BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

modafinil (Provigil®)/armodafinil (Nuvigil®)

Policy # 00361
Original Effective Date: 08/21/2013
Current Effective Date: 08/20/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider brand or generic modafanil (Provigil®)‡ or armodafanil (Nuvigil®)‡ products to be **eligible for coverage** when one of the below patient selection criteria is met.

Patient Selection Criteria
Coverage eligibility will be considered for brand or generic modafanil (Provigil) or armodafanil (Nuvigil) products when one of the following patient selection criteria is met:

- Patient has narcolepsy; or
- Patient has excessive sleepiness due to obstructive sleep apnea/hypopnea syndrome (OSAHS); and
    - Patient has tried continuous positive airway pressure (CPAP); or
      *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has excessive sleepiness due to shift work sleep disorder (SWSD); and
    - Patient works 5 or more overnight shifts per month; or
      *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has fatigue associated with multiple sclerosis; or
- Patient has excessive daytime sleepiness due to myotonic dystrophy; or
- Patient has excessive daytime sleepiness due to Parkinson's disease; or
- Patient has fatigue or sleepiness associated with chronic use of narcotic analgesics; and
    - Patient has tried one central nervous system (CNS) stimulant (e.g. methylphenidate, dextroamphetamine), unless use of a central nervous system (CNS) stimulant is clinically inappropriate (e.g. patients with anxiety, glaucoma, tics, serious cardiovascular disease, seizures, underlying psychosis, or history of substance abuse); or
      *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

- Patient has fatigue associated with human immunodeficiency virus (HIV) infection; and
    - Patient has tried one central nervous system (CNS) stimulant (e.g. methylphenidate, dextroamphetamine), unless use of a central nervous system (CNS) stimulant is clinically inappropriate (e.g. patients with anxiety, glaucoma, tics, serious cardiovascular disease, seizures, underlying psychosis, or history of substance abuse); or

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*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

- Patient has myasthenia gravis; or
- Adult patient with depression and Provigil or Nuvigil would be used as adjunctive/augmentation treatment (e.g. with an antidepressant such as a selective serotonin receptor inhibitor). Note: this does not include bipolar disorder or bipolar depression; or
- Patient has idiopathic hypersomnia; or
- Patient has cancer related fatigue; or
- Patient has attention deficit hyperactive disorder (ADHD) or attention deficit disorder (ADD) and is younger than 18 years of age; and
    - Patient has tried two alternative medications for attention deficit hyperactive disorder (ADHD) or attention deficit disorder (ADD). The medications used must come from two different medications/classes of medications listed below:
        - Methylphenidate products; or
        - Amphetamines; or
        - Straterra (atomoxetine); or
        - Wellbutrin (bupropion); or
        - Tricyclic antidepressants

      *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of brand or generic modafanil (Provigil) or armodafanil (Nuvigil) products when patient selection criteria are not met (with the exception of those denoted above as **not medically necessary****) to be **investigational.***

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of brand or generic modafanil (Provigil) or armodafanil (Nuvigil) products when ANY of the following criteria for their respective disease listed below (and denoted in the patient selection criteria above) are not met to be **not medically necessary**:**

- Excessive sleepiness due to obstructive sleep apnea/hypopnea syndrome (OSAHS)
    - Patient has tried continuous positive airway pressure (CPAP)
- Excessive sleepiness due to shift work sleep disorder (SWSD)
    - Patient works 5 or more overnight shifts per month
- Fatigue or sleepiness associated with chronic use of narcotic analgesics
    - Patient has tried one central nervous system (CNS) stimulant (e.g. methylphenidate, dextroamphetamine), unless use of a central nervous system (CNS) stimulant is clinically inappropriate (e.g. patients with anxiety, glaucoma, tics, serious cardiovascular disease, seizures, underlying psychosis, or history of substance abuse)
- Patient has fatigue or sleepiness associated with chronic use of narcotic analgesics

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- Patient has tried one central nervous system (CNS) stimulant (e.g. methylphenidate, dextroamphetamine), unless use of a central nervous system (CNS) stimulant is clinically inappropriate (e.g. patients with anxiety, glaucoma, tics, serious cardiovascular disease, seizures, underlying psychosis, or history of substance abuse)

- Patient has attention deficit hyperactive disorder (ADHD) or attention deficit disorder (ADD) and is younger than 18 years of age
  - Patient has tried two alternative medications for attention deficit hyperactive disorder (ADHD) or attention deficit disorder (ADD). The medications used must come from two different medications/classes of medications listed below:
    - Methylphenidate products; or
    - Amphetamines; or
    - Straterra (atomoxetine); or
    - Wellbutrin (bupropion); or
    - Tricyclic antidepressants

Background/Overview

Provigil (modafanil) and Nuvigil (armodafanil) are agents with wake promoting actions. They are similar to sympathomimetic agents and are indicated to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy, OSAHS, and SWSD. There are many other uses in the literature that have data supporting their use, however there are also other indications that don't have sufficient data to support use of these drugs. Both of these agents are Schedule IV controlled substances.

Rationale/Source

Provigil (modafanil) and Nuvigil (armodafanil) have the potential to be used off label for certain conditions that do not have sufficient evidence to support usage, such as fibromyalgia, spasticity due to cerebral palsy, alcoholic organic brain syndrome, seasonal effective disorder, and many more indications not listed here. There is very little clinical evidence to support the use of Provigil (modafanil) and Nuvigil (armodafanil) in conditions not listed in the above patient selection criteria. The purpose of this policy is to limit the use of Provigil (modafanil) and Nuvigil (armodafanil) to those uses mentioned in the patient selection criteria. Patient selection criteria are based on information collected in a review of the available data.

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Policy History

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08/01/2013 Medical Policy Committee review
08/21/2013 Medical Policy Implementation Committee approval. New policy.
08/07/2014 Medical Policy Committee review
08/20/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 08/2015

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.