Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Provigil® (modafinil) or Nuvigil® (armodafinil) when it is determined to be medically necessary because the following criteria have been met.

When Policy Topic is covered

Coverage of Nuvigil and Provigil (brand and generic) are recommended in those who meet one of the following criteria:

1. Narcolepsy.

   Step therapy rules have been developed to encourage the use of a stimulant medication, FDA approved for narcolepsy, prior to Provigil, Nuvigil, modafinil, or armodafinil. If the step therapy rule is not met at the point of service, coverage will be determined by prior authorization criteria.

   **Step 1**: methylphenidate HCl products (except Aptensio XR, Concerta, Metadate CD, Ritalin LA, QuilliChew ER, and Quillivant XR); amphetamine, amphetamine/dextroamphetamine immediate release, and dextroamphetamine products.

   **Step 2**: Provigil, modafinil, Nuvigil, armodafinil

Nuvigil and modafinil are indicated for the treatment of EDS associated with narcolepsy.1-2

2. Excessive Sleepiness Due to Obstructive Sleep Apnea/Hypoapnea Syndrome (OSAHS).

   Approve if the patient meets one of the following criteria (A or B):

   A) Nuvigil/modafinil will be used in conjunction with continuous positive airway pressure (CPAP); OR

   B) The patient is unable to initiate or tolerate CPAP therapy.

Nuvigil and modafinil are indicated for the treatment of EDS associated with OSAHS as an adjunct to standard treatment(s) of the underlying obstruction.1-2 According to product labeling, if CPAP is the treatment of choice for a patient, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating treatment with Nuvigil or modafinil. CPAP is the most uniformly effective therapy, and, to date, this is the only intervention for obstructive sleep apnea (OSA) shown to have favorable impacts on both cardiovascular and neurobehavioral morbidities.3 Modafinil, in patients compliant with nasal CPAP, consistently improved subjective and objective sleepiness, quality of life, and vigilance compared with placebo.

3. Excessive Sleepiness Due to Shift Work Sleep Disorder (SWSD). Approve in patients working at least five overnight shifts per month.
Nuvigil and modafinil are indicated for the treatment of EDS associated with SWSD.\textsuperscript{1-2} The primary pivotal trials supporting the use of Nuvigil and modafinil in treating SWSD evaluated volunteers who worked a minimum of five night shifts per month.

**Other Uses with Supportive Evidence**

4. **Adjunctive/Augmentation Treatment for Depression in Adults.** Approve if the patient is concurrently receiving other medication therapy for depression (e.g., selective serotonin reuptake inhibitors [SSRIs]).

According to the American Psychiatric Association (APA) practice guideline for the treatment of patients with major depressive disorder (MDD), modafinil (or methylphenidate) are potential treatments for sedation associated with antidepressant medications.\textsuperscript{4} The APA guidelines state that modafinil has shown benefit when combined with SSRIs, related to specific effects on residual symptoms such as fatigue and hypersomnia. The guidelines go on to note that there are no clear guidelines regarding the length of time modafinil should be coadministered. Various trials have used scales involving fatigue measurement to determine the effects of modafinil augmentation in patients with MDD or for sedation/sleepiness due to antidepressant therapy or the disease state.\textsuperscript{5-11} Some of the trials, which included retrospective analysis,\textsuperscript{6,11} open-label\textsuperscript{7-8} studies, and double-blind, placebo-controlled trials,\textsuperscript{9,10} revealed that modafinil may have benefits in depressed patients. In an 8-week, placebo-controlled study\textsuperscript{10} involving 311 patients with MDD considered partial responders to stabilized SSRI therapy, modafinil 200 mg once daily (QD) as adjunctive therapy improved the clinical condition as assessed by Clinical Global Impression of Improvement (CGI-I) scores compared with placebo (P = 0.02). A 12-week, open-label extension study\textsuperscript{7} of 245 patients who had completed an 8-week double-blind study of modafinil found that the agent continued to improve patients’ overall clinical condition and reduced fatigue and excessive sleepiness when given to augment SSRI therapy in patients with depression. Limited data have investigated modafinil as monotherapy for depression.\textsuperscript{12} While Nuvigil has not been studied for this use, expert opinion considers it to be interchangeable with modafinil for this condition.

