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PHARMACY / MEDICAL POLICY – 5.01.608

Pharmacologic Treatment of Postpartum Depression

BCBSA Ref. Policy: 5.01.33

Effective Date:	Mar. 1, 2025	RELATED MEDICAL POLICIES:	
Last Revised:	Feb. 24, 2025	5.01.520	Antidepressants: Pharmacy Medical Necessity Criteria for Brands
Replaces:	N/A	5.01.609	Spravato (esketamine) Nasal Spray

Select a hyperlink below to be directed to that section.

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Depression after the birth of a baby – postpartum depression – affects up to 20 percent of women. It's common to have mood swings for a few weeks after giving birth. This is commonly called "the baby blues." Postpartum depression, however, is longer lasting and is considered a major depressive episode. Postpartum depression can affect women of all ages and economic classes. Between 40 percent to 80 percent of postpartum depression cases are considered moderate to severe. The cause of postpartum depression is unknown. The symptoms of postpartum depression include sadness, loss of interest in activities, and a lower ability to feel pleasure. Other symptoms may be feelings of worthlessness or guilt, difficulty with thinking, or thoughts of suicide. This policy describes when medication for postpartum depression may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Medical Necessity
Zulresso (brexanolone) IV	**Zulresso (brexanolone) may be considered medically necessary for the treatment of postpartum depression when the following criteria are met:** • The individual is aged 15 years or older **AND** • Has medical record documentation of DSM-5 diagnostic criteria for Major Depressive Disorder with peripartum onset **AND** • Current episode of depression is moderate to severe as demonstrated by documentation of individual's symptoms and their severity or by one or more standardized depression rating scales **AND** • Is 6 months or less postpartum **AND** • Zulresso (brexanolone) is administered as a one-time 60-hour infusion per pregnancy **All other uses of Zulresso (brexanolone) for conditions not outlined in this policy are considered not medically necessary.**
Zurzuvae (zuranolone) oral	**Zurzuvae (zuranolone) may be considered medically necessary for the treatment of postpartum depression when the following criteria are met:** • The individual is aged 18 years or older **AND** • Has medical record documentation of DSM-5 diagnostic criteria for Major Depressive Disorder with peripartum onset **AND** • Current episode of depression is moderate to severe as demonstrated by documentation of individual's symptoms and their severity or by one or more standardized depression rating scales **AND** • Is 12 months or less postpartum **AND** • The treatment course is limited to 14 days

Drug	Medical Necessity
	All other uses of Zulresso (brexanolone) and Zurzuvae (zuranolone) for conditions not outlined in this policy are considered not medically necessary.

Drug	Investigational
As listed	**The medications listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.** **All other uses of the drugs listed in this policy for conditions not outlined in this policy are considered investigational.**

Length of Approval	
Approval	**Criteria**
Initial authorization	**Non-formulary exception reviews for all drugs listed in this policy may be approved up to 12 months.** **Zulresso (brexanolone) may be approved as a one-time infusion per pregnancy.** **Zurzuvae (zuranolone) may be approved as a 14-day single treatment course per pregnancy.**
Re-authorization criteria	**Future re-authorization of Zulresso (brexanolone) beyond a one-time infusion per pregnancy is considered not medically necessary.** **Future re-authorization of Zurzuvae (zuranolone) beyond 14 days in a single treatment course per pregnancy is considered not medically necessary.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the relevant history and physical evaluation information.

Coding

Code	Description
HCPCS	
J1632	Injection, brexanolone (Zulresso), 1 mg

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Definition of Terms

Diagnostic and Statistical Manual of Metal Disorders (DSM)-5 Diagnostic Criteria for a Major Depressive Episode

- Five (or more) of the following symptoms have been present during the same two-week period and represent a change from previous functioning; at least one of the symptoms is either (1) depressed mood or (2) loss of interest or pleasure. Do not include symptoms that are clearly attributable to another medical condition. Criteria A through C represent a major depressive episode. Responses to a significant loss (e.g., bereavement, financial ruin, losses from a natural disaster, a serious medical illness or disability) may include the feelings of intense sadness, rumination about the loss, insomnia, poor appetite, and weight loss noted in Criterion A, which may resemble a depressive episode. Although such symptoms may be understandable or considered appropriate to the loss, the presence of a major depressive episode in addition to the normal response to a significant loss should also be carefully considered. This decision inevitably requires the exercise of clinical judgement based on the individual's history and the cultural norms for the expression of distress in the context of loss.
    - Depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad, empty, hopeless) or observations made by others (e.g., appears tearful). (Note: In children and adolescents, can be irritable mood.)

- Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation).
- Significant weight loss when not dieting or weight gain (e.g., a change of more than 5% of body weight in a month) or decrease or increase in appetite nearly every day. (NOTE: In children, consider failure to make expected weight gain.)
- Insomnia or hypersomnia nearly every day.
- Psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down).
- Fatigue or loss of energy nearly every day.
- Feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick).
- Diminished ability to think or concentrate, or indecisiveness, nearly every day (either by their subjective account or as observed by others).
- Recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide.

- The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- The episode is not attributable to the direct physiological effects of a substance or to another medical condition.
- The occurrence of the major depressive episode is not better explained by schizoaffective disorder, schizophrenia, schizophreniform disorder, delusional disorder, or other specified and unspecified schizophrenia spectrum and other psychotic disorders.
- There has never been a manic or hypomanic episode. This exclusion does not apply if all of the manic-like or hypomanic-like episodes are substance-induced or are attributable to the physiological effects of another medical condition.

Rating Scales for Severity of Depression in Major Depressive Disorder

Score	Depression Severity
Hamilton Depression Rating Scale (HAM-D)	
<10	Remission
10-13	Mild
14-17	Mild to moderate
≥18	Moderate to severe
Montgomery-Asberg Depression Rating Scale (MADRS)	
0-6	None

Score	Depression Severity
7-19	Mild
20-34	Moderate
≥35	Severe
Quick Inventory of Depressive Symptomatology (QIDS-SR)	
0-5	None
6-10	Mild
11-15	Moderate
16-20	Severe
≥21	Very severe
Patient Health Questionnaire-9 (PHQ-9)	
0-4	None
5-9	Mild
10-14	Moderate
15-19	Moderately severe
≥20	Severe

PHQ-9 Depression Questionnaire

A PHQ-9 score of ≥10 indicates it is likely major depression with a score of 5 to 9 indicating mild, 10 to 14 indicating moderate, 15 to 19 moderately severe and ≥20 severe major depression.

- Over the last two weeks, how often have you been bothered by an of the following (Not at all = 0; Several days = 1; More than half the days = 2; Nearly every day =3):
  - Little interest or pleasure in doing things
  - Feeling down, depressed, or hopeless
  - Trouble falling or staying asleep, or sleeping too much
  - Feeling tired or having little energy
  - Poor appetite or overeating
  - Feeling bad about yourself, or that you are a failure, or that you have let yourself or your family down
  - Trouble concentrating on things, such as reading the newspaper or watching television
  - Moving or speaking so slowly that other people could have noticed? Or the opposite, being so fidgety or restless that you have been moving around a lot more than usual.

- Thoughts that you would be better off dead, or of hurting yourself in some way

Consideration of Age

Age limits specified in this policy are determined according to FDA-approved indications where applicable.

Benefit Application

Zulresso (brexanolone) is managed through the medical benefit and Zurzuvae (zuranolone) is managed through the pharmacy benefit.

Evidence Review

Background

Zulresso (brexanolone) and Zurzuvae (zuranolone) are neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulators indicated for the treatment of postpartum depression (PPD). Post-partum depression is the most common complication of childbirth and can result in considerable suffering for mothers, children, and families. Postpartum depression is estimated to affect 10–20% of women who give birth worldwide, and occurs in low-income, middle-income, and high-income countries. Approximately 40–80% of cases of post-partum depression are considered moderate to severe. In the USA, the estimated prevalence of post-partum depression in new mothers varies by state from 8–20%, with an overall mean prevalence of 11.5%.

The pathogenesis of postpartum depression is unknown. It is also not known to what degree the underpinnings of postpartum depression differ from those of nonperinatal depression, and whether postpartum depression represents a distinct (reproductive) subtype of depression. Factors involved in postpartum depression may include genetic susceptibility, epigenetic phenomena (e.g., DNA methylation), and hormonal changes, as well as psychological and social problems and stressful life events.

