MAXIMUS Federal Services

Case Number:	CM14-0047826		
Date Assigned:	06/25/2014	Date of Injury:	10/01/2002
Decision Date:	08/15/2014	UR Denial Date:	03/23/2014
Priority:	Standard	Application Received:	03/28/2014

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 Medicine & 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 43 year-old with a date of injury of 10/01/02. A progress report associated with the request for services, dated 01/21/14, identified subjective complaints of neck pain into the right arm and low back pain into the left leg. Objective findings included tenderness to palpation of the neck and low back as well as decreased range-of-motion. There was decreased sensation in the upper extremities and L5 dermatome. Diagnoses included cervical disc disease; lumbosacral radiculopathy; and shoulder pain. Treatment has included a cervical laminectomy as well as Soma, Ambien, and Percocet. A Utilization Review determination was rendered on 03/23/14 recommending non-certification of "Percocet 10/325 mg #180; Ambien 10 mg #30; Keto/Baclofen/Lido/Gaba one (1) bottle 10/1/4/10%; and Robaxin 750 mg #90".

IMR ISSUES, DECISIONS AND RATIONALES

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

Percocet 10/325 mg #180: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308,Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

Decision rationale: Percocet is a combination of the opioid oxycodone and acetaminophen. The California Medical Treatment Utilization Schedule (MTUS) 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. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. 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 documentation submitted lacked a number of the elements listed above, including the level of functional improvement afforded by the chronic opioid therapy. The 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 opioids in excess of 16 weeks.In this case, there is no documentation of the other elements of the pain assessment referenced above for necessity of therapy beyond 16 weeks, where the evidence is otherwise unclear. Therefore, there is no documented medical necessity for Percocet.

Ambien 10 mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Pain (Chronic).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Insomnia Treatment; and Mental Illness & Stress, Zolpidem (Ambien) Other Medical Treatment Guideline or Medical Evidence: www.Ambien.com.

Decision rationale: Ambien (zolpidem) is a non-benzodiazepine gamma-aminobutyric acid (GABA) agonist used for the short-term treatment of insomnia. The Medical Treatment Utilization Schedule (MTUS) does not specifically address zolpidem. The Official Disability Guidelines (ODG) states that treatment of insomnia should be through correction of underlying deficits. They further note that zolpidem is indicated for short-term treatment of insomnia. They note that zolpidem has multiple side effects and adults who use zolpidem have a greater than 3-fold increased risk for early death (Kripke, 2012). Likewise, the FDA has recommended lower doses for IR release products in women (10 mg to 5 mg) and a decrease from 12.5 mg to 6.25 mg for extended-release products (Ambien CR).In this case, Ambien has been used beyond the short-term; likewise, at greater than recommended doses. Therefore, the record does not document the medical necessity for Ambien.

Keto/Baclofen/Lido/Gaba one (1) bottle 10/1/4/10%: Upheld

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

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.

Decision rationale: The Medical Treatment Utilization Schedule (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."Ketoprofen 10% 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 or 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). In neuropathic pain, they are not recommended as there is no evidence to support their use. The Official Disability Guidelines (ODG) also does not recommend them for widespread musculoskeletal pain. The only FDA approved topical NSAID is diclofenac. Ketoprofen is not approved and "... has an extremely high incidence of photocontact dermatitis and photosensitization reactions."Gabapentin is an anti-epilepsy drug. The MTUS Guidelines state that gabapentin is: "Not recommended. There is no peer-reviewed literature to support use." The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, there is no documented medical necessity for the addition of gabapentin in the topical formulation for this patient.Lidocaine is a topical anesthetic. Lidocaine as a dermal patch has been used off-label for neuropathic pain. However, the guidelines note that no other form (creams, lotions, gels) are indicated. Further, the Guidelines note that lidocaine showed no superiority over placebo for chronic muscle pain. Also, the FDA has issued warnings about the safety of these agents.Baclofen is a muscle relaxant being used as a topical analgesic. The MTUS Guidelines specifically state that there is no evidence for baclofen or any other muscle relaxant as a topical product.The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, in this case, there is no documentation of the failure of conventional therapy, documented functional improvement, or recommendation for all the ingredients of the compound and therefore the medical necessity of the compounded formulation.

Robaxin 750 mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-66.

Decision rationale: Robaxin (methocarbamol) is an antispasmotic muscle relaxant whose mechanism of action is unknown. The Medical Treatment Utilization Schedule (MTUS) states that 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 record does not show any indications for methocarbamol beyond a short course. Therefore, in this case, the medical record does not document the medical necessity for Robaxin.