5. **Excessive Daytime Sleepiness (EDS) Due to Myotonic Dystrophy.** Approve.

Results from clinical trials evaluating the effectiveness of modafinil in treating EDS associated with myotonic dystrophy are equivocal.\textsuperscript{16-20} In a randomized, double-blind, placebo-controlled, 14-day, crossover trial\textsuperscript{18} modafinil was evaluated in 40 patients with myotonic dystrophy. Somnolence was reduced in patients receiving modafinil as noted by statistically significant improvements compared with placebo on the Epworth Sleepiness Scale (ESS) scores, and the Stanford Sleepiness Scale. In a randomized, double-blind, crossover trial\textsuperscript{19} in 19 patients with myotonic dystrophy use of modafinil improved the mean wakefulness scores. In a randomized, double-blind, placebo-controlled, multicenter, 4-week trial\textsuperscript{20} in 28 patients with myotonic muscular dystrophy type 1 (MMD1), modafinil had no significant effects on daytime somnolence. Guidelines from the American Academy of Sleep Medicine (AASM), updated in 2007, state that modafinil may be effective for the treatment of daytime sleepiness due to myotonic dystrophy.\textsuperscript{21} While Nuvigil has not been studied for this use, expert opinion considers it to be interchangeable with modafinil for this condition.

6. **Excessive Daytime Sleepiness (EDS) in Parkinson’s Disease (PD).** Approve.

EDS occurs frequently (up to 50\%) in PD patients and can be due to the disease state or due to use of dopaminergic drugs.\textsuperscript{22} Double-blind, randomized, controlled trials,\textsuperscript{23-25} an open-label trial,\textsuperscript{26} and case reports\textsuperscript{27} have studied modafinil in EDS associated with PD; many patients were receiving PD medication (e.g., pramipexole, levodopa-carbidopa, bromocriptine, amantadine, tolcapone, entacapone, ropinirole). In a double-blind, placebo-controlled crossover study\textsuperscript{23} in 21 patients with PD and an ESS score ≥ 10, patients received placebo and modafinil (200 mg QD) for 3 weeks, separated by a washout week. ESS scores were decreased by 3.4 points when modafinil was given compared with a 1.0 increase with placebo (P = 0.039). Another double-blind, randomized, crossover trial\textsuperscript{27} in 15 patients
with PD and an ESS score $\geq 10$ showed similar positive benefit with modafinil in ESS scores compared with placebo (P = 0.011). In contrast, a double-blind, placebo-controlled, 4-week, parallel-designed trial\textsuperscript{25} failed to show benefit of modafinil (200 to 400 mg/day given twice daily [BID]) over placebo in ESS scores in 40 patients with EDS related to PD (2.7 and 1.5 point decrease, respectively; P = 0.28). However, reviews addressing EDS and PD recommended modafinil along with other agents such as bupropion and dextroamphetamine, although published data with the latter are limited.\textsuperscript{22,28} Guidelines from the AASM, updated in 2007, state that modafinil may be effective for the treatment of daytime sleepiness due to PD.\textsuperscript{21} A practice parameter on the treatment of nonmotor symptoms of PD, published by the American Academy of Neurology (AAN) in 2011, states that for patients with PD and EDS, modafinil is effective in improving patients’ perception of wakefulness, but is ineffective in objectively improving EDS as measured by objective tests.\textsuperscript{29} The practice parameter recommendations indicate modafinil should be considered for patients to improve their subjective perception of EDS; however, it should be noted that patients may experience an improvement in sleep perception without an actual improvement in objective sleep measurements. While Nuvigil has not been studied for this use, expert opinion considers it to be interchangeable with modafinil for this condition.

