MAXIMUS Federal Services

Case Number:	CM15-0166443		
Date Assigned:	09/04/2015	Date of Injury:	01/14/2013
Decision Date:	10/09/2015	UR Denial Date:	07/30/2015
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 51 year old male, who sustained an industrial injury on 1-14-13. The diagnoses have included low back pain with radiating symptoms to the right lower extremity (RLE), right sacroiliac joint arthropathy, and rule out lumbar spondylosis. Treatment to date has included medications, heat, physical therapy, acupuncture and chiropractic. Currently, as per the physician progress note dated 7-28-15, the injured worker complains of low back pain that radiates to the right lower extremity (RLE) with numbness and tingling. The current medications included Norco, Flexeril and compound analgesic cream. The objective findings-physical exam reveals that there is tenderness over the spinous process of the lumbar spine, tenderness over the posterior superior iliac spine bilaterally, tenderness over the sacroiliac joints on the right side, and tenderness over the facet joints. The straight leg raise is positive on the right side at 50 degrees and causes back pain in the supine position. The Fabere test is positive on the right side, the range of motion of the lumbar spine with flexion is 45 out of 80 degrees, extension is 30 out of 45 degrees, right and left tilt is 40 out of 45 degrees, and right and left rotation is 40 out of 45 degrees. The physician requested treatment included Flexeril 5 mg quantity of 60, Norco 10-325 mg quantity of 60 and Analgesic cream (Flurbiprofen 15%, Cyclobenzaprine 10%, Baclofen 2%, Lidocaine 5%), 180 grams.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flexeril 5 mg Qty 60: 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): Muscle relaxants (for pain).

Decision rationale: With regard to muscle relaxants, the MTUS CPMTG states: "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement." Regarding Cyclobenzaprine: "Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects." Per p41 of the MTUS guidelines the effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Treatment is recommended for the treatment of acute spasm limited to a maximum of 2-3 weeks. UDS that evaluate for cyclobenzaprine can provide additional data on whether the injured worker is compliant, however in this case there is no UDS testing for cyclobenzaprine. The documentation submitted for review indicates that the injured worker has been using this medication since at least 4/2015. There is no documentation of the patients' specific functional level or percent improvement with treatment with cyclobenzaprine. As it is recommended only for short-term use, medical necessity cannot be affirmed.

Norco 10/325 mg Qty 60: 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 Norco nor 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. Furthermore, efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe

usage and establish medical necessity. There is no documentation comprehensively addressing this concern in the records available for my review. As MTUS recommends to discontinue opioids if there is no overall improvement in function, medical necessity cannot be affirmed.

Analgesic cream (Flurbiprofen 15%, Cyclobenzaprine 10%, Baclofen 2%, Lidocaine 5%), 180 grams: 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 CPMTG p113, "There is no evidence for use of any other muscle relaxant as a topical product. [besides baclofen, which is also not recommended]" Cyclobenzaprine is not 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 several components are not recommended, the compound is not medically necessary.