Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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Provigil (modafinil)

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

Medications	Quantity Limit
Provigil (modafinil) 100mg	Dose optimization of 1 tablet per day
Provigil (modafinil) 200mg	Quantity limit of 1 tablet per day

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 the following criteria:

I. Individual is 18 years of age or older; **AND**

II. Individual has a diagnosis of Narcolepsy type 1 (narcolepsy with cataplexy) confirmed by the presence of daily periods of irrepressible 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**

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Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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IV. Individual has a diagnosis of Narcolepsy type 2 confirmed by the following:

- **a.** Multiple sleep latency test (MSLT) with 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);

AND

- **b.** The absence of cataplexy; **AND**
- **c.** Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam and polysomnography.

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

I. Individual is 18 years of age or older; **AND**

II. Individual has a diagnosis of obstructive sleep apnea-hypopnea objectively confirmed by polysomnography (PSG) or home testing with portable monitor showing one of the following:

- **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 the following criteria:

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Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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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**
- **d.** Individual has one of the following:
  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).

If Provigil is requested and one of the above criteria is not met, then request will be forwarded to the plan for review.

*__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. According to the package insert, 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		
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2015. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 23, 2015.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

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 June 25, 2015.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2015; Updated periodically.

Morgenthaler TI, Kapur VK, Brown TM, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin: An American Academy of Sleep Medicine Report. *Sleep.* 2007; 30(12):1705-1711. Available from: http://www.aasmnet.org/resources/practiceparameters/PP_narcolepsy.pdf. Accessed June 23, 2015.

Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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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. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2082098/pdf/aasm.30.11.1445.pdf. Accessed June 25, 2015.

Sateia MJ. International classification of sleep disorders-third edition: highlights and modifications. Chest. 2014-11;146:1387-1394.