Clinical Policy: Atypical Antipsychotics
Reference Number: HIM.PA.59
Effective Date: 12/14
Last Review Date: 08/17
Line of Business: Health Insurance Marketplace

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The following are atypical antipsychotics requiring prior authorization: iloperidone (Fanapt®), paliperidone (Invega®), lurasidone (Latuda®), and asenapine (Saphris®).

FDA approved indication
Fanapt is indicated for the treatment of schizophrenia in adults.

Invega is indicated:
- For the treatment of schizophrenia in adults and adolescents age 12-17
- For the treatment of schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers and/or antidepressants in adults

Latuda is indicated:
- For the treatment of schizophrenia in adults and adolescents (13 to 17 years)
- For the treatment of depressive episodes associated with bipolar I disorder (bipolar depression), in adults as monotherapy and as adjunctive therapy with lithium or valproate

Saphris is indicated:
- For the treatment of schizophrenia in adults
- For the treatment of bipolar I disorder as acute monotherapy treatment of manic or mixed episodes, in adults and pediatric patients 10 to 17 years of age; as adjunctive treatment to lithium or valproate in adults; and as maintenance monotherapy treatment in adults

Policy/Criteria
*Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

I. Initial Approval Criteria
A. Schizophrenia or Schizoaffective Disorder (must meet all)**:**
1. Diagnosis of schizophrenia spectrum disorder including schizophrenia, schizoaffective disorder or schizophreniform disorder;
2. Failure of two formulary atypical antipsychotics (quetiapine, risperidone, ziprasidone, olanzapine, aripiprazole) at up to maximally indicated doses, each trialed for ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed the following (a, b, c, or d):
   a. Fanapt: 24 mg/day (2 tablets/day);
   b. Invega:
      i. Adults: 12 mg/day (1 tablet/day);

ii. Adolescents < 51 kg: 6 mg/day;
iii. Adolescents ≥ 51kg: 12 mg/day;
c. Latuda: 160 mg/day (1 tablet/day);
d. Saphris: 20 mg/day (2 tablets/day).

Approval duration: 12 months

B. Bipolar I Disorder (must meet all)**:**
1. Diagnosis of bipolar I disorder;
2. Failure of a ≥ 4 week trial of one generic atypical antipsychotic (quetiapine, risperidone, ziprasidone, olanzapine) at up to maximally indicated doses unless contraindicated or member experiences clinically significant adverse effects;
3. Request is for Latuda or Saphris;
4. Dose does not exceed the following (a or b):
   a. Latuda: 120 mg/day (1 tablet/day);
   b. Saphris: 20 mg/day (2 tablets/day).

Approval duration: 12 months

C. Other diagnoses/indications
1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized);

II. Continued Therapy

A. Schizophrenia or Schizoaffective Disorder (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Fanapt, Invega, Latuda, or Saphris for an FDA approved indication and has received this medication for at least 30 days;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed the following (a, b, c, or d):
   a. Fanapt: 24 mg/day (2 tablets/day);
   b. Invega:
      i. Adults: 12 mg/day (1 tablet/day);
      ii. Adolescents weight < 51 kg: 6 mg/day;
      iii. Adolescents weight ≥ 51kg: 12 mg/day;
   c. Latuda: 160 mg/day (1 tablet/day);
   d. Saphris: 20 mg/day (2 tablets/day).

Approval duration: 12 months

B. Bipolar I Disorder (must meet all):
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Latuda or Saphris for bipolar disorder and has received this medication for at least 30 days;
2. Documentation of positive response to therapy;
3. Dose does not exceed
   a. Latuda: 120 mg/day (1 tablet/day);
   b. Saphris: 20 mg/day (2 tablets/day).

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to HIM.PA.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
FDA: Food and Drug Administration

V. References

1. Fanapt Prescribing information. Washington, D.C.: Vanda Pharmaceuticals Inc.; May 2016. Available at: http://fanapt.com. Accessed April 4, 2017.
2. Invega Prescribing information. Titusville, NJ: Titusville, NJ: Janssen Pharmaceuticals, Inc; February 2017. Available at: http://www.invega.com. Accessed April 7, 2017.
3. Latuda Prescribing information. Marlborough, MA: Sunovion Pharmaceuticals Inc.; January 2017. Available at: http://www.latuda.com. Accessed April 7, 2017.
4. Saphris Prescribing information. Irvine, CA: Allergan USA, Inc.; February 2017. Available at: http://www.saphris.com/. Accessed April 7, 2017.
5. Clinical Pharmacology [database online] Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/default.aspx Accessed January 23, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Changed guideline to new format.	08/16	08/16
Removed requirement of medication being prescribed by a mental health provider Added aripiprazole as a formulary atypical antipsychotics that can be trialed for schizophrenia Changed trial from failure of 3 atypical antipsychotics to 2 for schizophrenia Removed age from bipolar disorder, as age is not an absolute contraindication Add max dose and updated references	04/17	08/17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.