POLICY AND PROCEDURE

POLICY TITLE: ***Provigil (Modafinil)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***April 2004***

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 Provigil (modafinil).

Provigil (modafinil) is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea (OSA), and shift work disorder (SWSD).

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, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Provigil (modafinil), is subject to the prior authorization process.

PROCEDURE
Initial Authorization Criteria:
Must meet all of the criteria listed under the respective diagnosis:

1. For Narcolepsy:

- Must have documentation of diagnosis through sleep study

- Must have a trial/failure of a Central Nervous System (CNS) stimulant (*i.e.,* methylphenidate, dextroamphetamine, amphetamine/dextroamphetamine) documented in pharmacy claims or through physician chart documentation

2. For Obstructive Sleep Apnea:

- Must have documentation of diagnosis through sleep study
- Must have documentation/compliance report from physician that the member is using a CPAP (continuous positive airway pressure) 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

3. For Shift-work Sleep Disorder:

- 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 10pm and 8am. Documentation of the shift work schedule must be provided.

Modafinil is also covered for the following non-FDA approved indications for which there is substantial literature to support its use:

4. For chronic fatigue due to Multiple Sclerosis (MS):

- Must have a diagnosis of chronic fatigue due to MS
- Must have a previous trial of a amantadine

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at one-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	• For SWSD: 6 months • All other diagnoses: 1 year
Reauthorization	Same as initial
Quantity Level Limit	
100mg	30 tablets per 30 days
200mg	60 tablets per 30 days

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. Bakshi R. Fatigue associated with multiple aclerosis: diagnosis, impact and management. *Multiple Sclerosis. 9(3);219-27,2003 Jun.*
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4. Zifko UA. RuppM. Schwarz S. Zipko HT. Maida EM. Modafinil in treatment of fatigue in multiple sclerosis. Results of an open-label study. *Journal of neurology. 249(8):983-7,2002 Aug.*
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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*