Anti Narcolepsy Agents: Armodafinil/modafinil/Sunosi/Wakix

WA.PHAR.124 Effective Date: 2/1/2024

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 publication of the Coordinated Care of Washington, Inc. Preferred Drug List (PDL), please visit: https://pharmacy.envolvehealth.com/content/dam/centene/envolve-pharmacy-solutions/pdfs/PDL/FORMULARY-CoordinatedCare_Washington.pdf

Medical necessity

Drug	Medical Necessity
Armodafinil (Nuvigil) Modafinil (Provigil) Pitolisant (Wakix) Solriamfetol (Sunosi)	**Anti-narcolepsy agents** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.

Clinical policy:

Clinical Criteria	
Narcolepsy with Excessive Daytime Sleepiness Armodafinil (Nuvigil) Modafinil (Provigil) Pitolisant (Wakix) Solriamfetol (Sunosi)	Armodafinil (Nuvigil), modafinil (Provigil), pitolisant (Wakix), or solriamfetol (Sunosi) may be approved when all of the following criteria 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. Patient is 18 years of age or older; **AND** 3. Prescribed by, or in consultation with a neurologist, psychiatrist, or sleep specialist; **AND** 4. Diagnosis of narcolepsy with excessive somnolence, confirmed with a sleep study and multiple sleep latency test (MSLT); **AND** 5. A quantitative assessment within the past 6 months is submitted (e.g. Epworth Sleepiness Scale, Maintenance of Wakefulness Test); **AND**

	6. If the request is for armodafinil, pitolisant, or solriamfetol: History of failure, contraindication, or intolerance to ALL of the following: a. For armodafinil (Nuvigil): i. Modafinil (Provigil) for a minimum of 60 consecutive days. b. For solriamfetol (Sunosi): i. Modafinil (Provigil) or armodafinil (Nuvigil) for a minimum of 60 consecutive days; **AND** ii. Amphetamine or methylphenidate-based stimulant for a minimum of 60 consecutive days. c. For pitolisant (Wakix): i. Modafinil or armodafinil for a minimum of 60 consecutive days; **AND** ii. Amphetamine or methylphenidate-based stimulant for a minimum of 60 consecutive days; **AND** iii. Solriamfetol (Sunosi) for a minimum of 30 consecutive days. If ALL criteria are met, the request will be authorized for **12 months.**
	Criteria (Reauthorization) Armodafinil (Nuvigil), modafinil (Provigil), pitolisant (Wakix), or solriamfetol (Sunosi) may be approved when all of the following criteria are met: 1. A quantitative assessment within the past 6 months (e.g. Epworth Sleepiness Scale, Maintenance of Wakefulness Test) is submitted demonstrating disease stability or a positive clinical response. If ALL criteria are met, the request will be authorized for **12 months.**
Narcolepsy with Cataplexy Pitolisant (Wakix)	Pitolisant (Wakix) may be approved when all of the following criteria 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. Patient is 18 years of age or older; **AND** 3. Prescribed by, or in consultation with a neurologist, psychiatrist, or sleep specialist; **AND** 4. Diagnosis of narcolepsy with cataplexy, confirmed with a sleep study and multiple sleep latency test (MSLT); **AND** 5. A quantitative assessment within the past 6 months is submitted (e.g. Epworth Sleepiness Scale, Maintenance of Wakefulness Test); **AND**

	6. Clinical documentation supports presence of cataplexy (e.g. documented episodes of sudden loss of muscle tone) and impairment/limitation of activities of daily living (e.g. unable to attend school, unable to drive) If ALL criteria are met, the request will be authorized for **12 months.**
	Criteria (Reauthorization) Pitolisant (Wakix) may be approved when all of the following criteria are met: 1. A quantitative assessment within the past 6 months (e.g. Epworth Sleepiness Scale, Maintenance of Wakefulness Test) is submitted demonstrating disease stability or a positive clinical response; **AND** 2. Clinical documentation is submitted showing a reduction in cataplexy events. If ALL criteria are met, the request will be authorized for **12 months.**
Obstructive Sleep Apnea with Excessive Daytime Sleepiness Armodafinil (Nuvigil) Modafinil (Provigil) Solriamfetol (Sunosi)	Armodafinil (Nuvigil), modafinil (Provigil) or solriamfetol (Sunosi) may be approved when all of the following criteria 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. Patient is 18 years of age or older; **AND** 3. Prescribed by, or in consultation with a neurologist, psychiatrist, or sleep specialist; **AND** 4. Diagnosis of obstructive sleep apnea with residual excessive somnolence, confirmed with a sleep study; **AND** 5. A quantitative assessment within the past 6 months is submitted (e.g. Epworth Sleepiness Scale, Maintenance of Wakefulness Test); **AND** 6. Clinical documentation is submitted demonstrating ONE of the following: a. Client has achieved normalized breathing, as evident by compliance data showing apnea-hypopnea index less than 5 incidents per hour, 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**

