

CAREMARK TrendsRx[®] Alert

What's new...What's next...What to do now

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PRE- DRUG APPROVAL

Nuvigil[™] (armodafinil)

Nuvigil (armodafinil, Cephalon, Inc.) is pending approval by the U.S. Food and Drug Administration (FDA) to improve wakefulness in patients suffering from excessive sleepiness associated with narcolepsy, shift work sleep disorder (SWSD), and obstructive sleep apnea/hypopnea syndrome (OSA/HS). It is anticipated that, upon approval, Nuvigil will be classified as a Schedule IV controlled substance.^{1,2} During clinical trials, Nuvigil was well tolerated. The most common side effects include headache, nausea, dizziness, trouble sleeping, and nervousness.³ Nuvigil is an oral formulation that is expected to receive approval and be available in pharmacies in the first quarter of 2006.²

If approved, Nuvigil will be the second product available for the treatment of conditions associated with excessive sleepiness.³ Provigil[®] (modafinil, Cephalon, Inc.) is currently approved to treat excessive sleepiness associated with narcolepsy, OSA/HS, and SWSD.⁴ Provigil and Nuvigil have similar ingredients.^{2,3} According to studies, Nuvigil promotes wakefulness later in the day, suggesting it has a long duration of action.³

BACKGROUND

Sleep is more than simply getting one's "beauty rest." It helps restore and rejuvenate the brain and organs so they work properly. A chronic lack of sleep can be harmful to a person's health and safety. It can also affect the person's performance. This may cause a person to move and think more slowly, make more mistakes, cause more accidents, and have trouble remembering things. The financial impact of being sleep deprived is estimated to be at least \$18 billion each year in the United States. Lack of sleep can also be linked to anxiety, depression, and irritability.⁵

BUDGET IMPACT

Caremark estimates Nuvigil will increase pharmacy budgets by approximately \$0.02 Per Member Per Month (\$0.19 Per Member Per Year) during its first year on the market.⁶ This estimate assumes the manufacturer, Cephalon, Inc., will successfully convert 20% of the current Provigil patients to Nuvigil patients before Provigil loses its patent protection in the first quarter of 2006. Nuvigil is expected to cost approximately \$10 per day, compared to approximately \$7 per day for Provigil, and have a comparable length of therapy, despite its longer half-life.⁷ The actual pharmacy budget impact will vary depending on your population's current use of medications for excessive sleepiness associated with narcolepsy, shift work sleep disorder, and obstructive sleep apnea/hypopnea syndrome.

Consult with your Caremark account representative on the best approach to manage Nuvigil in your population.

CAREMARK RESPONSE

Caremark recognizes the unique needs of plan participants with excessive sleepiness associated with narcolepsy, shift work sleep disorder (SWSD), and obstructive sleep apnea/hypopnea syndrome (OSA/HS). Based on currently available data, Caremark recommends for your consideration and at your discretion, the management of Nuvigil with the same clinical management tools you use for other medications for excessive sleepiness.

Caremark will continue to evaluate Nuvigil's appropriateness for clinical programs as more information on the final labeling is obtained from the FDA.

CAREMARK CONTACT

For more information, please contact your Caremark account representative.

Please Note: This document provides a brief overview of the subject. This review is provided as a reference only, and is based in part on information derived from third parties.

References

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