

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Provigil (modafinil)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

***Maryland Medicaid – see State Specific Mandates below**

Medications	Quantity Limit
Provigil (modafinil)	May be subject to Dose Optimization or Quantity Limit

APPROVAL CRITERIA

- I. Individual has been on Provigil (modafinil) in the past 180 days (medication samples/ coupons/ discount cards are excluded from consideration as a trial); **OR**

Requests for Provigil (modafinil) may be approved for the treatment of excessive daytime sleepiness associated with narcolepsy type 1 or type 2 based on if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis of Narcolepsy type 1 confirmed by the presence of daily periods of irrepensible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least **ONE** of the following:
- A. Clear cataplexy (defined as “more than one episode of generally brief [<2 min]) usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness”); **AND**
 - B. Multiple Sleep Latency Test (MSLT) showing **ONE** of the following:
 - 1. Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014); **OR**
 - 2. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG);
- OR**
- C. Cerebrospinal fluid hypocretin-1 deficiency (less than [$<$] 110 pg/mL or less than one-third of the normative values with the same standardized assay);

OR

- III. Individual is 18 years of age or older; **AND**
- IV. Individual has a diagnosis of Narcolepsy type 2 confirmed by the following:
- A. MSLT with **ONE** of the following:

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1. Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014); **OR**
2. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight PSG;

AND

- B. The absence of cataplexy; **AND**
- C. Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam and PSG.

Requests for Provigil (modafinil) may be approved for the treatment of Obstructive Sleep Apnea-Hypopnea based on if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis of obstructive sleep apnea-hypopnea objectively confirmed by PSG or home testing with portable monitor showing **ONE** of the following (ASM 2009):
 - A. Greater than 15 obstructive events (defined as apneas, hypopneas plus respiratory event related arousal) per hour of sleep; **OR**
 - B. Greater than 5 obstructive events per hour of sleep and individual reports any of the following:
 1. Unintentional sleep episodes during wakefulness
 2. Daytime sleepiness; **OR**
 3. Unrefreshing sleep; **OR**
 4. Fatigue; **OR**
 5. Insomnia; **OR**
 6. Waking up breath holding, gasping, or choking; **OR**
 7. Bed partner describing loud snoring, breathing interruptions or both; **OR**
 8. Presence of comorbid conditions including hypertension, mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation or type 2 diabetes mellitus;

AND

- III. Individual has an Epworth Sleepiness Scale score greater than or equal to 10, despite treatment with continuous positive airway pressure (CPAP).

Requests for Provigil (modafinil) may be approved for the treatment of Shift-Work Sleep Disorder (SWSD) based on if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis of shift-work sleep disorder (SWSD) confirmed by the following:
 - A. No other medical or mental disorder accounts for the symptoms; **AND**
 - B. Symptoms do not meet criteria for any other sleep disorder (such as jet lag)
 - C. Symptoms have occurred for at least 3 months; **AND**

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D. Individual has one of the following confirmed:

1. Individual has excessive sleepiness or insomnia associated with a work period that occurs during the usual sleep phase; **OR**
2. Polysomnography demonstrate loss of a normal sleep-wake pattern (such as disturbed chronobiological rhythmicity).

***NOTE:** The quantity limit for Provigil 200mg tablets can be increased from 200mg (30 tablets/30 days) to 400mg (60 tablets/30 days) after a trial of 200mg (30 tablets/30 days) per day with no success. Per manufacturer label, doses of 400mg per day given as a single dose have been well tolerated, but there is no consistent evidence that this dose confers additional benefit beyond that of the 200mg dose.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
Maryland		Maryland behavioral health is state carve out.

Key References:

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3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical Guideline for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults: Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. *J Clin Sleep Med* 2009; 5(3):263-276. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2699173/pdf/jcsm.5.3.263.pdf>. Accessed March 8, 2019.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
6. Wise MS, Arand DL, Auger RR, Brooks SN, Watson NF; American Academy of Sleep Medicine. Treatment of Narcolepsy and other Hypersomnias of Central Origin. *Sleep*. 2007 Dec 1;30(12):1712-27. Available from: http://www.aasmnet.org/Resources/PracticeParameters/Review_Narcolepsy.pdf. Accessed March 8, 2019.
7. Kapur VK, Auckley DH, Chowdhri S, et.al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: An American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2017; 13(3): 479-504. Available from: <https://aasm.org/resources/clinicalguidelines/diagnostic-testing-osa.pdf>. Accessed April 8, 2019.
8. Sateia MJ. International classification of sleep disorders – third edition: Highlights and modifications. *Chest*. 2014 Nov; 146(5): 1387-1394.

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