Xywav (calcium, magnesium, potassium, and sodium oxybates)

I. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. For initial requests, all of the following:
   I. Documentation of a sleep lab evaluation.
   II. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
   III. Documentation of the multiple sleep latency test (MSLT) showing fewer than two sleep onset rapid eye movement periods (SOREMPs) or no SOREMPs if the REM latency of the preceding polysomnogram was less than or equal to 15 minutes.
   IV. Mean sleep latency on MSLT of less than or equal to 8 minutes.
   V. Total 24-hour sleep time of greater than or equal to 660 minutes on 24-hour polysomnographic monitoring or by wrist actigraphy in association with a sleep log.

B. For continuation of therapy requests, chart notes or medical record documentation supporting a beneficial response to therapy (e.g., decrease in daytime sleepiness, decrease in cataplexy episodes from baseline).

II. CRITERIA FOR INITIAL APPROVAL

A. Cataplexy with Narcolepsy

Authorization of 6 months may be granted for treatment of cataplexy with narcolepsy when ALL OF the following criteria are met:

1. The member is 7 years of age or older.
2. The diagnosis of narcolepsy has been confirmed by a sleep lab evaluation as noted in the documentation included above.
3. The member meets criteria for narcolepsy (Criteria B).
    i. Criteria B – Member meets the following:
        a. Member is 7 years of age and less than 18 years of age:
            a. The member has experienced an inadequate treatment response or intolerance to at least two central nervous system (CNS) stimulants (e.g., amphetamine, dextroamphetamine, or methylphenidate).
            b. The member has a contraindication to at least two central nervous system (CNS) stimulants (e.g., amphetamine, dextroamphetamine, or methylphenidate).
        b. Member is 18 years of age or older:
            a. The member has experienced an inadequate treatment response or intolerance to modafinil or armodafinil OR the member has a contraindication to both modafinil and armodafinil

b. The member has experienced an inadequate treatment response or intolerance to at least two central nervous system (CNS) stimulants (e.g., amphetamine, dextroamphetamine, or methylphenidate) OR the member has a contraindication to at least two central nervous system (CNS) stimulants (e.g., amphetamine, dextroamphetamine, or methylphenidate).

4. Member has tried and failed at least 2 other options for cataplexy (i.e., duloxetine, venlafaxine, fluoxetine)
5. The member has a baseline history of at least 3 cataplexy attacks per week.

B. Excessive Daytime Sleepiness with Narcolepsy

Authorization of 6 months may be granted for treatment of excessive daytime sleepiness (EDS) with narcolepsy when ALL OF the following criteria are met:

1. The diagnosis of narcolepsy has been confirmed by a sleep lab evaluation as noted in the documentation included above.
2. If the member is 7 years of age or older
   i. The member has experienced an inadequate treatment response or intolerance with at least two central nervous system (CNS) stimulants (i.e., amphetamine, dextroamphetamine, methylphenidate) OR
   ii. The member has a contraindication with at least two central nervous system (CNS) stimulants (i.e., amphetamine, dextroamphetamine, methylphenidate)
3. If the member is 18 years of age or older:
   i. The member has experienced an inadequate treatment response or intolerance to armodafinil or modafinil OR
   ii. The member has a contraindication to both armodafinil and modafinil

C. Idiopathic hypersomnia

Authorization of 6 months may be granted for treatment of idiopathic hypersomnia when the diagnosis of idiopathic hypersomnia has been confirmed by all of the following:

1. The member is an adult (18 years of age or older)
2. The diagnosis of idiopathic hypersomnia has been confirmed by a sleep lab evaluation as noted in the documentation included above.
3. Presence of daytime lapses into sleep or daily irrepressible periods of need to sleep for at least 3 months
4. 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.
5. The member does not have cataplexy.
6. Hypersomnolence or multiple sleep latency test results are not better explained by another sleep disorder, other medical or psychiatric disorder, or use of drugs or medications.
7. The member has experienced an inadequate treatment response, intolerance, or contraindication with at least 2 central nervous system (CNS) stimulants (i.e., amphetamine, dextroamphetamine, methylphenidate)
8. Member must meet one of the following:
   i. The member has experienced an inadequate treatment response or intolerance to armodafinil or modafinil OR

ii. The member has a contraindication to both armodafinil and modafinil

III. CONTINUATION OF THERAPY

A. Cataplexy with Narcolepsy

Authorization of 12 months may be granted for continued treatment of cataplexy with narcolepsy when the member has demonstrated beneficial response to treatment as defined by a decrease in cataplexy episodes from baseline.

B. Excessive Daytime Sleepiness with Narcolepsy

Authorization of 12 months may be granted for continued treatment of excessive daytime sleepiness (EDS) with narcolepsy when the member has demonstrated beneficial response to treatment as defined by a decrease in daytime sleepiness with narcolepsy from baseline.

C. Idiopathic hypersomnia

Authorization of 12 months may be granted for continued treatment of idiopathic hypersomnia when the member has demonstrated beneficial response to treatment as defined by a decrease in daytime sleepiness from baseline.