Commercial/Healthcare Exchange PA Criteria

Effective: October 2012

Prior Authorization: Atypical Antipsychotics

Products Affected: Abilify MyCite (aripiprazole), Fanapt (iloperidone), Latuda (lurasidone), Saphris (asenapine), Vraylar (cariprazine), and Asenapine

Medication Description: The Atypical antipsychotics are indicated for many different psychiatric diagnoses, including, but not limited to: Bipolar Disorder, Schizophrenia, Irritability associated with autistic disorder, and Psychotic Disorders

Covered Uses:

1. Abilify MyCite (aripiprazole): Schizophrenia, Bipolar I Disorder (Acute treatment with manic and mixed episode as monotherapy and as an adjunct to lithium of valproate, or maintenance treatment as monotherapy and as an adjunct to lithium or valproate), Adjunctive treatment with Major Depressive Disorder
2. Fanapt (iloperidone): Schizophrenia
3. Latuda (lurasidone): Schizophrenia, Major depressive episode associated with bipolar I disorder (bipolar depression), adjunctive treatment with lithium or valproate in major depressive episode associated with bipolar I disorder (bipolar depression)
4. Saphris: Schizophrenia, Bipolar I disorder (acute monotherapy of manic or mixed episodes, adjunctive treatment to lithium or valproate, maintenance monotherapy)
5. Vraylar: schizophrenia, acute treatment of manic or mixed episodes associated with bipolar I disorder, treatment of depressive episodes associated with bipolar I disorder (bipolar depression)
6. Asenapine: Schizophrenia, Bipolar I disorder (acute monotherapy of manic or mixed episodes, adjunctive treatment to lithium or valproate, maintenance monotherapy)

Exclusion Criteria:

1. Saphris: Severe Hepatic Impairment

Required Medical Information:

1. Diagnosis
2. Previous therapies tried and failed

Prescriber Restriction: None

Age Restriction:

1. Abilify MyCite: 18 years and older
2. Fanapt: 18 years and older
3. Latuda:
    a. Schizophrenia 13 years and older;
    b. Monotherapy treatment of major depressive episode associated with bipolar I disorder (bipolar depression) 10 years and older;

   c. Adjunctive treatment with lithium or valproate with major depressive episode associated with bipolar I disorder (bipolar depression)- 18 years and older
4. Saphris:
   a. Schizophrenia: 18 years and older;
   b. Bipolar I disorder
      i. acute monotherapy of manic or mixed episodes: 10 years and older;
      ii. adjunctive treatment to lithium or valproate: 18 years and older;
      iii. maintenance monotherapy: 18 years and older
5. Vraylar: 18 years and older
6. Asenapine:
   a. Schizophrenia: 18 years and older;
   b. Bipolar I disorder
      i. acute monotherapy of manic or mixed episodes: 10 years and older;
      ii. adjunctive treatment to lithium or valproate: 18 years and older;
      iii. maintenance monotherapy: 18 years and older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

ConnectiCare considers **Asenapine, Fanapt, Latuda, Saphris and Vraylar** to be medically necessary in patients who meet the following criteria:

- Patient has had an intolerance to, or treatment failure of, **TWO** of the following 6 generic atypical antipsychotics (quetiapine, ziprasidone, risperidone, olanzapine, paliperidone or clozapine).

OR

- Previous use of **Asenapine**, **Fanapt, Latuda, Saphris or Vraylar**, at any time in the past with success and discontinued use, may receive authorization to restart the agent used in the past. *For example, a patient who has used Saphris in the past and discontinued its use may receive authorization for coverage of Saphris.*

ConnectiCare considers **Latuda and Vraylar** to be medical necessary **for the treatment of bipolar depression** in patients who meet the following criteria:

- Patient has had an intolerance to, or treatment failure of, Symbyax (olanzapine with fluoxetine)

OR

- Patient has had an intolerance to, or treatment failure of, Seroquel (quetiapine)

ConnectiCare will authorize **Asenapine, Fanapt, Latuda, Saphris or Vraylar** when used for an off-label diagnosis if the following criteria have been met:

- The member has tried and failed established FDA approved and/or clinical guideline recommended therapy unless contraindicated
- The drug is recognized for treatment of the requested indication in one of the standard reference compendia

ConnectiCare considers **Abilify MyCite** to be medically necessary in patients who meet the following criteria:

- Patient has had an intolerance to, or treatment failure of Abilify Maintena

Note: ConnectiCare requires prescribers to submit clinical documentation supporting the drug's effectiveness in treating the intended indication.

Based on the maximum daily dose the following quantities will be limited to:

- Abilify MyCite –30 tablets per month
- Fanapt -- 60 tablets per month Latuda -- 30 tablets per month
- Saphris/asenapine--60 sublingual tablets per month
- Vraylar -- 30 tablets per month

References:

1. Facts & Comparisons Online
2. Product Information: ABILIFY MYCITE(R) oral tablets with sensor, aripiprazole oral tablets with sensor. Otsuka America Pharmaceutical, Inc (per FDA), Rockville, MD, 2017.
3. Product Information: FANAPT(R) oral tablets, iloperidone oral tablets. Vanda Pharmaceuticals Inc (per manufacturer), Washington, DC, 2016.
4. Product Information: LATUDA(R) oral tablets, lurasidone HCl oral tablets. Sunovion Pharmaceuticals Inc (per manufacturer), Marlborough, MA, 2018.
5. Product Information: SAPHRIS(R) oral sublingual tablets, asenapine oral sublingual tablets. Allergan USA Inc.(per FDA), Irvine, CA, 2017.
6. Product Information: VRAYLAR(R) oral capsules, cariprazine oral capsules. Allergan USA, Inc. (per manufacturer), Madison, NJ, 2019.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	10/2012

2	Policy Updates-Old Template	P&T Review History		10/13, 10/14, 2/16, 5/16, 2/17, 1/18, 2/19
3	Policy Updates-Old Template	Revision Record		10/15, 1/16, 4/16, 9/16, 2/17, 2/19, 1/21
4	Policy Update	Move to new Template, added indications broken out by medication, Age Restrictions, and Exclusion Criteria	All	7/8/2022