

Case Number:	CM15-0133112		
Date Assigned:	07/21/2015	Date of Injury:	02/09/2004
Decision Date:	08/24/2015	UR Denial Date:	07/01/2015
Priority:	Standard	Application Received:	07/09/2015

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: Texas, California

Certification(s)/Specialty: Family Practice

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 75-year-old female patient who sustained an industrial injury on 02/09/2004. The diagnoses include early signs of Reflex Sympathetic Dystrophy Syndrome (RSD), left internal knee derangement, right patellofemoral arthralgia, left shoulder impingement, lumbar and cervical spine musculoligamentous sprain/strain and plantar fasciitis secondary to altered gait and carpal tunnel syndrome with diabetic peripheral neuropathy. According to the primary treating physician's progress report on June 12, 2015 she had complaints of low back and right lower extremity pain. The physical examination revealed right lower extremity pain with hypersensitivity and discoloration over the lower leg, ankle and foot, a pressure ulcer with redness, swelling and tactile warmth over the medial ankle, ambulates with a single point cane. The current medications list includes Tizanidine, Nuvigil and Lidoderm patch. She has undergone right ankle arthroscopy in 2005, right ankle fusion in 2008; removal of hardware in 2010; a left knee arthroscopy in 2004 and left elbow lateral release in 2008. Treatment to date has included diagnostic testing, surgery, physical therapy, home exercise program, home care assistance, ambulatory devices, trial spinal cord stimulator (SCS) and medications. Treatment plan consists of starting prophylactic antibiotic; continue with home care and transportation, permanent spinal cord stimulator (SCS) implant, home exercise program, medication regimen and the current request for Nuvigil.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nuvigil 250mg #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chapter: Pain (updated 07/15/15) Armodafinil (Nuvigil).

Decision rationale: Nuvigil 250mg #30; Per the cited guidelines armodafinil is not recommended solely to counteract sedation effects of narcotics. Armodafinil is used to treat excessive sleepiness caused by narcolepsy or shift work sleep disorder. It is very similar to Modafinil. Studies have not demonstrated any difference in efficacy and safety between armodafinil and modafinil. (Tembe, 2011) For more information see also Modafinil (Provigil), where it is not recommended solely to counteract sedation effects of narcotics until after first considering reducing excessive narcotic prescribing, and it is noted that there should be heightened awareness for potential abuse of and dependence on this drug. Recently Cephalon produced a campaign advertising Nuvigil's ability to help shift workers stay alert on the job without impeding their ability to sleep during the day. The FDA is conducting an investigation into the possibility that this advertising or promotional information may have violated current regulations. (SEC, 2011) A detailed clinical evaluation note documenting a diagnosis of narcolepsy is not specified in the records provided. Evidence of excessive daytime sleepiness associated with obstructive sleep apnea/hypopnea is not specified in the records provided. Evidence of excessive sleepiness associated with shift-work sleep disorder is not specified in the records provided. Any objective evidence of a specific measurable functional impairment due to sleep disturbances is not specified in the records provided. The medical necessity of Nuvigil 250mg #30 is not fully established for this patient.