

Case Number:	CM15-0195505		
Date Assigned:	10/09/2015	Date of Injury:	04/13/2011
Decision Date:	12/11/2015	UR Denial Date:	09/24/2015
Priority:	Standard	Application Received:	10/05/2015

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 57 year old male, who sustained an industrial injury on 4-13-11. The injured worker is being treated for right knee medial meniscus tear, chondromalacia of patella, left knee overuse syndrome, bilateral shoulder posttraumatic arthrosis of acromioclavicular joint, stress, depression, anxiety, insomnia, gastrointestinal disease, C5-6 (HNP) herniated nucleus pulposus, right wrist sprain, status post arthroscopic right knee surgery, status post left and right shoulder arthroscopic surgery. Urine drug screen performed on 5-29-15 was inconsistent for Xanax. Treatment to date has included right shoulder surgery, post-op physical therapy, oral medications including Norco, Xanax and Prilosec, topical Ketoprofen, Gabapentin and Tramadol; and activity modifications. On 6-25-15, the injured worker complained of severe pain in right shoulder, mild wrist pain, moderate left shoulder pain and mild pain in right knee and on 8-13-15, the injured worker complains of moderate shoulder pain on right and left side of neck, mild right wrist pain and mild right knee pain. He is not working. Physical exam performed on 6-25-15 revealed slightly restricted range of motion of right shoulder with diminished right hand grip and on 8-13-15 revealed slightly restricted range of motion of cervical spine with stiffness and diminished right hand grip. The treatment plan included continuation of physical therapy, refilling of Xanax 1mg #60, Prilosec 20mg #90, topical Ketoprofen, Gabapentin and Tramadol, functional capacity evaluation and urine toxicology test. On 9-24-15 request for Xanax 1mg #60, topical Ketoprofen, Gabapentin and Tramadol, functional capacity evaluation and urine toxicology test was non-certified by utilization review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Topical cream: Ketoprofen: 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 (Chronic)/Ketoprofen, topical.

Decision rationale: The request is for the use of Ketoprofen topically. The official disability guidelines state the following regarding this topic: Not recommended in the U.S., as there are currently no FDA-approved versions of this product, but it is a first-line drug in Europe. See Topical analgesics, Non-steroidal antiinflammatory agents (NSAIDs), and the ketoprofen topical listing, for more information and references. Topical NSAIDs are generally recommended for short-term use for acute sprain/strains and longer term for osteoarthritis of the knee and hand, particularly in individuals with risk for GI ulceration, but they are not indicated for treatment of the low back or neuropathic pain. At this time, the only available FDA-approved topical NSAID is diclofenac, but recent high quality studies have identified a dangerous increased risk profile with diclofenac, including topical formulations, making it a second-line recommended treatment in ODG. Topical ketoprofen has been approved by the European FDA (the European Medicines Agency), and the European EULAR and NICE guidelines state these approved formulations of topical ketoprofen should be a first-line treatment, and should be considered before oral NSAIDs because they have shown efficacy significantly superior to placebo and similar to oral NSAIDs, without the same risks of adverse effects. While there are no FDA approved formulations of topical ketoprofen available in the U.S., the product is available from compounding pharmacies. Compound medications are not FDA approved, but they are allowed under state pharmacy regulations. See Compound drugs. Because each compounding pharmacy may create their own version, FDA cannot be a source of information on safety and effectiveness of each version, or on generic equivalency. At this time, there are no high quality studies of any of the various pharmacy compounded formulations of topical ketoprofen available in the U.S. Also, while topical ketoprofen has been used extensively in Europe, in 2009 France removed this product from the market due to photosensitivity reactions. The drug has been reinstated, but this may be a serious problem. See the ketoprofen topical listing in Topical analgesics, Non-steroidal antiinflammatory agents. Note: Topical ketoprofen is not listed on the ODG Drug Formulary because the scope of the ODG Drug Formulary only includes FDA approved drugs. (Formulary Scope). In this case, the use of this medication is not guideline-supported. This is secondary to no FDA-approved versions of this product. As such, the request is not medically necessary.

Topical cream: Gabapentin 10gms and Tramadol 15gms: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: The request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients, which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The guidelines state "Gabapentin: Not recommended. There is no peer-reviewed literature to support use." In this case, the use of gabapentin is not indicated for use for the patient's condition. This is secondary to poor clinical evidence of efficacy. As such, the request is not medically necessary.

Urine toxicology screen: 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 (Chronic)/Urine drug testing (UDT).

