Effective Date: 04/01/2012
Last P&T Approval/Version: 04/27/2022
Next Review Due By: 04/2023
Policy Number: C4723-A

Narcolepsy Agents

PRODUCTS AFFECTED

Provigil (modafinil), Nuvigil (armodafinil)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
Narcolepsy, Obstructive Sleep Apnea, Shift Work Sleep Disorder

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. FOR ALL INDICAITONS:
1. (a) Documentation of diagnosis of narcolepsy, obstructive sleep apnea/hypopnea confirmed with sleep lab evaluation or polysomnography with respiratory monitoring
OR
(b) Documentation of shift work sleep disorder

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS

1. Documentation of symptom improvement and no reports of adverse side effects or toxicities

DURATION OF APPROVAL:

Initial authorization: 12 months. Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

None

AGE RESTRICTIONS:

17 years of age and older

QUANTITY:

30 tablets per 30 days

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral

DRUG CLASS:

Wakefulness-promoting agents

FDA-APPROVED USES:

Narcolepsy, Obstructive Sleep Apnea, Shift Work Sleep Disorder

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Nuvigil (armodafinil) and Provigil(modafinil) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy.

OTHER SPECIAL CONSIDERATIONS:

Stimulant medications (generic amphetamine/dextroamphetamine IR/ER and methylphenidate IR/ER) are preferred on the formulary. Some level of off label evidence exists for fatigue r/t MS, idiopathic hypersomnia, depression adjunct

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Modafinil: 100mg, 200mg tablets; Armodafinil: 50mg, 150mg, 200mg, 250mg tablets

REFERENCES

1. Provigil® [prescribing information]. Frazer, PA: Cephalon, Inc.; August 2021.
2. Nuvigil® tablets [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; July 2019.
3. Gelenberg A, Freeman MP, Markowitz JC, et al. Practice guideline for the treatment of patients with major depressive disorder, Third edition. American Psychiatric Association, November 2010. Available at: http://psychiatryonline.org/guidelines. Accessed on August 9, 2015.
4. Morgenthaler TI, Kapur VK, Brown T, et al, for the Standard of Practice Committee of the American Academy of Sleep Medicine. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. An American Academy of Sleep Medicine Report. Sleep. 2007;30(12):1705-1711

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Duration of Approval	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file