Effective date: 3/01/2021
Review date: 12/2020, 2/2021, 2/2022, 5/2023 Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

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

POLICY

I. INDICATIONS

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 Indication[1]
Treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy

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

II. 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

B. For continuation 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)

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by one of the following:

A. Sleep disorder specialist
B. Neurologist

IV. CRITERIA FOR INITIAL APPROVAL

Authorization of 6months may be granted when all of the following criteria are met:

1. Member is not being treated with sedative hypnotics that will be used concurrently with sodium oxybate
2. Member does not have a history of drug or alcohol abuse
3. Member meets either of the following:
   a. The requested drug is being prescribed for the treatment of cataplexy in narcolepsy in a member 7 years of age or older and all of the following criteria are met:
      i. The diagnosis is confirmed by sleep lab evaluation

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ii. The member has experienced an inadequate treatment response, intolerance, or contraindication to at least two of the following agents from a different medication class: atomoxetine, fluoxetine, protriptyline, clomipramine and/or venlafaxine

b. The requested drug is being prescribed for the treatment of excessive daytime sleepiness in a member 7 years of age or older with narcolepsy without cataplexy and all of the following criteria are met:
   i. The diagnosis is confirmed by sleep lab evaluation
   ii. The member has experienced an inadequate treatment response, intolerance, or contraindication to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate)
   iii. If the member is 18 years of age or older:
      a. The member experienced an inadequate treatment response orintolerance, to at least one central nervous system (CNS) wakefulness promoting drug (e.g., modafinil, armodafinil) OR
      b. The member has a contraindication to both armodafinil and modafinil

V. CONTINUATION OF THERAPY

A. Cataplexy with Narcolepsy[1-4]

Authorization of 6 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[1-3]

Authorization of 6 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.

VI. QUANTITY LIMIT

a. Xywav has a quantity limit of 18 ml per day.

VII. 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 July 2020.
4. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed July 2020.