

# Baloxavir Marboxil (XOFLUZA)

## Criteria for Use

### April 2021

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.* See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTERnet](#) or [PBM INTRAnet](#) site

## Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive baloxavir marboxil (XOFLUZA)

- Severe influenza requiring hospitalization unless oseltamivir/zanamivir is contraindicated or not tolerated\*
- Pregnancy

## Inclusion Criteria

- Patient with documented influenza by PCR/rapid flu test OR strongly suspected influenza during a time of significant influenza activity in the community (as evidenced by at least fever PLUS one or more of the following: severe fatigue, muscle aches, severe respiratory symptoms)
  - Presenting within 48 hours of onset of flu-like symptoms
  - Was exposed to a influenza as a household contact who is within 48 hours of symptom onset
- AND at least one of the following**
- prior intolerance and/or allergy to oseltamivir and/or zanamivir
  - Documented oseltamivir-resistant influenza in the community
  - Inability to receive oseltamivir within the 48-hour time window from symptom onset (such as CBOCs, or after pharmacy hours, shortages of oseltamivir limiting supply – see issues for consideration)

## Supplemental Information

- Baloxavir marboxil is given as a single oral dose taken with or without food (but should be separated from dairy products or di/trivalent cations). The recommended dosage is 40mg for patients weighing < 80kg and 80mg for those weighing ≥ 80kg
- Emergence of mutants with reduced susceptibility to baloxavir emerged in 3-11% of subjects receiving baloxavir in clinical trials.
- Use of baloxavir may be considered in situations where oseltamivir and zanamivir are contraindicated or not tolerated, or cannot be used due to logistical constraints which prevent adherence to or timely receipt of oseltamivir or zanamivir (such as homelessness, inability to fill prescription in a timely manner due to distance or after pharmacy hours, or other situations where directly observed therapy is preferred)

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