

Clinical Policy: Modafinil (Provigil)

Reference Number: ERX.NPA.22

Effective Date: 09.01.17

Last Review Date: 05.18

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

Description

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

FDA Approved Indication(s)

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

Limitation(s) 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 (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions[™] 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 \geq 17 years;
3. Failure of a 1 month trial of one of the following central nervous system 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. Dose does not exceed 400 mg/day.

Approval duration: 12 months

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

1. Diagnosis of OSA;
2. Age \geq 17 years;
3. Documented evidence of residual sleepiness despite compliant CPAP use as monotherapy;
4. Dose does not exceed 400 mg/day.

Approval duration: 12 months

C. Shift Work Disorder (must meet all):

1. Diagnosis of SWD;
2. Age \geq 17 years;
3. Dose does not exceed 200 mg/day.

Approval duration: 12 months

D. Fatigue Associated with Multiple Sclerosis (MS) (off-label) (must meet all):

1. Diagnosis of MS-related fatigue;
2. Age \geq 17 years;
3. Failure of 200 mg/day of amantadine and \geq 10 mg/day of methylphenidate, unless contraindicated or clinically significant adverse effects are experienced;

- Dose does not exceed 400 mg/day.

Approval duration: 12 months

E. Other diagnoses/indications

- Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all):

- Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
- Member is responding positively to therapy;
- If request is for a dose increase, new dose does not exceed:
 - Narcolepsy, OSA, and MS-related fatigue: 400 mg/day;
 - SWD: 200 mg/day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

- Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

- Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 or evidence of coverage documents.**

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CPAP: continuous positive airway pressure

FDA: Food and Drug Administration

MS: multiple sclerosis

OSA: obstructive sleep apnea

SWD: shift work disorder

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria.

The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Evekeo® (amphetamine)	Narcolepsy 5 to 60 mg/day PO in divided doses	60 mg/day
amphetamine/ dextroamphetamine (Adderall®)		
dextroamphetamine ER (Dexedrine® Spansule®)		
dextroamphetamine IR (Zenedi®, Procentra®)		
methylphenidate IR (Ritalin®, Methylin®)	Narcolepsy 10 to 60 mg/day PO in 2 to 3 divided doses	60 mg/day
	MS-related fatigue [†] Usual effective dose: 10-20 mg PO QAM and noon	

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
amantadine (Symmetrel®)	MS-related fatigue [†] 200 mg PO once daily or 100 mg PO twice daily	200 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

[†]Off-label indication

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Narcolepsy	200 mg PO QD as a single dose in the morning	400 mg/day
Obstructive sleep apnea		
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 (off-label)	200 mg orally once daily in the morning	400 mg/day

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.
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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
Policy split from ERX.NSMN.08 Armodafinil and modafinil (retired) and convert to new template. Narcolepsy: added that stimulant trial should have occurred within the last 6 months. OSA: added requirement of residual sleepiness despite compliant CPAP use as monotherapy. Added off-label criteria for MS-related fatigue.	06.17	08.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Modified generalized max dose/health plan approved QL requirement to specific max dose. Updated references.		
2Q 2018 annual review: No significant changes; Narcolepsy and MS: removed timeframe of trial within the last 6 months; References reviewed and updated.	01.18.18	05.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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