BlueCross BlueShield Federal Employee Program

PROVIGIL / NUVIGIL (modafinil / armodafinil)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Provigil and Nuvigil are central nervous system stimulants. The Drug Enforcement Administration (DEA) has listed Provigil and Nuvigil as Schedule IV drugs. The mechanism through which Provigil and Nuvigil promote wakefulness is unknown. They has wake-promoting actions similar to sympathomimetic agents including amphetamine and methamphetamine, but the pharmacologic profile is not identical to that of the sympathomimetic amines (1-2).

Regulatory Status

FDA-approved indications: (1-2)

- Provigil is indicated for improving wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea (OSA), or shift work disorder.
- Nuvigil is indicated for improving wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea (OSA), narcolepsy, or shift work disorder.

Limitations of Use: (1-2)

In OSA, Provigil and Nuvigil are indicated to treat excessive sleepiness and not as treatment for the underlying obstruction.

Off-Label Uses:

- Provigil and Nuvigil are used as adjuncts to standard treatments for OSA (3-4)
- Provigil has been found effective in the treatment of multiple sclerosis fatigue. Provigil is a unique wake-promoting agent that is chemically distinct from traditional stimulants. Results of a placebo-controlled study showed it to significantly improve fatigue and sleepiness and to be well tolerated by patients with multiple sclerosis (MS). For MS patients who experience significant fatigue there are several medications that have proven effective in this regard. Provigil is among the most commonly used medications for fatigue associated with MS and according to expert opinion, is currently a first-line drug for MS patients (5-6).

Idiopathic hypersomnia, a condition similar to narcolepsy, is characterized by constant or recurrent daytime sleepiness with no other cause of sleepiness, prolonged nocturnal sleep, difficulty awakening with sleep drunkenness, and long unrefreshing naps with no history of cataplexy.

Provigil has proven effective in treating idiopathic hypersomnia in one case series and several open-label trials. The practice parameters for the treatment of narcolepsy and other hypersomnias of central origin state that Provigil may be effective for the treatment of daytime sleepiness due to idiopathic hypersomnia. As there may be underlying causes/behaviors associated with EDS, a sleep specialist physician has the training to correctly recognize and diagnose this condition. While Nuvigil has not been studied for this use, expert opinion considers it to be interchangeable with Provigil for this condition (4).

Summary

Provigil and Nuvigil are central nervous system stimulants used to increase wakefulness in adult patients with narcolepsy, shift work sleep disorder, and obstructive sleep apnea. The Drug Enforcement Administration (DEA) has listed Provigil and Nuvigil as Schedule IV drugs. They are also used off-label to treat MS fatigue (1-6).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Provigil and Nuvigil while maintaining optimal therapeutic outcomes.

References

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4. Morgenthaler TI, Kapur VK, Brown T, et al.Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin: An American Academy of Sleep Medicine Report. *Sleep*. 2007;30(12):1705-1711.
5. Zifko UA, Rupp M, Schwarz S, et al. Modafinil in treatment of fatigue in multiple sclerosis. Results of an open-label study. *J Neurol*. 2002;249:983-987.
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