



Commercial/Healthcare Exchange PA Criteria

Effective: November 10, 2022

Prior Authorization: Auvelity

Products Affected: Auvelity (dextromethorphan and bupropion ER) tablets

Medication Description: Dextromethorphan hydrobromide/bupropion hydrochloride is a combination of dextromethorphan hydrobromide, an uncompetitive NMDA receptor antagonist and sigma-1 receptor agonist, and bupropion hydrochloride, an aminoketone and CYP2D6 inhibitor. The mechanism of dextromethorphan in the treatment of major depressive disorder (MDD) is unclear. The mechanism of action of bupropion in the treatment of MDD is unclear; however, it may be related to noradrenergic and/or dopaminergic mechanisms. Bupropion increases plasma levels of dextromethorphan by competitively inhibiting CYP2D6, which catalyzes a major biotransformation pathway for dextromethorphan. Bupropion is a relatively weak inhibitor of the neuronal reuptake of norepinephrine and dopamine and does not inhibit monoamine oxidase or the reuptake of serotonin

Covered Uses:

1. Treatment of major depressive disorder (MDD) in adults

Exclusion Criteria:

1. Seizure disorder
2. Current or prior diagnosis of bulimia or anorexia nervosa
3. Undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates and antiepileptic drugs
4. Concomitant use of an MAOI, including linezolid or IV methylene blue, or use within 14 days of stopping
5. Known hypersensitivity to bupropion, dextromethorphan, or other components of the product
6. Pregnancy
7. Severe hepatic impairment (Child-Pugh C)
8. Severe renal impairment (estimated GFR 15 to 29 mL/minute/1.73 m²)

Required Medical Information:

1. Diagnosis
2. Medical History
3. Previous therapies tried and failed

Prescriber Restriction: None

Age Restriction: 18 years and older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

November 2022



Confidential Information

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1. Major Depressive Disorder

- A. Patient has an intolerance to, or treatment failure of, at least one generic first line SSRI (citalopram, fluoxetine, fluvoxamine, paroxetine HCl immediate-release, sertraline); **AND**
- B. Patient has an intolerance to, or treatment failure of bupropion hydrochloride (Wellbutrin).

References:

- 1. Product Information: AUVELITY(TM) oral extended-release tablets, dextromethorphan hydrobromide bupropion HCl oral extended-release tablets. AXSOME Therapeutics Inc (per FDA), New York, NY, 2022.

Policy Revision history

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|--------------|-----------------------|--------------------------|--------------------------|-------------|
| 1 | New Policy | New Policy | All | 11/10/2022 |