ARBCBS Custom Criteria- Auvelity® (dextromethorphan HBr/bupropion HCl)

FDA-Approved Indication:

- Treatment of Major Depressive Disorder (MDD) in adults.

Required documentation:

- Medical records confirming a diagnosis of Major Depressive Disorder (MDD).
- Medications tried and failed.

Initial Prior Authorization Criteria:
The patient must meet all of the following criteria for initial approval:

- **Diagnosis:** The patient must have a documented diagnosis of Major Depressive Disorder (MDD).
- **Age:** The patient must be 18 years of age or older.
- **Treatment History:** The patient must have had an inadequate response, documented intolerance, or a clinical contraindication to a trial of at least **four (4)** other formulary antidepressants from 4 different drug classes as outlined below.
  - One of the 4 different trial must include **Bupropion.**
  - An "adequate trial" is defined as a minimum of **4 weeks** of treatment at a therapeutically effective dose.
  - Examples of antidepressant classes for trial-and-failure include, but are not limited to:
    - Selective Serotonin Reuptake Inhibitors (SSRIs) (e.g., citalopram, fluoxetine, sertraline)
    - Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs) (e.g., venlafaxine, duloxetine)
    - Atypical Antidepressants (e.g., bupropion, mirtazapine)
    - Tricyclic Antidepressants (TCAs) (e.g., amitriptyline, nortriptyline)
- **Absence of Contraindications:** The patient must have no history of the following absolute contraindications:
  - A seizure disorder or conditions that increase the risk of seizures (e.g., severe head injury, bulimia, or anorexia nervosa).
  - Use of a monoamine oxidase inhibitor (MAOI) within the past 14 days.
  - Abrupt discontinuation of alcohol, benzodiazepines, barbiturates, or antiepileptic drugs.
  - Known hypersensitivity or allergic reaction to dextromethorphan, bupropion, or any of the inactive ingredients in Auvelity.
  - Concurrently prescribed bupropion

Continuation Criteria:
A request for continuation will be approved if the patient has met the initial approval criteria and the following criteria are met:

1. Initial dosing utilizing samples is not considered for continuation of therapy.
2. **Clinical Response:** The patient has demonstrated a therapeutic response to Auvelity

therapy, by a documented improvement or stabilization of their MDD symptoms, as ***evidenced in clinical documentation submitted.***

3. **Continued Adherence:** The patient is adhering to the prescribed treatment plan and dosage.
4. **Absence of Side Effects:** The patient has not experienced unmanageable or severe adverse effects from the medication.

Clinical documentation required to be submitted with the initial and continuation PA request.

Dosing: The requested dosage must align with the FDA-approved labeling.

Duration of Approval:

- **Initial Approval:** 6 months.
- **Reauthorization:** 12 months.

Exclusions:
Auvelity is considered not medically necessary and will be denied for the following:

- Any indication other than Major Depressive Disorder (MDD).
- Patients who have not met the step-therapy requirements.
- Patients with any of the absolute contraindications listed above.
- Use in pediatric patients (under 18 years of age).

References:

1. Auvelity [package insert]. New York, NY: Axsome Therapeutics, Inc.; December 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed May 14, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 05/10/2024).
4. American Psychiatric Association (2010). Practice Guideline for the Treatment of Patients with Major Depressive Disorder. Available from: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. Accessed May 14, 2024.