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| Effective date: 3/01/2021 |
| Review date: 12/2020, 2/2021, 2/2022 |
| 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 Indication¹

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. PRESCRIBER SPECIALTIES

- a. Must be prescribed by a Sleep Disorder Specialist OR Neurologist

III. 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
 - 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:
 - 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:

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- a. The member experienced an inadequate treatment response, intolerance, or contraindication 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

IV. CONTINUATION OF THERAPY

A. Cataplexy with Narcolepsy¹⁻⁴

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 Narcolepsy¹⁻³

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.

V. QUANTITY LIMIT

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

VI. 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.