	7. If the request is for armodafinil or solriamfetol: History of failure, contraindication, or intolerance to ALL of the following: a. For Armodafinil (Nuvigil): Modafinil (Provigil) for a minimum of 60 consecutive days. b. For Solriamfetol (Sunosi): Modafinil (Provigil) or armodafinil (Nuvigil) for a minimum of 60 consecutive days. If ALL criteria are met, the request will be authorized for **12 months.** **Criteria (Reauthorization)** Armodafinil (Nuvigil), modafinil (Provigil) or solriamfetol (Sunosi) may be approved when all of the following criteria are met: 1. A quantitative assessment within the past 6 months (e.g. Epworth Sleepiness Scale, Maintenance of Wakefulness Test) is submitted demonstrating disease stability or a positive clinical response. 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 authorized for **12 months.**
Shift Work Sleep Disorder Armodafinil (Nuvigil) Modafinil (Provigil)	Armodafinil (Nuvigil) or modafinil (Provigil) may be approved when all of the following criteria 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. Patient 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. If the request is for armodafinil: History of failure, contraindication, or intolerance to ALL of the following: a. Modafinil for a minimum of 60 consecutive days. If ALL criteria are met, the request will be authorized for **3 months.** **Criteria (Reauthorization)** Armodafinil (Nuvigil) or modafinil (Provigil) may be approved when all of the following criteria are met:

	1. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g. improvement or stability of symptoms which include improvement in their ability to complete activities of daily living or stay awake]. If ALL criteria are met, the request will be authorized for **6 months.**

Dosage and quantity limits

Drug	Indication	FDA Approved Dosing	Dosage Form and Quantity Limit
Armodafinil (Nuvigil)	Narcolepsy with excessive daytime sleepiness	Up to 250 mg once daily	• 50 mg tablets: 2 tablets per day • 150 mg tablets: 1 tablet per day • 200 mg tablets: 1 tablet per day • 250 mg tablets: 1 tablet per day
Armodafinil (Nuvigil)	Obstructive sleep apnea with excessive daytime sleepiness	Up to 250 mg once daily	• 50 mg tablets: 2 tablets per day • 150 mg tablets: 1 tablet per day • 200 mg tablets: 1 tablet per day • 250 mg tablets: 1 tablet per day
Armodafinil (Nuvigil)	Shift work sleep disorder	150 mg once daily	• 150 mg tablets: 1 tablet per day
Modafinil (Provigil)	Narcolepsy with excessive daytime sleepiness	Up to 400 mg per day	• 100 mg tablets: 2 tablets per day • 200 mg tablets: 2 tablet per day
Modafinil (Provigil)	Obstructive sleep apnea with excessive daytime sleepiness	Up to 400 mg per day	• 100 mg tablets: 2 tablets per day • 200 mg tablets: 2 tablet per day
Modafinil (Provigil)	Shift work sleep disorder	Up to 400 mg per day	• 100 mg tablets: 2 tablets per day • 200 mg tablets: 2 tablets per day
Pitolisant (Wakix)	Narcolepsy with cataplexy	Up to 35.6 mg per day	• 4.45 mg tablets: 14 tablets per 7 days • 17.8 mg tablets: 2 tablets per day
Pitolisant (Wakix)	Narcolepsy with excessive daytime sleepiness	Up to 35.6 mg per day	• 4.45 mg tablets: 14 tablets per 7 days • 17.8 mg tablets: 2 tablets per day
Solriamfetol (Sunosi)	Narcolepsy with excessive daytime sleepiness	Up to 150 mg per day	• 75 mg tablets: 1 tablet per day • 150 mg tablets: 1 tablet per day
Solriamfetol (Sunosi)	Obstructive sleep apnea with excessive daytime sleepiness	Up to 150 mg per day	• 75 mg tablets: 1 tablet per day • 150 mg tablets: 1 tablet per day

