

<b>Case Number:</b>	CM13-0068036		
<b>Date Assigned:</b>	01/03/2014	<b>Date of Injury:</b>	10/10/2010
<b>Decision Date:</b>	05/06/2014	<b>UR Denial Date:</b>	12/12/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/18/2013

### 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 Family Practice, has a subspecialty in Pain Management and is licensed to practice in California. 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:

51 years old male sustained an industrial related neck and hand injury on October 10, 2010, resulting in cervical spine degenerative changes. He had developed carpal tunnel syndrome and had surgical release. He also received epidural steroid injections for cervical spine stenosis and radiculopathy. An office visit on 10/10/2013 with the pain specialist had noted the claimant had difficulty sleeping and was using Klonopin for several months. A chiropractic note on 11/21/13 noted he was also on Sentra PM for sleep aid. A prior note on 5/15/13 noted both Klonopin and Sentra PM for sleep.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**KLONOPIN 0.5MG, #30:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

**Decision rationale:** Klonopin is a benzodiazepine. The claimant had been using the medication for sleep according to the medication lists. Sleep was not mentioned in the chief complaints in

the notes provided. There is no documentation on sleep hygiene instructions, sleep therapy evaluation or response to medications. According to the MTUS guidelines Benzodiazepines are not recommended for long-term use because its efficacy is unproven and there is a risk of addiction. Most guidelines limit its use to 4 weeks and its range of action includes: sedation, anxiolytic, anticonvulsant and muscle relaxant. Long-term use may increase anxiety. According to the ODG guidelines: 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 days). 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. 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. Furthermore, according to the ODG guidelines - FDA-approved benzodiazepines for sleep maintenance insomnia include estazolam (ProSom®), flurazepam (Dalmane®), quazepam (Doral®), and temazepam (Restoril®). Triazolam (Halcion®) is FDA-approved for sleep-onset insomnia. 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. Based on the above guidelines and claimant's use history and clinical documentation, Klonopin 0.5MG, #30 is not medically necessary and appropriate for the dates in question.

**SENTRA PM #60:** 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) Mental and Stress Chapter and Pain Chapter, Sentra PM.

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

**Decision rationale:** Sentra PM is a nutraceutical sleep aid. According to the ODG guidelines: Sentra PM is a medical food from [REDACTED], intended for use in management of sleep disorders associated with depression, that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. 5-hydroxytryptophan: This supplement has been found to be possibly effective in treatment of anxiety disorders,

fibromyalgia, obesity and sleep disorders. It has been found to be effective for depression. In alternative medicine it has been used for depression, anxiety, insomnia, obesity, aggressive behavior, eating disorders, fibromyalgia, chronic headaches and various pain disorders. It should be used with caution in individuals using SSRI (Selective Serotonin Reuptake Inhibitor) antidepressants. This product has been linked to a contaminant that causes a condition called eosinophilia-myalgia syndrome. The ODG considers this supplement to be a medical food and recommended as indicated below. Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. In this case there is inadequate documentation of a nutritional deficiency relating to sleep that requires Sentra PM. In addition, the documentation does not state the response, tolerance or thorough evaluation of the sleep disorder and the use of the supplement. As a result Sentra PM #60 is not medically necessary and appropriate.