

Louisiana Medicaid Depression - Antidepressants (Other)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request:

- Prior authorization for non-preferred antidepressants (other) for recipients 7 years of age and older; **OR**
- Clinical authorization for **all** preferred and non-preferred agents for recipients younger than 7 years of age; **OR**
- Clinical authorization for esketamine (Spravato[®]™); **OR**
- Clinical authorization for brexanolone (Zulresso[®])

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria for Initial and Reauthorization Requests for Non-Preferred Agents for Recipients 7 Years of Age and Older

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
 - The recipient has had a *treatment failure* with at least one preferred product; **OR**
 - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
 - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**
 - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
 - The recipient is established on the requested medication with positive clinical outcomes; **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial and reauthorization approval: 12 months

Approval Criteria for Initial and Reauthorization Requests for *ALL* Agents (Preferred and Non-Preferred) When Requested for Behavioral Health for Recipients Younger Than 7 Years of Age

- **ONE** of the following is true and is **stated on the request**:
 - The recipient has been treated in the past or is *currently receiving treatment with the requested medication with a positive response to treatment without evidence of adverse effects*, and this information is stated on the request; **OR**
 - The recipient has not previously used this medication; however, the prescriber is citing references supporting the use of the medication for the recipient's age and diagnosis (for example, a peer-reviewed journal article demonstrating the safety and efficacy of the requested medication for the indication); **OR**
 - **ALL** medication options that are appropriate for both the age and diagnosis of this recipient:
 - have been tried, resulting in **EITHER** *treatment failure* **OR** *intolerable side effects*; **OR**
 - have not been tried because of a *documented contraindication to the remaining medication options that are appropriate for the age and condition being treated*; **AND**
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product – **ONE** of the following is required:
 - The recipient has had *treatment failure* with at least one preferred product; **OR**
 - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
 - The recipient has a *documented contraindication* to all of the preferred products that are appropriate for the condition being treated; **OR**
 - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
 - The recipient is established on the medication with positive clinical outcomes; **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - If the requested medication is being added to any other behavioral health medication, the recipient has been adherent to the established medication therapy without adequate resolution of symptoms; **AND**
 - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial and reauthorization approval: 12 months

Esketamine (Spravato®TM)

Approval Criteria

- Recipient is 18 years of age or older on the date of the request; **AND**
- Recipient has **ONE** of the following diagnoses:
 - Depression for which **the current depressive episode** has not responded adequately to at least **TWO** different antidepressants of adequate dose and duration (treatment-resistant depression); **OR**
 - Depressive symptoms with major depressive disorder (MDD) with acute suicidal ideation or behavior; **AND**
- Esketamine is being given in conjunction with an oral antidepressant; **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - The recipient has no concomitant drug therapies or disease states that limit the use of esketamine and will not be receiving esketamine in combination with any medication that is contraindicated or not recommended per FDA labeling; **AND**
 - All requirements of the SpravatoTM REMS program will be met.

Reauthorization Criteria

- Prescriber evaluation of the recipient at the end of the induction phase (week 4 of treatment) shows evidence of therapeutic benefit, and the prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy; **AND**
- The recipient continues to meet all initial approval criteria.

Duration of initial authorization approval: 4 weeks

Duration of reauthorization approval: 6 months

Brexanolone (Zulresso®)

Approval Criteria

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of moderate to severe postpartum depression determined by a standardized screening tool for depression [such as, but not limited to, Edinburgh Postnatal Depression Scale (EPDS), Patient Health Questionnaire (PHQ-9), Beck Depression Inventory (BDI), Hamilton Depression Rating Scale (HAM-D)]; **AND**
- If the recipient has moderate postpartum depression, **ONE** of the following must be **stated on the request**:

- The recipient has tried and failed a 4-week trial of an oral antidepressant medication [include medication name along with begin and end dates of treatment]; **OR**
- Recipient has a documented *adverse reaction, intolerance, or contraindication* to treatment with an oral antidepressant; **AND**
- The **time period of the onset of postpartum depression symptoms is stated on the request**, and onset of symptoms occurred during the third trimester of pregnancy up to four weeks after delivery (the third trimester is from the beginning of pregnancy week 27 to the end of the pregnancy); **AND**
- The recipient is ≤ 6 months postpartum on the date of the request (**state date of delivery on the request**); **AND**
- The prescriber **states on the request** that the recipient has not previously received brexanolone for the postpartum depressive episode from the most recent pregnancy; **AND**
- Brexanolone (Zulresso®) is being prescribed by a psychiatrist **OR** an obstetrician-gynecologist; **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - Recipient has no concomitant drug therapies or disease states that limit the use of brexanolone (Zulresso®).

Duration of approval: 30 days [Only one authorization per pregnancy]

References

ACOG Committee Opinion No. 757 : Screening for Perinatal Depression. Obstetrics & Gynecology 2018;132(5):e208–e212. <https://www.acog.org/-/media/Committee-Opinions/Committee-on-Obstetric-Practice/co757.pdf?dmc=1&ts=20181024T2023437995>

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DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. Pharmacotherapy: A Pathophysiologic Approach, 10e New York, NY: McGraw-Hill; <https://accesspharmacy.mhmedical.com/book.aspx?bookid=1861>

Spravato (esketamine) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; July 2020. <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SPRAVATO-pi.pdf>

Stewart CM and Vigod S. Postpartum depression. N Engl J Med. 2016;375:2177-2186. https://www.nejm.org/doi/full/10.1056/NEJMcp1607649?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed

Zulresso (brexanolone) [package insert]. Cambridge, MA: Sage Therapeutics Inc; June 20~~22~~¹⁹.
<https://assets.sagerx.com/zulresso/prescribing-information.pdf>

Revision / Date	Implementation Date
Single PDL Implementation	May 2019
Separated “Select Therapeutic Classes (Established)” into individual therapeutic class documents / November 2019	January 2020
Combined Spravato™ criteria and Zulresso® criteria with Depression - Antidepressants (Other) criteria, formatting changes / June 2020	July 2020
Update Spravato™ criteria to include new diagnosis, formatting changes, updated references, modified to apply new age requirement for behavioral health clinical authorization / August 2020	January 2021
Formatting changes / November 2021	January 2022
<u>Updated age indication for Zulresso®, updated references / June 2022</u>	<u>January 2023</u>