7. **Fatigue Associated with Human Immunodeficiency Virus (HIV) Infection.** Approve after the patient has tried one central nervous system (CNS) stimulant (e.g., methylphenidate, dextroamphetamine), unless use of a CNS stimulant is not clinically appropriate (e.g., patients with anxiety, glaucoma, tics, serious cardiovascular disease, seizures, underlying psychosis, or history of substance abuse).

A 4-week, open-label study\textsuperscript{30} evaluated the efficacy of modafinil for fatigue in 30 patients with HIV with clinically significant fatigue currently taking antiretroviral medications with no medical conditions known to cause fatigue. After 4 weeks of treatment, 80% were rated as responders (defined as demonstrating a statistically significant improvement on all measures of fatigue, symptoms of depression, and executive function). In one randomized, double-blind, placebo-controlled trial in patients with HIV with clinically significant fatigue, significantly more modafinil-treated patients were responders (based on the CGI-I) vs. placebo-treated patients (73% vs. 28%, respectively; P < 0.0001; number-needed-to-treat [NNT] = 2.3) at 4 weeks.\textsuperscript{31} In a similarly designed study using Nuvigil in patients with HIV and clinically significant fatigue, significantly more Nuvigil-treated patients were responders (based on the CGI-I) vs. placebo-treated patients (75% vs. 26%, respectively; P < 0.0001; NNT = 2.1) at Week 4.\textsuperscript{32} There are published placebo-controlled trials demonstrating the effectiveness of methylphenidate and dextroamphetamine in treating fatigue in patients with HIV.\textsuperscript{33-35}

8. **Fatigue Associated with Multiple Sclerosis (MS).** Approve.

Results from clinical trials evaluating the effectiveness of modafinil in the treatment of fatigue associated with MS are equivocal.\textsuperscript{36-39} Modafinil was shown to be effective in treating fatigue associated with MS in one open-label\textsuperscript{36} and one randomized, placebo-controlled study.\textsuperscript{37} In one randomized, placebo-controlled, double-blind, 5-week, parallel-group trial (n = 115)\textsuperscript{38} modafinil and placebo both showed similar effectiveness in treating MS fatigue as rated by the Modified Fatigue Impact Scale (baseline score at screening = 63, and decreased to 52.3 for modafinil and 49.2 for placebo on Day 35; P < 0.001 for both groups vs. baseline and P = 0.27 between groups). In one randomized, double-blind, placebo-controlled, 8-week study (n = 121) the mean change in fatigue severity score (FSS) was not significantly improved with modafinil vs. placebo.\textsuperscript{39} Modafinil is among the most commonly used medications for fatigue associated with MS\textsuperscript{40} and, according to expert opinion, is currently a first-line drug for MS patients. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin, updated in 2007 by the AASM, state that modafinil may be effective for the treatment of daytime sleepiness due to MS.\textsuperscript{21} Another well-studied agent is amantadine but this drug may have tolerability issues in this patient population.\textsuperscript{38,40-41} Other agents used in MS fatigue include pemoline, aspirin, antidepressants (e.g., sertraline, bupropion, fluoxetine, venlafaxine), methylphenidate, and dextroamphetamine; however, these agents are limited by side effects (i.e., pemoline) or have a paucity of clinical data. Although the results with modafinil in clinical trials are heterogeneous, expert opinion considers it to be a first-line anti-fatigue drug for MS patients.
While Nuvigil has not been studied for this use, expert opinion considers it to be interchangeable with modafinil for this condition.

9. Fatigue or Sleepiness Associated with Chronic use of Narcotic Analgesics. Approve after the patient has tried one CNS stimulant (e.g., methylphenidate, dextroamphetamine), unless use of a CNS stimulant is not clinically appropriate (e.g., patients with anxiety, glaucoma, tics, serious cardiovascular disease, seizures, underlying psychosis, or history of substance abuse).

