UnitedHealthcare Individual & Family ACA Marketplace Plans
Clinical Pharmacy Program Guidelines for Atypical Antipsychotics

Program	Step Therapy
Medication	Asenapine (generic Saphris) Latuda (lurasidone)
Issue Date	9/2020
Pharmacy and Therapeutics Approval Date	6/2023
Effective Date	8/2023

1. Background:

Asenapine (generic Saphris) is an atypical antipsychotic indicated for the treatment of Schizophrenia in adults; and Bipolar I disorder as acute monotherapy treatment of manic or mixed episodes in adults and pediatric patients 10 to 17 years of age, adjunctive treatment to lithium or valproate in adults, and maintenance monotherapy treatment in adults.[1,2]

Latuda (lurasidone) is an atypical antipsychotic indicated for the treatment of Schizophrenia in adults and adolescents (13 to 17 years); Depressive episode associated with Bipolar I Disorder (bipolar depression) in adults and pediatric patients (10 to 17 years) as monotherapy; and Depressive episode associated with Bipolar I Disorder (bipolar depression) in adults as adjunctive therapy with lithium or valproate.[3]

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try generic atypical antipsychotic alternative(s) prior to receiving coverage for asenapine (generic Saphris) or Latuda (lurasidone).

2. Coverage Criteria [a]:

A. Initial Authorization

1. **Asenapine** will be approved based on the following criteria:
   a. **ONE** of the following:

      (1) History of failure, contraindication, or intolerance to **TWO** of the following (list reason for therapeutic failure, contraindication, or intolerance):

         (a) olanzapine oral or orally disintegrating tablets,
         (b) quetiapine oral immediate release or extended release tablets
         (c) risperidone oral solution, oral disintegrating, or tablets
         (d) ziprasidone oral capsules
         (e) aripiprazole immediate release tablets

-OR-

(2) Treatment was initiated at a recent behavioral inpatient admission, and the member is currently stable on therapy

-OR-

(3) The member is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and currently stabilized on therapy

Authorization will be issued for 12 months

B. Reauthorization

1. Documentation of positive clinical response

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

A. Initial Authorization

1. Latuda will be approved based on **one** of the following criteria:

a. **BOTH** of the following:

(1) Patient has a diagnosis of schizophrenia or schizoaffective disorder

-AND-

(2) **ONE** of the following

(a) History of failure, contraindication, or intolerance to **THREE** of the following:

- olanzapine oral or orally disintegrating tablets
- quetiapine oral immediate release or extended release tablets
- risperidone oral solution, oral disintegrating tablets, or tablets
- aripiprazole immediate release tablets

-OR-

(b) Treatment was initiated at a recent behavioral inpatient admission, and the member is currently stable on therapy

-OR-

(c) The member is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and currently stabilized on therapy

-OR-

b. **BOTH** of the following:

(1) Patient has a diagnosis of depressive episodes associated with Bipolar I Disorder (bipolar depression)

-AND-

(2) **ONE** of the following:

(a) History of failure, contraindication, or intolerance to **BOTH** of the following:

- fluoxetine used in combination with olanzapine oral or orally disintegrating tablets
- quetiapine oral immediate release or extended release tablets

-OR-

(b) Treatment was initiated at a recent behavioral inpatient admission, and the member is currently stable on therapy

-OR-

(c) The member is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and currently stabilized on therapy

Authorization will be issued for 12 months

B. Reauthorization

1. Documentation of positive clinical response

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Saphris [package insert]. Allergan Pharmaceuticals Inc. Madison, NJ. October 2021.
2. Asenapine [package insert]. Peapack, NJ: Greenstone, LLC.; February 2017.
3. Latuda [package insert]. Marlborough, MA. Sunovion Pharmaceuticals Inc.; May 2022.

Program	Step Therapy – Atypical Antipsychotics
Change Control	
Date	Change
10/2020	New program – Created from E&I Saphris ST, C&S Quetiapine ER ST, and E&I Antipsychotic PA policies.
11/2020	Updated ST Descriptions and alternatives to align build file and set up for UHC Value & Balance Exchange for 1/2021 implementation.
1/2021	Renumbered Latuda section with no changes to clinical intent.
2/2021	Added generic asenapine (Saphris) to the policy.
9/2021	Removed markets in scope box and step therapy definitions. Removed time frame and documentation requirement for behavioral inpatient admissions. Updated brand and generic language to align with 2022 guidance.
5/2022	Removed quetiapine ER as a step therapy agent (formulary change). Added quetiapine ER as a option for trial/failure for generic Saphris and Latuda
5/2023	Annual review, updated references.