AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Xywav	Page:	1 of 4
Effective Date:	8/10/2023	Last Review Date:	5/25/2023

Applies to:	☒Illinois	☐Florida	☒Florida Kids
	☒New Jersey	☐Maryland	☐Michigan
	☒Pennsylvania Kids	☒Virginia	☐Texas

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Xywav under the patient's prescription drug benefit.

Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Xywav is indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.
2. Xywav is indicated for the treatment of idiopathic hypersomnia in adults.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Xywav

Policy/Guideline:

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

A. For initial requests, all of the following (if applicable):
   1. Documentation of a sleep lab evaluation
   2. 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
   3. 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
   4. Mean sleep latency on MSLT of less than or equal to 8 minutes
   5. 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)

Prescriber Specialty:
This medication must be prescribed by or in consultation with a sleep specialist.

Criteria for Initial Approval:

A. Cataplexy with Narcolepsy

Authorization of 12 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
3. The member has a baseline history of at least 14 cataplexy attacks in a typical 2-week period

B. Excessive Daytime Sleepiness with Narcolepsy

Authorization of 12 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
2. If the member is 7 years of age or older and less than 18 years of age:
   i. The member has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) stimulant (amphetamine, dextroamphetamine, methylphenidate) OR
   ii. The member has a contraindication to at least one central nervous system (CNS) stimulant (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
      a. Note: armodafinil is the formulary preferred product for all plans except Illinois. Illinois' formulary preferred product is modafinil.

C. Idiopathic hypersomnia

Authorization of 12 months may be granted for treatment of idiopathic hypersomnia when the diagnosis of idiopathic hypersomnia has been confirmed by all of the following:

1. Presence of daytime lapses into sleep or daily irrepressible periods of need to sleep for at least 3 months

2. 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
3. A multiple sleep latency test (MSLT) documents 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
4. Presence of at least one of the following:
   i. Mean sleep latency on MSLT of less than or equal to 8 minutes
   ii. 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
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

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.

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit: Xwav – 540 mL (270 grams) per 30 days

References:

1. Xywav [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; August 2021.
2. Morgenthaler TI, Vishesh KK, Brown T, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin. *Sleep* 2007; 30(12):1705-11.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed March 11, 2022.
4. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed March 11, 2022.
5. Satela, M. International Classification of Sleep Disorders- third edition: highlights and modifications. *Chest.* Nov 2014; 146(5)L 1387-1394.
6. Maski K, Trotti LM, Kotagal S, Auger RR, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* Published online September 1, 2021.