Medical Policy

Zulresso™ (brexanolone)	
MEDICAL POLICY NUMBER	Med_Clin_Ops-062
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

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PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Zulresso® (brexanolone) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Coverage for Zulresso will be provided for 1 treatment session (60 hour infusion) and may **NOT** be renewed.

1. Patient has a diagnosis of postpartum depression; **AND**
2. Patient is 18 years of age or older; **AND**
3. Zulresso is prescribed by or in consultation with a psychiatrist or an obstetrician/gynecologist; **AND**
4. Patient has a confirmed diagnosis of a major depressive episode using DSM criteria; **AND**
5. The patient has moderate to severe postpartum depression with a HAM-D total score of

>20, or Montgomery-Åsberg depression rating scale (MADRS) with a score of >20, or as scored by a comparable standardized rating scale that reliably measures depressive symptoms. Scores must be documented by a psychiatrist; **AND**

6. The patient has onset of depressive symptoms no sooner than the third trimester of pregnancy and no later than within 4 weeks after delivery; **AND**
7. The patient is ≤ 6 months postpartum at screening; **AND**
8. The patient does not have active psychosis, or history of seizure, or schizophrenia, or bipolar disorder, or schizo affective disorder; **AND**
9. The patient is not currently pregnant; **AND**
10. Brexanalone (Zulresso) will be administered at a brexanalone (Zulresso) Center of Excellence
11.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Repeat administration

BACKGROUND

Zulresso® (brexanolone), a neuroactive steroid gamma-aminobutric acid (GABA) A receptor positive modulator, is indicated for the treatment of postpartum depression in adults. Zulresso was approved under a priority review by the FDA and was granted a breakthrough therapy designation. The active ingredient of Zulresso, brexanolone, is chemically identical to endogenous allopregnanolone. Plasma concentrations of allopregnanolone increase during pregnancy and decrease substantially after childbirth in both rodents and humans, and fluctuations in allopregnanolone have demonstrated effects on anxiety and depression in animal models. The mechanism of action of Zulresso is not fully understood but it has been shown to modulate GABA-mediated currents from recombinant human GABAA receptors in mammalian cells expressing α1β2γ2, α4β3δ, and α6β3δ receptor subunits.

DEFINITIONS

1. ZULRESSO™ (brexanolone) injection, for intravenous use, CIV. Initial U.S. Approval: 2019
    a. ZULRESSO injection is supplied as 100 mg brexanolone in 20 mL (5 mg/mL) single-dose vials containing a sterile, preservative-free, clear, colorless solution.

CODING

Applicable NDC Codes	
72152-0547-20	Brexanolone (Zulresso) 100 mg/20 mL Intravenous Solution

Applicable Procedure Code	
J1632	Injection, brexanolone, 1 mg (Zulresso)

Applicable ICD-10 Codes	
F53.0	Postpartum depression

EVIDENCE BASED REFERENCES

1. Product Information: ZULRESSO(TM) intravenous injection, brexanolone intravenous injection. Sage Therapeutics, Inc (per FDA), Cambridge, MA, 2019.

POLICY HISTORY

Original Effective Date	May 24, 2021
Revised Date	November 1, 2021: Annual review – no changes made. November 8, 2022: Annual review – no changes made. March 1, 2023: Adopted by MA UM Committee – no changes made. January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)

Approved by Pharmacy and Therapeutics Committee on 11/8/2022