pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
December 14, 2020	January 5, 2021	*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:

1. Inform providers that the Department of Human Services (Department) will require prior authorization of prescriptions for Xywav (calcium, magnesium, potassium, and sodium oxybates).
2. Issue 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.

*01-20-58	09-20-57	27-20-53	33-20-54
02-20-51	11-20-51	30-20-50	
03-20-51	14-20-52	31-20-58	
08-20-61	24-20-52	32-20-50	

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 website at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

BACKGROUND:

The Department's Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective Drug Use Review and Retrospective Drug Use Review programs.

DISCUSSION:

Xywav (calcium, magnesium, potassium, and sodium oxybates) was recently approved by the U.S. Food and Drug Administration for the treatment of cataplexy and excessive daytime sleepiness in patients with narcolepsy. Xywav (calcium, magnesium, potassium, and sodium oxybates) is in the same pharmacologic class as Xyrem (sodium oxybate). The Department has required prior authorization for Xyrem (sodium oxybate) since October 17, 2011.

During the October 21, 2020, meeting, the DUR Board recommended that the Department require prior authorization of Xywav (calcium, magnesium, potassium, and sodium oxybates) to ensure appropriate patient selection and drug utilization. The board also recommended combining the requirements for prior authorization of Xywav (calcium, magnesium, potassium, and sodium oxybates) and Xyrem (sodium oxybate) into one guideline.

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 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 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 a history of substance abuse, addiction, or diversion; **AND**

7. For narcolepsy with excessive daytime sleepiness (EDS), **both** of the following:

    a. Was evaluated and treated for other etiologies for EDS

    b. **One** of the following:

        i. For a beneficiary under 18 years of age, has a documented history of therapeutic failure[1] with maximum tolerated doses of or a contraindication or intolerance to **both** of the following:

            a) Modafinil or armodafinil

[1] Therapeutic failure is defined as an Epworth Sleepiness Scale of greater than or equal to 10 or repeated maintenance of wakefulness test (MWT) or multiple sleep latency test (MSLT) with a mean sleep latency of 8 minutes or less.

b) Methylphenidate, methamphetamine, or dextroamphetamine

ii. For a beneficiary age 18 years and older, has a documented history of therapeutic failure with maximum tolerated doses of or a contraindication or intolerance to **all** of the following:

a) Modafinil or armodafinil,
b) Methylphenidate, methamphetamine, or dextroamphetamine,
c) Sunosi (solriamfetol),
d) Wakix (pitolisant);

AND

8. For narcolepsy with cataplexy, **one** of the following:

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

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

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

AND

9. For Xywav (calcium, magnesium, potassium, and sodium oxybates), has a documented clinical 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 narcolepsy with EDS, has a documented reduction in daytime sleepiness as evidenced by an improved Epworth Sleepiness Scale, MWT, or MSLT; **AND**

2. For narcolepsy with cataplexy, has a documented reduction in the incidence of cataplexy attacks; **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 a recent 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 a history of substance abuse, addiction, or diversion; **AND**

7. 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**

8. 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.
6. Xywav [prescribing information]. Jazz Pharmaceuticals, Inc. July 2020.