PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
ANTIDEPRESSANTS, OTHER

Proposed Effective Date: July 15, 2024

Revisions are noted with a ~~strikethrough~~ for deletions and **bold and underline** for additions.

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.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Revisions to 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. 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,

ii. 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,

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

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

v. Does not have a contraindication to the prescribed medication;

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. 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. Has documentation of improvement in disease severity since initiating treatment,
   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.**