Washington State Health Care Authority

ADHD/Anti-Narcolepsy: Stimulants – Misc – Armodafinil/Modafinil

Medical policy no. 61.40.00.AA-1 Effective Date: TBD

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Background:

Modafinil and Armodafinil are wakefulness-promoting agents FDA approved to improved wakefulness in patients with excessive sleepiness associated with narcolepsy, shift work disorder, and obstructive sleep apnea.

Medical necessity

Drug	Medical Necessity
Armodafinil **(Nuvigil)** Modafinil **(Provigil)**	**Armodafinil (Nuvigil) and modafinil (Provigil)** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration. Clients new to Apple Health or new to an MCO, who are requesting regimens for continuation of therapy should be reviewed following the reauthorization criteria listed below.

Clinical policy:

Clinical Criteria	
Narcolepsy	Armodafinil (Nuvigil) or modafinil (Provigil) may be authorized when **ALL** of the following are met: 1. Clients 17 years of age or younger require a second opinion review with the agency-designated mental health specialist from the Second Opinion Network (SON); **OR** 2. Client is 18 years of age or older; **AND**

	3. Diagnosis of narcolepsy with excessive somnolence, confirmed with a sleep study and multiple sleep latency test (MSLT); **AND** 4. For armodafinil, trial and failure of modafinil for a minimum of 60 days **If ALL criteria are met, the request will be approved for 12 months.** If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration.
	Criteria (Reauthorization) Armodafinil (Nuvigil) or modafinil (Provigil) may be reauthorized when **ALL** of the following are met: 1. Documentation is submitted demonstrating a positive clinical response. **If ALL criteria are met, the request will be authorized for 12 months.** If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the reauthorization duration.
Obstructive Sleep Apnea	Armodafinil (Nuvigil) or modafinil (Provigil) may be authorized when **ALL** of the following are met: 1. Clients 17 years of age or younger require a second opinion review with the agency-designated mental health specialist from the Second Opinion Network (SON); **OR** 2. Client is 18 years of age or older; **AND** 3. Diagnosis of obstructive sleep apnea with residual excessive somnolence, confirmed with a sleep study; **AND** 4. Clinical documentation is submitted demonstrating the following: a. Client has achieved normalized breathing and oxygenation with continuous positive airway pressure (CPAP) therapy; **AND** b. Documentation within the past 6 months demonstrating client is adherent to CPAP therapy. Client is determined to be adherent when CPAP is used for 70% of nights for a minimum of 4 hours per night; **AND** 5. For armodafinil, trial and failure of modafinil for a minimum of 60 days **If ALL criteria are met, the request will be approved for 6 months.** If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration.

	Criteria (Reauthorization)
	Armodafinil (Nuvigil) or modafinil (Provigil) may be reauthorized when **ALL** of the following are met: 1. Documentation is submitted demonstrating a positive clinical response. 2. Documentation within the past 6 months demonstrating client continues to be adherent to CPAP therapy. Client is determined to be adherent when CPAP is used for 70% of nights for a minimum of 4 hours per night. **If ALL criteria are met, the request will be approved for 6 months.**

Dosage and quantity limits

Indication	Dose and Quantity Limits
Narcolepsy	• Modafinil: Up to 400 mg per day, max 2 tablet per day. • Armodafinil: Up to 250mg per day, max 1 tablet per day.
Obstructive Sleep Apnea	• Modafinil: Up to 400 mg per day, max 2 tablet per day. • Armodafinil: Up to 250mg per day, max 1 tablet per day.

History

Date	Action and Summary of Changes
06.07.2021	New policy

Washington State Health Care Authority

Armodafinil/Modafinil

Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

Apple Health Preferred Drug list: *https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx*

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength	Directions for use	Qty/Days supply	

1. Is this request for a continuation of existing therapy? ☐ Yes ☐ No
   If yes, does patient have documentation of positive clinical response? ☐ Yes ☐ No

2. Please indicate patient's diagnosis:
   ☐ Narcolepsy with excessive somnolence, confirmed with a sleep study and multiple sleep latency test (MSLT).
   ☐ Obstructive Sleep Apnea with residual excessive somnolence, confirmed with a sleep study.
   ☐ Other. Specify: _____

3. For armodafinil, has patient tried and failed modafinil for a minimum of 60 days? ☐ Yes ☐ No

4. For patients 17 years of age or younger: Has an agency-designated mental health specialist from the Second Opinion Network (SON) performed a required second opinion review? ☐ Yes ☐ No

For diagnosis of Obstructive Sleep Apnea, please answer the following:

5. Has patient achieved normalized breathing and oxygenation with continuous positive airway pressure (CPAP) therapy? ☐ Yes ☐ No

6. Does patient have documentation within the past 6 months, demonstrating adherence (CPAP is used for 70% of nights for a minimum of 4 hours per night) to CPAP therapy? ☐ Yes ☐ No

For continuation of therapy, documentation of positive clinical response and chart notes are required. Obstructive Sleep Apnea also requires compliance report of usage for the last 6 months.

For diagnosis of Narcolepsy, provide the following:

- sleep study and multiple sleep latency test (MSLT)
- chart notes

For diagnosis of Obstructive Sleep Apnea, provide the following:

- sleep study
- documentation of CPAP compliance (compliance report of usage) in the last 6 months
- chart notes

Prescriber signature	Prescriber specialty	Date