Brexanolone (Zulresso®)

<u>Place of Service</u> Hospital Administration

HCPCS: J1632 per 1 mg

## Condition(s) listed in policy (see criteria for details)

Postpartum depression

AHFS therapeutic class: antidepressants, miscellaneous

**Mechanism of action:** neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator

### (1) Special Instructions and Pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Zulresso® (brexanolone) must be sent for clinical review and receive authorization for both brexanolone and for hospital admission prior to drug administration or claim payment.

#### Postpartum depression

- 1. Prescribed by or in consultation with a psychiatrist, AND
- 2. Patient is at least 15 years of age, AND
- 3. Documentation of DSM-5 for major depressive disorder (MDD) with peripartum onset

#### **Covered Doses**

- Continuous intravenous (IV) infusion over 60 hours (2.5 days) as follows:
  - 0 to 4 hours: up to 30 mcg/kg/hour
  - 4 to 24 hours: up to 60 mcg/kg/hour
  - 24 to 52 hours: up to 90 mcg/kg/hour (if tolerated)
  - 52 to 56 hours: up to 60 mcg/kg/hour
  - 56 to 60 hours: up to 30 mcg/kg/hour

#### Coverage period

One treatment course per pregnancy

ICD-10:

F53.0

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Zulresso® (brexanolone) must be sent for clinical review and receive authorization for both brexanolone and for hospital admission prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s):

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

PHP Medi-Cal Brexanolone (Zulresso®)

Effective: 04/03/2024 Page 1 of 2

# (5) Additional Information

How supplied:

• 100 mg/20 mL (5 mg/mL) single-dose vial

### (6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at <a href="http://www.micromedexsolutions.com/home/dispatch">http://www.micromedexsolutions.com/home/dispatch</a>
- Zulresso® (brexanolone) [Prescribing Information]. Cambridge, MA: Sage Therapeutics, Inc.; 6/2022.

# (7) Policy Update

Effective: 04/03/2024

Date of last review: 4Q2023 Date of next review: 4Q2024

Changes from previous policy version:

• No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity Reviewed by P&T Committee

PHP Medi-Cal Brexanolone (Zulresso®)

Page 2 of 2