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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** (brexpiprazole), **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 obtainment 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.
- Vraylar [*prescribing information*]. Irvine, CA: Allergan USA Inc.; May 2019.
- Secuado [*prescribing information*]. Miami, Florida: Noven Therapeutics, LLC.; October 2019.

- Caplyta (lumateperone tosylate) [prescribing information]. New York, NY: Intra-Cellular Therapies Inc; December 2019.
- American Psychiatric Association. Practice guideline for the treatment of patients with schizophrenia. *Am J Psychiatry*. 2004; 161: (Suppl) 1-56. Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf. Accessed December 2019.
- American Psychiatric Association. Practice Guideline for the treatment of patients with major depressive disorder, Third Edition. October 2010. Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. Accessed March 2019.
- American Psychiatric Association. Practice Guideline for the treatment of patients with bipolar disorder, Second Edition. April 2002. Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf. Accessed March 2019.
- American Psychiatric Association. Practice Guideline for the Treatment of Patients with Schizophrenia, 2019 Draft. Available at: <https://www.psychiatry.org/psychiatrists/practice/clinical-practice-guidelines>. Accessed June 2020.
- Huhn M et al. Comparative efficacy and tolerability of 32 oral antipsychotics for the acute treatment of adults with multi-episode schizophrenia: a systematic review and network meta-analysis. *Lancet*. 2019;394(10202):939-951.
- American Psychiatric Association. Treating Bipolar Disorder: A Quick Reference Guide. Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar-guide.pdf. Accessed June 2020.
- Hirschfeld RM. Guideline Watch: Practice Guideline for the Treatment of Patients with Bipolar Disorder, 2nd Edition. Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar-watch.pdf. Accessed June 2020.
- Yatham LN et al. Canadian Network for Mood and Anxiety Treatments (CANMAT) and International Society for Bipolar Disorders (ISBD) 2018 guidelines for the management of patients with bipolar disorder. *Bipolar Disorders*. 2018;20:97-170.
- Bahji A et al. Comparative efficacy and tolerability of pharmacological treatments for the treatment of acute bipolar depression: A systematic review and network meta-analysis. *Journal of Affective Disorders*. 2020;269:154-184.
- VA/DoD. Clinical Practice Guideline for the Management of Major Depressive Disorder, Version 3.0. Available at: <https://www.healthquality.va.gov/guidelines/MH/mdd/VADoDMDDCPGFINAL82916.pdf>. Accessed June 2020.

POLICY HISTORY

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