

<b>DRUG</b>	Provigil (modafinil)
<b>POLICY #</b>	11136
<b>INDICATIONS</b>	<p>Provigil is FDA-approved for the treatment of (excessive daytime sleepiness) EDS associated with narcolepsy.</p> <p>Provigil is FDA-approved for the treatment of EDS associated with OSAHS as an adjunct to standard treatment(s) of the underlying obstruction. According to product labeling, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating treatment with modafinil. CPAP is the most common treatment for moderate to severe sleep apnea.</p> <p>Provigil is FDA-approved for the treatment of EDS associated with SWSD.</p>
<b>CRITERIA</b>	<p><b>ConnectiCare considers Provigil medically necessary in the treatment of Narcolepsy when the following criteria are met:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Documentation (by a sleep study) to support the diagnosis of narcolepsy</li> <li><input type="checkbox"/> The medication is being prescribed by a specialist</li> </ul> <p><b>ConnectiCare considers Provigil medically necessary in the treatment of Obstructive Sleep Apnea when the following criteria are met:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Presence of residual excessive sleepiness defined as an Epworth Sleepiness Scale (ESS) score of greater than or equal to 10</li> <li><input type="checkbox"/> Documentation (sleep study) to support the diagnosis of obstructive sleep apnea/hypopnea syndrome</li> <li><input type="checkbox"/> Documentation that the patient has been on CPAP for at least 2 months and is using it on average greater than or equal to 4 hours per night.</li> </ul> <p><b>ConnectiCare considers Provigil medically necessary in the treatment of Shift Work Disorder when the following criteria are met:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Patient is experiencing excessive sleepiness and working a minimum of five (or more) overnight shifts per month. Documentation of current work schedule is required.</li> </ul>
<b>LIMITATIONS</b>	<p>Initial authorization is limited to a 6-month time frame. Reauthorization up to a 6-12 month timeframe may be considered. For patients with Shift Work Disorder, the patient must continue to work a schedule that contributes to this diagnosis.</p> <p>Quantities will be limited to 2 tablets per day (60 tablets per month)</p>

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<b>REFERENCES</b>	<ol style="list-style-type: none"> <li>1. Provigil® [package insert]. West Chester, PA: Cephalon, Inc.</li> <li>2. National Institutes of Health. National Heart, Lung, and Blood Institute. Sleep apnea: how is sleep apnea treated? Available at <a href="http://www.nhlbi.nih.gov/health/dci/Diseases/SleepApnea/SleepApnea_Treatments.html">http://www.nhlbi.nih.gov/health/dci/Diseases/SleepApnea/SleepApnea_Treatments.html</a>.</li> <li>3. Dinges DF, Wright KP, Walsh JK, et al. Modafinil improves psychomotor vigilance performance in shift work sleep disorder [abstract 0215C]. <i>Sleep</i>. 2003;26(Suppl):A87.</li> <li>4. Czeisler CA, Dinges DF, Walsh JK, et al. Modafinil for the treatment of excessive sleepiness in chronic shift work sleep disorder [abstract 0281E]. <i>Sleep</i>. 2003;26(Suppl):A114.</li> </ol>
<b>P&amp;T REVIEW HISTORY</b>	6/05, 6/07, 6/08, 9/09, 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 5/16, 2/17, 1/18
<b>REVISION RECORD</b>	7/09, 11/14, 2/16