Clinical Policy: Iloperidone (Fanapt)

Reference Number: AZ.CP.PMN.32
Effective Date: 10.06.2016
Last Review Date: 01.20
Line of Business: Arizona Medicaid

Revision Log

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

Description

Iloperidone (Fanapt®) is an atypical antipsychotic.

FDA Approved Indication(s)

Fanapt is indicated for the treatment of schizophrenia in adults.

Policy/Criteria

Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Arizona Complete Health that Fanapt is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Schizophrenia Spectrum Disorder (must meet all)**:**

1. Diagnosis of schizophrenia spectrum disorder (schizophrenia, schizoaffective disorder, schizophreniform disorders)
2. Age ≥ 18 years;
3. Failure of 3 preferred atypical antipsychotics (e.g., aripiprazole, clozapine, Latuda, olanzapine, quetiapine, risperidone, ziprasidone) at maximum indicated doses, each trialed for ≥ 4 weeks, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 24 mg per day (2 tablets per day).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): AZ.CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Schizophrenia Spectrum Disorder (must meet all)**:**

1. Currently receiving medication via Centene benefit or documentation supports that member is currently receiving Fanapt and has received this medication for schizophrenia spectrum disorder for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 24 mg per day (2 tablets/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): AZ.CP.PMN.53 for Medicaid.

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 policies – AZ.CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

Not applicable

Appendix B: Therapeutic Alternatives

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
aripiprazole (Abilify®)	10-30 mg by mouth daily	30 mg/day
Clozapine	12.5 mg-450 mg in divided doses	900mg/day
ziprasidone (Geodon®)	40-80 mg by mouth twice daily	160 mg/day
Latuda® (lurasidone)	40 mg- 160 mg once daily with food.	160 mg/day
risperidone (Risperdal®)	1-4 mg by mouth daily to twice daily	16 mg/day
Quetiapine (Seroquel®)	400-800 mg/day by mouth twice daily to three times daily in divided doses	800 mg/day
olanzapine (Zyprexa®)	10-20 mg by mouth daily	20 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: General Information

Schizophrenia Spectrum and other psychotic disorders include schizophrenia, and other psychotic disorders and schizotypal (personality) disorder. They are defined by abnormalities in one or more of the following 5 domains: Delusions, hallucinations, disorganized thinking, grossly disorganized or abnormal motor behavior including catatonia, and negative symptoms.

Fanapt has a black box warning for increased mortality in elderly patients with dementia-related psychosis. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Fanapt is not approved for use in patients with dementia-related psychosis.

Fanapt is indicated for the acute treatment of schizophrenia in adults. Fanapt has been associated with prolongation of the QTc interval, which may limit its place in therapy to situations where other antipsychotics drugs have been tried first without success. Due to the slow titration schedule recommended for Fanapt, control of symptoms may be delayed during the first 1 to 2 weeks of therapy, compared to other antipsychotic drugs that do not require a slow titration

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Schizophrenia	12 to 24 mg/day twice daily	24 mg/day

VI. Product Availability

Tablets: 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg

VII. References

1. Fanapt Prescribing Information. Washington, D.C: Vanda Pharmaceuticals Inc.; February 2017. Available at: https://www.fanapt.com/. Accessed December 30, 2019
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed May 2018
3. American Psychiatric Association: Guideline Watch (September 2009): Practice Guideline for the Treatment of Patients with Schizophrenia, 2009. http://psychiatryonline.org/guidelines. Accessed May 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Updated references	05.18	07.18
Added more examples of AHCCCS preferred atypical antipsychotics; minor changes of formatting	04.19	04.19
Renumbered; Updated logo; Removed Saphris from the preferred drug list	01.20	01.20

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 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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.