Background:

Obstructive sleeping apnea (OSA) is a common sleep-related breathing disorder defined as having five or more apnea or hypopnea even per hour of sleep. Patients with OSA often experience excessive daytime sleepiness which significantly limits their ability to maintain wakefulness and alertness during day. The American Academy of Sleep Medicine (AASM) guidelines strongly recommend positive airway pressure (PAP) to treat OSA with excessive sleepiness. Oral appliances and surgical intervention are alternative options. For patients who still experience excessive daytime sleepiness despite adequate OSA treatment, AASM recommends trial of wakefulness-promoting agents. Medications approved to treat excessive somnolence in the setting of OSA include modafinil, armodafinil, and solriamfetol. Solfiamfetol has not been compared to any other treatment option (e.g, modafinil, armodafinil); therefore, the comparative safety and efficacy is unknown. Notably, other stimulants (e.g. methylphenidate and amphetamines) have not been studied in this disease state.

"Narcolepsy is a neurological disorder that affects the brain's ability to control sleep. People with narcolepsy experience excessive daytime sleepiness throughout the day which affects activities of daily living. Some people also experience cataplexy, a sudden loss of muscle tone which leads to weakness and loss of voluntary muscle control."[8] For adults, the AASM guidelines strongly recommend the use of modafinil, pitolisant, sodium oxybate and solriamfetol and conditionally recommends the use of armodafinil and dextroamphetamine for the treatment of narcolepsy in patients without cataplexy. For patients experiencing narcolepsy with cataplexy, the AASM guidelines strongly recommend the use of pitolisant and sodium oxybate and conditionally recommends dextroamphetamine. For pediatrics, the AASM conditionally recommends modafinil and sodium oxybate for the treatment of narcolepsy without cataplexy. For pediatrics with narcolepsy and cataplexy, sodium oxybate is conditionally recommended.

"Shift work sleep disorders are caused by shift work, defined as non-standard work schedules, including permanent or intermittent night work, early morning work, and rotating schedules."[7] These work schedules may cause difficulties with sleep which impact wakefulness and ability to perform activities of daily living. The AASM guidelines recommend non-pharmacologic and pharmacologic interventions for the treatment of shift work sleep disorders. Non-pharmacologic interventions include planned napping and timed light exposure to improve alertness with night shift work. Pharmacologic therapies include modafinil, caffeine, and stimulants with modafinil and caffeine having established safety in situations where therapy is needed. Stimulants were shown to have less evidence and chronic use may lead to abuse potential. Modafinil and armodafinil and the only products supported in compendia.

Sleep deprivation is caused when one's sleep requirements are not met. The amount of sleep one needs varies but on average, adults typically need 7 to 8 hours of sleep per day. This results in excessive daytime sleepiness which impacts one's performance, mood, and health and can become a safety hazard (e.g. falling asleep while driving, causing a workplace injury). The AASM provided a statement on the use of stimulants to modify performance during sleep loss. The stimulants evaluated include caffeine, amphetamine, methamphetamine, d-amphetamine, methylphenidate, pemoline and modafinil. Of these, only modafinil is supported by compendia (off-label). These therapies may be used in situations where sleep is not possible to reduce the effects of sleep deprivation. It is emphasized that one must consider all the risks associated with treatment and postponement of sleep.

