Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 201.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Zulresso (brexanolone)

I. Policy:
Zulresso (brexanolone)

II. Purpose/Objective:
To provide a policy of coverage regarding Zulresso (brexanolone)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age

DESCRIPTION:
Zulresso (brexanolone) is a gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression in adults. The exact mechanism of action is not fully understood but is thought to be related to positive allosteric modulation of GABA-A receptors.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Zulresso (brexanolone) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Prescribed by (or in consultation with) a psychiatrist **AND**
- Medical record documentation of age greater than or equal to 15 years **AND**
- Medical record documentation of a diagnosis postpartum depression (PPD) as defined by ALL of the following:
    - Patient has a diagnosis of a major depressive episode **AND**
    - Patient experienced onset of symptoms within the third trimester or within 4 weeks of delivery

  AND
- Medical record documentation that patient is less than or equal to 6 months postpartum **AND**
- Medical record documentation that current depressive episode is moderate to severe based on a standardized and validated questionnaire/scale (e.g. a score of greater than 10 on the Patient Health Questionnaire (PHQ-9), a score of greater than or equal to 17 on the Hamilton Depression Rating Scale (HAM-D), etc.)

AUTHORIZATION DURATION: One-time authorization of one 60-hour infusion of Zulresso

Note: The safety and efficacy of repeated Zulresso infusions have not been studied. Additional infusion(s) of Zulresso for future cases of PPD associated with additional pregnancies will be reviewed for medical necessity based on the above criteria. More than one administration of Zulresso per pregnancy/birth is considered investigational and not covered.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 9/17/19

Revised: 11/18/19 (per DHS), 6/23/22 (Medicaid PARP statement), 9/20/22 (updated age, LOB carve out)

Reviewed: 8/26/20, 7/26/21