

Case Number:	CM15-0125260		
Date Assigned:	07/09/2015	Date of Injury:	10/06/2014
Decision Date:	08/11/2015	UR Denial Date:	06/24/2015
Priority:	Standard	Application Received:	06/29/2015

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
 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 27-year-old female, who sustained an industrial injury on October 6, 2014. Treatment to date has included stellate ganglion blocks, medications, and occupational therapy. Currently, the injured worker complains of right elbow pain and right wrist pain. She describes the pain as aching, burning and shooting with radiation of pain to the right shoulder, right elbow, right wrist and right hand. She reports that her sleep level is decreased and quality of sleep is poor. Her sleep aide is no longer helping her with sleep. Her pain is moderate to severe in nature and she reports that medications are not effective. She reports abdominal pain as a medication side effect. She rates her pain a 7 on a 10-point scale and she reports that her pain level has remained unchanged since her previous evaluations. On physical examination the injured worker has a restricted cervical spine range of motion and painful range of motion on the right. She has increased radiculopathy on the right. She has right upper extremity hyperalgesia and limited no indication of cardiac injury on electrocardiogram and no elevation in the beneficiary's initial troponin level. She exhibits a decreased motor strength on the right upper extremity. Her current medications include bupropion, Lunesta, cyclobenzaprine, and pantoprazole. The diagnoses associated with the request include reflex sympathetic dystrophy of the upper limb and chronic pain syndrome. The treatment plan includes discontinuation of cyclobenzaprine, discontinuation of Lunesta, initiation of Ambien, Norflex, omeprazole, tramadol, 2nd stellate ganglion block, psychological therapy and physical therapy to the right shoulder and right upper extremity.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ambien 5mg tablet, #30: 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), Pain, Zolpidem (Ambien).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter Zolpidem.

Decision rationale: Based on ODG guidelines, Zolpidem is a prescription short-acting non-benzodiazepine hypnotic, which is recommended for short-term (7-10 days) treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain. Various medications may provide short-term benefit. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. (Feinberg, 2008) See Insomnia treatment. Ambien CR offers no significant clinical advantage over regular release Zolpidem. Ambien CR is approved for chronic use, but chronic use of hypnotics in general is discouraged, as outlined in Insomnia treatment. Ambien CR causes a greater frequency of dizziness, drowsiness, and headache compared to immediate release zolpidem. (Ambien & Ambien CR package insert) Cognitive behavioral therapy (CBT) should be an important part of an insomnia treatment plan. A study of patients with persistent insomnia found that the addition of zolpidem immediate release to CBT was modestly beneficial during acute (first 6 weeks) therapy, but better long-term outcomes were achieved when zolpidem IR was discontinued and maintenance CBT continued. (Morin, 2009) Due to adverse effects, FDA now requires lower doses for zolpidem. The dose of zolpidem for women should be lowered from 10 mg to 5 mg for IR products (Ambien, Edluar, Zolpimist, and generic) and from 12.5 mg to 6.25 mg for ER products (Ambien CR). The ER product is still more risky than IR. In laboratory studies, 15% of women and 3% of men who took a 10-milligram dose of Ambien had potentially dangerous concentrations of the drug in their blood eight hours later. Among those who took Ambien CR, the problem was more common: 33% of women and 25% of men had blood concentrations that would raise the risk of a motor vehicle accident eight hours later. Even at the lower dose of Ambien CR now recommended by the FDA, 15% of women and 5% of men still had high levels of the drug in their system in the morning. (FDA, 2013) According to SAMHSA, Zolpidem is linked to a sharp increase in ED visits, so it should be used safely for only a short period of time. See the Mental Chapter. In this case, the patient has tried Lunesta and did not achieve adequate sleep. Also, the patient does suffer from depression and is currently being treated for it, and Zolpidem is known to worsen depression. Lastly, Zolpidem is only recommended for short term use, 7-10 days. Therefore, based on the evidence in this case and ODG guidelines, the request for Ambien 5 mg #30 is not medically necessary.

Norflex 100mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter Muscle Relaxants.

Decision rationale: Based on ODG guidelines, ANTISPASMODICS: Used to decrease muscle spasm in conditions such as LBP although it appears that these medications are often used for the treatment of musculoskeletal conditions whether spasm is present or not. The mechanism of action for most of these agents is not known. Cyclobenzaprine: Recommended for a short course of therapy. Immediate release recommended over extended release due to recommended 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. 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. A recent RCT found that time to relief was better with immediate release compared to extended release cyclobenzaprine. 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) Methocarbamol (Robaxin, Relaxin, generic available): The mechanism of action is unknown, but appears to be related to central nervous system depressant effects with related sedative properties. This drug was approved by the FDA in 1957. Side Effects: Drowsiness, dizziness and lightheadedness. Dosing: 1500 mg four times a day for the first 2-3 days, then decreased to 750 mg four times a day. Metaxalone is reported to be a relatively non-sedating muscle relaxant. The exact mechanism of action is unknown, but the effect is presumed to be due to general depression of the central nervous system. Metaxalone was approved by the FDA in 1964 and data to support approval were published in the mid-1960s. Side Effects: Dizziness and drowsiness, although less than that compared to other skeletal muscle relaxants. Other side effects include headache, nervousness, nausea, vomiting, and GI upset. A hypersensitivity reaction (rash) has been reported. Use with caution in patients with renal and/or hepatic failure. Dosing: 800 mg three to four times a day Chlorzoxazone : this drug works primarily in the spinal cord and the subcortical areas of the brain. The mechanism of action is unknown but the effect is thought to be due to general depression of the central nervous system. Advantages over other muscle relaxants include reduced sedation and less evidence for abuse. Side Effects: Drowsiness and dizziness. Urine discoloration may occur. Avoid use in patients with hepatic impairment. Dosing: 250-750 mg three times a day to four times a day. Carisoprodol: Not recommended in ODG. Suggested by the manufacturer for use as an adjunct to rest, physical therapy, analgesics, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. (AHFS, 2008) A 250 mg formulation was FDA approved in 9/07 for treatment of acute, painful musculoskeletal conditions such as backache. 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. Side Effects: drowsiness, psychological and physical dependence, & withdrawal with acute discontinuation. Orphenadrine (Norflex, Banflex, Antiflex, Mio-Rel, Orphenate, generic available): This drug is similar to diphenhydramine, but has greater anticholinergic effects. The mode of action is not clearly understood. Effects are thought to be secondary to analgesic and anticholinergic properties. This drug was approved by the FDA in 1959. Side Effects: Anticholinergic effects (drowsiness, urinary retention, dry mouth). Side effects may limit use in the elderly. This medication has been reported in case studies to be abused for euphoria and to have mood elevating effects. In general, this class of medication is recommended only for short term use. The patient has been on Flexeril for at least a couple of months, which exceeds the short-term (2-3 weeks) recommendation based on the ODG guidelines. Therefore, based on the evidence in this case, and the ODG guidelines, the request for Norflex 100 mg #60 is not medically necessary.