The safety and efficacy of armodafinil (Nuvigil) was established for obstructive sleep apnea (OSA), narcolepsy and shift work disorder in two, one, and one double-blind, placebo-controlled clinical trials, respectively. For OSA, participants were required to be compliant with CPAP, using it for 4 or more hours per night for 70% or more of nights. In the first trial (n=395) and second trial (n=264), the armodafinil groups showed a significant improvement in both the Maintenance of Wakefulness Test (MWT) and Clinical Global Impression of Change (CGI-C). The change in MWT from baseline (shown as change/baseline) was 1.7/21.5, 2.2/23.3, and -1.7/23.2 for study 1 for the armodafinil 150 mg group, armodafinil 250 mg group, and placebo group, respectively. The change in MWT from baseline in trial 2 was 2.3/23.7 and -1.3/23.3 for the armodafinil 150 mg and placebo groups, respectively. For the CGI-C endpoint, 71%, 74% and 37% of patients in trial 1 had an improvement in CGI-C at final visit for the armodafinil 150 mg, armodafinil 250 mg, and placebo groups, respectively. In trial 2, 71% and 53% of patients had an improvement in CGI-C at final visit for the armodafinil 150 mg and placebo groups, respectively. In the one trial evaluating armodafinil for narcolepsy with excessive sleepiness (n=196), MWT and CGI-C were significantly improved in the armodafinil group vs placebo. The change in MWT from baseline (shown as change/baseline) was 1.3/12.1, 2.6/9.5, and -1.9/12.5 for the armodafinil 150 mg, armodafinil 250 mg and placebo groups, respectively. For the CGI-C endpoint, 69%, 73% and 33% of patients had an improvement in the CGI-C at final visit for the armodafinil 150 mg, armodafinil 250 mg, and placebo groups, respectively. In the one trial evaluating armodafinil for shift work disorder (n=254), the Multiple Sleep Latency Test (MSLT) and CGI-C were significantly improved in the armodafinil group vs placebo. The change in MSLT (shown as change/baseline) was 3.1/2.3 and 0.4/2.4 for the armodafinil 150 mg group and placebo group, respectively. 79% in the armodafinil and 59% in the placebo group experienced an improvement in the CGI-C. The adverse effects profile >2% for armodafinil include headache, nausea, dizziness, insomnia, anxiety, diarrhea, dry mouth, depression, dyspepsia, fatigue, palpitations, rash, and upper abdominal pain. In addition, serious dermatologic reactions have been reported in association with use of armodafinil or modafinil. This includes Stevens-Johnson Syndrome and toxic epidermal necrosis which have been reported with an incidence of 0.8% in pediatric patients in clinical trials. These reports have continued worldwide post-marketing.

The safety and efficacy of modafinil (Provigil) was established for narcolepsy, obstructive sleep apnea, and shift work disorder in two, two, and one placebo-controlled trials, respectively. Off-label compendia support was established from a review by the Sleep Deprivation and Stimulant Task Force of the American Academia of Sleep Medicine. For narcolepsy with excessive daytime sleepiness (EDS), two 9-week, placebo controlled trials (n=558), the primary outcomes of sleep latency (assessed by MWT) and change in overall diseases status (assessed by change in CGI-C) were significantly improved compared to placebo. Change in MWT (shown as change/baseline) for trial 1 was 2.3/5.8, 2.3/6.6 and -0.7/5.8 for modafinil 200mg, modafinil 400 mg, and placebo, respectively. For trial 2 change in MWT (shown as change/baseline) was 2.2/6.1, 2.0/5.9, and -0.7/6.0 for modafinil 200 mg, 400 mg, and placebo, respectively. For the CGI-C endpoint in trial 1, 64%, 72%, and 37% of patients had an improvement in the CGI-C at final visit for modafinil 200 mg, 400 mg, and placebo, respectively. For trial 2, 58%, 60%, and 38% of patients in the modafinil 200 mg, 400 mg, and placebo achieved an improvement in CGI-C, respectively. For OSA, the first trial (n=327) was 12 weeks and the primary outcomes included sleep latency (assessed by MWT) and change in overall disease status (assessed by CGI-C). The change in MWT (shown as change/baseline) was 1.6/13.1, 1.5/13.6, and -1.1/13.8 for modafinil 200 mg, modafinil 400 mg, and placebo, respectively. The percent of patients who had improvement in CGI-C at final visit was 61%, 68%, and 37% for modafinil 200 mg, modafinil 400 mg, and placebo, respectively. The second trial (n=157) was 4 -weeks and the primary outcome was change in Epworth Sleepiness Scale (ESS) from baseline. There was significant difference in ESS at week 4 with a reduction of (shown as change/baseline) of 4.6/14.2 and 2.0/14.4 for modafinil 400 mg and placebo, respectively. For shift work disorder one trial (n=209) showed significant differences in sleep latency (assessed by MSLT during a simulated night shift) and change in overall disease status (assessed by CGI-C). The change in MSLT (shown as change/baseline) was 1.7/2.1 and 0.3/2.0 for modafinil 200 mg and placebo, respectively. The percent of patients who showed improvement in the CGI-C was 74% and 36% for modafinil 200 mg and placebo, respectively. For sleep deprivation, 9 of 10 clinical studies, at the time of review, found that reaction time or response time was found to be significantly improved during sleep-deprivation periods from 36 to 88 hours after receiving modafinil. In addition, 5 of 5 studies showed significant increases in the MSLT and MWT sleep-latency tests when compared to placebo. Common adverse effects ≥2% include headache, nausea, nervousness, rhinitis, back pain, diarrhea, anxiety, dizziness, dyspepsia, insomnia, anorexia, dry mouth, pharyngitis, chest pain, hypertension, abnormal liver function, constipation, depression, palpitation, paresthesia, somnolence, tachychardia, and vasodilation. In addition, serious dermatologic reactions including Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis have been reported with an incidence of 0.8% in pediatric patients in clinical trials. These reports have continued worldwide post-marketing.

