

## **Clinical Policy: Modafinil (Provigil)**

Reference Number: MDN.CP.PMN.39

Effective Date: 04.01.22

Last Review Date: 04.22

Line of Business: Illinois Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Modafinil (Provigil<sup>®</sup>) 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 Centene Corporation<sup>®</sup> 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. Prescribed by or in consultation with a neurologist or sleep medicine specialist;
3. Age  $\geq$  17 years;
4. Failure of a 1-month trial of one of the following generic central nervous system stimulant-containing agent at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced: amphetamine, dextroamphetamine, or methylphenidate;  
*\*Prior authorization may be required for CNS stimulants*
5. Member must use generic modafinil, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 400 mg (2 tablets) per 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. Member must use generic modafinil, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 400 mg (2 tablets) per day.

**Approval duration: 12 months**

**C. Shift Work Disorder (SWD) (must meet all):**

1. Diagnosis of SWD;
2. Age  $\geq$  17 years;
3. Member must use generic modafinil, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 200 mg (1 tablet) per day.

**Approval duration: 12 months**

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

1. Diagnosis of MS-associated 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;
4. Member must use generic modafinil, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 400 mg (2 tablets) per day.

**Approval duration: 12 months**

**E. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

**II. Continued Therapy**

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Member must use generic modafinil, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, new dose does not exceed:
  - a. Narcolepsy, OSA, and MS-associated fatigue: 400 mg (2 tablets) day;
  - b. SWD: 200 mg (1 tablet) day.

**Approval duration: 12 months**

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.  
**Approval duration: Duration of request or 12 months (whichever is less);** or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

**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 policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

CPAP: continuous positive airway pressure	MS: multiple sclerosis
FDA: Food and Drug Administration	OSA: obstructive sleep apnea
IR: immediate-release	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 for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
amphetamine (Evekeo®)	<b>Narcolepsy</b> 5 to 60 mg/day PO in divided doses	60 mg/day
amphetamine/ dextroamphetamine (Adderall®)		
dextroamphetamine ER (Dexedrine® Spansule®)		
dextroamphetamine IR (Zenedi®, Procentra®)		
methylphenidate (Ritalin® LA or SR, Concerta®, Metadate® CD or ER, Methylin® ER, Daytrana®)	<b>Narcolepsy</b> Dosing varies; 10-60 mg PO divided 2 to 3 times daily 30-45 min before meals	60 mg/day
	<b>MS-related fatigue</b> <sup>†</sup> Usual effective dose: 10-20 mg PO QAM and noon	
amantadine (Symmetrel®)	<b>MS-related fatigue</b> <sup>†</sup> 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.*

<sup>†</sup>Off-label indication

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): known hypersensitivity to modafinil or armodafinil
- Boxed warning(s): none reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Narcolepsy	200 mg PO QD as a single dose in the morning	400 mg/day
OSA		
SWD	200 mg orally once a day as a single dose approximately 1 hour prior to the start of work shift	200 mg/day
MS-associated fatigue (off-label)	200 mg PO 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.; January 2015. Available at: [www.fda.gov](http://www.fda.gov). Accessed January 29, 2021.
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.
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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.
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6. Management of MS-Related Fatigue. Expert Opinion Paper. National Multiple Sclerosis Society; 2006. Available at: <http://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/Opinion-Paper-Management-of-MS-Related-Fatigue.pdf>.
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8. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed January 29, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created, adapted from CP.PMN.39 to align with HFS PDL	03.15.22	04.22

**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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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