessary.

Extra Corporal Shock Wave Therapy (ESWT) to the right knee once a week for 4 weeks:
Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Knee Chapter, Extracorporeal shock wave therapy (ESWT)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG: Knee and Leg: Extracorporeal Shockwave Therapy(ESWT)

Decision rationale: MTUS Chronic pain and ACOEM Guidelines do have any sections that relate to this topic. As per Official Disability Guidelines, ESWT is under study for patellar tendinopathy and for long-bone hypertrophic nonunions. This patient does not have a diagnosis of findings that meets current guidelines for treatment. ESWT for R knee is not medically necessary.

Urine Toxicology: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78.

Decision rationale: As per MTUS Chronic pain guidelines, drug screening may be appropriate as part of the drug monitoring process. There is no concern for abuse. Patient had a recent UDS

done on 12/14 that was benign. There is no rationale documented for request. Urine Toxicology Screen is not medically necessary.