JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS083
		Effective Date	05/01/2014
		Review Date	07/19/2023
	Subject **Xyrem, Lumryz, and Xywav**	*Revision Date*	07/19/2023
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Lumryz, Xyrem, Xywav

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I. POLICY

A. Xyrem (sodium oxybate), Lumryz (sodium oxybate extended release), and Xywav (calcium, magnesium, potassium, and sodium oxybates) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Xyrem** may be approved for patients meeting the following:
   1. Patient is 7 years of age or older
   2. Documentation has been submitted showing the following:
      a. Patient has been diagnosed with one of the following:
         I. Narcolepsy with cataplexy
         II. Narcolepsy without cataplexy
      b. Diagnosis is supported by polysomnogram and mean sleep latency time (MSLT) objective testing
      c. Patient has symptoms of excessive daytime sleepiness
      d. Patient has had trial and inadequate response, or intolerance, with at least two oral medications commonly used to treat narcolepsy-related excessive daytime sleepiness

B. **Lumryz** may be approved for patients meeting the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing the following:
      a. Patient has been diagnosed with one of the following:
         I. Narcolepsy with cataplexy
         II. Narcolepsy without cataplexy
      b. Diagnosis is supported by polysomnogram and mean sleep latency time (MSLT) objective testing

c. Patient has symptoms of excessive daytime sleepiness
d. Patient has had trial and inadequate response, or intolerance, with at least two oral medications commonly used to treat narcolepsy-related excessive daytime sleepiness

C. **Xywav** may be approved for patients meeting the following:
1. Narcolepsy
a. Patient is 7 years of age or older
b. Documentation has been submitted showing the following:
I. Patient has been diagnosed with one of the following:
i. Narcolepsy with cataplexy
ii. Narcolepsy without cataplexy
II. Diagnosis is supported by polysomnogram and mean sleep latency time (MSLT) objective testing
III. Patient has symptoms of excessive daytime sleepiness
IV. Patient has had trial and inadequate response, or intolerance, with at least two oral medications commonly used to treat narcolepsy-related excessive daytime sleepiness
2. Hypersomnia
a. Patient is 18 years of age or older
b. Documentation has been submitted showing the following:
I. Patient has been diagnosed with Idiopathic Hypersomnia (IH)
II. Diagnosis is supported by polysomnogram and mean sleep latency time (MSLT) objective testing
III. Patient has experienced symptoms of IH, such as excessive daytime sleepiness, sleep drunkenness, unfreshing sleep, or cognitive impairment
IV. Patient has had trial and inadequate response, or intolerance, with at least two oral medications commonly used to treat hypersomnia

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
B. Continuation of therapy may be approved in 12-month intervals with evidence of the patient's clinical improvement as supported by documentation of at least one of the following:
1. Reduction in frequency of cataplexy attacks
2. Reduction in excessive daytime sleepiness symptoms

IV. EXCLUSIONS

A. Xyrem, Lumryz, Xywav will not be approved for the following:
1. Concurrent use with alcohol, or other CNS depressants
2. Excessive daytime sleepiness not associated with narcolepsy
3. Hypersomnia that is associated with another medical, behavioral, or psychiatric disorder
4. Fibromyalgia
5. Insomnia
6. Any indications or uses that are not FDA-approved or guideline-supported
B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Xyrem [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2023

2. Xywav [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2023
3. Lumryz [prescribing information]. Chesterfield, MO: Avadel CNS Pharmaceuticals, LLC; May 2023.
4. Trotti LM. Idiopathic Hypersomnia. Sleep Med Clin. 2017;12(3):331-344.
5. Khan Z, Trotti LM. Central Disorders of Hypersomnolence: Focus on the Narcolepsies and Idiopathic Hypersomnia. Chest. 2015 Jul;148(1):262-273.

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2016	Removed background information
05/19/2017	Clarified reauthorization criteria
07/27/2017	Updated Exclusions section regarding physician samples
07/01/2018	Removed EHP Line of Business
07/15/2020	Revised criteria and layout based on FDA-approved labeling
01/19/2022	Added criteria for Xywav based on FDA-approved prescribing information
07/19/2023	Added criteria for Lumryz based on FDA-approved prescribing information

Review/Revision Dates: 04/16/2014, 04/20/2016, 05/19/2017, 07/27/2017, 07/01/2018, 07/15/2020, 01/19/2022, 07/19/2023