

Title: modafinil (Provigil) and armodafinil (Nuvigil)

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| Origination: 08/23/10 | Revised: 04/05/12 | Annual Review: 12/15/11 |
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Provigil (modafinil) is a wakefulness promoting agent with action similar to amphetamine and methylphenidate. Nuvigil (armodafinil) is the R-enantiomer of modafinil (Provigil). The exact mechanism of action of armodafinil is unknown, but it binds to the dopamine transporter and inhibits dopamine reuptake, which may result in increased extracellular dopamine levels in the brain.
- Modafinil and armodafinil are indicated to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome (OSAHS), and shift work sleep disorder (SWSD).
- Modafinil and armodafinil have unlabeled indications for fatigue in Multiple Sclerosis (MS) and in the diagnosis of sleepiness and/or fatigue due to opioid analgesics.
- The recommended dose of Provigil (modafinil) is 200mg given once a day. For Members with narcolepsy and obstructive sleep apnea/hypopnea syndrome (OSAHS), modafinil should be taken as a single dose in the morning. For Members with shift work sleep disorder (SWSD), modafinil should be taken approximately one (1) hour prior to the start of their shift.
- The recommended dose of Nuvigil (armodafinil) for OSA/HS or narcolepsy is 150mg or 250mg given as a single dose in the morning. For SWSD, the recommended dose is 150mg daily, given approximately one (1) hour prior to the start of the work shift.

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefit coverage (i.e., self-injectable rider) within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

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Procedure:

- 1.0 Request for *initial therapy* with **Nuvigil** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:
 - 1.1 Member is at least 16 years of age; **AND**
 - 1.2 Member has at least one (1) of the following diagnoses:
 - 1.2.1 Narcolepsy;
 - 1.2.2 Idiopathic Hypersomnia;
 - 1.2.3 Obstructive Sleep Apnea/Hypopnea Syndrome (OSAHS);
 - 1.2.4 Excessive Sleepiness associated with Shift Work Sleep Disorder (SWSD);
 - 1.2.5 Sleepiness and/or fatigue due to Multiple Sclerosis;
- OR**
- 1.2 Diagnosis of sleepiness and/or fatigue due to opioid analgesics; **AND**
- 1.3 Member with a medication history or clinical documentation from the requesting independent practitioner indicating a current fill for at least one (1) of the following medications or its generic equivalent:
 - 1.3.1 Avinza, Kadian, MS Contin;
 - 1.3.2 Demerol;
 - 1.3.3 Dilaudid;
 - 1.3.4 Dolophine;
 - 1.3.5 Duragesic;
 - 1.3.6 Levo-dromoran;
 - 1.3.7 Lortab, Vicodin/ES;
 - 1.3.8 Opana, Opana ER;
 - 1.3.9 OxyIR;
 - 1.3.10 Oxycontin;
 - 1.3.11 Percocet/Tylox;
 - 1.3.12 Percodan;
 - 1.3.13 Rms-supp, Roxanol, MSIR;
 - 1.3.14 Synalgos DC;
 - 1.3.15 Talwin NX;
 - 1.3.16 Vicoprofen;
 - 1.3.17 Wygesic; **AND**
- 1.4 Member with a medication history or clinical documentation from the requesting independent practitioner indicating a previous fill and treatment failure for at least one (1) of the following medications:
 - 1.4.1 Dexadrine, Dextrostat;
 - 1.4.2 Methylin ER, Metadate ER/CD, Ritalin LA/SR, Concerta, Daytrana, Vyvanse;
- 1.5 If criteria are met, therapy may be approved for up to six (6) months.

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Procedure, continued:

2.0 Request for *initial therapy* with **Provigil** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:

2.1 Member has a medication history or clinical documentation from the requesting independent practitioner indicating a trial and failure of Nuvigil; **AND**

2.2 Member is at least 16 years of age; **AND**

2.3 Member has at least one (1) of the following diagnoses:

2.3.1 Narcolepsy;

2.3.2 Idiopathic Hypersomnia;

2.3.3 Obstructive Sleep Apnea/Hypopnea Syndrome (OSAHS);

2.3.4 Excessive Sleepiness associated with Shift Work Sleep Disorder (SWSD);

2.3.5 Sleepiness and/or fatigue due to Multiple Sclerosis;

OR

2.3 Diagnosis of sleepiness and/or fatigue due to opioid analgesics; **AND**

2.4 Member with a medication history or clinical documentation from the requesting independent practitioner indicating a current fill for at least one (1) of the following medications:

2.4.1 Avinza, Kadian, MS Contin;

2.4.3 Dilaudid;

2.4.5 Duragesic;

2.4.7 Lortab, Vicodin/ES;

2.4.9 OxyIR;

2.4.11 Percocet/Tylox;

2.4.13 Rms-supp, Roxanol, MSIR;

2.4.15 Talwin NX;

2.4.17 Wygesic; **AND**

2.4.2 Demerol;

2.4.4 Dolophine;

2.4.6 Levo-dromoran;

2.4.8 Opana, Opana ER;

2.4.10 Oxycontin;

2.4.12 Percodan;

2.4.14 Synalgos DC;

2.4.16 Vicoprofen;

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Procedure, continued:

2.0 Request for *initial therapy* with **Provigil** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following, continued:

OR

2.4 Member with a medication history or clinical documentation from the requesting independent practitioner indicating a previous fill and treatment failure for at least one (1) of the following medications:

2.4.1 Dexadrine, Dextrostat;

2.4.2 Methylin ER, Metadate ER/CD, Ritalin LA/SR, Concerta, Daytrana;

2.5 If criteria are met, therapy may be approved for up to six (6) months.

3.0 Request for *continuation of therapy* beyond initial authorization period for both **Nuvigil and Provigil** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the Member is responding to therapy:

3.1 If criteria are met, therapy may be approved for up to one (1) year.

References:

1. Provigil[®] (modafinil) [package insert]. Frazer, PA: Cephalon, Inc. July 2008.
2. Nuvigil[®] (armodafinil) [package insert]. Frazer, PA: Cephalon, Inc. March 2008.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.