Reference number(s)
6313-A

Standard Medicare Part B Management Zulresso

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Zulresso	brexanolone	all

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 Indications[1]

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 criteria should be accompanied by supporting evidence from Medicare approved compendia.

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Coverage Criteria

Postpartum Depression[1]

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:

- 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.)
- Member is 6 months postpartum or less
- Member will not receive more than one infusion per pregnancy/childbirth

Summary of Evidence

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

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

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

Explanation of Rationale

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

References

1. Zulresso [package insert]. Cambridge, MA: Sage Therapeutics, Inc.; July 2024.
2. Clinical Consult: CVS Caremark Clinical Program Review. Focus on Behavioral Health Clinical Programs. December 2020.
3. Clinical Consult: CVS Caremark Clinical Program Review. Focus on Behavioral Health Clinical

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