

Case Number:	CM15-0131698		
Date Assigned:	07/17/2015	Date of Injury:	04/30/1998
Decision Date:	08/18/2015	UR Denial Date:	06/16/2015
Priority:	Standard	Application Received:	07/07/2015

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:

This 56-year-old woman sustained an industrial injury on 4/30/1998. The mechanism of injury is not detailed. Diagnoses include cervicobrachial syndrome, myofascial pain, and chronic pain syndrome, which are all described as worsening. Treatment has included oral medications. Physician notes on a PR-2 dated 4/5/2015 show complaints of neck and low back pain rated 4/10. Recommendations include continue Kadian, Clonidine, Neurontin, Pamelor, cognitive behavior therapy, and follow up in four to six weeks.

IMR ISSUES, DECISIONS AND RATIONALES

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

Clonidine 0.1mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consult.

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 Clonidine, intrathecal and Other Medical Treatment Guidelines On line Version Medscape: Dosing and uses for Clonidine.

Decision rationale: Based on ODG guidelines, intrathecal clonidine, is not recommended except as an end-stage treatment alternative for selected patients for specific conditions, and only after a short-term trial indicates pain relief in patients refractory to opioid monotherapy or opioids with local anesthetic. See Implantable drug-delivery systems (IDDSs). There is no recommendation for its use as there is little evidence that this medication provides long-term pain relief (when used in combination with opioids approximately 80% of patients had < 24 months of pain relief) and no studies have investigated the neuromuscular, vascular or cardiovascular physiologic changes that can occur over long period of administration. Side effects include hypotension, and the medication should not be stopped abruptly due to the risk of rebound hypertension. The medication is FDA approved with an orphan drug intrathecal indication for cancer pain only. Clonidine is thought to act synergistically with opioids. Most studies on the use of this drug intrathecally for chronic non-malignant pain are limited to case reports. (Ackerman, 2003) Clonidine (Catapres) is a direct-acting adrenergic agonist prescribed historically as an anti-hypertensive agent, but it has found new uses, including treatment of some types of neuropathic pain. Additional studies: One intermediate quality randomized controlled trial found that intrathecal clonidine alone worked no better than placebo. It also found that clonidine with morphine worked better than placebo or morphine or clonidine alone. Also, Clonidine for Opioid Withdrawal is an off label use. Therefore, based on the information in this case and the ODG guidelines along with the drug information from the online Medscape version, Clonidine 0.1 mg #30 is not medically necessary.

Pamelor 10mg #60: Upheld

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

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

Decision rationale: Based on ODG guidelines, regarding insomnia treatment, it is recommended that treatment be based on the etiology, with the medications recommended below. See Insomnia. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning. See the Pain Chapter for detailed recommendations and references. Pharmacologic Treatment: There are four main categories of pharmacologic treatment: (1) Benzodiazepines; (2) Non-benzodiazepines; (3) Melatonin receptor agonists; & (4) Sedating antihistamines (primarily over-the-counter medications). (1) Benzodiazepines: These medications are only recommended for short-term use due to risk of tolerance, dependence, and adverse events (daytime drowsiness, anterograde amnesia, next-day sedation, impaired cognition, impaired psychomotor function, and rebound insomnia). These drugs have been associated with sleep-related activities such as sleep driving, cooking and eating food, and making phone calls (all while asleep). Particular concern is noted for patients at risk for abuse or addiction. Withdrawal occurs with abrupt discontinuation or large decreases in dose. Decrease slowly and monitor for withdrawal symptoms. Benzodiazepines are similar in efficacy to benzodiazepine-receptor agonists; however, the less desirable side-effect profile limits their

use as a first-line agent, particularly for long-term use. (2) Non- Benzodiazepine sedative-hypnotics (Benzodiazepine-receptor agonists): First-line medications for insomnia. Although direct comparisons between benzodiazepines and the non- benzodiazepine sedative-hypnotics have not been studied, it appears that the non- benzodiazepines have similar efficacy to the benzodiazepines with fewer side effects and short duration of action. Zolpidem (Ambien (generic available), Ambien CR, Edluar, Intermezzo) is indicated for the short-term treatment of insomnia with difficulty of sleep onset (7-10 days). Ambien CR is indicated for treatment of insomnia with difficulty of sleep onset and/or sleep maintenance. Longer-term studies have found Ambien CR to be effective for up to 24 weeks in adults. FDA has also approved sublingual zolpidem (Edluar). (FDA, 2009) FDA approved zolpidem tartrate sublingual tablets (Intermezzo) for use as needed for insomnia characterized by middle-of-the-night waking followed by difficulty returning to sleep. (FDA, 2011) 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 and from 12.5 mg to 6.25 mg for ER products. (FDA, 2013) The ER product is still more risky than IR. See the Pain Chapter. Zaleplon (Sonata) reduces sleep latency. Because of its short half-life (one hour), may be re-administered upon nocturnal waking provided it is administered at least 4 hours before wake time. This medication has a rapid onset of action. Short-term use (7-10 days) is indicated with a controlled trial showing effectiveness for up to 5 weeks. Eszopicolone (Lunesta) has demonstrated reduced sleep latency and sleep maintenance. The only benzodiazepine-receptor agonist FDA approved for use longer than 35 days. Sedating antidepressants (e.g., amitriptyline, trazodone, mirtazapine) have also been used to treat insomnia; however, there is less evidence to support their use for insomnia, but they may be an option in patients with coexisting depression. Trazodone is one of the most commonly prescribed agents for insomnia. Side effects of this drug include nausea, dry mouth, constipation, drowsiness, and headache. Improvements in sleep onset may be offset by negative next-day effects such as ease of awakening. Tolerance may develop and rebound insomnia has been found after discontinuation. See also Sentra PM." (3) Melatonin-receptor agonist: Ramelteon (Rozerem) is a selective melatonin agonist (MT1 and MT2) indicated for difficulty with sleep onset; is nonscheduled (has been shown to have no abuse potential). One systematic review concluded that there is evidence to support the short- term and long-term use of ramelteon to decrease sleep latency; however, total sleep time has not been improved. (4) Sedating antihistamines (primarily over-the-counter medications): Sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine (Benadryl, OTC in U.S.), promethazine (Phenergan, prescription in U.S., OTC in other countries)). Tolerance seems to develop within a few days. Next-day sedation has been noted as well as impaired psychomotor and cognitive function. This RCT determined that diphenhydramine has been shown to build tolerance against its sedation effectiveness very quickly, with placebo-like results after a third day of use. (Richardson, 2002) Due to adverse effects, the U.S. National Committee for Quality Assurance (NCQA) has included diphenhydramine in the HEDIS (Healthcare Effectiveness Data and Information) recommended list of high-risk medications to avoid in the elderly. (NCQA, 2012) In this case, the request is for Pamelor 10 mg daily which is a sedating antidepressant and that is recommended for insomnia with coexisting depression. In this case, there is no documentation that the patient also has coexisting depression and therefore the request for Pamelor 10 mg #60 is not medically necessary.