Xyrem (sodium oxybate)
Xywav (oxybate salts [calcium, magnesium, potassium, and sodium])
Wakix (pitolisant)
Effective 05/01/2022

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions			

Overview
Xyrem, Xywav, and Wakix are approved for cataplexy or excessive daytime sleepiness in narcolepsy. Xywav is additionally approved for idiopathic hypersomnia in adults.

Coverage Guidelines
Authorization may be reviewed for members new to AllWays Health Partners who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Wakix (pitolisant)

Documentation of all of the following is required:

1. Appropriate diagnosis
2. Member is ≥ 18 years of age
3. Medical records documenting the results of the sleep study used to confirm narcolepsy [polysomnogram (PSG) or Multiple Sleep Latency Test (MSLT)]
4. Requested dose does not exceed the quantity limit of two units/day
5. Paid claim or physician attestation of inadequate response or adverse reaction to **THREE** of the following, or contraindication to **ALL** of the following:
    a. armodafinil or modafinil
    b. cerebral stimulant agent

c. Sunosi
d. Xyrem.

Xyrem (sodium oxybate) and Xywav (oxybate salts)
Documentation of all of the following is required:

1. Member has ONE of the following diagnosis:
    a. Narcolepsy with cataplexy
    b. Excessive daytime sleepiness (EDS) due to narcolepsy (without cataplexy)
    c. Idiopathic hypersomnia
2. Medical records documenting the results of the sleep study used to confirm diagnosis [polysomnogram (PSG) or Multiple Sleep Latency Test (MSLT)]
3. Prescriber is a neurologist or sleep specialist, or consult notes from a neurologist or sleep specialist are provided
4. For diagnosis of Narcolepsy with cataplexy: paid claims or physician attestation of inadequate response or adverse reaction to one, or contraindication to all of the following: tricyclic antidepressant, SSRI, venlafaxine
5. For diagnosis of EDS due to narcolepsy (without cataplexy) member must meet BOTH of the following:
    a. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to one cerebral stimulant agent
    b. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to armodafinil or modafinil
6. For a diagnosis of idiopathic hypersomnia member must meet ALL the following:
    a. The member is not currently utilizing a drug that can cause EDS
    b. The member does not have hypersomnia due to another medical, behavioral, or psychiatric disorder
    c. Paid claims of physician attestation of inadequate response, adverse reaction, or contraindication to one cerebral stimulant agent
    d. Paid claims of physician attestation of inadequate response, adverse reaction, or contraindication to armodafinil or modafinil
7. Requested quantity does not exceed the quantity limit of nine grams (18 mL)/day
8. for Xywav, medical necessity for use instead of Xyrem

Continuation criteria:
Reauthorization requires physician documentation of continuation of therapy and positive response to therapy. Physician documents decreased daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.
2. Quantity limits may apply

Drug	Quantity Limit
Xyrem	540mL per 30 days
Xywav	540mL per 30 days
Wakix	60 tablets per 30 days

References

1. Xyrem [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; October 2018.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed October 2018.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed October 2018.
4. 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.
5. American Academy of Sleep Medicine. International Classification of Sleep Disorders: Diagnostic and Coding Manual. 3rd edition. Westchester, IL: American Academy of Sleep Medicine; 2014.
6. Krahn, L, Hershner S, et al. Quality Measures for the Care of Patients with Narcolepsy; Journal of Clinical Sleep Medicine; 2015; 11(3): 335-55.
7. Nuvigil [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; July 2018.
8. Provigil [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; April 2018.
9. Xywav (calcium, magnesium, potassium, and sodium oxybate) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals Inc; July 2020.

Review History

01/23/2020 – Reviewed and Updated Jan P&T, Transitioned from SGM to Custom Criteria, added PA and QL Xywav to criteria.
05/01/2021 – Xywav added to specialty.
11/17/2022 – Reviewed and Updated November P&T; Updated criteria to match MH criteria. Effective Date: 1/1/2022
03/16/2022 – Reviewed and Updated for March P&T; removed UM criteria under coverage guidelines and continued with drug specific criteria to match MH; added new indication of idiopathic hypersomnia Effective 05/01/2022.

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