Clinical Policy: Clozapine Orally Disintegrating Tablet (Fazaclo)

Reference Number: IL.ERX.PMN.12
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois Medicaid

Revision Log

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

Description

Clozapine orally disintegrating tablet (Fazaclo®) is an atypical antipsychotic.

FDA Approved Indication(s)

Fazaclo is indicated for:

- Treatment-resistant schizophrenia
- Reducing suicidal behavior in patients with schizophrenia or schizoaffective disorder

Policy/Criteria

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

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Fazaclo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Schizophrenia or Schizoaffective Disorder (must meet all)**:**

1. Diagnosis of schizophrenia or schizoaffective disorder;
2. Age ≥ 18 years;
3. Failure of a ≥ 4 week trial of olanzapine orally disintegrating tablet at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Medical justification supports member's inability to use regular (non-orally disintegrating) clozapine tablets;
5. Dose does not exceed 900 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or documentation supports that member is currently receiving Fazaclo for schizophrenia or schizoaffective disorder 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 900 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 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 – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

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

Appendix B: Contraindications/Boxed Warnings

- Contraindication(s): Known serious hypersensitivity to clozapine or any other component of Fazaclo
- Boxed warning(s):
  - Severe neutropenia: Clozapine can cause severe neutropenia, which can lead to serious and fatal infections. Patients initiating and continuing treatment with Fazaclo must have a baseline blood absolute neutrophil count measured before treatment initiation and regular absolute neutrophil count monitoring during treatment.
  - Fazaclo is available only through a restricted program called the Clozapine REMS.
  - Orthostatic hypotension, bradycardia, and syncope: Risk is dose related. Starting dose is 12.5 mg. Titrate gradually and use divided dosages.
  - Seizure: Risk is dose-related. Titrate gradually and use divided doses. Use with caution in patients with history of seizure or risk factors for seizure.
  - Myocarditis and cardiomyopathy: Can be fatal. Discontinue and obtain cardiac evaluation if findings suggest these cardiac reactions.
  - Increased mortality in elderly patients with dementia-related psychosis: Fazaclo is not approved for this condition.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Schizophrenia/ schizoaffective disorder	12.5 mg PO QD or BID. Titrate the total daily dosage in increments of 25 mg to 50 mg per day, to a target dose of 300 mg to 450 mg per day, in divided doses, by the end of 2 weeks.	900 mg/day

VI. Product Availability

Orally disintegrating tablets: 12.5 mg, 25 mg, 100 mg, 150 mg, 200 mg

VII. References

1. Fazaclo Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; February 2017. Available at: http://pp.jazzpharma.com/pi/fazaclo.en.USPI.pdf. Accessed October 30, 2018.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: www.clinicalpharmacology-ip.com.
3. Clozapine REMS Web site. https://www.clozapinerems.com/. Accessed October 30, 2018.
4. 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.
5. American Psychiatric Association: Guideline Watch (September 2009): Practice Guideline for the Treatment of Patients with Schizophrenia, 2009. http://psychiatryonline.org/guidelines. Accessed October 30, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.15.21	05.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.