

<b>Case Number:</b>	CM15-0198387		
<b>Date Assigned:</b>	10/13/2015	<b>Date of Injury:</b>	09/10/2012
<b>Decision Date:</b>	11/20/2015	<b>UR Denial Date:</b>	09/08/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/08/2015

### 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: Preventive Medicine, Occupational 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:

The injured worker is a 63 year old male, who sustained an industrial injury on 9-10-12. Medical records indicate that the injured worker is undergoing treatment for post-traumatic stress disorder, major depressive disorder with prominent anxiety symptoms and head syndrome to include headache, difficulty with memory and concentration, ringing in the ears, dizziness and forgetfulness. The injured worker was noted to be temporarily totally disabled. On (6-19-15) the injured worker noted that he fell asleep easily or "conked out" during the day. The injured worker also noted tremors and weakness of the left arm. The injured worker was noted to not have a seizure disorder. Treatment and evaluation to date has included medications, psychological testing, psychiatric assessments and a craniotomy. Current medications include Welbutrin, Pristiq, Namenda, Abilify and Androgel. The current treatment request is for Nuvigil 250 mg # 30. The Utilization Review documentation dated 9-8-15 non-certified the request for Nuvigil 250 mg # 30.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Nuvigil 250mg 1 tab every morning #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 (ODG), Pain Chapter (updated 09/03/2015) - Online version, Armodafinil (Nuvigil).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain/Armodafinil and Other Medical Treatment Guidelines  
[https://www.excellusbcbs.com/wps/wcm/connect/ffe13cd9-8e93-4c5a-bb41-dab10f834b02/Provigil\\_Nuvigil+07202015.pdf?MOD=AJPERES&CACHEID=ffe13cd9-8e93-4c5a-bb41-dab10f834b02](https://www.excellusbcbs.com/wps/wcm/connect/ffe13cd9-8e93-4c5a-bb41-dab10f834b02/Provigil_Nuvigil+07202015.pdf?MOD=AJPERES&CACHEID=ffe13cd9-8e93-4c5a-bb41-dab10f834b02).

**Decision rationale:** MTUS Guidelines do not address this issue. ODG Guidelines address this issue in relationship for use with opioid induced somnia and do not recommend its use for this purpose. The ODG Guidelines recommend its use limited to the FDA approved indications of narcolepsy, difficult to treat sleep apnea and shift work related somnia. Other insurers have reviewed its use for unlabeled indications and a recent review (7/20/15) does allow for its use in several off label indications, however treatment of post traumatic brain injury is not one of them. The insurance policy specifically notes it had no benefits over a placebo for post traumatic brain injury. Under these circumstances, the Nuvigil 250mg 1 tab every morning #30 is not supported by Guidelines and is not supported in other standard up-to-date drug policies. It is not medically necessary.