VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

Armodafinil (Nuvigil)

Effective Date: 7/21/2020
Date Developed: 7/21/2020 by Dr. H. Taekman
Last Approval Date: 8/18/2020; 8/3/2021, 2/1/22, 1/31/23, 2/13/24, 2/18/25

Armodafinil is the R-enantiomer of modafinil, which is a wakefulness promoting agent for oral administration. The exact mechanism of action is unknown. It does not appear to bind to or inhibit the most common receptors or enzymes that are relevant for sleep/wake regulation. It is known to generally inhibit dopamine reuptake.

Pre-Authorization Criteria:

A documented diagnosis of one of the following:

- Narcolepsy, confirmed by sleep lab evaluation **OR**
- Obstructive sleep apnea/hypopnea syndrome (OSAHS), confirmed by polysomnography (a study on sleep cycles and behavior) **AND** one of the following:
  - Member is currently using an oral/dental appliance
  - Member has undergone a~~n~~ uvulopalatopharyngoplasty (UPPP)
  - Member is greater than or equal to 65 yrs of age
  - Member has already had an adequate therapeutic trial of twelve weeks of continuous positive airway pressure (CPAP)/ bilevel positive airway pressure (BiPAP) treatment and meets ALL of the following:
    - Member is compliant with and currently using CPAP/BiPAP treatment
    - Member is experiencing excessive sleepiness despite CPAP/BiPAP use

Shift-work disorder: To improve wakefulness in patients with excessive sleepiness associated with shift-work disorder.

Precautions: Serious and life-threatening rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported; not recommended in patients with a history of left ventricular hypertrophy or patients with mitral valve prolapse who have developed mitral valve prolapse syndrome with previous CNS stimulant use; dosage reduction is recommended with severe hepatic impairment; Use caution in patients with a history of psychosis, depression, or mania; use reduced doses in elderly patients; check for drug interactions; Armodafinil is present in breast milk; patients who may become pregnant should avoid armodafinil use or use

effective contraception during armodafinil therapy (risk of major fetal congenital malformations and spontaneous abortion)
Note: Significant drug interactions exist, requiring dose/frequency adjustment or avoidance. Consult drug interactions database for more information.

Dosing: Adult

Narcolepsy: Oral: 150 to 250 mg once daily in the morning

Obstructive sleep apnea (OSA): Oral: 150 to 250 mg once daily in the morning; doses >150 mg have not been shown to have an increased benefit.

Shift-work disorder: Oral: 150 mg given once daily ~1 hour prior to work shift.

REFERENCES

1. Alertec (modafinil) [product monograph]. Toronto, Ontario, Canada: Teva Canada Limited; June 2019.
2. Ghaffari N, Robertson PA. Caution in prescribing modafinil and armodafinil to individuals who could become pregnant. JAMA Intern Med. 2021;181(2):277-278. doi:10.1001/jamainternmed.2020.4206
3. Holfinger S, Roy A, Schmidt M. Stevens-Johnson syndrome after armodafinil use. J Clin Sleep Med. 2018;14(5):885-887. doi:10.5664/jcsm.7132
4. Kaplan S, Braverman DL, Frishman I, Bartov N. Pregnancy and fetal outcomes following exposure to modafinil and armodafinil during pregnancy. JAMA Intern Med. 2021;181(2):275-277
5. Nuvigil (armodafinil) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals; December 2022

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Revision	Content	Contributors	Review/Revision Notes

Date	Revised (Yes/No)		
8/18/20	NEW	Howard Taekman, MD	NEW
8/3/21	Yes	Howard Taekman, MD; Robert Sterling, MD	Updated pre-authorization criteria with additional diagnoses.
2/1/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
1/31/23	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/13/24	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Updated Armodafinil definition, precautions section. Added references.