Reference number(s)
6181-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☑
Standard Control – Choice (SCCF)	☑
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☑
Advanced Control Specialty – Choice (ACSCF)	☑
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☑

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Narcolepsy

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), and Value Formulary (VF).

Plan Design Summary

This program applies to the narcolepsy products specified in this document. Coverage for the targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Narcolepsy Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	• Lumryz (sodium oxybate) • Wakix (pitolisant) • Xywav (calcium, magnesium, potassium, and sodium oxybates)
Target	• sodium oxybate (generic) • Xyrem (sodium oxybate)

Exception Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Excessive Daytime Sleepiness with Narcolepsy

Coverage for a targeted product is provided when both of the following criteria are met:

- Member has had a documented intolerable adverse event to the preferred product Lumryz, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
- Member has a documented inadequate response or intolerable adverse event with both of the preferred products, Wakix and Xywav.

Cataplexy with Narcolepsy

Coverage for a targeted product is provided when either of the following criteria is met:

- Member is less than 18 years old and meets both of the following criteria:
  - Member has had a documented intolerable adverse event to the preferred product Lumryz, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
  - Member has a documented inadequate response or intolerable adverse event to the preferred product Xywav.
- Member is 18 years old or older and meets both of the following criteria:
  - Member has had a documented intolerable adverse event to the preferred product Lumryz, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
  - Member has a documented inadequate response or intolerable adverse event with both of the preferred products, Wakix and Xywav.

References

1. Lumryz [package insert]. Chesterfield, MO: Avadel CNS Pharmaceuticals; October 2024.
2. Sodium oxybate [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; April 2023.
3. Wakix [package insert]. Plymouth Meeting, PA: Harmony Biosciences, LLC; June 2024.
4. Xyrem [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2023.

5. Xywav [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2023.