

STANDARD MEDICARE PART B MANAGEMENT

ZULRESSO (brexanolone)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Treatment of postpartum depression (PPD) in patients 15 years and older.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Postpartum depression

Authorization of 30 days for a one-time infusion may be granted for the treatment of moderate to severe postpartum depression in members 15 years of age or older when all of the following criteria are met:

- A. Member has moderate to severe postpartum depression and had a major depressive episode that began no earlier than the third trimester of pregnancy and no later than the first 4 weeks following delivery, documented by standardized rating scales that reliably measure depressive symptoms (e.g., Beck Depression Inventory [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], etc.)
- B. Member is 6 months postpartum or less
- C. Lactation has ceased or breastmilk produced will not be used for feedings during the infusion and up to 4 days following infusion completion
- D. Member will not receive more than one infusion per pregnancy/childbirth

III. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Zulresso.
2. The available compendium
 - a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
 - b. Micromedex DrugDex
 - c. American Hospital Formulary Service- Drug Information (AHFS-DI)
 - d. Lexi-Drugs
 - e. Clinical Pharmacology

Reference number(s)
6313-A

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Zulresso are covered.

IV. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

V. REFERENCES

1. Zulresso [package insert]. Cambridge, MA: Sage Therapeutics, Inc.; June 2022.