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I. Medication Description

Modafinil and armodafinil are wakefulness-promoting medications with effects similar, but not identical to, CNS stimulants such as amphetamine and methylphenidate.

II. Position Statement

Coverage is provided immediately when prescribed by a neurologist or pulmonologist at FDA-approved doses (with an additional quantity limit on Provigil/modafinil 100mg tablets – covered at up to 30 per each 30 days).

Coverage is determined through a prior authorization process with supporting clinical documentation for every other request.

III. Policy

Formulary 1: See Section A

Formulary 2: See Section A

Formulary 3/Exclusive: See Sections A and B

Formulary 4/AON: See Section A

A. Coverage is provided:
   • Upon request or recommendation of a neurologist, pulmonologist, or other certified sleep specialist (Certified International Sleep Specialist or Diplomat of the American Board of Sleep Medicine).
   • For all other situations, coverage is provided in accord with the following:
     o Narcolepsy: Where diagnosis is confirmed via neurologist/pulmonologist consult or polysomnography
     o Obstructive Sleep Apnea:
       ▪ Which results in residual daytime sleepiness AND
       ▪ Where member is compliant with nasal continuous positive airway pressure (CPAP) or BiPAP therapy
     o Shift-Work Sleep Disorder
     o Idiopathic Hypersomnia:
       ▪ Diagnosis confirmed by polysomnography with rule out of other conditions including narcolepsy, obstructive sleep apnea, posttraumatic hypersomnia, unnecessary use of sedating medications
     o Fatigue or excessive sleepiness associated with depression:
       ▪ Member must currently be treated with antidepressant therapy
o Fatigue associated with multiple sclerosis
o Fatigue or excessive daytime sleepiness associated with Parkinson’s disease

B. Additionally, coverage is provided for Nuvigil or armodafinil in situations where the member has experienced treatment failure or intolerance with the plan-preferred medication (modafinil) OR when the following criteria are met:

• When requesting coverage of a brand medication for which an A/B rated generic is available, there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results AND
• At least one of the following is met:
  o The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
  o The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.
  o The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
  o The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected due to the availability of a drug sample or a coupon card).
  o The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily activities.

IV. Quantity Limitations

• Nuvigil/armodafinil 50mg : 30 tablets per month
• Nuvigil/armodafinil 150mg : 30 tablets per month
• Nuvigil/armodafinil 200mg : 30 tablets per month
• Nuvigil/armodafinil 250mg : 30 tablets per month
• Provigil/modafinil 100mg : 30 tablets per month
• Provigil/modafinil 200mg : 60 tablets per month

V. Coverage Duration

Coverage will be granted indefinitely through the life of this policy once the initial criteria are met.

VI. Coverage Renewal Criteria

n/a
VII. Billing/Coding Information

- Nuvigil: 50mg, 150mg, 200mg, and 250mg tablets
- Provigil: 100mg and 200mg tablets

VIII. Summary of Policy Changes

- 1/1/12:
  - Specialist notes/polysomnography required for narcolepsy diagnosis
  - Coverage duration for narcolepsy increased to 2 years
- 1/2012: approval duration extended
- 9/15/2012: approval duration extended, modafinil added to policy
- 12/15/2012:
  - Certified sleep specialists added for specialist approval
  - Warnings updated
  - Shift work sleep disorder changed to allow for prescriber-confirmed diagnosis
  - Step therapy criteria added for Medicaid/FHP members
- 12/15/2013: no policy changes
- 1/1/15: Nuvigil 200mg added, quantity limit for 200mg tablet added
- 7/1/15: formulary distinctions made
- 12/15/15: no policy changes
- 9/15/16: no policy changes
- 5/1/17:
  - Step therapy criteria added,
  - Coverage criteria updated to exclude trials with traditional stimulants
  - Additional indications such as fatigue associated with multiple sclerosis and Parkinson’s disease added
- 10/11/17: quantity limits updated

IX. References

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.