Wakix (pitolisant)

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 requests: documentation to support one of the following:
   I. For excessive daytime sleepiness with narcolepsy: chart notes or medical record documentation supporting a beneficial response to therapy as demonstrated by a decrease in symptoms of daytime sleepiness from baseline.
   II. For cataplexy with narcolepsy: chart notes or medical record documentation supporting a beneficial response to therapy as demonstrated by a decrease in cataplexy episodes from baseline.

II. CRITERIA FOR INITIAL APPROVAL

A. Excessive Daytime Sleepiness with Narcolepsy

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

1. The diagnosis of narcolepsy is confirmed by a sleep lab evaluation as noted in the documentation included above.
2. The member is 6 years to less than 18 years of age and meets one of the following:
   i. The member has experienced an inadequate treatment response or intolerance with at least two central nervous system (CNS) stimulants (e.g., amphetamine, dextroamphetamine, methylphenidate) **OR**
   ii. The member has a contraindication with at least two central nervous system (CNS) stimulants (e.g., amphetamine, dextroamphetamine, methylphenidate).
3. The member is 18 years of age or older and meets one of the following:
   i. The member has experienced an inadequate treatment response or intolerance to armodafinil or modafinil.

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

B. Cataplexy with Narcolepsy

Authorization of 6 months may be granted for treatment of cataplexy in adult patients with narcolepsy when all of the following criteria are met:

1. The diagnosis of narcolepsy is confirmed by a sleep lab evaluation as noted in the documentation included above.
2. The member meets criteria for narcolepsy (Criteria A).
    i. The member has experienced an inadequate treatment response, intolerance to armodafinil or modafinil OR the member has a contraindication to both armodafinil and modafinil.
    ii. The member has experienced an inadequate treatment response, intolerance to 2 CNS stimulants, OR the member has a contraindication to CNS stimulants (e.g., amphetamine, dextroamphetamine, methylphenidate).
3. The member experiences at least 3 cataplexy attacks per week.
4. The member has experienced an inadequate treatment response, intolerance, or contraindication to two options for cataplexy: a tricyclic antidepressant (TC) [e.g., amitriptyline, desipramine, imipramine], a selective serotonin reuptake inhibitor (SSRI) [e.g., fluoxetine, sertraline, paroxetine], or venlafaxine.

III. CONTINUATION OF THERAPY

A. 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 symptoms of daytime sleepiness from baseline.

B. 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.