pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
July 2, 2024	July 15, 2024	*See below

SUBJECT	BY
Prior Authorization of Antidepressants, Other – Pharmacy Services	Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs

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.pa.gov/en/agencies/dhs/resources/for-providers/promise/promise-provider-enrollment.html.

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 Antidepressants, Other submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Antidepressants, Other will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Antidepressants, Other to the appropriate managed care organization.

BACKGROUND:

*01-24-09	09-24-09	27-24-06	33-24-09
02-24-05	11-24-04	30-24-04	
03-24-04	14-24-05	31-24-10	
08-24-10	24-24-07	32-24-04	

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.pa.gov/en/agencies/dhs/resources/for-providers/ma-for-providers/contact-information-for-ma-providers.html.

The Department of Human Services' (Department) Drug Utilization Review (DUR) Board meets 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 DUR and Retrospective DUR programs.

DISCUSSION:

During the May 16, 2024, meeting, the DUR Board recommended revising the guidelines to determine medical necessity of prescriptions for Antidepressants, Other to include medical necessity and dose and duration of therapy guidelines specific to Zulresso (brexanolone) and Zurzuvae (zuranolone).

The revisions to the guidelines to determine medical necessity of prescriptions for Antidepressants, Other 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 Antidepressants, Other 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 Antidepressants, Other) 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.pa.gov/en/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements.html

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/clinical-guidelines.html

I. Requirements for Prior Authorization of Antidepressants, Other

A. Prescriptions That Require Prior Authorization

Prescriptions for Antidepressants, Other that meet any of the following conditions must be prior authorized:

1. A non-preferred Antidepressant, Other. See the Preferred Drug List (PDL) for the list of preferred Antidepressants, Other at: https://papdl.com/preferred-drug-list.

2. An Antidepressant, Other with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antidepressant, Other, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For Zulresso (brexanolone) and Zurzuvae (zuranolone), **all** of the following:

   a. Is prescribed Zulresso (brexanolone) or Zurzuvae (zuranolone) for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,

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

   c. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

   d. Will not use Zulresso (brexanolone) and Zurzuvae (zuranolone) concomitantly,

   e. For a diagnosis of postpartum depression (PPD), **all** of the following:

      i. Has depression with onset in the third trimester through 4 weeks postpartum,
      ii. Has moderate to severe PPD based on a validated depression rating scale (e.g., PHQ-9/EPDS, HAMD-17),
      iii. Is ≤12 months postpartum,
      iv. Is not actively psychotic, manic, or hypomanic,
      v. Is not currently pregnant;

   AND

2. For all other non-preferred Antidepressants, Other, **one** of the following:

   a. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antidepressant, Other (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)

   b. **All** of the following:

      i. Is prescribed the Antidepressant, Other for the treatment of a diagnosis that is indicated in the FDA-approved package labeling or a medically accepted indication,

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

      iii. Is prescribed a dose and frequency that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

      iv. Does not have a contraindication to the prescribed medication,

      v. At least **two** of the following:

         a) Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antidepressants, Other approved or medically accepted for the beneficiary's diagnosis at maximally tolerated doses for a duration of ≥6 weeks,
         b) Has a history of therapeutic failure of or a contraindication or an intolerance to the Antidepressants, SSRIs approved or medically accepted for the beneficiary's diagnosis at maximally tolerated doses for a duration of ≥6 weeks,
         c) Has a history of therapeutic failure of or a contraindication or an intolerance to augmentation therapy (e.g., lithium, antipsychotic, stimulant) in combination with an antidepressant approved or medically accepted for the beneficiary's diagnosis at maximally tolerated doses for a duration of ≥6 weeks;

AND

3. For Spravato (esketamine), **all** of the following:

   a. Is prescribed Spravato (esketamine) by or in consultation with a psychiatrist,
   b. Is prescribed Spravato (esketamine) in conjunction with a therapeutic dose of an oral antidepressant,
   c. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
   d. Does not have severe hepatic impairment (Child-Pugh class C);

AND

4. If a prescription for an Antidepressant, Other 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.

   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 ANTIDEPRESSANTS, OTHER: The determination of medical necessity of a request for renewal of a prior authorization for an Antidepressant, Other that was previously approved will take into account whether the beneficiary:

1. For Spravato (esketamine), **all** of the following:

   a. Has documentation of improvement in disease severity since initiating treatment,
   b. Is prescribed Spravato (esketamine) by or in consultation with a psychiatrist,
   c. Is prescribed Spravato (esketamine) in conjunction with a therapeutic dose of an oral antidepressant,
   d. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
   e. Does not have severe hepatic impairment (Child-Pugh class C)

   AND

2. If a prescription for an Antidepressant, Other 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.

   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. Dose and Duration of Therapy

Requests for prior authorization of Zulresso (brexanolone) and Zurzuvae (zuranolone) will be approved for one treatment course per pregnancy based on FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

D. 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 an Antidepressant, Other. 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.

E. References

1. Spravato (esketamine) [package insert]. Titusville, NJ. Janssen Pharmaceuticals, Inc.: October 2023.
2. Treatment and Management of Mental Health Conditions During Pregnancy and Postpartum: ACOG Clinical Practice Guideline No. 5:. Obstetrics & Gynecology 141(6):p 1262-1288, June 2023.
3. Screening and Diagnosis of Mental Health Conditions During Pregnancy and Postpartum: ACOG Clinical Practice Guideline No. 4:. Obstetrics & Gynecology 141(6):p 1232-1261, June 2023.
4. Zulresso (brexanolone) [package insert]. Cambridge, MA. Sage Therapeutics, Inc.: June 2022.
5. Zurzuvae (zuranolone) [package insert]. Cambridge, MA. Biogen Inc.: August 2023.