

Case Number:	CM13-0060075		
Date Assigned:	01/08/2014	Date of Injury:	07/01/2011
Decision Date:	04/30/2014	UR Denial Date:	11/12/2013
Priority:	Standard	Application Received:	12/02/2013

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. The expert reviewer is Board Certified in Internal and Emergency Medicine and is licensed to practice in Florida. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This patient is a 36 year-old with a date of injury of 07/01/11. A progress report associated with the request for services, dated 10/31/13, identified subjective complaints of low back pain radiating into the lower extremities. Objective findings included tenderness to palpation of the lumbar spine with decreased sensation and weakness in both lower extremities. Diagnoses included lumbar disc disease with radiculitis. The assessment states that the patient's condition was "unimproved". Treatment has included physical therapy and oral analgesics that provide "mild relief of his symptoms." A Utilization Review determination was rendered on 11/12/13 recommending non-certification of, 60 FLEXERIL 7.5MG, 1 TWICE A DAY; 30 SOMNICIN, 1 AT BEDTIME; FLURBI CREAM, 180 GRAMS; 120 NORCO 10/325MG, 1 EVERY 6 HOURS AS NEEDED FOR PAIN.

IMR ISSUES, DECISIONS AND RATIONALES

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

60 FLEXERIL 7.5MG, 1 TWICE A DAY: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 64.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41-42, 63-66.

Decision rationale: Flexeril (cyclobenzaprine) is a non-sedating muscle relaxant. The Medical Treatment Utilization Schedule (MTUS) states that non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations of low back pain. They note that in most low-back pain cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also, there is no additional benefit shown in combination of NSAIDs. Likewise, the efficacy diminishes over time. The MTUS states that cyclobenzaprine (Flexeril), is indicated as a short course of therapy. Limited, mixed evidence does not allow a recommendation for cyclobenzaprine for chronic use. Though it is noted that cyclobenzaprine is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. They further state that treatment should be brief and that addition of cyclobenzaprine to other agents is not recommended. The Guidelines do note that cyclobenzaprine has been shown to produce a moderate benefit in the treatment of fibromyalgia. The record does not show any evidence of fibromyalgia, and other indications for cyclobenzaprine beyond a short course are not well supported. Likewise, it is being used in combination with other agents for which no additional benefit has been shown. Therefore, in this case, the medical record does not document the medical necessity for cyclobenzaprine (Flexeril).

30 SOMNICIN, 1 AT BEDTIME: 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), Medical Food

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Mental Illness & Stress; Insomnia Treatment, Insomnia Treatment

Decision rationale: Somnicin is a product of [REDACTED] and contains the active ingredients melatonin, a naturally occurring hypnotic, 5-HTP, which increases the levels of serotonin, L-tryptophan, an amino acid that may be useful as a sleep aid, vitamin B6, which promotes the production of serotonin, and magnesium, which the company states supports sleep. The Medical Treatment Utilization Schedule (MTUS) Guidelines do not specifically address hypnotics or these agents. The Official Disability Guidelines (ODG) state that treatment should be based upon etiology and only after careful evaluation of the potential causes of sleep disturbance. They do not specifically address the agents in Somnicin nor affirm their efficacy. Additionally, Somnicin contains agents that are available at recommended levels in a normal diet. In this case, there is no documentation of insomnia. Therefore, the medical record does not document the medical necessity for Somnicin.

FLURBI CREAM, 180 GRAMS: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical/Compound Analgesics Page(s): 111-112.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Topical Analgesics. GESICS, 111-113

Decision rationale: The MTUS Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." Flurbiprofen is an NSAID being used as a topical analgesic. The MTUS Guidelines note that the efficacy of topical NSAIDs in clinical trials has been inconsistent and most studies are small and of short duration. Recommendations primarily relate to osteoarthritis where they have been shown to be superior to placebo during the first two weeks of treatment, but either not afterward, or with diminishing effect over another two week period. The Guidelines also state that there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. They are indicated for relief of osteoarthritis pain in joints that lend themselves to treatment (ankle, elbow, foot, hand, knee, and wrist). The only FDA approved topical NSAID is diclofenac. The strength and frequency of the compound is not specified. Also in this case, there is no documented functional improvement for the medical necessity of flurbiprofen as an NSAID topical agent.

120 NORCO 10/325MG, 1 EVERY 6 HOURS AS NEEDED FOR PAIN: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 91.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-82. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Opioids for Chronic Pain

Decision rationale: Norco 10/325 is a combination drug containing acetaminophen and the opioid hydrocodone. The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines related to on-going treatment of opioids state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. The guidelines note that a recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of the key outcome goals including pain relief, improved quality of life, and/or improved functional capacity (Eriksen 2006). The Chronic Pain Guidelines also state that with chronic low back pain, opioid therapy "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (> 16 weeks), but also appears limited." Additionally, "There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain (Martell - Annals, 2007)." The MTUS Guidelines further state that opioid therapy is not recommended for the low back beyond 2 weeks. The patient has been on Norco in excess of 16 weeks. The Official Disability Guidelines (ODG) state: "While long-term opioid therapy may benefit some patients with severe suffering that has been refractory to other medical and psychological treatments, it is not generally effective achieving the original goals of complete pain relief and functional restoration." Therapy with Norco appears to be ongoing. The documentation submitted lacked a

number of the elements listed above, including the level of functional improvement afforded by the chronic opioid therapy. Therefore, the record does not demonstrate medical necessity for Norco.