

<b>Case Number:</b>	CM14-0160563		
<b>Date Assigned:</b>	10/06/2014	<b>Date of Injury:</b>	08/05/2013
<b>Decision Date:</b>	12/03/2014	<b>UR Denial Date:</b>	09/05/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/30/2014

### 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 Family Medicine 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:

This is a 70-year-old male patient who reported an industrial injury on 8/5/2013, 15 months ago, attributed to the performance of his usual and customary job tasks. The patient complained of headaches, balance difficulties, and vertigo after a reported head injury. The patient was diagnosed with a concussion. The patient reported symptoms and included headaches and difficulties with short-term memory and a reduced attention span subsequent to the head trauma. The objective findings on examination indicated the patient had a normal mental status examination; no aphasia; no motor deficits; and no ataxia. The patient underwent a CT scan of the head, which was interpreted as normal. The patient was prescribed Zolpidem 10 mg #30 with refill; Melatonin 3 mg #30 with two refills; and a medical food Vertigoheel #100 with one refill.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Zolpidem 10 mg #30 with 1 refill:** Upheld

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

insomnia and on Other Medical Treatment Guideline or Medical Evidence: Zolpidem  
<http://www.drugs.com/ambien.html>

**Decision rationale:** Zolpidem 10 mg #30 is recommended only for the short-term treatment of insomnia for two to six weeks. The Zolpidem 10 mg has been prescribed to the patient for a prolonged period of time. The use of Zolpidem or any other sleeper has exceeded the ODG guidelines. The prescribing physician does not provide any rationale to support the medical necessity of Zolpidem for insomnia or documented any treatment of insomnia to date. The patient is being prescribed the Zolpidem for insomnia due to chronic ankle/foot pain simply due to the rationale of chronic pain without demonstrated failure of over the counter remedies. There is no provided subjective/objective evidence to support the use of Zolpidem 10 mg over the available over the counter remedies. The patient has exceeded the recommended time period for the use of this short-term sleep aide. There is no demonstrated functional improvement with the prescribed Zolpidem. There is no documentation of alternatives other than Zolpidem have provided for insomnia or that the patient actually requires sleeping pills. The patient is not documented with objective evidence to have insomnia or a sleep disorder at this point in time or that conservative treatment is not appropriate for treatment. There is no evidence that sleep hygiene, diet and exercise have failed for the treatment of sleep issues. There is no demonstrated failure of the multiple sleep aids available over the counter. The CA MTUS and the ACOEM Guidelines are silent on the use of sleeping medications. The ODG does not recommend the use of benzodiazepines in the treatment of chronic pain. Zolpidem is not a true benzodiazepine; however retains some of the same side effects and is only recommended for occasional use and not for continuous nightly use. There is no medical necessity for the prescribed Zolpidem 10 mg #30.

**Vertigoheel po #100 with 1 refill:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation  
<http://dailymed.nlm.nih.gov/dailymed/lookup.cmf?setid=da56ea63-2dd9-4f2b-b50b-cf3f06749c33> Official Disability Guidelines, Head: Vestibular PT Rehabilitation

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods

**Decision rationale:** Vertigoheel is a prescription medical food formulated for the nutritional management of vertigo; dizziness and mild cognitive impairment. The exact mechanism of injury is not known or fully understood. Vertigoheel is a formulation of the following botanical, zoological, and mineral substances: Conium maculatum; Cocculus indicus; Ambra grisea; and Petroleum. Vertigoheel is reported to be effective in treating vertigo nausea do in part to its ability to stimulate the central nervous system. Vertigoheel is reported to activate the vestibular regulatory systems located in the brain same area, which may facilitate more accurate communication between the peripheral vestibular system in the brain. The homeopathic product has not been evaluated by the FDA for safety or efficacy. The FDA is not aware of scientific evidence to support homeopathy as effective. There is no rationale by the prescribing physician

supported by objective evidence to support the medical necessity of the prescribed Vertigoheel. There is no objective evidence that the prescription of Vertigoheel will reduce the effects of a concussion or post-concussion syndrome. There is no objective evidence to support the efficacy of the prescribed homeopathic remedy. Evidence-based guidelines report that medical foods are not evaluated for safety or efficacy by the federal FDA. According to the FDA, medical foods have significant health risk that can lead to permanent injury or death. The California state legislature stated: "The legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods." The prescribed medical food or homeopathic product Vertigoheel is not demonstrated to be medically necessary for the treatment of the cited diagnoses of this patient.