

Pharmacy Medical Necessity Guidelines: Zulresso™ (brexanolone)

Effective: July 20, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED	Department to Review	PRECERT /MM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan 			<p>Fax Numbers:</p> <p>MM: 888.415.9055</p> <p>PRECERT: 617.972.9409</p>

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Zulresso (brexanolone) is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression in adults.

COVERAGE GUIDELINES

The plan may authorize coverage of Zulresso™ (brexanolone) when of the following criteria are met:

- A. The medication is being administered at an acute inpatient or psychiatric hospital
- OR**
- B. Documentation of All of the following:
1. Diagnosis of Moderate to severe Postpartum Depression
 - AND**
 2. Member is postpartum for less than 6 months at the time of request
 - AND**
 3. Onset of depressive episode is between 3rd trimester and 4 weeks following delivery
 - AND**
 4. The prescriber is a mental health specialist (e.g. psychiatrist, nurse prescriber with a specialty in behavioral health)
 - AND**
 5. Documentation that member had not responded adequately to least ONE of the following:
 - i. A generic oral antidepressant at an adequate therapeutic dose used for at least 6 weeks
 - OR**
 - ii. Electroconvulsive therapy

LIMITATIONS

- Approval is limited to a single 60 hours infusion per postpartum period.
- Tufts Health Plan does not cover Zulresso™ (brexanolone) for any indications other than those listed on this Medical Necessity Guidelines.
- Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception but will be considered on an individual basis for prior authorization.

CODES

Code	Description
J1632	INJECTION BREXANOLONE 1 MG

REFERENCES

1. Amick HR, Gartlehner G, Gaynes BN et al. Comparative benefits and harms of second generation antidepressants and cognitive behavioral therapies in initial treatment of major depressive disorder: systematic review and meta-analysis. *BMJ*. 2015; 351:h6019.
2. Food and Drug Administration. FDA approves first treatment for post-partum depression. 2019d March. URL: [/NewsEvents/Newsroom/PressAnnouncements/ucm633919.htm](#). Available from Internet. Accessed 2019 April 1.
3. Gartlehner G, Gaynes BN, Amick HR et al. Comparative benefits and harms of antidepressant, psychological, complementary, and exercise treatments for major depression: an evidence report for a clinical practice guideline from the American College of Physicians. *Ann Intern Med*. 2016; 164(5):331-41.
4. Gautam S, Jain A, Gautam M et al. Clinical practice guidelines for the management of depression. *Indian J Psychiatry*. 2017; 59(Suppl 1):S34-S50.
5. Meltzer-Brody S, Colquhoun H, Riesenber R et al. Brexanolone injection in post-partum depression: Two multicentre, double-blind, randomised, placebo-controlled, phase 3 trials. *Lancet*. 2018; 392(10152):1058-70.
6. Molyneaux E, Telesia LA, Henshaw C et al. Antidepressants for preventing postnatal depression. *Cochrane Database Syst Rev*. 2018; 4:CD004363.
7. Stewart D, Vigod S. Postpartum depression. *N Engl J Med*. 2016; 375:2177-86.
8. Zulresso prescribing information. Cambridge, MA: Sage Therapeutics; 2019 Mar.

APPROVAL HISTORY

September 10, 2019: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. July 14, 2020: Added the following limitation: Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception but will be considered on an individual basis for prior authorization.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.