This policy applies to the following lines of business: (Check those that apply.)

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I. POLICY

It is the policy of UPMC 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, Modafinil (Provigil), is subject to the prior authorization process.

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the Prior Authorization Process for Modafinil (Provigil).

IV. SCOPE

This policy applies the Pharmacy Services Department.
V. PROCEDURE

Modafinil is FDA approved for members with excessive sleepiness associated with Narcolepsy, Obstructive Sleep Apnea/ Hypopnea Syndrome, and Shift Work Sleep disorder.

Criteria:

UPMC Health Plan will cover Modafinil for members with these diagnoses per FDA approved indications if all of the following criteria are met:

1) For a diagnosis of **Narcolepsy**:
   - Documentation of diagnosis through sleep study
   - Trial/failure of a Central Nervous System (CNS) stimulant (*i.e.*, methylphenidate, Dexedrine, generic Adderall) documented in pharmacy claims or through physician chart documentation

   If the member meets the above approval criteria for narcolepsy, then the request will be authorized for 1 year.

2) For a diagnosis of **Obstructive Sleep Apnea**:
   - Documentation of diagnosis through sleep study
   - 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

   If the member meets the above approval criteria for Obstructive Sleep Apnea, then the request will be authorized for 1 year.

3) For diagnosis of **Shift-work Sleep Disorder** (SWSD):
   - 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 (a minimum of 5 night shifts per month) 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).

If the member meets the above approval criteria for SWSD, then the request will be authorized for 1 year.

4) UPMC Health Plan will also cover Modafinil for the following non-FDA approved indication for which there is substantial literature to support its use:
   o Member has a diagnosis of chronic fatigue due to Multiple Sclerosis;
     AND
   o Member has had a previous trial of a amantadine

If the member meets the above approval criteria for chronic fatigue due to Multiple Sclerosis, then the request will be authorized for 1 year.

Reauthorization Criteria:
All prior authorization renewals will be reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at one-year intervals based upon chart documentation from the prescriber that the member’s Disease has improved based upon the prescriber’s assessment while on therapy.

Limitations:
If a member does not meet the above approval criteria, the prior authorization request will be sent for review by a UPMC Health Plan Medical Director.

VI. BIBLIOGRAPHY