Clinical Policy: Modafinil (Provigil)

Reference Number: PA.CP.PMN.39
Effective Date: 01/18
Last Review Date: 04/18

Coding Implications
Revision Log

Description
Modafinil (Provigil®) is a wakefulness-promoting agent.

FDA approved indication
Provigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with:

- Narcolepsy
- Obstructive sleep apnea (OSA)
- Shift work disorder (SWD)

Limitation of use: In OSA, Provigil is indicated to treat excessive sleepiness and not as treatment for the underlying obstruction. If continuous positive airway pressure (CPAP) is the treatment of choice for a patient, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating and during treatment with Provigil for excessive sleepiness.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that Provigil is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Narcolepsy (must meet all)**:**

1. Diagnosis of narcolepsy;
2. Age ≥ 17 years;
3. Failure of a 1 month trial of one of the following central nervous system (CNS) stimulants: amphetamine immediate release (IR), amphetamine; dextroamphetamine IR, dextroamphetamine, or methylphenidate IR, at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of ≥ 1 month trial of armodafinil (Nuvigil) at up to maximally indicated doses, unless clinically significant side effects are experienced (*Note: Armodafinil requires prior authorization)*;
5. Dose does not exceed 400 mg/day.

Approval duration: 12 months

B. Obstructive Sleep Apnea/Hypopnea Syndrome (OSAHS) (must meet all)**:**

1. Diagnosis of obstructive sleep apnea;
2. Age ≥ 17 years;
3. Documented evidence of residual sleepiness despite compliant CPAP use as monotherapy;

4. Failure of ≥ 1 month trial of armodafinil (Nuvigil) at up to maximally indicated doses, unless clinically significant side effects are experienced (*Note: Armodafinil requires prior authorization)*;
5. Dose does not exceed 400 mg/day.

Approval duration: 12 months

C. Shift Work Disorder (SWD) (must meet all)**:**
1. Diagnosis of shift work disorder;
2. Age ≥ 17 years;
3. Failure of ≥ 1 month trial of armodafinil (Nuvigil) at up to maximally indicated doses, unless clinically significant side effects are experienced (*Note: Armodafinil requires prior authorization)*;
4. Dose does not exceed 200 mg/day.

Approval duration: 12 months

D. Fatigue Associated with Multiple Sclerosis (MS) (must meet all)**:**
1. Diagnosis of MS-related fatigue;
2. Age ≥ 17 years;
3. Failure of 200 mg/day of amantadine and ≥ 10 mg/day of methylphenidate, one of which must be within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of ≥ 1 month trial of armodafinil (Nuvigil) at up to maximally indicated doses, unless clinically significant side effects are experienced *(Note: Armodafinil requires prior authorization)*;
5. Dose does not exceed 400 mg/day.

Approval duration: 12 months

E. Other diagnoses/indications
1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care Policy, PA.LTSS.PHAR.01, applies;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed:
    a. Narcolepsy, OSA, and MS-related fatigue: 400 mg/day;
    b. SWD: 200 mg/day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy, PA.LTSS.PHAR.01, applies; or

2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CNS: central nervous system
CPAP: continuous positive airway pressure
FDA: Food and Drug Administration
MS: multiple sclerosis
OSA: obstructive sleep apnea
OSAHS: obstructive sleep apnea/hypopnea syndrome
SWD: shift work disorder

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Narcolepsy Obstructive sleep apnea	200 mg orally once a day as a single dose in the morning	400 mg/day
Shift work disorder	200 mg orally once a day as a single dose approximately 1 hour prior to the start of work shift	200 mg/day
MS-related fatigue†	200 mg orally once daily in the morning	400 mg/day

†*Off-label indication*

VI. Product Availability

Tablets: 100 mg and 200 mg

VII. References

1. Provigil Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; December 2016. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed January 17, 2018.
2. Morgenthaler TI, Kapur VK, Brown T, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin An American Academy of Sleep Medicine Report: An American Academy of Sleep Medicine Report. Sleep. 2007;30(12):1705-1711.

3. Epstein LJ, Kristo D, Strollo PJ Jr, et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. J Clin Sleep Med. 2009 Jun 15;5(3):263-76.
4. Morgenthaler TI, Lee-Chiong 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. 2007;30(11):1445-1459.
5. Billiard M, Dauvilliers Y, Dolenc-Groselj L, Lammers GJ, Mayer G, Sonka K. Management of narcolepsy in adults. In: Gilhus NE, Barnes MP, Brainin M, editor(s). European handbook of neurological management. 2nd ed. Vol. 1. Oxford (UK): Wiley-Blackwell; 2011. p. 513-28. [118 references]
6. Management of MS-Related Fatigue. Expert Opinion Paper. National Multiple Sclerosis Society; 2006. http://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/Opinion-Paper-Management-of-MS-Related-Fatigue.pdf.
7. Braley TJ; Chervin RD. Fatigue in multiple sclerosis: mechanisms, evaluation, and treatment. SLEEP 2010;33(8):1061-1067.
8. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2018 annual review modified initial approval duration from 6 months to 12 months; Narcolepsy and MS-related fatigue: removed timeframe of trial within the last 6 months; references reviewed and updated.	01.16.18	