MAXIMUS Federal Services

Case Number:	CM15-0166872		
Date Assigned:	09/04/2015	Date of Injury:	09/03/2008
Decision Date:	11/02/2015	UR Denial Date:	08/17/2015
Priority:	Standard	Application Received:	08/25/2015

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, District of Columbia, Maryland
Certification(s)/Specialty: Anesthesiology, Pain Management

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 48-year-old male who sustained an industrial injury on September 03, 2008. A secondary treating office visit dated June 29, 2015 reported previous authorization received to undergo lumbar spine surgery and on the day of presentation, his blood pressure dropped cancelling the procedure. He has subsequently been treated by cardiology with note of having an elevated A1C hemoglobin level putting him at high risk for surgery. He then had to undergo a small procedure to drain an abscess and his blood pressure dropped significantly again which could be related to poorly-controlled diabetes. He continues with subjective complaint of pain in left leg lateral thigh and posterior thigh. The following diagnoses were applied to this visit: low back and left leg radicular pain; left sided herniated disc; broad-bulging disc with moderate stenosis. The plan of care noted considering surgery if diabetes is controlled. A recent primary treating office visit dated July 22, 2015 reported chief subjective complaint of lower back pain. It radiates down into the left leg with weakness and numbness. The plan of care is with recommendation for follow up visit at the end of September, and topical compound cream containing: Flurbiprofen, Baclofen, Lidocaine cream 180GM. The following noted prescribed this visit: Tylenol #3 9 Codeine and Acetaminophen. Primary follow up dated February 27, 2015 reported the following prescribed at this visit: Tylenol #3 "in attempt to have some pain control for the patient as he is a surgical candidate regarding the spine and pathology in the right knee." Subjective complaint stated: persistent pain in the lower back", along with "pain in the right knee". On March 03, 2015 a request for services involving medications: topical compound cream containing Flurbiprofen, Baclofen, and Lidocaine cream 180GM, and Tylenol #3 #90 1-2 tablets every 6-8 hours as needed for pain was modified to offer only #60 and topical compound cream with non- certification. Previous review noted short acting Opioids use for short term as a second

line of treatment. Topical compounds are used for neuropathic pain when trials of anti-convulsant and anti-depressants have failed.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tylenol #3 (codeine/APAP acetaminophen 30/300 mg) Qty 90, 1-2 every 6-8 hrs as needed for pain: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

Decision rationale: Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding on-going management of opioids "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: Pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug related behaviors. These domains have been summarized as the "4 A's" (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." Review of the available medical records reveals no documentation to support the medical necessity of Tylenol #3 or any documentation addressing the "4 A's" domains, which is a recommended practice for the on-going management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement, appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. UDS dated 1/23/15 was negative for prescribed Hydrocodone. It was noted that this was because it was not covered by insurance and the injured worker could not afford to pay it on his own. As MTUS recommends discontinuing opioids if there is no overall improvement in function, the request is not medically necessary.

Flurbiprofen 20%, Baclofen 5%, Lidocaine 4%, in cream base, 180gm: Upheld

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

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

Decision rationale: Per MTUS with regard to Flurbiprofen (p112), "These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." Flurbiprofen may be indicated. Per MTUS p113 with

regard to topical Baclofen, "Baclofen: Not recommended. There is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical Baclofen. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Baclofen is not indicated. Regarding topical lidocaine, MTUS states (p112) "Neuropathic pain: Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. (Scudds, 1995)." Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. As Baclofen is not recommended, the compound is not medically necessary.