PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**NARCOLEPSY AGENTS**
BRAND NAME (generic)	**PROVIGIL (modafinil)**

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS
Provigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea (OSA), or shift work disorder (SWD).

Limitations of Use
In OSA, Provigil is indicated to treat excessive sleepiness and not as treatment for the underlying obstruction. If continuous positive airway pressure (CPAP) is the treatment of choice for a patient, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating and during treatment with Provigil for excessive sleepiness.

Compendial Uses/Limited Treatment Option
Fatigue related to multiple sclerosis[8,9]
Idiopathic hypersomnia[6]

COVERAGE CRITERIA

Idiopathic Hypersomnia
Authorization may be granted when the requested drug is being prescribed for idiopathic hypersomnia when ALL of the following criteria are met:

- The requested drug is being prescribed by, or in consultation with, a sleep specialist
- The patient has experienced the presence of daytime lapses into sleep or daily irrepressible periods of need to sleep for at least 3 months
- Insufficient sleep syndrome has been ruled out such as by lack of improvement of sleepiness after an adequate trial of increased nocturnal time in bed, preferably confirmed by at least a week of sleep log with wrist actigraphy
- A multiple sleep latency test (MSLT) documented fewer than two sleep onset rapid eye movement periods (SOREMPs) or no SOREMPs if the REM latency on the preceding polysomnogram was less than or equal to 15 minutes
- Sleep lab evaluation showed at least ONE of the following: mean sleep latency on MLST of less than or equal to 8 minutes, total 24-hour sleep time of greater than or equal to 660 minutes on 24-hour polysomnographic monitoring after correcting any chronic sleep deprivation or by wrist actigraphy in association with a sleep log and averaged over at least 7 days of unrestricted sleep
- The patient does NOT have cataplexy
- Hypersomnolence or MSLT results are not better explained by ANY of the following: another sleep disorder, other medical or psychiatric disorder, use of drugs or medications

Multiple Sclerosis-Related Fatigue
Authorization may be granted when the requested drug is being prescribed for multiple sclerosis-related fatigue.

Narcolepsy
Authorization may be granted for a diagnosis of excessive sleepiness associated with narcolepsy when ALL of the following criteria are met:

- The requested drug is being prescribed by, or in consultation with, a sleep specialist
- The diagnosis is confirmed by sleep study

Obstructive Sleep Apnea (OSA)
Authorization may be granted for a diagnosis of excessive sleepiness associated with obstructive sleep apnea (OSA) when ALL of the following criteria are met:

- The requested drug is being prescribed by, or in consultation with, a sleep specialist
- The diagnosis has been confirmed by polysomnography
- The patient has been receiving treatment for the underlying airway obstruction (continuous positive airway pressure [CPAP] or bilevel positive airway pressure [BIPAP]) for at least one month
- The patient will continue to use CPAP or BIPAP after the requested drug is started

Shift Work Disorder (SWD)
Authorization may be granted for a diagnosis of excessive sleepiness associated with shift work disorder (SWD) when ALL of the following criteria are met:

- The requested drug is being prescribed by, or in consultation with, a sleep specialist
- A sleep log and actigraphy monitoring have been completed for at least 14 days and show a disrupted sleep and wake pattern
- Symptoms have been present for 3 or more months

CONTINUATION OF THERAPY

Idiopathic Hypersomnia
Authorization may be granted when the requested drug is being prescribed for idiopathic hypersomnia when the following criteria is met:

- The patient has achieved or maintained a positive response to treatment from baseline

Multiple Sclerosis-Related Fatigue
Authorization may be granted when the requested drug is being prescribed for multiple sclerosis-related fatigue when the following criteria is met:

- The patient has achieved or maintained a positive response to treatment from baseline

Narcolepsy
Authorization may be granted for a diagnosis of excessive sleepiness associated with narcolepsy when the following criteria is met:

- The patient has achieved or maintained a positive response to treatment from baseline

Obstructive Sleep Apnea (OSA)
Authorization may be granted for a diagnosis of excessive sleepiness associated with obstructive sleep apnea (OSA) when ALL of the following criteria are met:

- The patient has achieved or maintained a positive response to treatment from baseline
- The patient is compliant with using continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP)

Shift Work Disorder (SWD)
Authorization may be granted for a diagnosis of excessive sleepiness associated with shift work disorder (SWD) when ALL of the following criteria are met:

- The patient has achieved or maintained a positive response to treatment from baseline
- The patient is still a shift-worker

Quantity Limits apply.
60 tablets per 25 days* or 180 tablets per 75 days*
**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

Duration of Approval (DOA):

- 178-C: DOA: 12 months
- 2814-C: DOA: 12 months

REFERENCES

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