

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>.

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:
 1. 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)

2. **All** of the following:

- a. 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,
- b. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
- c. Is prescribed a dose and frequency that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
- d. Does not have a contraindication to the prescribed medication,
- e. At least **two** of the following:
 - i. 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,
 - ii. 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,
 - iii. 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);

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:

- i. For a non-preferred Antidepressant, Other with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic that would not be expected to occur with the requested drug; **AND**
- ii. For Spravato (esketamine), **all** of the following:
 - 1. Has documentation of improvement in disease severity since initiating treatment,
 - 2. Is prescribed Spravato (esketamine) by or in consultation with a psychiatrist,
 - 3. Is prescribed Spravato (esketamine) in conjunction with a therapeutic dose of an oral antidepressant,
 - 4. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - 5. Does not have severe hepatic impairment (Child-Pugh class C)

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.

ANTIDEPRESSANTS, OTHER PRIOR AUTHORIZATION FORM (form effective 7/15/2024)

| | | | | |
|--------------------------------------|--|-------------------|------------------|------------------|
| <input type="checkbox"/> New request | <input type="checkbox"/> Renewal request | # of pages: _____ | Prescriber name: | |
| Name of office contact: | | | Specialty: | |
| Contact's phone number: | | | NPI: | State License #: |
| LTC facility contact/phone: | | | Street address: | |
| Beneficiary name: | | | City/state/zip: | |
| Beneficiary ID#: | DOB: | Phone: | Fax: | |

CLINICAL INFORMATION

| | | | |
|---|-----------|--|--|
| Drug requested: | Strength: | Dosage form: | |
| Dose/directions: | Quantity: | Refills: | |
| Diagnosis (submit documentation): | | Dx code (required): | |
| Is the beneficiary currently being treated with the requested medication? | | <input type="checkbox"/> Yes – date of last dose: _____ Submit documentation. <input type="checkbox"/> No | |

Complete all sections that apply to the beneficiary and this request. *Check all that apply and submit documentation for each item.*

INITIAL requests

1. For ZULRESSO (brexanolone) and ZURZUVAE (zuranolone):

- ☐ Is being treated for postpartum depression (PPD) AND:
- ☐ Has depression with onset in the 3rd trimester through 4 weeks postpartum.
 - ☐ Has moderate to severe PPD based on a validated depression rating scale (e.g., PHQ-9/EPDS, HAMD-17).
 - ☐ Is less than or equal to 12 months postpartum.
 - ☐ Is not actively psychotic, manic, or hypomanic.
 - ☐ Is not currently pregnant.

2. For ALL OTHER NON-PREFERRED Antidepressants, Other (except Zulresso and Zurzuvae):

- ☐ Tried and failed or has a contraindication or an intolerance to the preferred Antidepressants, Other that are FDA-approved or medically accepted for the treatment of the beneficiary's diagnosis at maximally tolerated doses for at least 6 weeks. (Refer to <https://papdl.com/preferred-drug-list> for a list of preferred Antidepressants, Other.)
- ☐ Tried and failed or has a contraindication or an intolerance to the Antidepressants, SSRIs that are FDA-approved or medically accepted for the treatment of the beneficiary's diagnosis at maximally tolerated doses for at least 6 weeks.
- | | |
|---|---|
| <input type="checkbox"/> citalopram (e.g., Celexa) | <input type="checkbox"/> fluvoxamine (e.g., Luvox) |
| <input type="checkbox"/> escitalopram (e.g., Lexapro) | <input type="checkbox"/> paroxetine (e.g., Paxil, Pexeva) |
| <input type="checkbox"/> fluoxetine (e.g., Prozac, Sarafem) | <input type="checkbox"/> sertraline (e.g., Zoloft) |
- ☐ Tried and failed or has a contraindication or an intolerance to augmentation therapy (e.g., lithium, antipsychotic, stimulant) in combination with an antidepressant that is FDA-approved or medically accepted for the treatment of the beneficiary's diagnosis at maximally tolerated doses for at least 6 weeks.

3. For SPRAVATO (esketamine):

- ☐ Is prescribed Spravato by or in consultation with a psychiatrist.
- ☐ Will use Spravato in conjunction with a therapeutic dose of an oral antidepressant.
- ☐ Does not have severe hepatic impairment (Child-Pugh class C).

RENEWAL requests

1. For SPRAVATO (esketamine):

- ☐ Is prescribed Spravato by or in consultation with a psychiatrist.
- ☐ Will use Spravato in conjunction with a therapeutic dose of an oral antidepressant.
- ☐ Does not have severe hepatic impairment (Child-Pugh class C).
- ☐ Has documentation of improvement in disease severity since starting treatment.

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:

Date:

Confidentiality Notice: The documents accompanying this telecopy may contain confidential information belonging to the sender. The information is intended only for the use of the individual named above. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or taking of any telecopy is strictly prohibited.