

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

*FHK- Florida Healthy Kids

Nuvigil (armodafinil)

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

Medications	Quantity Limit
Nuvigil (armodafinil) 50mg	2 tablets per day
Nuvigil (armodafinil) 150mg, 200mg, 250mg tablets	1 tablet per day

APPROVAL CRITERIA

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

Requests for Nuvigil (armodafinil) 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**

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

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WEB-PEC-0610-17

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- 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 Nuvigil (armodafinil) 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 Nuvigil (armodafinil) may be approved for the treatment of Shift-Work Sleep Disorder (SWSD) based on the following criteria:

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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).

Once one of the criteria is met, there is a quantity limit based on the manufacturer's recommended dosage.

If Nuvigil (armodafinil) is requested and one of the above criteria is not met, then requests will be reviewed on a case by case basis.

State Specific Mandates		
N/A	N/A	N/A

Key References:

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