Xyrem (sodium oxybate)
Xywav (oxibate salts [calcium, magnesium, potassium, and sodium])
Effective 05/01/2021

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	Xyrem is available at non-Specialty Pharmacies.		

Overview
Xyrem and Xywav are mediated by $GABA_B$ receptor activity at noradrenergic, dopaminergic, and thalamocortical neurons. These medications are approved for cataplexy or excessive daytime sleepiness in narcolepsy.

Coverage Guidelines
Authorization may be reviewed for members new to AllWays Health Partners who are currently receiving treatment with Xyrem or Xywav 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:

1. The member has a diagnosis of cataplexy or excessive daytime sleepiness in narcolepsy
2. The member is 7 years of age or older
3. The diagnosis is confirmed by sleep lab evaluation
4. The member has had inadequate response, intolerance, or contraindication to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, or methylphenidate)
5. For members 18 years of age or older, the member has had an inadequate response, intolerance, or contraindication to at least one CNS wakefulness promoting drug (e.g., modafinil, armodafinil)

<u>Continuation criteria:</u>

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

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. Xyway (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 Xyway to criteria.
05/01/2021 – Xywav added to specialty.

Disclaimer

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