pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
January 11, 2022	February 1, 2022	*See below

SUBJECT

Prior Authorization of Xyrem (sodium oxybate)/Xywav (calcium, magnesium, potassium, and sodium oxybates) – Pharmacy Services

BY

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IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Xyrem (sodium oxybate)/Xywav (calcium, magnesium, potassium, and sodium oxybates) submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Xyrem (sodium oxybate)/Xywav (calcium, magnesium, potassium, and sodium oxybates) to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (Department) Drug Utilization Review (DUR) Board meets to review provider prescribing and dispensing practices for efficacy, safety, and

*01-22-04	09-22-03	27-22-02	33-22-03
02-22-02	11-22-03	30-22-02	
03-22-02	14-22-02	31-22-04	
08-22-04	24-22-02	32-22-02	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs Web site at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective DUR and Retrospective DUR programs.

DISCUSSION:

During the November 3, 2021, meeting, the DUR Board recommended the following revisions to the guidelines to determine medical necessity of prescriptions for Xyrem (sodium oxybate)/Xywav (calcium, magnesium, potassium, and sodium oxybates):

- Revision of the guidelines that address history of substance abuse, addiction, or diversion;
- Revision of the guidelines for the treatment of narcolepsy with excessive daytime sleepiness;
- Revision of the guidelines for the treatment of narcolepsy with cataplexy;
- Addition of guidelines that address the recent FDA approval of Xywav (calcium, magnesium, potassium, and sodium oxybates) for the treatment of idiopathic hypersomnia; and
- Removal of the guideline regarding urine drug screening from the requests for renewal of prior authorization section.

The revisions to the guidelines to determine medical necessity of prescriptions for Xyrem (sodium oxybate)/Xywav (calcium, magnesium, potassium, and sodium oxybates) submitted for prior authorization, as recommended by the DUR Board, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Xyrem (sodium oxybate)/Xywav (calcium, magnesium, potassium, and sodium oxybates) are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Xyrem (sodium oxybate)/Xywav (calcium, magnesium, potassium, and sodium oxybates)) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs and products that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I

Pharmacy Prior Authorization General Requirements
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx

I. Requirements for Prior Authorization of Xyrem (sodium oxybate)/Xywav (calcium, magnesium, potassium, and sodium oxybates)

A. Prescriptions That Require Prior Authorization

All prescriptions for Xyrem (sodium oxybate)/Xywav (calcium, magnesium, potassium, and sodium oxybates) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Xyrem (sodium oxybate)/Xywav (calcium, magnesium, potassium, and sodium oxybates), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the requested medication for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Does not have a contraindication to the prescribed medication; **AND**

5. Has results of a recent urine drug screen (UDS) (including testing for licit and illicit drugs with the potential for abuse, including specific testing for oxycodone, fentanyl, and tramadol) that is consistent with prescribed controlled substances; **AND**

6. Does not have active or untreated substance abuse or addiction or a history of diversion; **AND**

7. For a beneficiary with a diagnosis of narcolepsy, at least **one** of the following**:**

    a. For treatment of excessive daytime sleepiness (EDS) in narcolepsy, **both** of the following:

        i. Was evaluated and treated for other etiologies for EDS

        ii. **One** of the following:

            a) For a beneficiary under 18 years of age, has a history of therapeutic failure with maximum tolerated doses of or a contraindication or an intolerance to modafinil or armodafinil

b) For a beneficiary age 18 years or older, has a history of therapeutic failure with maximum tolerated doses of or a contraindication or an intolerance to **all** of the following:

(i) Modafinil or armodafinil,
(ii) Sunosi (solriamfetol),
(iii) Wakix (pitolisant)

b. For treatment of cataplexy in narcolepsy, **one** of the following:

i. For a beneficiary under 18 years of age, has a history of therapeutic failure of or a contraindication or an intolerance to an antidepressant (i.e., SSRI, SNRI, or TCA)

ii. For a beneficiary age 18 years or older, has a history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:

a) An antidepressant (i.e., SSRI, SNRI, or TCA)
b) Wakix (pitolisant);

