# **PRIOR AUTHORIZATION CRITERIA**

DRUG CLASS	ATYPICAL ANTIPSYCHOTICS
BRAND NAME (generic)	
(9)	CAPLYTA
	(lumateperone)
	FANAPT
	(iloperidone)
	LATUDA
	(lurasidone)
	LYBALVI
	(olanzapine and samidorphan)
	REXULTI
	(brexpiprazole)
	SAPHRIS
	(asenapine)
	SECUADO
	(asenapine transdermal)
	VRAYLAR
	(cariprazine)
Status: CVS Caremark Criteria	
Type: Initial Prior Authorization	

# POLICY

## FDA-APPROVED INDICATIONS

#### Caplyta

Caplyta is indicated for the treatment of schizophrenia in adults.

#### Fanapt

Fanapt tablets are indicated for the treatment of adults with schizophrenia. Efficacy was established in two short-term (4and 6-week) placebo- and active-controlled studies of adult patients with schizophrenia. When deciding among the alternative treatments available for this condition, the prescriber should consider the finding that Fanapt is associated with prolongation of the QTc interval. Prolongation of the QTc interval is associated in some other drugs with the ability to cause torsade de pointes-type arrhythmia, a potentially fatal polymorphic ventricular tachycardia which can result in

Atypical Antipsychotics PA Policy 1340-A 03-2021 v2.doc

©2021 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

sudden death. In many cases this would lead to the conclusion that other drugs should be tried first. Whether Fanapt will cause torsade de pointes or increase the rate of sudden death is not yet known. Patients must be titrated to an effective dose of Fanapt. Thus, control of symptoms may be delayed during the first 1 to 2 weeks of treatment compared to some other antipsychotic drugs that do not require a similar titration. Prescribers should be mindful of this delay when selecting an antipsychotic drug for the treatment of schizophrenia. The effectiveness of Fanapt in long-term use, that is, for more than 6 weeks, has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use Fanapt for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

## Latuda

Latuda is indicated for:

- Treatment of adult and adolescent patients age 13 to 17 years with schizophrenia
- Monotherapy treatment of adult and pediatric patients (10 to 17 years) with major depressive episodes associated with Bipolar I disorder (bipolar depression)
- Adjunctive treatment with lithium or valproate in adult patients with major depressive episodes associated with Bipolar I disorder (bipolar depression)

### Lybalvi

Lybalvi is indicated for the treatment of:

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

## Rexulti

Rexulti is indicated for:

- Adjunctive treatment of major depressive disorder (MDD)
- Treatment of schizophrenia

## Saphris

Saphris is indicated for:

- Schizophrenia in adults
- Bipolar I disorder
  - Acute monotherapy of manic or mixed episodes, in adults and pediatric patients 10 to 17 years of age
  - Adjunctive treatment to lithium or valproate in adults
  - Maintenance monotherapy treatment in adults

#### 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

#### **COVERAGE CRITERIA**

The requested drug will be covered with prior authorization when the following criteria are met:

- Caplyta, Fanapt or Secuado is being prescribed for the treatment of schizophrenia OR
- Rexulti is being prescribed for any of the following: A) Treatment of schizophrenia, B) Adjunctive treatment of major depressive disorder (MDD) OR

Atypical Antipsychotics PA Policy 1340-A 03-2021 v2.doc

©2021 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

- Saphris or Lybalvi is being prescribed for any of the following: A) Treatment of schizophrenia, B) Acute treatment
  of manic or mixed episodes associated with Bipolar I disorder as monotherapy or adjunctive treatment to lithium
  or valproate, C) Maintenance monotherapy treatment in Bipolar I disorder
   OR
- Vraylar is being prescribed for any of the following: A) Treatment of schizophrenia, B) Acute treatment of manic or mixed episodes associated with bipolar I disorder, C) Treatment of depressive episodes associated with bipolar I disorder (bipolar depression)
   OR
- Latuda is being prescribed for any of the following: A) Treatment of schizophrenia, B) Adjunctive treatment with lithium or valproate for major depressive episodes associated with Bipolar I disorder (bipolar depression),
   C) Monotherapy treatment of major depressive episodes associated with Bipolar I disorder (bipolar depression)

## AND

• The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following: A) aripiprazole, B) olanzapine, C) paliperidone, D) quetiapine, E) quetiapine extended release, F) risperidone, G) ziprasidone

## **REFERENCES**

- 1. Caplyta [package insert]. New York, NY: Intra-Cellular Therapies, Inc.; December 2019
- 2. Fanapt [package insert]. Washington, DC: Vanda Pharmaceuticals.; January 2016.
- 3. Latuda [package insert]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; December 2019.
- 4. Lybalvi [package insert]. Waltham, MA: Alkermes, Inc.; May 2021.
- 5. Rexulti [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; March 2020.
- 6. Saphris [package insert]. Irvine, CA: Allergan USA Inc.; February 2017.
- 7. Secuado [package insert]. Miami, Florida: Noven Therapeutics, LLC,; October 2019
- 8. Vraylar [package insert]. Madison, NJ: Allergan USA, Inc.; May 2019.
- 9. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: UpToDate, Inc.;2021 Accessed January 12, 2021.
- 10. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com. Accessed February 2021.
- 11. American Psychiatric Association. Practice guideline for the treatment of patients with schizophrenia. Third Edition. 2021. Available at: https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890424841. Accessed February 2021.
- 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 February 2021.
- 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 February 2021.

- 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.
- McClellan J, 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 depressive disorders. J Am Acad Child Adolesc Psychiatry. 2007 November 46 (11): 1503-1526.
- McClellan J, 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 bipolar disorder. J Am Acad Child Adolesc. Psychiatry, 2007 January; 46 (1):107-125

Atypical Antipsychotics PA Policy 1340-A 03-2021 v2.doc

©2021 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.