Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Nuvigil (armodafanil)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***July 2009 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Nuvigil (armodafanil).

Nuvigil (armodafanil) is indicated to improve wakefulness in patients with excessive sleepiness associated with Narcolepsy, Obstructive Sleep Apnea/ Hypopnea Syndrome, and Shift Work Sleep disorder.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Nuvigil (armodafanil), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. **Narcolepsy:**
   - Must have documentation of diagnosis through sleep study
   - Must have a trial and failure of a Central Nervous System (CNS) stimulant (i.e., methylphenidate, dextroamphetamine, amphetamine/dextroamphetamine) documented in pharmacy claims or through physician chart documentation
   - Must have a trial and failure of modafinil (Provigil) documented in pharmacy claims or through physician chart documentation

2. **Obstructive Sleep Apnea (OSA):**
   - Must have documentation of diagnosis through sleep study
   - Must have documentation/compliance report from physician that the member is using a CPAP machine on a regular basis, defined by at least four (4) hours a night on at least 70% of the nights, and symptoms still persist
   - Must have trial and failure of modafinil (Provigil) documented in pharmacy claims or through physician chart documentation

3. **Shift-work Sleep Disorder (SWSD):**
   - Must have a trial and failure of modafinil (Provigil) documented in pharmacy claims or through physician chart documentation
   - Must meet the International Classification of Sleep Disorders (ICSD-10) criteria for chronic SWSD (which are consistent with the American Psychiatric Association DSM-IV criteria for Circadian Rhythm Sleep Disorder: Shift Work Type). The criteria includes:
     - Either a primary complaint of excessive sleepiness or insomnia which is temporally associated with a work period that occurs during the habitual sleep phase OR polysomnography and the Multiple Sleep Latency Test (MSLT) demonstrate loss of a normal sleep-wake pattern
     - No other medical or mental disorder accounts for the symptoms

  - The symptoms do not meet criteria for any other sleep disorder producing insomnia or excessive sleepiness (e.g., time zone change [jet lag] syndrome)
- Must work 5 or more night shifts per month. At least 4 hours of the shift must occur between 10 pm and 8 am. Documentation of the shift work schedule must be provided.

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis (or every 6 months for SWSD) to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year (or 6-month for SWSD) intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Narcolepsy and OSA: Up 1 year • SWSD: Up to 6 months
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Provigil [package literature]. Cephalon, Inc; February 2004.
2. Nuvigil [package literature]. Cephalon, Inc; July 2008.
3. Erman MK, Seiden DJ, Yang R, et al. Efficacy and Tolerability of Armodafinil. *J Occup Environ Med*. 2011 Dec; 53(12): 1460-5.
4. Tembe DV, Dhavale A, Desai H, et al. Armodafinil versus Modafinil in patients of excessive sleepiness associated with shift work sleep disorder: A randomized double blind multicentric clinical trial. *Neurol Res Int.* 2011; 2011: 1-6.
5. Czeisler CA, Walsh JK, Wesnes KA, et al. Armodafinil for treatment of excessive sleepiness associated with shift work disorder: a randomized controlled study. *Mayo Clin Proc*. 2009 Nov; 84(11): 958-72.
6. Erman MK, Rosenberg R, Modafinil Shift Work Sleep Disorder Study Group. Modafinil for excessive sleepiness associated with chronic shift work sleep disorder: effects on patient functioning and health-related quality of life. *Prim Care Companion J Clin Psychiatry*. 2007; 9(3): 188-94.
7. Czeisler CA, Walsh JK, Roth T, et al. Modafinil for excessive sleepiness associated with shift-work sleep disorder. *N Engl J Med.* 2005 Aug; 353(5): 476-86.

8. Morgenthaler TI, Lee-Chion T, Alessi C, et al. Practice parameters for the clinical evaluation and treatment of circadian rhythm sleep disorders. An American Academy of Sleep Medicine Report. *Sleep*. Vol. 30, No. 11, 2007: 1445-59.
9. Morgenthaler TI, Kapur VK, Brown TM, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. An American Academy of Sleep Medicine Report. *Sleep*. Vol. 30, No. 12, 2007: 1705-11.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*