CareSource

PHARMACY POLICY STATEMENT Georgia Medicaid	
DRUG NAME	**Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybates)**
BILLING CODE	**Must use valid NDC**
BENEFIT TYPE	**Pharmacy**
SITE OF SERVICE ALLOWED	**Home**
COVERAGE REQUIREMENTS	**Prior Authorization Required (Non-Preferred Products) QUANTITY LIMIT— 540mL per 30 days**
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	**Click Here**

Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybates) are non-preferred products and will only be considered for coverage under the pharmacy benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

NARCOLEPSY WITH EXCESSIVE DAYTIME SLEEPINESS (EDS)

For initial authorization:

1. **Member is 7 years old or older; AND**
2. **Medication must be prescribed by or in consultation with a neurologist or sleep specialist; AND**
3. **Member has a diagnosis of narcolepsy with EDS confirmed by sleep studies: polysomnogram and MSLT (multiple sleep latency test); AND**
4. Member's current score on the Epworth Sleepiness Scale (ESS) is documented in chart **notes; AND**
5. **a) Age 18 years or older: Member has had a compliant trial and failure for at least 30 days for each of the following at maximally tolerated doses: modafinil OR armodafinil, AND Sunosi; AND at least 60 days of Wakix, unless not tolerated or contraindicated; OR**
   b) Less than 18 years of age: Member has had a compliant trial and failure for at least 30 days each for at least two stimulant medications (such as methylphenidate, amphetamine), OR one stimulant medication AND modafinil, unless not tolerated or contraindicated; AND
6. **Member is not using any alcohol or sedative hypnotic agents (such as zolpidem).**
7. **Dosage allowed: 9g per day (4.5g per dose).**

If member meets all the requirements listed above, the medication will be approved for 6 months.

For reauthorization:

1. **Chart notes must show the member has an improved score on the Epworth Sleepiness Scale and/or improved signs and symptoms of daytime sleepiness; AND**
2. **Member must continue to abstain from alcohol and any sedative hypnotic agents; AND**
3. **Member tolerates therapy and does not experience unmanageable or severe adverse effects; AND**
4. **Chart notes must not reveal any evidence or concerns of abuse, misuse, or diversion.**

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

NARCOLEPSY WITH CATAPLEXY

For initial authorization:

1. **Member is 7 years old or older; AND**
2. **Medication must be prescribed by or in consultation with a neurologist or sleep specialist; AND**
3. **Member must have a diagnosis of narcolepsy with cataplexy confirmed by sleep studies: polysomnogram and MSLT (multiple sleep latency test); AND**
4. **Member's current score on the Epworth Sleepiness Scale and baseline frequency of cataplexy attacks (e.g. weekly rate) must be documented; AND**
5. **Member must have, unless specifically contraindicated, a compliant trial and failure of at least one of the following cataplexy treatments for no less than 30 days: A tricyclic antidepressant (such as clomipramine), selective serotonin reuptake inhibitor (such as fluoxetine), or serotonin-norepinephrine reuptake inhibitor (such as venlafaxine); AND**
6. **Members 18 years of age and older must have a trial and failure of Wakix for at least 60 days; AND**
7. **Member is not using any alcohol or sedative hypnotic agents (such as zolpidem).**
8. **Dosage allowed: 9g per day (4.5g per dose).**

If member meets all the requirements listed above, the medication will be approved for 6 months.

For reauthorization:

1. **Chart notes must show decreased frequency and/or severity of cataplexy attacks; AND**
2. **Member must continue to abstain from alcohol and any sedative hypnotic agents; AND**
3. **Member tolerates therapy and does not experience unmanageable or severe adverse effects; AND**
4. **Chart notes must not reveal any evidence of abuse, misuse, or diversion.**

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybates) not medically necessary for the treatment of diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
5/26/2020	New policy for Xyrem created.
01/28/2021	Xywav added to policy. For cataplexy section: reduced trial of antidepressants from 2 to 1; added step through Wakix for adults.

References:

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3. IPD analytics. Accessed January 28, 2021.
4. Lecendreux M, Bruni O, Franco P, et al. Clinical experience suggests that modafinil is an effective and safe treatment for paediatric narcolepsy. Journal of Sleep Research. 2012;21(4):481-483. doi:10.1111/j.1365-2869.2011.00991.x
5. Lehert P, Falissard B. Multiple treatment comparison in narcolepsy: a network meta-analysis. Sleep. 2018;41(12). doi:10.1093/sleep/zsy185
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7. Xywav [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc; 2020.
8. Bogan RK, Thorpy MJ, Dauvilliers Y, et al. Efficacy and safety of calcium, magnesium, potassium, and sodium oxybates (lower-sodium oxybate [LXB]; JZP-258) in a placebo-controlled, double-blind, randomized withdrawal

study in adults with narcolepsy with cataplexy [published online ahead of print, 2020 Oct 14]. Sleep. 2020;zsaa206. doi:10.1093/sleep/zsaa206
9. Barateau, L., & Dauvilliers, Y. (2019). Recent advances in treatment for narcolepsy. Therapeutic advances in neurological disorders, 12, 1756286419875622. https://doi.org/10.1177/1756286419875622
10. Thorpy MJ, Bogan RK. Update on the pharmacologic management of narcolepsy: mechanisms of action and clinical implications. Sleep Med. 2020;68:97-109. doi:10.1016/j.sleep.2019.09.001

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