AND

8. For treatment of idiopathic hypersomnia, **all** of the following:

a. Was diagnosed with idiopathic hypersomnia by or in consultation with a sleep specialist,
b. Was evaluated and treated for other etiologies of EDS,
c. Has a history of therapeutic failure with maximum tolerated doses of or a contraindication or an intolerance to modafinil or armodafinil;

AND

9. For Xywav (calcium, magnesium, potassium, and sodium oxybates), has a medical reason why the beneficiary is unable to take Xyrem (sodium oxybate); **AND**

10. Has documentation that the prescriber or the prescriber's delegate conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for the beneficiary's controlled substance prescription history; **AND**

11. If a prescription for Xyrem (sodium oxybate)/Xywav (calcium, magnesium, potassium, and sodium oxybates) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the

professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR XYREM (SODIUM OXYBATE)/XYWAV (CALCIUM, MAGNESIUM, POTASSIUM, AND SODIUM OXYBATES): The determination of medical necessity of a request for renewal of a prior authorization for Xyrem (sodium oxybate)/Xywav (calcium, magnesium, potassium, and sodium oxybates) that was previously approved will take into account whether the beneficiary:

1. For a beneficiary with a diagnosis of narcolepsy, at least **one** of the following:

   a. For treatment of EDS in narcolepsy, has a reduction in daytime sleepiness
   b. For treatment of cataplexy in narcolepsy, has a reduction in the incidence of cataplexy attacks;

   AND

2. For treatment of idiopathic hypersomnia, has a reduction in daytime sleepiness; **AND**

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Does not have a contraindication to the prescribed medication; **AND**

5. Does not have active or untreated substance abuse or addiction or a history of diversion; **AND**

6. Has documentation that the prescriber or the prescriber's delegate conducted a search of the PDMP for the beneficiary's controlled substance prescription history; **AND**

7. If a prescription for Xyrem (sodium oxybate)/Xywav (calcium, magnesium, potassium, and sodium oxybates) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Xyrem (sodium oxybate)/Xywav (calcium, magnesium, potassium, and sodium oxybates). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Xyrem (sodium oxybate)/Xywav (calcium, magnesium, potassium, and sodium oxybates) will be approved as follows:

1. Initial requests for prior authorization of Xyrem (sodium oxybate)/Xywav (calcium, magnesium, potassium, and sodium oxybates) will be approved for up to 4 months.

2. Renewals of requests for prior authorization of Xyrem (sodium oxybate)/Xywav (calcium, magnesium, potassium, and sodium oxybates) will be approved for up to 6 months.

E. References

1. Eichler, A.F. et al. What's new in sleep medicine. Up To Date, accessed September 30, 2020.
2. Littner, MR et al. Practice Parameters for Clinical Use of the Multiple Sleep Latency Test and the Maintenance of Wakefulness Test An American Academy of Sleep Medicine Report Standards of Practice Committee of the American Academy of Sleep Medicine Sleep. 2005; 28 (1).
3. Morgenthaler TI; Kapur VK; Brown T; Swick TJ; Alessi C; Aurora RN; Boehlecke B; Chesson AL; Friedman L; Maganti R; Owens J; Pancer J; Zak R; Standards of Practice Committee of the AASM. Practice param-eters for the treatment of narcolepsy and other hypersomnias of central origin. SLEEP 2007;30(12):1705-1711.
4. Scammell, T.E. et al. Treatment of narcolepsy in adults. Up To Date, accessed September 30, 2020.
5. Xyrem Package Insert, Jazz Pharmaceuticals, Inc. July 2020.
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7. Chervin RD. Idiopathic Hypersomnia. Up To Date, accessed October 12, 2021.
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9. Maski K et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. Journal of Clinical Sleep Medicine 2021; 17(9): 1881-1893.
10. Bassetti CLA et al. European guideline and expert statements on the management of narcolepsy in adults and children. Eur J Neurol. 2021;28:2815–2830.