**Louisiana Medicaid**
**Brexanolone (Zulresso®)**

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for brexanolone (Zulresso®).

Additional Point-of-Sale edits may apply.

*Zulresso® has a **Black Box Warning** and is subjected to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to prescribing information for details.*

## 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 $\leq$ 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. Retrieved from https://www.acog.org/-/media/Committee-Opinions/Committee-on-Obstetric-Practice/co757.pdf?dmc=1&ts=20181024T2023437995

Stewart CM and Vigod S. Postpartum depression. N Engl J Med. 2016;375:2177-2186. Retrieved from 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 2019. https://assets.sagerx.com/zulresso/prescribing-information.pdf

| Revision | Date |
|---|---|
| Policy created. | January 2020 |
| Policy implemented. | May 2020 |