

Case Number:	CM15-0023681		
Date Assigned:	02/13/2015	Date of Injury:	02/22/2002
Decision Date:	03/27/2015	UR Denial Date:	01/29/2015
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: District of Columbia, Virginia
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 70 year old male, who sustained an industrial injury on 2/22/2002. He has reported right leg and lower back. The diagnoses have included lumbosacral spine disc syndrome with radiculopathy, left knee multiple internal derangements including meniscus tear, left femoral neuropathy, and chronic pain syndrome with idiopathic insomnia. Treatment to date has included medication therapy. Currently, the Injured Worker complains of low back and left knee pain with good response to medication but documented as partial response. Physical examination from 1/14/15 documented reduced Range of Motion (ROM) lumbosacral spine and left knee with tenderness, reeducated sensation and strength left S1 nerve root, and reduced strength left femoral nerve. The plan of care included continuation of previously prescribed medications, and topical cream to reduce pain and inflammation. On 1/29/2015 Utilization Review non-certified Flexeril 10mg #60, Ketoprofen topical cream 1 TUBE, Norco 10/325mg #180, and Soma 350mg #350, noting the lack of documented response to prior treatment. The MTUS Guidelines were cited. On 2/9/2015, the injured worker submitted an application for IMR for review of Flexeril 10mg #60, Ketoprofen topical cream 1 TUBE, Norco 10/325mg #180, and Soma 350mg #350.

IMR ISSUES, DECISIONS AND RATIONALES

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

60 tablets of Flexeril 10mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792
Page(s): 41-42,64.

Decision rationale: Per MTUS: Cyclobenzaprine (Flexeril) Recommended as an option, using a short course of therapy. See Medications for 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. 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 Ortho McNeil Pharmaceutical. Cyclobenzaprine (Flexeril, Amrix, Fexmid, generic available): 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. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement. The greatest effect appears to be in the first 4 days of treatment. (Browning, 2001) (Kinkade, 2007) (Toth, 2004) See Cyclobenzaprine. Cyclobenzaprine has been shown to produce a modest benefit in treatment of fibromyalgia. Cyclobenzaprine-treated patients with fibromyalgia were 3 times more likely to report overall improvement and to report moderate reductions in individual symptoms (particularly sleep). A meta-analysis concluded that the number needed to treat for patients with fibromyalgia was 4.8. (ICSI, 2007) (Tofferi, 2004) Side Effects: Include anticholinergic effects (drowsiness, urinary retention and dry mouth). Sedative effects may limit use. Headache has been noted. This medication should be avoided in patients with arrhythmias, heart block, heart failure and recent myocardial infarction. Side effects limit use in the elderly. (See, 2008) (Toth, 2004) Dosing: 5 mg three times a day. Can be increased to 10 mg three times a day. This medication is not recommended to be used for longer than 2-3 weeks. (See, 2008) From the clinical documentation provided, it is not clear the duration for which this medication would be recommended. The patient was prescribed two muscle relaxants, soma and flexeril, and it is not clear why this would be medically indicated.

Ketoprofen topical cream (KW30 and K2030 creams): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792
Page(s): 72,112.

Decision rationale: Per MTUS: Ketoprofen 50, 75 mg, Ketoprofen ER 200 mg: Dosing: Osteoarthritis: Regular release capsule 50mg four times per day or 75mg three times per day (max 300mg/day). XR capsule 200mg once daily. Mild to moderate pain: Regular release capsule 50mg every 6 to 8 hours (Max 300mg/day), Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. (Krummel 2000) As per guidelines cited, this medication is not approved in the topical form and would not be recommended.

180 tablets of Norco 10/325mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792
Page(s): 75,79-94.

Decision rationale: Per MTUS, Hydrocodone/Acetaminophen (Anexsia, Co-Gesic, Hycet; Lorcet, Lortab; Margesic-H, Maxidone; Norco, Stagesic, Vicodin, Xodol, Zydone; generics available): Indicated for moderate to moderately severe pain. Note: there are no FDA-approved hydrocodone products for pain unless formulated as a combination. Side Effects: See opioid adverse effects. Analgesic dose: The usual dose of 5/500mg is 1 or 2 tablets PO every four to six hours as needed for pain (Max 8 tablets/day). For higher doses of hydrocodone (>5mg/tab) and acetaminophen (500mg/tab) the recommended dose is usually 1 tablet every four to six hours as needed for pain. Hydrocodone has a recommended maximum dose of 60mg/24 hours. The dose is limited by the dosage of acetaminophen, which should not exceed 4g/24 hours. The duration for which this patient has been on this medication was not established from the clinical documentation provided. A weaning procedure should be initiated as this medication has habit-forming effects.

350 tablets of Soma 350mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792
Page(s): 65.

Decision rationale: Per MTUS: Carisoprodol (Soma, Soprodal 350, Vanadom, generic available): Neither of these formulations is recommended for longer than a 2 to 3 week period. Carisoprodol is metabolized to meprobamate an anxiolytic that is a schedule IV controlled substance. Carisoprodol is classified as a schedule IV drug in several states but not on a federal level. It is suggested that its main effect is due to generalized sedation as well as treatment of anxiety. This drug was approved for marketing before the FDA required clinical studies to prove safety and efficacy. Withdrawal symptoms may occur with abrupt discontinuation. (See, 2008) (Reeves, 2003) For more details, see Carisoprodol, where it is Not recommended. See also Weaning of medications. Side Effects: drowsiness, psychological and physical dependence, & withdrawal with acute discontinuation. Dosing: 250 mg-350 mg four times a day. (See, 2008). This medication is recommended for a short trial and beyond that it would not be recommended. Furthermore, the duration for which the patient were to be on this medication is not clear from the clinical documentation provided.