HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

WAKEFULNESS AGENTS

Generic	Brand	HICL	GCN	Exception/Other
MODAFINIL	PROVIGIL	10865		
ARMODAFINIL	NUVIGIL	34868		

CUSTOMER SERVICE REPRESENTATIVE (CSR)
PA COORDINATOR (PAC)

This is a Rhode Island (RI) member or prescriber determination for behavioral health and substance abuse requests:

1. Does the member live in Rhode Island **or** is the prescribing physician's office located in Rhode Island?

   If yes, continue to #2.
   If no, continue to review using the clinical determination criteria below. For Customer Service, all other requests require a Medication Request Form (MRF) be submitted for review.

2. Is the requested medication non-formulary?

   If yes, continue to review using the clinical determination criteria below. For Customer Service, all other requests require a Medication Request Form (MRF) be submitted for review.
   If no, **approve for 24 months by HICL.**

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CLINICAL DETERMINATION CRITERIA

NOTE: Prior authorization guidelines must be met in order to get either drug. In order to get brand name Provigil (modafinil), or brand name Nuvigil (armodafinil), patients must have tried Nuvigil (armodafinil) and modafinil.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL OR QUANTITY LIMITATION, SEE BELOW)

1. Is the requested agent being prescribed solely for a non-medical condition such as, but not limited to, the following?
   - Shift work sleep disorder (works night shift, etc.), and/or
   - Generalized fatigue, and/or
   - Travel induced sleep disorder (jet lag, etc.), and/or
   - Sleep-deprivation (i.e., military or academic).

   If yes, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Wakefulness Agents guideline, this medication is only covered when prescribed for certain medical conditions, such as obstructive sleep apnea, or excessive daytime sleepiness associated with Narcolepsy or Multiple Sclerosis. This medication is not covered for situations such as shift work, general fatigue, jet-lag, or sleep deprivation. Your provider did not indicate that you are being treated for a medical condition and therefore your request was not approved.
   If no, continue to #2.

2. Does the patient have at least **ONE** of the following conditions?
   - Excessive daytime sleepiness associated with Narcolepsy OR Idiopathic Hypersomnia
   - Obstructive Sleep Apnea/Hypopnea Syndrome
   - Attention Deficit Hyperactivity Disorder (ADHD)
   - Excessive daytime sleepiness associated with Depression
   - Excessive daytime sleepiness associated with Multiple Sclerosis
   - Cancer patient being treated with chemotherapy

   If yes, continue to #3.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Wakefulness Agents guideline, this medication is only covered when prescribed for certain medical conditions, such as obstructive sleep apnea, or excessive daytime sleepiness associated with Narcolepsy or Multiple Sclerosis. This medication is not covered for situations such as shift work sleep disorder, general fatigue, jet-lag, or sleep deprivation. Your provider did not indicate that you are being treated for a covered medical condition and therefore your request was not approved.

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WAKEFULNESS AGENTS

INITIAL CRITERIA (CONTINUED)

3. Is the request for generic modafinil or armodafinil?

   If yes, continue to #5.
   If no, continue to #4.

4. Has the member tried and failed therapy with the preferred formulary alternatives, generic modafinil and generic armodafinil within the previous 365 days?

   If yes, continue to #5.
   If no, do not approve. Please use status code #238 and denial text provided.
   Please enter a proactive approval for the generic(s) as follows, but if the request is for a quantity that exceeds an MDD of 1, please proceed to the quantity limit criteria as well.

   Please enter a proactive approval for the generic(s) for 12 months by HICL. (If neither armodafinil nor modafinil were first tried, please enter approvals for generic modafinil and for generic armodafinil. If armodafinil was not yet tried, please enter an approval for generic armodafinil. If modafinil was not yet tried, please enter an approval for generic modafinil.)

   DENIAL TEXT (IF NEITHER GENERIC WAS TRIED): Per your health plan's Wakefulness Agents guideline, a trial with both generic modafinil and generic armodafinil is required prior to approving coverage for the requested medication. Your provider did not indicate that you were previously treated with armodafinil or modafinil and therefore your request was not approved. Generic armodafinil and modafinil have been approved for your condition for a quantity of 30 tablets per 30 day supply for a 12-month period.

   DENIAL TEXT (IF ARMODAFINIL NOT YET TRIED): Per your health plan's Wakefulness Agents guideline, a trial with both generic modafinil and generic armodafinil is required prior to approving coverage for the requested medication. Your provider did not indicate that you were previously treated with armodafinil and therefore your request was not approved. Generic armodafinil has been approved for your condition for a quantity of 30 tablets per 30 day supply for a 12-month period.

   DENIAL TEXT (IF MODAFINIL NOT YET TRIED): Per your health plan's Wakefulness Agents guideline, a trial with both generic modafinil and generic armodafinil is required prior to approving coverage for the requested medication. Your provider did not indicate that you were previously treated with modafinil and therefore your request was not approved. Generic modafinil has been approved for your condition for a quantity of 30 tablets per 30 day supply for a 12-month period.

5. Is the request for a quantity that exceeds one tablet per day (MDD = 1)?

   If yes, continue to the below Quantity Limit criteria.
   If no, continue to #6.

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WAKEFULNESS AGENTS

INITIAL CRITERIA (CONTINUED)

6. **Approve for 24 months by HICL.** (The quantity of one tablet per day is hard-coded) Please use status code #056 and the approval text provided.

   Requests for products on formulary with a restriction:

   APPROVAL TEXT: [Requested medication] has been approved for your condition for a quantity of 30 tablets per 30 day supply for a 24-month period.