A case series report in patients (n = 11) being treated with opioids for chronic, nonmalignant pain reported modafinil effective in combating opioid-induced sedation. Several review articles on opioid-induced sedation generally state that a paucity of data exist for the treatment of this condition. However, if non-pharmacologic options fail, some agents that may be useful, in addition to modafinil, include methylphenidate and dextroamphetamine. The 2008 American Pain Society (APS) guidelines on analgesic use in treatment of acute pain and cancer pain indicate that sedation during chronic narcotic analgesic treatment may be partially counteracted by adding a stimulant such as caffeine, dextroamphetamine, methylphenidate, or modafinil. It is also noted that modafinil may be a second-line drug. The NCCN guidelines on adult cancer pain (version 2.2015) state that sedation may hinder the achievement of dose titration of opioids to levels that provide adequate analgesia. If opioid-induced sedation develops and persists for over 1 week, consider use of psychostimulants (i.e., methylphenidate, dextroamphetamine, or modafinil) or caffeine. While Nuvigil has not been studied for this use, expert opinion considers it to be interchangeable with modafinil for this condition.

10. Idiopathic Hypersomnia. Approve if the diagnosis is confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders (i.e., sleep center).

Idiopathic hypersomnia, a condition similar to narcolepsy, is characterized by constant or recurrent daytime sleepiness with no other cause of sleepiness, prolonged nocturnal sleep, difficulty awakening with sleep drunkenness, and long unrefreshing naps with no history of cataplexy. Modafinil was proven effective in treating idiopathic hypersomnia in one case series and several open-label trials. The practice parameters for the treatment of narcolepsy and other hypersomnias of central origin, updated in 2007, state that modafinil may be effective for the treatment of daytime sleepiness due to idiopathic hypersomnia. As there may be underlying causes/behaviors associated with EDS, a sleep specialist physician has the training to correctly recognize and diagnose this condition. While Nuvigil has not been studied for this use, expert opinion considers it to be interchangeable with modafinil for this condition.


One open-label study in 52 patients with myasthenia gravis found that a regimen consisting of L-phenylalanine or L-tyrosine, desipramine, buspirone, propranolol, and adrafinil or modafinil resulted in acute and late sustained improvements in myasthenia gravis symptoms. The way that modafinil (100 mg to 200 mg) was administered in this study is ambiguous as it was described as being “frequently” prescribed during the last 6 months. The goal of this study was to “enhance noradrenergic neural transmission” by “supplementing the neural sympathetic deficit” seen in myasthenia gravis patients. There was no declaration of primary or secondary outcome parameters and results were simply reported as clinical findings, immunological findings, or neurochemical findings. According to the authors, no patients experienced relapses, experienced new myasthenia gravis crisis, or required new plasmapheresis after treatment was initiated. In addition, immunological abnormalities disappeared in a select subset of patients and all neurochemical abnormalities were reverted. While Nuvigil has not been studied for this use, expert opinion considers it to be interchangeable with modafinil for this condition.

