Market Applicability					
Market	**GA**	**KY**	**MD**	**NJ**	**NY**
Applicable	X	NA	X	X	X

Nuvigil (armodafinil)

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

Medications	Quantity Limit
Nuvigil (armodafinil)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Nuvigil (armodafinil) 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 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:
    A. 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**

Market Applicability					
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Applicable	X	NA	X	X	X

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 Nuvigil (armodafinil) 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 Nuvigil (armodafinil) 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)

Market Applicability					
Market	**GA**	**KY**	**MD**	**NJ**	**NY**
Applicable	X	NA	X	X	X

C. Symptoms have occurred for at least 3 months; **AND**
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).

Key References:

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11. Drugs@FDA:FDA Approved Drug Products. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/. Accessed on July 31, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.