The hypothalamic-pituitary-adrenal (HPA) axis, perinatal hormonal fluctuations, and γ-aminobutyric acid (GABA) signaling have been implicated in the pathophysiology of post-

partum depression, and previous studies have identified associations between these potential mechanisms. In mouse models of GABA dysfunction, mice were found to have postpartum depression-like maternal behaviors and defects in HPA axis regulation, indicating an association between GABA and HPA regulation. Additionally, plasma concentrations of allopregnanolone, a potent positive allosteric modulator of synaptic and extra synaptic GABA type A (GABA-A) receptors, which are an endogenous progesterone metabolite, decrease considerably following childbirth, indicating an association between perinatal hormonal fluctuations and GABA regulation.

Summary of Evidence

Zulresso (brexanolone)

Efficacy

The efficacy of brexanolone was evaluated in 138 postpartum women in two moderate quality, phase 3, randomized, double blinded, placebo-controlled clinical trials: Hummingbird 202B and 202C. Eligible individuals were randomized (1:1:1) to receive brexanolone 90 ug/kg, brexanolone 60 ug/kg, or placebo. The primary endpoint was the change from baseline in the 17-item Hamilton Depression Rating Score (HAM-D) total score at 60 hours, assessed in all individuals who started infusion of study drug or placebo. Secondary endpoints included mean HAM-D total score and least-squares mean change from baseline; Clinical Global Impression-Improvement (CGI-I) response; and change in baseline of Montgomery-Asberg Depression Rating Scale (MADRS).

Results from Hummingbird202B showed a least-squares mean reduction in HAM-D total score from baseline of 19.5 points in brexanolone 60 ug/kg, 17.7 points in brexanolone 90 ug/kg, compared with 14.0 points in placebo (difference of -5.5, [95% CI -8.8 to -2.2], p=0.0013 for brexanolone 60 ug/kg; -3.7 [95% CI -6.9 to -0.5], p=0.0252 for brexanolone 90 ug/kg). In Hummingbird 202C, the least-squares mean reduction in HAM-D total score at 60 hours from baseline was 14.6 points (SE 0.8) in the brexanolone 90 ug/kg group compared with 12.1 points (SE 0.8) for the placebo group (difference –2.5 [95% CI –4.5 to –0.5], p=0.0160).

The efficacy of brexanolone was also evaluated in 21 postpartum women in a moderate quality, phase 2, randomized, double blinded, active-controlled clinical trial. Eligible women were randomly assigned (1:1), via a computer-generated randomization program, to receive either a single, continuous intravenous dose of brexanolone or placebo for 60 hours. The primary efficacy endpoint was the change from baseline in the 17-item HAM-D total score at 60 hours.

Secondary endpoints included mean HAM-D total score and least-squares mean change from baseline; CGI-I response; and change in baseline of MADRS.

Results from this phase 2 study showed a reduction in HAM-D total score from baseline was 21.0 points (SE 2.9) in the brexanolone group compared with 8.8 points (SE 2.8) in the placebo group (difference –12.2, 95% CI –20.77 to –3.67; p=0.0075; effect size 1.2) at 60 hours.

Safety

Serious Adverse Events

In the phase 3 trials, the most impactful serious adverse event reported was suicidal ideation and intentional overdose in one individual on brexanolone. Across groups, 4 individuals receiving brexanolone experienced excessive sedation and loss of consciousness without respiratory and hemodynamic compromise. In three cases, the infusion was continued and completed without recurrence.

Other Adverse Events

In Hummingbird 202B, 19 individuals in the brexanolone 60 ug/kg group and 22 individuals in the brexanolone 90 ug/kg group had adverse events compared with 22 individuals in the placebo group. In study 2, 25 individuals in the brexanolone 90 ug/kg group had adverse events compared with 24 individuals in the placebo group. The most common treatment emergent adverse events in the brexanolone groups were headache (n=7 brexanolone 60 ug/kg group and n=6 brexanolone 90 ug/kg group vs n=7 placebo group for study 1; n=9 brexanolone 90 ug/kg group vs n=6 placebo group for study 2), dizziness (n=6 brexanolone 60 ug/kg group and n=6 brexanolone 90 ug/kg group vs n=1 placebo group for study 1; n=5 brexanolone 90 ug/kg group vs n=4 placebo group for study 2), and somnolence (n=7 brexanolone 60 ug/kg group and n=2 brexanolone 90 ug/kg group vs n=3 placebo group for study 1; n=4 brexanolone 90 ug/kg group vs n=2 placebo group for study 2).

