SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Zulresso® (brexanolone) Injection (J1632)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

- ❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Approval Limit: one-time, 60-hour infusion per pregnancy. Member's ≤ 90kg: 5 vials.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member is 15 years of age or older
- ❑ Medication is prescribed by, or in consultation with a **psychiatrist**

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- ❑ Member is diagnosed with **moderate to severe** postpartum depression supported by **ALL** of the following:
  - ❑ Member meets DSM-5 criteria for major depressive disorder (single or recurrent episode)
  - ❑ Member has a clinical diagnosis, made by a psychiatrist or other specialist in the field of psychiatry (e.g., PNP), of moderate to severe postpartum depression
  - ❑ Diagnosis and severity of depression is supported by a validated rating scale **(scale and date completed must be attached)**
  - ❑ Onset of symptoms occurred no earlier than the third trimester of pregnancy, no later than 4 months postpartum
- ❑ Member is 6 months or less postpartum

  Date of Delivery: _____
- ❑ Member must have experienced clinical failure with at least **ONE** oral antidepressant therapy. Failure must meet the following criteria:
  - ❑ Adequate dose (maximally tolerated)
  - ❑ Adequate duration (at least 6 weeks)
  - ❑ Adherent fills required (verified by pharmacy claims)
  - ❑ Failures must occur during current depressive episode

  Drug: _____
- ❑ Member does **NOT** have active psychosis or a history of bipolar disorder
- ❑ Healthcare facility, pharmacy, and patient are registered with the REMS program

  Healthcare Facility: _____
- ❑ Member will be appropriately monitored for the duration of the infusion
  - ❑ Healthcare provider will be available on site
  - ❑ Hypoxia monitoring using continuous pulse oximetry equipped with an alarm
  - ❑ Excessive sedation monitoring every two hours during planned, non-sleep periods
- ❑ Dose will not exceed 90 mcg/kg per hour over 60 hours (2.5 days) as follows:
  - ❑ 0 to 4 hours: Initiate with a dosage of 30 mcg/kg per hour
  - ❑ 4 to 24 hours: Increase dosage to 60 mcg/kg per hour
  - ❑ 24 to 52 hours: Increase dosage to 90 mcg/kg per hour (alternatively consider a dosage of 60 mcg/kg per hour for those who do not tolerate 90 mcg/kg per hour)
  - ❑ 52 to 56 hours: Decrease dosage to 60 mcg/kg per hour
  - ❑ 56 to 60 hours: Decrease dosage to 30 mcg/kg per hour

****NOTE: Zulresso® is considered not medically necessary when the above criteria is not met and investigational for all other uses****

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Medication being provided by a Specialty Pharmacy - PropriumRx

- ❑ **Location/site of drug administration:** _____
- ❑ **NPI or DEA # of administering location**: _____

OR

- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee:** ~~10/17/2019; (MDLC 11/12/2019);~~ **9/15/2022**
REVISED/UPDATED: ~~11/29/2019; 10/08/2020;~~ **10/4/2022**