

Zulresso® (brexanalone)

Date of Origin: 5/22/19

Last Review Date: 6/26/19

Effective Date: 07/01/2019

Dates Reviewed: 5/22/19, 6/26/19

Developed By: Medical Criteria Committee

I. Length of Authorization

Coverage is provided for a single 60-hour infusion and may not be renewed.

II. Dosing Limits

A. Max Units (per dose and over time) [Medical Benefit]:

- 500 mg for a one-time infusion

III. Initial Approval Criteria

Post-partum Depression (PPD)†

- Patient is 18 years of age or older; **AND**
- Brexanalone (Zulresso) has been prescribed by, or in consultation with, a psychiatrist; **AND**
- The patient has a confirmed diagnosis of severe PPD documented by a standardized evidence-based depression rating scale that reliably measures depressive symptoms [e.g. DSM-5 diagnostic criteria for a major depressive episode, Edinburgh postnatal Depression Scale (EPDS), Patient Health Questionnaire-9 (PHQ-9), Beck Depression Inventory (BDI-II)] ; **AND**
- The patient has experienced a major depressive episode with onset no earlier than the third trimester of pregnancy and no later than four weeks after delivery; **AND**
- The patient does not have any of the following:
 - Active psychosis; **OR**
 - History of seizure; **OR**
 - History of schizophrenia; **OR**
 - History of bipolar disorder; **OR**
 - History of schizoaffective disorder; **AND**
- Brexanalone (Zulresso) will be administered at a brexanalone (Zulresso) Center of Excellence

†FDA Approved Indication(s), ‡ Compendia recommended indication

IV. Renewal Criteria

Brexanalone (Zulresso) cannot be renewed.

V. Dosage/Administration

Indication	Dose
Post-Partum Depression	<p>Brexanalone (Zulresso) is administered as a continuous intravenous (IV) infusion over a total of 60 hours (2.5 days) as follows:</p> <ul style="list-style-type: none">• 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 (a reduction in dosage to 60 mcg/kg/hour may be considered during this time period for patients 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 <p>If excessive sedation occurs at any time during the infusion, stop the infusion until the symptoms resolve. The infusion may be resumed at the same or lower dose as clinically appropriate.</p>

VI. Billing Code/Availability Information

Jcode:

- J3490 – Unclassified drugs
- C9399 – Unclassified drugs or biologics (Medicare hospital outpatient setting)

NDC:

- Brexanalone 100 mg/20 mL (5 mg/mL) single-dose vials: 72152-547-xx

VII. References

1. Meltzer-Brody S, Colquhoun H, Riesenber R, et al. Brexanalone injection in post-partum depression: two multicenter, double-blind, randomised, placebo-controlled, phase 3 trials. *Lancet* 2018; 392: 1058-70. PMID: 30177236
2. Zulresso [package insert]. Cambridge, MA: Sage Therapeutics; March 2019

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
F53.0	Postpartum depression

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corporation (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corporation (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC