

## SPECIALTY GUIDELINE 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 adults

All other indications are considered experimental/investigational and not medically necessary.

##### II. CRITERIA FOR INITIAL APPROVAL

Authorization of 1 infusion may be granted for treatment of moderate to severe postpartum depression in members 18 years of age or older when all of the following criteria are met:

- A. Member has 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 Scale [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], etc.)
- B. Diagnosis is verified by a psychiatrist
- C. Member is 6 months postpartum or less
- D. Lactation has ceased or breastmilk produced will not be used for feedings during the infusion and up to 4 days following infusion completion
- E. Member will not receive more than one infusion per pregnancy/childbirth

##### III. REFERENCES

1. Zulresso [package insert]. Cambridge, MA: Sage Therapeutics, Inc.; June 2019.