

<b>Case Number:</b>	CM14-0124030		
<b>Date Assigned:</b>	08/08/2014	<b>Date of Injury:</b>	07/09/2002
<b>Decision Date:</b>	09/11/2014	<b>UR Denial Date:</b>	07/31/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/05/2014

### 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 Pain Management 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:

A progress note dated 6/12/14 indicates pain in the cervical, lumbar, wrists, elbows and patella bilaterally. Pain is throbbing, aching sensation with intermittent nature and worsens with use. Pain has not improved with TENS, physical therapy, and pharmacologic therapy. Medications were listed as Valium, Imitrex, Duragesic, Morphine sulfate immediate release (MSIR), Lyrica, and Ambien. 5/15/14 note indicated the same pain and reported failure to respond to medication, physical therapy, and TENS unit.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Diazepam 10mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain, benzodiazepines Other Medical Treatment Guideline or Medical Evidence: Not recommended for long-term use because long-term efficacy is unproven and there is a risk of psychological and physical dependence or frank addiction. Most guidelines limit use to 4 weeks. Benzodiazepines are a major cause of overdose, particularly as they act synergistically with other drugs such as opioids (mixed overdoses are often a cause of fatalities).

Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly (3-14 day). Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. Tolerance to lethal effects does not occur and a maintenance dose may approach a lethal dose as the therapeutic index increases. The best prevention for substance use disorders due to benzodiazepines is careful prescribing. (Baillargeon, 2003) (Ashton, 2005) (Dickinson, 2009) (Lader, 2009) Adults who use hypnotics, including benzodiazepines such as temazepam, have a greater than 3-fold increased risk for early death, according to results of a large matched cohort survival analysis. The risks associated with hypnotics outweigh any benefits of hypnotics, according to the authors. In 2010, hypnotics may have been associated with 320,000 to 507,000 excess deaths in the U.S. alone. A dose-response effect was evident, with a hazard ratio of 3.60 for up to 18 pills per year, 4.43 for 18-132 pills per year, and 5.32 for over 132 pills per year. (Kripke, 2012) The AGS updated Beers criteria for inappropriate medication use includes benzodiazepines. (AGS, 2012) See also Anxiety medications in chronic pain; & Insomnia treatment. Benzodiazepines that are commonly prescribed include the following: alprazolam, chlordiazepoxide, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, & triazolam. (Clinical Pharmacology, 2010).

**Decision rationale:** The medical records provided for review indicate the insured has not had improvement in pain from any pharmacologic therapy. There is no documentation of functional benefit from Valium in support of continued use. There is no documentation of an anxiety condition and Benzodiazepines are not supported for chronic use.

**MSIR 15mg #120:** 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) pain, opioids Other Medical Treatment Guideline or Medical Evidence: CRITERIA FOR USE OF OPIOIDS Therapeutic Trial of Opioids<sup>1</sup>) Establish a Treatment Plan. The use of opioids should be part of a treatment plan that is tailored to the patient. Questions to ask prior to starting therapy:(a) Are there reasonable alternatives to treatment, and have these been tried?(b) Is the patient likely to improve? Examples: Was there improvement on opioid treatment in the acute and subacute phases? Were there trials of other treatment, including non-opioid medications?(c) Has the patient received a screen for the risk of addiction? Is there likelihood of abuse or an adverse outcome? Specific questions about current use of alcohol, illegal drugs, other prescription drugs, and over-the-counter drugs should be asked. Obtaining a history of personal and/or family substance abuse issues is important. See Substance abuse (tolerance, dependence, addiction). See Opioids, screening for risk of addiction. (Webster, 2008) (Ballyantyne, 2007)(d) Ask about Red Flags indicating that opioids may not be helpful in the chronic phase: (1) Little or no relief with opioid therapy in the acute and subacute phases. (2) The patient has been given a diagnosis in one of the particular diagnostic categories that have not been shown to have good success with opioid therapy: conversion disorder; somatization disorder; pain disorder associated with psychological factors (such as anxiety or depression, or a previous history of substance abuse). Patients may misuse opioids prescribed for pain to obtain relief from depressed feelings, anxiety, insomnia, or discomfiting memories. There are better treatments for this type of pathology. (Sullivan, 2006)

(Sullivan, 2005) (Wilsey, 2008) (Savage, 2008)(e) When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.2) Steps to Take Before a Therapeutic Trial of Opioids:(a) Attempt to determine if the pain is nociceptive or neuropathic. Also attempt to determine if there are underlying contributing psychological issues. Neuropathic pain may require higher doses of opioids, and opioids are not generally recommended as a first-line therapy for some neuropathic pain.(b) A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics.(c) Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals.(d) Baseline pain and functional assessments should be made. Function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical.

