**PROVIGIL (modafinil)**

**Diagnoses Considered for Coverage:**
- All FDA-approved indications not otherwise excluded from Part D
- Treatment of fatigue associated with Multiple Sclerosis (MS)
- Treatment of fatigue associated with Parkinson’s disease
- Treatment of refractory depression
- Bipolar depression

**Coverage Criteria:**

1) **Narcolepsy:**
   - Intolerance to or contraindication to Nuvigil that would not be expected with Provigil, AND
   - Patient has a positive polysomnography (sleep study) for narcolepsy, AND
   - Dose does not exceed FDA label maximum for the diagnosis, AND
   - Request must be reviewed with a Blue Shield Pharmacist.

2) **Obstructive Sleep Apnea/Hypopnea Syndrome (OSAHS):**
   - Intolerance to or contraindication to Nuvigil that would not be expected with Provigil, AND
   - Patient has a positive polysomnography, AND
   - Patient has treatment failure or intolerance to CPAP, AND
   - Dose does not exceed FDA label maximum for the diagnosis, AND
   - Request must be reviewed with a Blue Shield Pharmacist.

3) **Shift Work Sleep Disorder (SWSD):**
   - Intolerance to or contraindication to Nuvigil that would not be expected with Provigil, AND
   - Dose does not exceed FDA label maximum for the diagnosis, AND
   - One of the following:
     - Patient is a night shift worker with hours of 11pm-7am, OR
     - Patient is an early morning shift worker with starting hours between 4am - 7am, OR
     - Patient is a rotating shift worker with night shifts.

4) **Fatigue associated with Multiple Sclerosis or Parkinson’s Disease:**
   - Dose does not exceed FDA label maximum for the diagnosis.

5) **Refractory depression:**
   - One of the following:
     - Prescribed or recommended by a Psychiatrist, AND
     - Dose does not exceed FDA label maximum for the diagnosis

OR
Patient has failed therapy with one prior antidepressant regimen (either as monotherapy or combination therapy), AND
Patient is experiencing symptoms of fatigue or excessive daytime sedation while on the current antidepressant regimen, AND
Provigil will be added to current regimen (either as monotherapy or combination therapy), AND
Dose does not exceed FDA label maximum for the diagnosis.

6) Bipolar depression:
   • Prescribed or recommended by a Psychiatrist, AND
   • Dose does not exceed FDA label maximum for the diagnosis.

Coverage Duration: Annual

Updated 01/2011