

Clinical Policy: Baloxavir Marboxil (Xofluza)

Reference Number: CP.PMN.185

Effective Date: 12.01.18

Last Review Date: 11.20

Line of Business: Commercial, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Baloxavir marboxil (Xofluza[™]) is an antiviral polymerase acidic (PA) endonuclease inhibitor.

FDA Approved Indication(s)

Xofluza is indicated for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours and who are:

- otherwise healthy, or
- at high risk of developing influenza-related complications.

Limitation(s) of use: Influenza viruses change over time, and factors such as the virus type or subtype, emergence of resistance, or changes in viral virulence could diminish the clinical benefit of antiviral drugs. Consider available information on drug susceptibility patterns for circulating influenza virus strains when deciding whether to use Xofluza.

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.

It is the policy of health plans affiliated with Centene Corporation[®] that Xofluza is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria**A. Influenza Treatment** (must meet all):

1. Diagnosis of influenza virus infection;
2. Age \geq 12 years;
3. Symptoms have been present for \leq 48 hours;
4. Medical justification supports inability to use oseltamivir;
5. Dose does not exceed one of the following (a or b):
 - a. Weight 40 kg to < 80 kg: 40 mg (2 tablets) once;
 - b. Weight \geq 80 kg: 80 mg (2 tablets) once.

Approval duration: 4 weeks (one dose only)

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): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Influenza Treatment

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

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): CP.CPA.09 for commercial and 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 – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

PA: polymerase acidic

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
oseltamivir (Tamiflu [®])	<p>Treatment of acute, uncomplicated influenza A and B in patients 2 weeks of age and older who have been symptomatic for no more than 48 hours</p> <p>Adults and adolescents age \geq 13 years: 75 mg PO BID for 5 days</p> <p>Pediatrics:</p> <ul style="list-style-type: none"> • Age \leq 2 weeks: 1 mg/kg/dose PO BID for 5 days* • Age 2 weeks to less than 1 year: 3 mg/kg PO BID for 5 days • Age 1 to 12 years: weight-based dosing ranging from 30 mg to 75 mg PO BID for 5 days 	150 mg/day for 5 days

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.

**Off-label use*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): history of hypersensitivity to baloxavir marboxil or any of its ingredients
- Boxed warning(s): none reported

Appendix D: General Information

- Diagnosis of influenza can be made via laboratory confirmation or by symptom evaluation. Influenza signs and symptoms typically include fever 100.4°F or higher or feeling feverish/chills and at least one of the following:
 - Cough
 - Sore throat
 - Headaches and/or body aches
 - Difficulty breathing or shortness of breath
 - Fatigue
 - Runny or stuffy nose

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Influenza treatment	Adults and adolescents ≥ 12 years: Weight 40 kg to < 80 kg: 40 mg PO once Weight ≥ 80 kg: 80 mg PO once	80 mg once

VI. Product Availability

Tablets: 20 mg, 40 mg

VII. References

1. Xofluza Prescribing Information. South San Francisco, CA: Genentech, Inc.; October 2019. Available at: <https://www.gene.com/patients/medicines/xofluza>. Accessed July 1, 2020.
2. Centers for Disease Control and Prevention. Information for Clinicians on Influenza Virus Testing. February 26, 2018. <https://www.cdc.gov/flu/professionals/diagnosis/index.htm>. Accessed July 1, 2020.
3. Fiore AE, Fry A, Shay D, et al. Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP). Morbidity and Mortality Weekly Report (MMWR): Recommendations and Reports. 2011. 60(RR01);1-24.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: <http://www.clinicalpharmacology-ip.com/>.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.30.18	11.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.08.19	11.19
Revised dose optimization of tablets in criteria.	02.14.20	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2020 annual review: no significant changes; updated FDA Approved Indication section with revised indication to specify use in healthy or high risk patients; references reviewed and updated.	07.01.20	11.20

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 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.

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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.

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