   Requests for products not on formulary:

   APPROVAL TEXT: [Requested medication] has been approved for your condition for a quantity of 30 tablets per 30 day supply for a 24-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

QUANTITY LIMITATION CRITERIA (For members that have met HPHC PA criteria):

1. Can the requested dose be attained with once daily dosing of a higher strength of the requested drug (i.e., dose optimization)?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the patient currently stabilized on the requested dose or did the provider indicate a previous trial with the lower quantity was insufficient for this member?

   If yes, continue to #4.
   If no, continue to #3.

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WAKEFULNESS AGENTS

QUANTITY LIMITATION CRITERIA (CONTINUED)

3. **Partially deny and enter a proactive prior authorization for 24 months by HICL.** Do not approve the higher quantity because a quantity of one tablet per day is hard-coded for all strengths. Please use status code #238 and the denial text provided.

   Requests for products on formulary with a restriction,
   PARTIAL DENIAL TEXT: [Requested medication] has been partially approved for your condition for a quantity of 30 tablets per 30 day supply for a 24-month period. A quantity greater than one tablet per day would be covered if a higher strength were not available or if your provider indicated a previous trial with **[medication and strength]** was insufficient for you. Your provider did not indicate that this medication and quantity was insufficient for you, and therefore your request for the higher quantity was not approved.

   Requests for products not on formulary,
   PARTIAL DENIAL TEXT: [Requested medication] has been partially approved for your condition for a quantity of 30 tablets per 30 day supply for a 24-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier. A quantity greater than one tablet per day would be covered if a higher strength were not available or if your provider indicated a previous trial with **[medication and strength]** was insufficient for you. Your provider did not indicate that this medication and quantity was insufficient for you, and therefore your request for the higher quantity was not approved.

4. **Approve for 24 months by HICL for the approved daily quantity.** Please use status code #056 and the approval text provided.

   Requests for products on formulary with a restriction, please enter the approved daily quantity and override with an 'F'.

   APPROVAL TEXT: [Requested medication] has been approved for your condition for a quantity of ____ tablets per ____ day supply for a 24-month period.

   Requests for products not on formulary, please enter the approved daily quantity and override with an 'F'.

   APPROVAL TEXT: [Requested medication] has been approved for your condition for a quantity of ____ tablets per ____ day supply for a 24-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

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WAKEFULNESS AGENTS

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Did the provider indicate an effective response with this medication or the need for continued therapy?

   If yes, continue to #2.
   If no, do not approve. Please use status code #238 and denial text provided.
   DENIAL TEXT: Per your health plan's Wakefulness Agents guideline, your provider must send us documentation that you have responded to this therapy or that there is a continued medical need. Your provider did not indicate that this therapy has been effective or that there is a medical need for continued coverage and therefore your request was not approved.

2. Is the request for brand name Nuvigil or Provigil?

   If yes, continue to #3.
   If no, continue to #4.

3. Is there clinical rationale for not using the generic of the requested medication at this time?

   If yes, continue to #4.
   If no, do not approve. Please use status code #238 and denial text provided.
   Please enter a proactive approval for the generic for 12 months by HICL. If the approved maximum daily dose exceeds one, please enter an override with an 'F'.
   DENIAL TEXT (FOR PROVIGIL REQUEST): Per your health plan's Wakefulness Agents guideline, a clinical reason why you cannot use the generic of Provigil is required prior to approving coverage of the brand name medication. Your provider did not indicate there was a clinical reason why you could not use the generic, modafinil. Generic modafinil has been approved for your condition for a quantity of ____ tablets per 30 day supply for a 12-month period.

   DENIAL TEXT (FOR NUVIGIL REQUEST): Per your health plan's Wakefulness Agents guideline, a clinical reason why you cannot use the generic of Nuvigil is required prior to approving coverage of the brand name medication. Your provider did not indicate there was a clinical reason why you could not use the generic, armodafinil. Generic armodafinil has been approved for your condition for a quantity of ____ tablets per 30 day supply for a 12-month period.

4. Is the request for the same quantity as previously approved?

   If yes, continue to #5.
   If no, please refer to above Quantity Limit criteria.

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WAKEFULNESS AGENTS

RENEWAL CRITERIA (CONTINUED)

5. **Approve for 24 months by HICL for the approved daily quantity.** Please use status code #056 and the approval text provided.

   Requests for products on formulary with a restriction, if the approved maximum daily dose exceeds one, please enter an override with an 'F'.

   APPROVAL TEXT: [Requested medication] has been approved for your condition for a quantity of ____ tablet(s) per ____ day supply for a 24-month period.

   Requests for products not on formulary, if the approved maximum daily dose exceeds one, please enter an override with an 'F'.

   APPROVAL TEXT: [Requested medication] has been approved for your condition for a quantity of _____ tablet(s) per _____ day supply for a 24-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

RATIONALE

To ensure that these agents are used only when medically necessary. Coverage is not provided for non-medical situation such as jet-lag, shift work sleep disorder, sleep deprivation, or generalized fatigue. To ensure cost-effective care, Harvard Pilgrim requires that members first demonstrate trial and failure of both modafinil and armodafinil before approval of either Provigil or Nuvigil. A quantity limit is in place to encourage dose-optimization for medications available in progressive dose strengths.

FDA APPROVED INDICATIONS

Provigil and Nuvigil are indicated to improve wakefulness in patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome, and shift work sleep disorder.

REFERENCES

- Provigil Product Information. Teva Pharmaceuticals. North Wales, PA. January 2015.
- Nuvigil Product Information. Teva Pharmaceuticals. North Wales, PA. January 2015.

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