Washington State Health Care Authority

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

Medical policy no. 61.40.00.AA-1 Effective Date: February 1, 2022

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 improve wakefulness in patients with excessive sleepiness associated with narcolepsy, shift work sleep 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 **ONE** of the following: a. Client has achieved normalized breathing and oxygenation with continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP)therapy; **AND** i. Documentation within the past 6 months demonstrating client is adherent to CPAP or BIPAP therapy. Client is determined to be adherent when CPAP or BIPAP is used for 70% of nights for a minimum of 4 hours per night; **OR** b. Documentation within the past 6 months demonstrating that client is adherent to mandibular advancement device; **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; **AND** 2. Documentation demonstrating **ONE** of the following: a. Documentation within the past 6 months demonstrating client continues to be adherent to CPAP or BIPAP therapy. Client is determined to be adherent when CPAP or BIPAP is used for 70% of nights for a minimum of 4 hours per night; **OR** b. Documentation within the past 6 months demonstrating client continues to be adherent to mandibular advancement device. **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 reauthorization duration.
Shift Work Sleep Disorder	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 shift work sleep disorder; **AND** 4. Clinical documentation demonstrates concomitant use of nonpharmacologic interventions (i.e. counseling, sleep hygiene); **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 3 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 3 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.
Sleep Deprivation	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 sleep deprivation; **AND** 4. Clinical documentation demonstrates concomitant use of nonpharmacologic interventions (i.e. counseling, sleep hygiene); **AND** 5. Clinical documentation demonstrates medically necessary purpose for sleep deprivation therapy. **If ALL criteria are met, the request will be approved for 1 month.** 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)** 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 1 month.** 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.

Dosage and quantity limits

Indication	Dose and Quantity Limits
Narcolepsy	• Modafinil: Up to 400 mg per day, max 2 tablets 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 tablets per day. • Armodafinil: Up to 250mg per day, max 1 tablet per day.
Shift Work Sleep Disorder	• Modafinil: Up to 200 mg per day, max 1 tablet per day. • Armodafinil: Up to 150 mg per day, max 1 tablet per day.
Sleep Deprivation	• Modafinil: Up to 400 mg per day, max 2 tablets per day

References

History

Date	Action and Summary of Changes
10/15/2021	Added implementation date of 2/1/2022
09/03/2021	Updating policy to include bilevel positive airway pressure and mandibular advancement devices as options demonstrating treatment for obstructive sleep apnea. Updating clinical policy and dosage and quantity limits to include shift work sleep disorder and sleep deprivation as compendia-supported indications.
08/18/2021	Approved by DUR Board
06/07/2021	New policy