MAXIMUS Federal Services

Case Number:	CM15-0210515		
Date Assigned:	10/29/2015	Date of Injury:	06/27/2015
Decision Date:	12/15/2015	UR Denial Date:	09/29/2015
Priority:	Standard	Application Received:	10/26/2015

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: Internal 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 54 year old female, who sustained an industrial injury on 6-27-2015. Diagnoses include head pain, cervical, thoracic, and lumbosacral strain-sprain, bilateral shoulder strain-sprain, bilateral hand strain, bilateral knee strain, rule out bilateral knee meniscal tear, and bilateral ankle strain. Treatments to date include activity modification, medication therapy, and physical therapy. On 9-3-15, she complained of ongoing pain in the neck, mid and upper back; lower back, bilateral shoulders, knees, and ankles. Pain was rated 5 out of 10 VAS, improved from 7 out of 10 VAS at the last visit. The physical examination documented tenderness, muscle spasms and restricted range of motion and multiple findings consistent with subjective complaints. The records submitted did not include any documentation regarding prior urine toxicology evaluation(s). The plan of care included continued physical therapy, prescriptions for Relafen and Fexmid, and a urine toxicology test for medication monitoring. The appeal requested authorization for one urine toxicology (unclear if qualitative or quantitative testing is requested.) The Utilization Review dated 9-29-15, modified the request to allow one urine toxicology screen (qualitative study only unless unexpected outcome.)

IMR ISSUES, DECISIONS AND RATIONALES

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

Urine Toxicology (Unclear if qualitative or quantitative testing is requested): 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).

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: Based on ODG guidelines, the Criteria for Use of Urine Drug Testing is as follow: Urine drug tests may be subject to specific drug screening statutes and regulations based on state and local laws, and the requesting clinician should be familiar with these. State regulations may address issues such as chain of custody requirements, patient privacy, and how results may be used or shared with employers. The rules and best practices of the U.S. [redacted] should be consulted if there is doubt about the legally defensible framework of most jurisdictions. [redacted], 2010) 1. A point-of-contact (POC) immunoassay test is recommended prior to initiating chronic opioid therapy. This is not recommended in acute care situations (i.e. for treatment of nociceptive pain). There should be documentation of an addiction-screening test using a formal screening survey in the records prior to initiating treatment. If the test is appropriate, confirmatory lab testing is not required. See Opioids, screening tests for risk of addiction & misuse. 2. Frequency of urine drug testing should be based on documented evidence of risk stratification including use of a testing instrument. See Opioids, tools for risk stratification & monitoring. An explanation of "low risk," "moderate risk," and "high risk" of addiction/aberrant behavior is found under Opioids, tools for risk stratification & monitoring and Opioids, screening tests for risk of addiction & misuse. 3. 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. 4. 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. 5. 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. 6. If a urine drug test is negative for the prescribed scheduled drug, confirmatory testing is strongly recommended for the questioned drug. If negative on confirmatory testing the prescriber should indicate if there is a valid reason for the observed negative test, or if the negative test suggests misuse or non-compliance. Additional monitoring is recommended including pill counts. Recommendations also include measures such as prescribing fewer pills and/or fewer refills. A discussion of clinic policy and parameters in the patient's opioid agreement is recommended. Weaning or termination of opioid prescription should be considered in the absence of a valid explanation. See Opioids, dealing with misuse & addiction. 7. If a urine drug test is positive for a non-prescribed scheduled drug or illicit drug, lab confirmation is strongly recommended. In addition, it is recommended to obtain prescription drug monitoring reports. If there is evidence of problems with cross-state border drug soliciting in your area, reports from surrounding states should be obtained if possible. Other options

