Clinical Policy: Clozapine ODT (Fazaclol®)
Reference Number: NE.PMN.12
Effective Date: 01/17
Last Review Date: 11/15

IMPORTANT REMINDER
This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough 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 the policy; and other indicia of medical necessity. Centene Corporation makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this policy.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This policy is current at the time of approval, may be updated and therefore is subject to change. 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.

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Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene medical policy for clozapine ODT (Fazaclol®).

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® that clozapine ODT (Fazaclol®) is medically necessary for members meeting the following criteria:

Initial Approval Criteria (must meet all):
A. Diagnosis of schizophrenia or schizoaffective disorder;
B. Age > 18 years;
C. Failure of two formulary generic atypical antipsychotics, which are FDA approved for member's diagnosis- each agent must be used for > 4 weeks, unless contraindicated;
D. Documentation supporting member's inability to use regular clozapine tablets (non-ODT tablet);
E. Request does not exceed FDA approved limit for member's diagnosis.
CLINICAL POLICY

clozapine ODT (Fazaclo®)

Approval duration: 12 months

Continued Approval (must meet all as applicable):
Note: Claim may auto-adjudicate via the Smart PA approval process if the criteria below are met and can be validated through the US Script pharmacy benefit management system

A. If request is for a dose increase, member must be adherent to current regimen and request does not exceed the FDA approved limit for diagnosis.

Approval duration: 12 months

Background
Fazaclio (clozapine ODT) is indicated for the treatment of severely ill patients with schizophrenia. Because of the significant risk of agranulocytosis and seizure associated with its use, Fazaclio should be used only in patients who have failed to respond adequately to standard antipsychotic treatment. Clozapine is an oral atypical antipsychotic agent. It is an atypical antipsychotic of dibenzodiazepine derivation, with properties that differ from traditional antipsychotic agents. The clinical effects of antipsychotics are mostly due to antagonism of dopamine receptors in the central nervous system.

References (or Bibliography)

Reviews, Revisions, and Approvals

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<th>New guideline created — replaces CP.PMN.56</th>
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<th>Removed requirement for failure of clozapine tablet and modified criteria to require failure of 2 generic formulary agents FDA approved for member's diagnosis; Modified criteria D to request for documentation supporting member's inability to use regular clozapine tablet</th>
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