When Policy Topic is not covered

Nuvigil and Provigil (brand and generic) have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the
following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Adjunctive Therapy in the Treatment of Schizophrenia.** Studies have examined the effects of modafinil and Nuvigil in schizophrenia.53-60 One randomized, double-blind, placebo-controlled trial in 20 stable outpatients with schizophrenia on stabilized doses of neuroleptics reported modafinil effective in significantly improving select cognition measurement items on a comprehensive neuropsychological test battery.53 In a 4-week, open-label study in 11 stable outpatients with schizophrenia receiving antipsychotic therapy, modafinil was effective in improving global functioning, overall clinical condition and fatigue.54 An 8-week, double-blind, placebo-controlled study in patients with schizophrenia or schizoaffective disorder receiving antipsychotic medication found that modafinil 200 mg QD (n = 10) and placebo (n = 10) both improved fatigue (P < 0.01) over time; however, there were no differences between groups on changes in fatigue, positive and negative symptoms, or cognition.55 An 8-week, double-blind, placebo-controlled trial involving 20 patients with schizophrenia found little benefit from use in this patient population.56 Another 8-week, double-blind, placebo-controlled trial involving 35 patients with schizophrenia treated with clozapine found that modafinil (up to 300 mg/day) did not reduce negative symptoms or wakefulness/fatigue or improve cognition vs. placebo.58 An additional randomized, double-blind, placebo-controlled, 8-week study in patients with schizophrenia or schizoaffective disorder receiving stable doses of second-generation antipsychotic medications (n = 24) found that modafinil did not improve excessive daytime sleepiness, psychiatric symptoms or cognition.59 In one randomized, double-blind, placebo-controlled trial in 60 patients with schizophrenia receiving stable doses of novel psychotropics, Nuvigil was not associated with an improvement in cognitive measures.60 Small but statistically significant improvements in negative symptoms were seen with patients treated with Nuvigil 200 mg/day vs. placebo. In another randomized, double-blind, placebo-controlled study in 60 patients with clinically stable schizophrenia, augmentation with Nuvigil (150 mg/day) was not associated with significant differences in neurocognitive measures vs. placebo.60 There are multiple other medication options in schizophrenia and due to the mixed and low-level of evidence for modafinil and Nuvigil, more data are needed regarding these agents in schizophrenia before either can be recommended in this patient population.

2. **Attention Deficit/Hyperactivity Disorder (ADD/ADHD).** The American Academy of Pediatrics (AAP) clinical practice guidelines for the treatment of ADD/ADHD in children and adolescents does not address the use of modafinil/Nuvigil.62-63 These guidelines note that with the greater availability of approved medications for children/adolescents with ADHD, it has become increasingly unlikely that clinicians need to consider the off-label use of other medications. Two published studies, both of which involved approximately 20 adult patients with ADHD, preliminarily suggested that modafinil may be useful for this condition.64-65 However, a 9-week, randomized, double-blind, placebo-controlled, parallel-group, dose-finding study in adults with ADHD (n = 338) evaluated modafinil doses of 255 mg to 510 mg and did not find significant benefit in reducing ADHD symptoms, as measured by the change from baseline at final visit in the Adult ADHD Investigator Symptom Rating Scale (AISRS) total score.66 Many options exist for the treatment of ADHD in adults (e.g., methylphenidate, dextroamphetamine) and further large scale trials that demonstrate benefit for modafinil in adults with ADHD are needed.

3. **Bipolar Disorder, including Bipolar Depression.** Limited data (one small study [n = 85] and case reports [n = 2]) are available that describe the use of modafinil for bipolar disorder and bipolar depression.67-69 In one study (n = 257) Nuvigil was not more effective than placebo in treating bipolar depression.70 Only limited data supports modafinil for this condition and more data are needed.

4. **Cancer-Related Fatigue.** The National Comprehensive Cancer Network (NCCN) guidelines on cancer-related fatigue (version 2.2015) no longer consider modafinil to be effective for the treatment of cancer-related fatigue and recommend against its use.47 A randomized, double-blind, placebo-controlled trial involving 631 patients with cancer receiving chemotherapy found modafinil useful in
5. **Chronic Fatigue Syndrome.** Limited data characterize modafinil therapy in those with chronic fatigue syndrome. In a randomized, double-blind, crossover study in 14 patients with chronic fatigue syndrome, use of modafinil for 20 days had minimal effects on cognitive function and no significant effects on fatigue, health-related quality of life, or mood. More data are required to assess efficacy in this patient population.

6. **Excessive Daytime Sleepiness (EDS) Associated with Primary Insomnia.** One randomized, placebo-controlled study found that neither combination therapy with modafinil and cognitive behavioral therapy nor modafinil as monotherapy significantly decreased daytime sleepiness associated with primary insomnia.

7. **Enhancement of Performance in Situations of Induced Sleep Deprivation.** Studies are needed to define the role/appropriateness of modafinil in these situations for the general population (as opposed to military personnel, etc.). Studies have shown that modafinil may enhance performance and sustain alertness in individuals subjected to situations that deprive sleep (e.g., military aviation, emergency physicians). Further studies are needed before its use in the general population in these types of situations can be promoted.

