CareSource

| PHARMACY POLICY STATEMENT<br>**Ohio Medicaid** | |
|---|---|
| DRUG NAME | Xyrem (sodium oxybate) |
| BILLING CODE | Must use valid NDC code |
| BENEFIT TYPE | Pharmacy |
| SITE OF SERVICE ALLOWED | Home |
| COVERAGE REQUIREMENTS | Prior Authorization Required (Non-Preferred Product)<br>QUANTITY LIMIT— 540mL per 30 days |
| LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY | Click Here |

Xyrem (sodium oxybate) is a **non-preferred** product 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 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 chart notes have been provided that show the member has improved signs and symptoms of disease; 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.***

## 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 number of cataplexy attacks must be documented; AND
5. Member must have, unless specifically contraindicated, a compliant trial and failure of at least **two** of the following cataplexy treatments for no less than 30 days each: a tricyclic antidepressant (such as clomipramine), selective serotonin reuptake inhibitor (such as fluoxetine), or serotonin-norepinephrine reuptake inhibitor (such as venlafaxine); 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 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) 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. |

References:


1. Xyrem [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc; 2018.
2. Xyrem. Micromedex Solutions. Greenwood Village, CO: Truven Health Analytics. http://micromedex.com/. Updated April 10, 2020. Accessed May 15, 2020.
3. IPD analytics. Accessed May 18, 2020.
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
6. Morgenthaler TI, Kapur VK, Brown TM, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin. *Sleep*. 2007;30(12):1705-1711. doi:10.1093/sleep/30.12.1705


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