Decision rationale: The request is for a urine drug screen. The ODG states the following regarding this topic: Recommended as a tool to monitor compliance with prescribed substances, identify use of undisclosed substances, and uncover diversion of prescribed substances. The test should be used in conjunction with other clinical information when decisions are to be made to continue, adjust or discontinue treatment. This information includes clinical observation, results of addiction screening, pill counts, and prescription drug monitoring reports. The prescribing clinician should also pay close attention to information provided by family members, other providers and pharmacy personnel. The frequency of urine drug testing may be dictated by state and local laws. Indications for UDT: At the onset of treatment: (1) UDT is recommended at the onset of treatment of a new patient who is already receiving a controlled substance or when chronic opioid management is considered. Urine drug testing is not generally recommended in acute treatment settings (i.e. when opioids are required for nociceptive pain). (2) In cases in which the patient asks for a specific drug. This is particularly the case if this drug has high abuse potential, the patient refuses other drug treatment and/or changes in scheduled drugs, or refuses generic drug substitution. (3) If the patient has a positive or "at risk" addiction screen on evaluation. This may also include evidence of a history of comorbid psychiatric disorder such as depression, anxiety, bipolar disorder, and/or personality disorder. See Opioids, screening tests for risk of addiction & misuse. (4) If aberrant behavior or misuse is suspected and/or detected. See Opioids, indicators for addiction & misuse. Ongoing monitoring: (1) If a patient has evidence of a "high risk" of addiction (including evidence of a comorbid psychiatric disorder (such as depression, anxiety, attention-deficit disorder, obsessive-compulsive disorder, bipolar disorder, and/or schizophrenia), has a history of aberrant behavior, personal or family history of substance dependence (addiction), or a personal history of sexual or physical trauma, ongoing urine drug testing is indicated as an adjunct to monitoring along with clinical exams and pill counts. See Opioids, tools for risk stratification & monitoring. (2) If dose increases are not

decreasing pain and increasing function, consideration of UDT should be made to aid in evaluating medication compliance and adherence. The frequency of drug testing is indicated below: Patients at "low risk" of addiction/aberrant behavior should be tested within six months of initiation of therapy and on a yearly basis thereafter. There is no reason to perform confirmatory testing unless the test is inappropriate or there are unexpected results. If required, confirmatory testing should be for the questioned drugs only. Patients at "moderate risk" for addiction/aberrant behavior are recommended for point-of-contact screening 2 to 3 times a year with confirmatory testing for inappropriate or unexplained results. This includes patients undergoing prescribed opioid changes without success, patients with a stable addiction disorder, those patients in unstable and/or dysfunction social situations, and for those patients with comorbid psychiatric pathology. Patients at "high risk" of adverse outcomes may require testing as often as once per month. This category generally includes individuals with active substance abuse disorders. In this case, a urine drug screen is not supported by the guidelines. This is secondary to inadequate documentation of risk level commensurate to the frequency of evaluation requested. As such, it is not medically necessary.

Functional capacity evaluation (FCE): 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) Fit for Duty/Functional capacity evaluation.

Decision rationale: The request is for a functional capacity evaluation. The MTUS guidelines are silent regarding this issue. The ODG state the following: Guidelines for performing an FCE: Recommended prior to admission to a Work Hardening (WH) Program, with preference for assessments tailored to a specific task or job. If a worker is actively participating in determining the suitability of a particular job, the FCE is more likely to be successful. A FCE is not as effective when the referral is less collaborative and more directive. It is important to provide as much detail as possible about the potential job to the assessor. Job specific FCEs are more helpful than general assessments. The report should be accessible to all the return to work participants. Consider an FCE if 1) Case management is hampered by complex issues such as: Prior unsuccessful RTW attempts. Conflicting medical reporting on precautions and/or fitness for modified job. Injuries that require detailed exploration of a worker's abilities. 2) Timing is appropriate: Close or at MMI/all key medical reports secured. Additional/secondary conditions clarified. Do not proceed with an FCE if The sole purpose is to determine a worker's effort or compliance. The worker has returned to work and an ergonomic assessment has not been arranged. (WSIB, 2003) In this case a functional capacity evaluation is not indicated. There is inadequate documentation of the patient and employer actively participating in determining the suitability of a particular job. As such, the request is not medically necessary.

Xanax 1mg, #60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Benzodiazepines.

Decision rationale: The request is for the use of a medication in the category of benzodiazepines. It is usually indicated to treat anxiety disorders but has been used short-term as a muscle relaxant. The MTUS guidelines state the following: Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005) In this case, a medication in this class would not be advised for continued use due to the duration of therapy. As such, the request is not medically necessary. All benzodiazepine medications should be titrated down slowly to prevent an acute withdrawal syndrome.