The safety and efficacy of solriamfetol (Sunosi) was established in two randomized phase 3, double-blind, placebo-controlled clinical trials. The first trial (n=239) demonstrated that solriamfetol 150 mg daily significantly improved ability to stay awake during the Maintenance of Wakefulness Test (MWT) after 12 weeks in the setting of narcolepsy. In the setting of OSA (n=476), all doses of solriamfetol (37.5mg, 75mg, and 150mg) similarly improved WMT after 12 weeks. For both trials, the effect was observed after one week. Common adverse effects (≥2%) include decreased appetite, insomnia, anxiety, irritability, headache, heart palpitations, nausea, abdominal pain, dry mouth, dizziness, and constipation. Certain adverse effects, including headache, nausea, decreased appetite, and anxiety, occurred more frequently at higher doses. Eleven participants (3%) discontinued Sunosi during the clinical trial compared to <1% for placebo. Discontinuation reasons included anxiety, heart palpitations, and restlessness. Notably, blood pressure should also be monitored while taking Sunosi.

The safety and efficacy of pitolisant (Wakix) was established in two randomized, double-blind, placebo-controlled studies, NCT01067222 and NCT01638403. In NCT01067222 (n=95), pitolisant demonstrated a significant improvement in Epworth sleepiness scale (ESS) score (-3.1; 95% CI [-5.73, -0.46]) compared to placebo after an 8 week treatment period. In NCT01067222, pitolisant was also compared to modafinil and pitolisant failed to demonstrate non-inferiority. In NCT01638403 (n=166), pitolisant demonstrated a significant improvement in ESS compared to placebo (-2.2; 95%CI [-4.17, -0.22]) after 8 weeks of treatment. Cataplexy reduction was evaluated in NCT01800045 (n=106) and pitolisant demonstrated a significant reduction in the weekly cataplexy rate (75%) when compared to the placebo group (38%), with a rate ratio of 0.51 (0.44-0.60, p<0.0001). Common adverse effects ≥2% include headache, insomnia, nausea, upper respiratory tract infection, musculoskeletal pain, anxiety, increased heart rate, hallucinations, irritability, abdominal pain, sleep disturbance, decreased appetite, cataplexy, dry mouth, and rash. Pitolisant is contraindicated in patients with severe hepatic impairment due to its metabolism by the liver. Pitolisant also causes QT prolongation and should be avoided.

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History

Approved Date	Effective Date	Version	Action and Summary of Changes
8/16/2023	2/1/2024	61.40.00-2	Approved by DUR Board on 8/16/2023 Policy Update -Updating policy to new HCA clinical policy format. -Updating policy to include clinical criteria for pitolisant and solriamfetol. -Removed sleep deprivation from policy as it was determined not to be medically necessary.
8/18/2021	2/1/2022	61.40.00.AA-1	Approved by DUR Board on 8/18/2021. New policy created -Policy was updated 9/3/2021 to include bilevel positive airway pressure and mandibular advancement devices as options demonstrating treatment for obstructive sleep apnea. -Updated dosing limits for Armodafinil and Modafinil to include shift work sleep disorder and sleep deprivation as compendia-supported indications.