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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.

FDA-Approved Indications

Caplyta

Caplyta is indicated for:

- Treatment of schizophrenia in adults
- Depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate.

Rexulti

Rexulti is indicated for:

- Adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults
- Treatment of schizophrenia in adults and pediatric patients ages 13 years and older

Secuado

Secuado is indicated for the treatment of adults with schizophrenia

Vraylar

- Treatment of schizophrenia in adults
- Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults
- Treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults

Lybalvi

- Treatment of schizophrenia in adults
- Treatment of Bipolar I disorder in adults
 - Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate
 - Maintenance monotherapy treatment

POLICY

Initial Criteria for Approval

- I. **Caplyta** (umateperone) and **Secuado** (asenapine) 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 schizophrenia in adults.

Approval will be for 24 months

- III. **Rexulti** (brexpiprazole) may be considered **medically necessary** for the treatment of schizophrenia in patients 13 years of age and older.

Approval will be for 24 months

- IV. **Lybalvi** (olanzapine and samidorphan) may be considered **medically necessary** for the treatment of schizophrenia in adult patients when the following criteria is met:
 - Patient has ***tried and failed*** at least three generically available antipsychotics, one of which being generic olanzapine, unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).
 - Patient does not have a known opioid use disorder or is dependent on opioids for a chronic health condition.
 - Patient is not undergoing acute opioid withdrawal.

Approval will be for 24 months

- V. **Vraylar** (cariprazine) may be considered **medically necessary** for the treatment of manic or mixed episodes and depressive episodes associated with bipolar I disorder in adults.

- VI. **Caplyta** (lumateperone) may be considered medically necessary for the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) in adult patients as monotherapy and as adjunctive therapy with lithium or valproate who have ***tried and failed*** at least three generically available antipsychotics unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).

- VII. **Lybalvi** (olanzapine and samidorphan) may be considered **medically necessary** as monotherapy for the acute treatment of manic or mixed episodes and as adjunct to lithium or valproate or as

maintenance monotherapy for the treatment of bipolar I disorder in adult patients when the following criteria is met:

- Patient has **tried and failed** at least three generically available antipsychotics, one of which being generic olanzapine, unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).
- Patient does not have a known opioid use disorder or is dependent on opioids for a chronic health condition.
- Patient is not undergoing acute opioid withdrawal.

Approval will be for 24 months

VIII. **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

Approval will be for 24 months

IX. 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), **Vraylar** (cariprazine) and **Lybalvi** (olanzapine and samidorphan) 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

Lybalvi 30 tablets 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; December 2021.
- 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 2021.
- Lybalvi [*prescribing information*]. Waltham, MA: Alkermes, Inc.; May 2021.

- Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed March 2020.
- Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed March 2020.
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- 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 2020.
- 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 2020.
- McClellan J, Stock S, American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Quality Issues (CQI). Practice parameter for the assessment and treatment of children and adolescents with schizophrenia. *J Am Acad Child Adolesc Psychiatry*. 2013 Sep;52(9):976-90.

POLICY HISTORY

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