Clinical Policy Title:	iloperidone
Policy Number:	RxA.126
Drug(s) Applied:	Fanapt®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Iloperidone (Fanapt®) is an atypical antipsychotic. It is indicated for the treatment of schizophrenia in adults.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
iloperidone (Fanapt®)	Schizophrenia	Initial: 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg PO twice daily on consecutive days from Day 1 to Day 7. Maintenance: 12 to 24 mg/day PO twice daily.	24 mg/day

Dosage Forms

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

Clinical Policy

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

I. Initial Approval Criteria

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

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

Approval Duration

Commercial: 12 months

Medicaid: 12 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or documentation supports that member is currently receiving Fanapt® for schizophrenia and has received this medication 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 (2 tablets) per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
aripiprazole (Abilify®)	10 to 15 mg PO once daily	30 mg/day
olanzapine (Zyprexa®)	Initial: 5 to 10 mg PO once daily; target: 10 mg PO once daily	20 mg/day
quetiapine (Seroquel®)	Initial: 25 mg PO twice daily; target: 400 to 800 mg/day	800 mg/day
risperidone (Risperdal®)	Initial: 1 mg PO twice daily or 2 mg PO once daily; target: 4 to 8 mg PO once daily	16 mg/day
ziprasidone (Geodon®)	20 mg PO twice daily	160 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. *Maximum dose of the drug, not indication specific.*

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Known hypersensitivity to Fanapt® or to any components in the formulation.

- Boxed Warning(s):
  - 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.

APPENDIX D: General Information
The dose of Fanapt® should be reduced in patients co-administered a strong CYP2D6 or CYP3A4 inhibitor.

References

1. Fanapt® Prescribing Information. Washington, D.C: Vanda Pharmaceuticals Inc.; February 2017. Available at: https://www.fanapt.com/. Accessed January 11, 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at:

http://www.clinicalpharmacology-ip.com/.
3. Lehman AF, Lieberman JA, Dixon LB et al. Practice guideline for the treatment of patients with schizophrenia, second edition. Am J Psychiatry. 2004 Feb;161(2 Suppl):1-56.
4. American Psychiatric Association: Guideline Watch (September 2009): Practice Guideline for the Treatment of Patients with Schizophrenia, 2009. http://psychiatryonline.org/guidelines. Accessed January 11, 2021.
5. UpToDate [internet database]. Iloperidone: Drug Information. Wolters Kluwer; 2020. Updated periodically. Accessed January 11, 2021.
6. American Psychiatric Association. Practice Guideline For The Treatment Of Patients With Schizophrenia, Third Edition, 2019. Available at: https://doi.org/10.1176/appi.books.9780890424841. Accessed January 22, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established.	01/2020	02/07/2020
Policy was reviewed - references updated.	4/2020	05/20/2020
Policy was reviewed: 1. Policy title table was updated. 2. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 3. Approval duration was updated in initial as well as in continued therapy approval. 4. Appendix B standard text updated. 5. References were updated.	01/11/2021	03/09/2021