include contacting pharmacies and different providers (depending on the situation). Reiteration of an opioid agreement should occur. Weaning or termination of opioid prescription should be considered in the absence of a valid explanation. 8. Urine drug testing positive for illicit drugs places a patient in a "high risk" category. 9. If unexpected results are found, documentation of the ensuing conversation, including patient's exp lanation should be made. 10. Documentation should make evident the reason(s) that confirmatory tests are required. This includes information about the actual classes of drugs requested for testing. 11. There should be specific documentation for the necessity of confirmatory testing of drug class panels such as antidepressants, benzodiazepines, acetaminophen and salicylates. Routine confirmatory screening of these classes of drugs is generally reserved for emergency department testing for overdose patients. 12. If UDT is a standard protocol for in-office use, it is recommended that the clinician establish a routine immunoassay panel. Standard drug classes recommended include cocaine metabolite, amphetamines, opiates (morphine, codeine and 6-MAM), opioids (oxycodone and methadone), marijuana (delta-9-THC), barbiturates and benzodiazepines. In settings where there is frequent use of other drugs, particularly semi-synthetic or synthetic opioids, these should be added. Drugs of abuse in your community should also be included. 13. Prescribers may wish to request limit of detection testing (i.e. decreased thresholds) to increase the likelihood of detecting prescribed drugs. This is particularly important for patients on intrathecal drugs as well as for patients on fentanyl patches. In this case, there is no documentation of aberrant behavior or misuse of medications. The request for urine toxicology was modified and approved for a qualitative test. Therefore, based on ODG guideline and the evidence in this case, the request for Urine toxicology is not medically necessary.

Relafen (Nabumetone)750mg 1 tab PO BID with food # 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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): Nabumetone, NSIADs.

Decision rationale: Based on ODG guidelines, the indications for is as follows: Nabumetone (Relafen, generic available): 500, 750 mg. Dosing: Osteoarthritis: The recommended starting dose is 1000 mg PO. The dose can be divided into 500 mg PO twice a day. Additional relief may be obtained with a dose of 1500 mg to 2000 mg per day. The maximum dose is 2000 mg/day. Patients weighing less than 50 kg may be less likely to require doses greater than 1000 mg/day. The lowest effective dose of nabumetone should be sought for each patient. Use for moderate pain is off-label. As far as NSAIDs go, the indications are as follows: For Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection

is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008) Back Pain - Acute low back pain & acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative evidence that NSAIDs are more effective than acetaminophen for acute LBP. (van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain, this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in patients with neuropathic pain. (Namaka, 2004) (Gore, 2006) See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & Medications for acute pain (analgesics). Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. (Maro on, 2006) The risks of NSAIDs in older patients, which include increased cardiovascular risk and gastrointestinal toxicity, may outweigh the benefits of these medications. In this case, the patient has been on Nabumetone for at least 3 months and there is no documentation failure with acetominophen. NSAIDs are only recommended for short-term use and not for ongoing chronic pain. Therefore, based on the evidence in this case and the ODG guidelines, the request for Nabumetone 750 mg 1 tab po bid with food #60 is not medically necessary.

Fexmid (Cyclobenzaprine) 15 mg 1 Tab PO QHS PRN #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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): Cyclobenzaprine (Flexeril).

Decision rationale: Based on ODG guidelines, Flexeril is recommended as an option, using a short course of therapy. See Medications for subacute & chronic pain for other preferred options. Cyclobenzaprine (Flexeril) is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief; this medication is not recommended for longer than 2-3 weeks. There is also a post-op use. The addition of cyclobenzaprine to other agents is not recommended. (Clinical Pharmacology, 2008) Cyclobenzaprine-treated patients with fibromyalgia were 3 times as likely to report overall improvement and to report moderate reductions in individual symptoms, particularly sleep. (Tofferi, 2004) Note: Cyclobenzaprine is closely related to the tricyclic antidepressants, e.g., amitriptyline. See Antidepressants. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement in LBP and is associated with drowsiness and dizziness. (Kinkade, 2007) Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant that is marketed as Flexeril by [redacted]. In this case, the patient has been on cyclobenzaprine for at least 3 months with some benefit. However, muscle relaxants are only recommended for short-term use for no longer than 2-3 weeks. Therefore, based on ODG guidelines and the evidence in this case, the request for Fexmid (Cylcobenzaprine) 15 mg 1 tab po QHS #30 is not medically necessary.