Tolerability

Of 147 individuals included in the ALL-brexanolone study results, the most common adverse events were: headache (n=22), dizziness (n=19), and somnolence (n=15). These events were typically mild in severity and did not commonly lead to discontinuation of treatment.

Administration

Zulresso should be administered as a continuous intravenous infusion over 60 hours (2.5 days) as follows:

- 0 to 4 hours: Initiate with a dosage of 30 mcg/kg/hour
- 4 to 24 hours: Increase dosage to 60 mcg/kg/hour
- 24 to 52 hours: Increase dosage to 90 mcg/kg/hour (alternatively consider a dosage of 60 mcg/kg/hour for those who do not tolerate 90 mcg/kg/hour)
- 52 to 56 hours: Decrease dosage to 60 mcg/kg/hour
- 56 to 60 hours: Decrease dosage to 30 mcg/kg/hour

Zurzuvae (zuranolone)

Efficacy

Zuranolone was studied in two Phase 3 trials with differing doses. In both studies, zuranolone was significantly more effective than placebo. No comparisons with active treatment are available. Breast feeding was not allowed during the studies and study drug was not administered during pregnancy.

The ROBIN study was a multicenter, randomized, placebo-controlled, double-blind, Phase 3 trial in 153 women with PPD who were ≤6 months postpartum. Individuals met DSM-5 criteria for MDD and a baseline HAMD-17 score ≥26 (severe depression). Individuals were randomized to zuranolone or placebo for 2 weeks followed by an observation period of 45 days. The primary endpoint of change from baseline in Day 15 least squares mean (LSM) HAMD-17 score was -17.8 with zuranolone 30 mg and -13.6 with placebo (effect size 0.53 [medium], p=0.003). While secondary outcomes were not adjusted for multiplicity and p-values were considered nominal, all secondary outcomes favored zuranolone at 15 days. Secondary endpoints noted initial efficacy at 3 days which was maintained to 45 days.

The SKYLARK study was a multicenter, randomized, placebo-controlled, double-blind, Phase 3 trial in 200 women with PPD who were ≤12 months postpartum. Individuals met DMS-5 criteria for MDD; however, a baseline HAMD-17 score required for inclusion was not specified. Like the ROBIN study, study drug was administered for 2 weeks and follow-up was continued for 45 days. In the SKYLARK trial, individuals were randomized to a higher dose of zuranolone (50 mg

po QD) or placebo. The primary endpoint of LSM change in HAMD-17 score at day 15 was significantly improved with zuranolone 50 mg vs placebo (-15.6 vs -11.6; p=0.0007). Efficacy was maintained to 45 days and was initially noted at 3 days. The study is available as data on file only and reporting was incomplete.

Safety

Serious Adverse Events

Serious adverse events occurred in 1.0%-2.8% of individuals across clinical trials with zuranolone. Sedation and loss of consciousness were of interest in zuranolone trials as brexanolone carries a boxed warning for excessive sedation or sudden loss of consciousness and has a Risk Evaluation and Mitigation Strategy (REMS) program requiring continuous monitoring throughout the 60-hour infusion. In the ROBIN trial with zuranolone, one individual discontinued the trial due to sedation and one individual experienced confusion. No loss of consciousness was reported in any of the zuranolone trials. Zuranolone does have a boxed warning regarding driving impairment due to central nervous system (CNS) depressant effects. Individuals are advised not to drive or engage in other potentially hazardous activities until at least 12 hours after administration.

Other Adverse Events

Common adverse events with zuranolone 50 mg included somnolence (26.5%), dizziness (13.3%), sedation (11.2%), and headache (9.2%).