**Decision rationale:** The medical records provided for review indicate the insured has not had improvement in pain from any pharmacologic therapy. There is no indication of ongoing Opioid mitigation process for long term Opioid use. There is no documentation of functional benefit from Opioids in support of continued use.

**Ambien 10mg #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: Medscape and PDR references.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain, zolpidem Other Medical Treatment Guideline or Medical Evidence: Zolpidem is a prescription short-acting nonbenzodiazepine hypnotic, which is approved for the short-term (usually two to six weeks) 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.

**Decision rationale:** Zolpidem is a prescription short-acting non-Benzodiazepine hypnotic, which is approved for the short-term (usually two to six weeks) 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. Records do not support failure of at least 6 months sleep hygiene program in support of use of Zolpidem for sleep aid. The requested treatment is not medically necessary and appropriate.

**Cyclobenzaprine 10% / Gabapentin 10% cream 30gm: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines chronic pain, topicals Page(s): 111.

**Decision rationale:** Topical combination Flexeril and Gabapentin is not supported as a single use agent for treatment of pain. The medical records provided for review indicate failure of pharmacologic agents and does not support any functional benefit from therapies to date. Topical medications are not supported under California Medical Treatment Utilization Schedule (MTUS) guidelines for noted condition.

**Flurbiprofen 20% cream 30gm: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines chronic pain, topicals Page(s): 111.

**Decision rationale:** Topical non-steroidal anti-inflammatory drugs (NSAIDs) are not supported as a single use agents for treatment of pain. The medical records provided for review indicate failure of pharmacologic agents and does not support any functional benefit from therapies to date. Topical medications are not supported under California Medical Treatment Utilization Schedule (MTUS) guidelines for noted condition.

**Tramadol 20% cream 30gm:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines chronic pain, topicals Page(s): 111.

**Decision rationale:** Topical Tramadol is not supported as a single use agents for treatment of pain. The medical records provided for review indicate failure of pharmacologic agents and does not support any functional benefit from therapies to date. Topical medications are not supported under California Medical Treatment Utilization Schedule (MTUS) guidelines for noted condition.

**Retro (DOS missing): Quazepam 15mg #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation DailyMed.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain, benzodiazepines Other Medical Treatment Guideline or Medical Evidence: Not recommended for long-term use because long-term efficacy is unproven and there is a risk of psychological and physical dependence or frank addiction. Most guidelines limit use to 4 weeks. Benzodiazepines are a major cause of overdose, particularly as they act synergistically with other drugs such as opioids (mixed overdoses are often a cause of fatalities). Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly (3-14 day). Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. Tolerance to lethal effects does not occur and a maintenance dose may approach a lethal dose as the therapeutic index increases. The best prevention for substance use disorders due to benzodiazepines is careful prescribing. (Baillargeon, 2003) (Ashton, 2005) (Dickinson, 2009) (Lader, 2009) Adults who use hypnotics, including benzodiazepines such as temazepam, have a greater than 3-fold increased risk for early death, according to results of a large matched cohort survival analysis. The risks associated with hypnotics outweigh any benefits of hypnotics, according to the authors. In 2010, hypnotics may have been associated with 320,000 to 507,000 excess deaths in the U.S. alone. A dose-response effect was evident, with a hazard ratio of 3.60 for up to 18 pills per year, 4.43 for 18-132 pills per year, and 5.32 for over 132 pills per year. (Kripke, 2012) The AGS updated Beers criteria for inappropriate medication use includes benzodiazepines. (AGS, 2012) See also Anxiety medications in chronic pain; & Insomnia treatment. Benzodiazepines that are commonly prescribed include the following: alprazolam, chlordiazepoxide, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, & triazolam. (Clinical

Pharmacology, 2010).

**Decision rationale:** The medical records provided for review indicate the insured has not had improvement in pain from any pharmacologic therapy. There is no documentation of functional benefit from Quazepam support of continued use. There is no documentation of an anxiety condition and Benzodiazepines are not supported for chronic use.