

## PHARMACY POLICY STATEMENT

### Marketplace

<b>DRUG NAME</b>	<b>Zulresso (brexanolone)</b>
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Zulresso, initially approved in 2019, is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression (PPD) in patients 15 years and older. The mechanism of action of Zulresso in the treatment of postpartum depression is thought to be associated with its positive allosteric modulation of GABAA receptors. With approximately 1 in 8 moms experiencing symptoms of postpartum depression (PPD), it is one of the most common pregnancy-related medical conditions. In clinical studies, adults who took Zulresso experienced a greater improvement in depressive symptoms vs placebo in 2.5 days as measured by a standard depression scale.

Zulresso (**brexanolone**) will be considered for coverage when the following criteria are met:

#### Postpartum Depression (PPD)

For **initial** authorization:

1. Member is 15 years of age or older; AND
2. Medication must be prescribed by or in consultation with a psychiatrist or obstetrician-gynecologist (OB/GYN); AND
3. Member has diagnosis of moderate to severe PPD as defined by current DSM criteria or an appropriate depression rating scale (e.g. HAM-D, PHQ-9, etc); AND
4. Member is ≤ 6 months postpartum; AND
5. Member has had a major depressive episode that began no earlier than the third trimester and no later than the first 4 weeks following delivery; AND
6. Member has previously tried and failed an antidepressant medication (e.g. SSRI, SNRI); OR
7. Prescriber attests the severity of depression would place the health of the mother or infant at significant risk; AND
8. If the member is breastfeeding, provider attests that the risks and benefits of breastfeeding while on Zulresso have been discussed; AND
9. Member has not received Zurzuvae for the current depressive episode; AND
10. Member is unable to use Zurzuvae for current depressive episode; AND
11. Member's weight is provided for dose calculation
12. **Dosage allowed:** Administered as a continuous infusion over 60 hours per package insert.

***If all the above requirements are met, the medication will be approved for 1 month.***

For **reauthorization**:

1. Zulresso is a one-time infusion (per pregnancy) and will not be reauthorized.

**CareSource considers Zulresso (brexanolone) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
08/12/2019	New policy for Zulresso created.
05/26/2022	Transferred to new template. Updated references. Added site of service and J code. Expanded the type of baseline depression scale acceptable for diagnosis. Added a trial of first-line antidepressants or documentation of PPD severity.
07/08/2022	Lowered age to 15 years old per package insert update.
01/03/2024	Added SNRI as example of antidepressant medication; added that member has not received Zuruva in the current depressive episode; removed criteria that member cannot be breastfeeding and added criteria that if member is breastfeeding, they have been counseled on risks/benefits; simplified dosing to refer to package insert; specified in reauthorization criteria that it is a one-time infusion per pregnancy; added submission of weight; removed contraindications; added/updated/removed references
03/26/2024	Added that member is unable to use Zuruva

References:

1. Zulresso [prescribing information]. Cambridge, MA: Sage Therapeutics, Inc.; 2022.
2. Meltzer-Brody S, Colquhoun H, Riesenbergr R, et al. Brexanolone injection in post-partum depression: two multicentre, double-blind, randomised, placebo-controlled, phase 3 trials [published correction appears in *Lancet*. 2018 Sep 29;392(10153):1116]. *Lancet*. 2018;392(10152):1058-1070. doi:10.1016/S0140-6736(18)31551-4
3. Langan R, Goodbred AJ. Identification and Management of Peripartum Depression. *Am Fam Physician*. 2016;93(10):852-858.
4. Treatment and Management of Mental Health Conditions During Pregnancy and Postpartum: ACOG Clinical Practice Guideline No. 5. *Obstet Gynecol*. 2023;141(6):1262-1288. doi:10.1097/AOG.0000000000005202
5. Guille C, Newman R, Fryml LD, Lif ton CK, Epperson CN. Management of postpartum depression. *J Midwifery Womens Health*. 2013;58(6):643-653. doi:10.1111/jmwh.12104

Effective date: 07/01/2024

Revised date: 03/26/2024