Administration

The recommended dose of Zurzuvae is 50 mg taken orally once daily in the evening for 14 days. If the individual experiences CNS depressant effects within the 14-day period, the dose may be reduced to 40 mg once daily in the evening within the 14-day period. For individuals using a strong CYP3A4 inhibitor, or those with severe hepatic impairment (Child-Pugh C) or severe renal impairment (eGFR <60 mL/min/1.73 m^2) the recommended dose is 30 mg taken orally once daily in the evening for 14 days.

Ongoing and Unpublished Clinical Trials for Zulresso

Some currently unpublished trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT03665038[a]	A study to assess the safety and efficacy of brexanolone in the treatment of adolescent female subjects with postpartum depression	80	Completed
NCT02477618	A study with SAGE-547 for super-refractory status epilepticus	132	Completed
NCT02285504	Evaluate SAGE-547 in female patients with severe postpartum depression	4	Completed
NCT02277106	Evaluate SAGE-547 in patients with essential tremor	24	Completed
NCT02052739	Study to evaluate SAGE-547 injection as adjunctive therapy for the treatment of super-refractory status epilepticus	25	Completed

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

US Preventive Services Task Force Recommendations

The US Preventive Services Task Force Recommendations (USPSTF) recommendations apply to pregnant persons and persons who are less than 1 year postpartum who do not have a current diagnosis of depression but are at increased risk of developing depression.

The USPSTF recommends (category B recommendation) screening for depression in the general adult population, including pregnant and postpartum women. The USPSTF also recommends screening for depression in adolescents aged 12 to 18 years and found insufficient evidence to recommend for or against screening in children 11 years or younger.

The USPSTF recommends that clinicians provide or refer pregnant and postpartum persons who are at increased risk of perinatal depression to counseling interventions (category B recommendation).

2020 Update

Reviewed prescribing information for Zulresso (brexanolone) and conducted a literature search for the treatment of postpartum depression. No new evidence found that would change this policy.

2021 Update

Reviewed prescribing information for Zulresso (brexanolone) and conducted a literature search for the treatment of postpartum depression. No new evidence found that would change this policy.

2022 Update

Reviewed prescribing information for Zulresso (brexanolone) and updated criteria from 18 years of age or older to 15 years of age or older. Use of Zulresso in individuals 15 to 17 years of age was supported by evidence from adequate and well-controlled studies in adults with PPD, pharmacokinetic data in adults and individuals 15 to 17 years, and safety data in individuals 15 to 17 years. Also, added additional info to define moderate to severe depression which can be demonstrated by documentation of individual's symptoms and their severity or by one or more standardized depression rating scales.

2023 Update

Reviewed prescribing information for Zulresso (brexanolone). No new evidence found that would change this policy.

2024 Update

Reviewed prescribing information for Zulresso (brexanolone) and Zurzuvae (zuranolone). No new evidence found that would change this policy.

2025 Update

Reviewed prescribing information for Zulresso (brexanolone) and Zurzuvae (zuranolone). Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information.

References

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2. Zurzuvae (zuranolone). Prescribing Information. Cambridge, MA. Sage Therapeutics, Inc. Revised July 2024.
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History

Date	Comments
06/01/19	New policy, approved May 14, 2019. Add to Prescription Drug section. Zulresso (brexanolone) may be considered medically necessary when criteria are met, considered not medically necessary when criteria are not met.
10/01/20	Annual Review, approved September 1, 2020. No changes to policy statement. Added HCPCS J1632. Removed HCPCS J3490.
11/01/21	Annual Review, approved October 5, 2021. No changes to policy statement.
10/01/22	Annual Review, approved September 26, 2022. Updated criteria from 18 years of age or older to 15 years of age or older and added additional info to define moderate to severe depression. Changed the wording from "patient" to "individual" throughout the policy for standardization.
07/01/23	Annual Review, approved June 26, 2023. No changes to policy statement.
11/01/23	Interim Review, approved October 10, 2023. Added Zurzuvae (zuranolone) for the treatment of postpartum depression in adults.
02/01/24	Annual Review, approved January 22, 2024. Correction made to quantity limit for Zurzuvae (zuranolone).
03/01/25	Annual Review, approved February 24, 2025. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.