Clinical Policy: armodafinil (Nuvigil®) and modafinil (Provigil®)

Reference Number: ERX.NSMN.08
Effective Date: 06/15
Last Review Date: 09/16

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Description
The intent of the criteria is to ensure that patients follow selection elements established by Envolve Pharmacy Solutions for the use of armodafinil (Nuvigil®) and modafinil (Provigil®).

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that armodafinil (Nuvigil®) and modafinil (Provigil®) are medically necessary for members meeting the following criteria:

Initial Approval Criteria (must meet all):
A. Diagnosis of narcolepsy, obstructive sleep apnea, or shift work disorder;
B. Age ≥ 17 years;
C. If diagnosis is narcolepsy, failure of 30-day trial of amphetamine or methylphenidate at 60 mg/day, unless contraindicated;
D. Request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

Approval duration: 12 months

Continued Approval (must meet all):
A. Previously received medication via health plan benefit or member has previously met all initial approval criteria;
B. If request is for a dose increase, request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

Approval duration: 12 months
Background

Description/Mechanism of Action
Armodafinil and modafinil are psychostimulants and are schedule C-IV controlled substances. The mechanism(s) through which they promote wakefulness is unknown. Both have wake-promoting actions similar to sympathomimetic agents including amphetamine and methylphenidate, although their pharmacologic profiles are not identical to that of the sympathomimetic amines. Armodafinil is the R-enantiomer of modafinil.

FDA Approved Indications
Nuviogil and Provigil are indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea (OSA), or shift work disorder (SWD). Neither are indicated for treatment of the underlying obstruction in OSA.

References

Reviews, Revisions, and Approvals

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<thead>
<tr>
<th>Description</th>
<th>Date</th>
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<tbody>
<tr>
<td>Policy created.</td>
<td>06/15</td>
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<tr>
<td>Updated to new template (converted algorithm to bulleted criteria, added background and references). Removed preferencing for modafinil as both armodafinil and modafinil are generic PDL agents.</td>
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