DRUG POLICY

Atypical Antipsychotics

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Atypical Antipsychotics drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. Rexulti is approved by the Food and Drug Administration (FDA) for the treatment of schizophrenia and as an adjunct to antidepressant medication for the treatment of major depressive disorder (MDD). Vraylar is approved for the treatment of schizophrenia and the acute treatment of manic or mixed episodes associated with bipolar disorder. Caplyta and Secuado are approved for the treatment of adults with schizophrenia.

POLICY

Initial Criteria for Approval

I. Caplyta (umateperone), Rexulti (brexiprazole), Secuado (asenapine), and Vraylar (cariprazine) may be considered medically necessary for the treatment of schizophrenia in adult patients who have tried and failed at least three generically available antipsychotics unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer’s patient assistance programs).

Approval will be for 24 months

II. Vraylar (cariprazine) may be considered medically necessary for the treatment of bipolar disorder in adult patients who have tried and failed at least three generically available antipsychotics unless the patient is currently receiving a positive therapeutic outcome Vraylar through health insurance (excludes obtainment as samples or via manufacturer’s patient assistance programs).

Approval will be for 24 months
III. **Rexulti** (brexpiprazole) may be considered **medically necessary** for the adjunctive treatment of major depressive disorder in adult patients when the following criteria is met:

- Patient is currently taking and will continue to take an antidepressant for the treatment of major depressive disorder
- Must have an inadequate response, despite demonstrated adherence with, current antidepressant therapy, when the patient has previously **tried and failed** the following unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtaining as samples or via manufacturer’s patient assistance programs):
  - 2 or more antidepressants (e.g. selective serotonin reuptake inhibitors [SSRI], serotonin norepinephrine reuptake inhibitors [SNRI]) at target therapeutic dosing for a minimum of 4 weeks each; **AND**
  - 1 or more guideline recommended, or evidence based, augmentation or combination strategies for treatment resistant depression (e.g. the addition of buspirone, mirtazapine, bupropion, triiodothyronine/liothyronine, tricyclic antidepressant, or lithium) unless all are contraindicated for use; **AND**
  - 1 generically available atypical antipsychotic with evidence to support use as an adjunctive treatment option for MDD (e.g. aripiprazole, quetiapine, risperidone, olanzapine, ziprasidone), unless all are contraindicated for use

**Approval** will be for 24 months

IV. The aforementioned drugs are considered **not medically necessary** for patients who do not meet the criteria set forth above.

**Continuation of Therapy**

I. **Caplyta** (umateperone), **Rexulti** (brexpiprazole), **Secuado** (asenapine), and **Vraylar** (cariprazine) may be considered **medically necessary** when the Initial Criteria for Approval is met and the patient has achieved or maintained a positive clinical response to therapy.

**Approval** will be for 24 months

**Quantity Limits Apply**
- Rexulti 30 tablets per 30 days
- Vraylar 30 capsules per 30 days
- Secuado 30 patches per 30 days
- Caplyta 30 capsules per 30 days

**PROCEDURES AND BILLING CODES**

*To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD-CM diagnostic codes.*

- Code(s), if applicable

**REFERENCES**

- Rexulti [*prescribing information*]. Rockville (MD): Otsuka America Pharmaceutical; February 2018.
- Secuado [*prescribing information*]. Miami, Florida: Noven Therapeutics, LLC.; October 2019.
• Caplyta (lumateperone tosylate) [prescribing information]. New York, NY: Intra-Cellular Therapies Inc; December 2019.


POLICY HISTORY

Policy #: 05.01.94
Policy Creation: November 2015
Reviewed: April 2020
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