8. **Fatigue and Excessive Daytime Sleepiness (EDS) in Chronic Traumatic Brain Injury (TBI).** In a single-center, double-blind, placebo-controlled, crossover trial involving 53 patients suggests that overall, modafinil was not beneficial in relieving fatigue and EDS in such patients. In a small (n = 20) randomized, placebo-controlled trial, modafinil improved EDS vs. placebo in patients with TBI; however, modafinil did not improve fatigue compared with placebo. Additional data are needed to determine effectiveness in this setting.

9. **Fibromyalgia.** Limited data are available regarding the use of modafinil in fibromyalgia with most of the data being observational. Larger-sized, randomized, placebo-controlled trials are required to better assess and validate the efficacy of modafinil in patients with fibromyalgia before it can be recommended as a therapeutic modality.

10. **Hypersonmia, Fatigue or Sleepiness Due to Other Conditions (not Idiopathic Hypersonmia, see Other Uses with Supportive Evidence).** More data are needed in specific conditions to define the role of modafinil and Nuvigil.

11. **Patients < 17 years of age.** Nuvigil and modafinil are indicated in patients ≥ 17 years of age. The safety and effectiveness of Nuvigil and modafinil in patients < 17 years of age have not been established. Serious rash has been seen in pediatric patients receiving modafinil.

12. **Post-Stroke Sleep-Wake Disorders or Sleep Disorders.** Sleep-wake disorders occur in approximately 20% to 40% of patients that have experienced a stroke, which includes hypersonmia and EDS. Very limited data (i.e., case reports) have explored the use of modafinil in these patients to improve alertness. More data are needed to determine effectiveness in this condition.

13. **Spasticity Due to Cerebral Palsy.** An open-label, pilot trial exposed 10 pediatric patients with cerebral palsy to modafinil over a 4-week treatment period. Seven of the nine patients that completed the study experienced a decrease in spasticity (P = 0.008), as evaluated by the Modified Ashworth Scale. Ambulation speed improved in six of the nine patients (P = 0.0192). A retrospective review of 30 pediatric patients with cerebral palsy who were given modafinil reported that 76% of patients experienced diminished spasticity with treatment. A retrospective review of 59 patients with spastic cerebral palsy documented that gait was improved with use of modafinil in approximately 50% of patients, with some improvements in ambulation being dramatic. A small, randomized, double-blind, crossover trial exposed 10 pediatric patients with cerebral palsy to
modafinil or placebo for 8 weeks, followed by a 4-week washout period, and another 8-week treatment period. The study did not find evidence that modafinil reduces spasticity or has a positive impact on quality of life in the eight children with spastic cerebral palsy who completed the study. Quality of life was statistically significantly in favor of placebo. Many other drugs have been used to treat this condition, including benzodiazepines, baclofen, dantrolene, tizanidine and botulinum toxin. More data are needed to determine effectiveness in this condition.

14. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Considerations
Provigil, Nuvigil (brand and generics) are a pharmacy benefit

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

Description of Procedure or Service
Nuvigil and modafinil, agents with wake-promoting actions that are similar to sympathomimetic agents (e.g., amphetamine and methylphenidate), are indicated to improve wakefulness in patients with excessive daytime sleepiness (EDS) associated with narcolepsy; obstructive sleep apnea/hypoapnea syndrome (OSAHS) [approved as adjunctive therapy]; and shift work sleep disorder (SWSD). Nuvigil and modafinil are Schedule IV controlled substances. Review of the medical literature notes many other uses of modafinil that are considered off-label or investigational. While Nuvigil has not been studied off-label to the same extent as modafinil, it is expected that Nuvigil will have similar clinical efficacy for these uses.

Rationale

References


**Other References Utilized**

**Billing Coding/Physician Documentation Information**

N/A Pharmacy benefit

**Additional Policy Key Words**

Policy Number: 5.01.534
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