

# Post Limit Prior Authorization Influenza Treatment & Prevention

### **Products Referenced by this Document**

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Relenza	zanamivir
Tamiflu	oseltamivir
Xofluza	baloxavir marboxil

## Indications

### **FDA-approved Indications**

#### Relenza

#### **Treatment of Influenza**

Relenza (zanamivir) inhalation powder is indicated for treatment of uncomplicated acute illness due to influenza A and B virus in adults and pediatric patients aged 7 years and older who have been symptomatic for no more than 2 days.

#### **Prophylaxis of Influenza**

Relenza is indicated for prophylaxis of influenza in adults and pediatric patients aged 5 years and older.

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#### Important Limitations of Use

- Relenza is not recommended for treatment or prophylaxis of influenza in individuals with underlying airways disease (such as asthma or chronic obstructive pulmonary disease) due to risk of serious bronchospasm.
- Relenza has not been proven effective for treatment of influenza in individuals with underlying airways disease.
- Relenza has not been proven effective for prophylaxis of influenza in the nursing home setting.
- Relenza is not a substitute for early influenza vaccination on an annual basis as recommended by the Centers for Disease Control's Immunization Practices Advisory Committee.
- Influenza viruses change over time. Emergence of resistance mutations could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use Relenza.
- There is no evidence for efficacy of zanamivir in any illness caused by agents other than influenza virus A and B.
- Patients should be advised that the use of Relenza for treatment of influenza has not been shown to reduce the risk of transmission of influenza to others.

#### **Compendial Uses**

Treatment of influenza A or B viral infection when administered after 48 hours in patients aged 7 years and older who are at higher risk for influenza complications or in patients aged 7 years and older with severe, complicated, or progressive illness.<sup>6,7</sup>

#### Tamiflu

#### **Treatment of Influenza**

Tamiflu is indicated for the treatment of acute, uncomplicated illness due to influenza A and B infection in patients 2 weeks of age and older who have been symptomatic for no more than 48 hours.

#### **Prophylaxis of Influenza**

Tamiflu is indicated for the prophylaxis of influenza A and B in patients 1 year and older.

#### **Limitations of Use**

- Tamiflu is not a substitute for early influenza vaccination on an annual basis as recommended by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices.
- Influenza viruses change over time. Emergence of resistance substitutions could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use Tamiflu.
- Tamiflu is not recommended for patients with end-stage renal disease not undergoing dialysis.

#### **Compendial Uses**

Treatment of influenza A or B viral infection when administered after 48 hours in patients who are at higher risk for influenza complications or in patients with severe, complicated, or progressive illness<sup>6,7</sup>

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Prophylaxis of influenza A or B viral infection in patients 3 months to 1 year of age, if necessary, after exposure to another person with influenza.<sup>4,6</sup>

#### Xofluza

#### **Treatment of Influenza**

Xofluza is indicated for treatment of acute uncomplicated influenza in patients 5 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.

#### Post-Exposure Prophylaxis of Influenza

Xofluza is indicated for post-exposure prophylaxis of influenza in persons 5 years of age and older following contact with an individual who has influenza.

#### **Limitations 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.

# **Coverage Criteria**

### Influenza

Authorization may be granted for the requested drug when ONE of the following criteria are met:

- The requested drug is being prescribed for ANY of the following: treatment of acute uncomplicated influenza in a patient 5 years of age or older who is otherwise healthy or at high risk of developing influenza-related complications, post-exposure prophylaxis of influenza in a patient 5 years of age or older and the following criteria is met:
  - The request is for Xofluza (baloxavir marboxil).
- The requested drug is being prescribed for the prophylaxis of influenza A or B viral infection in a patient 3 months of age or older during a community outbreak and the following criteria is met:
  - The request is for Tamiflu (oseltamivir).
- The requested drug is being prescribed for the prophylaxis of influenza A or B viral infection in a patient 5 years of age or older during a community outbreak and the following criteria is met:
  - The request is for Relenza (zanamivir).
- The requested drug, (i.e., Tamiflu or Relenza), is being prescribed for the prophylaxis (prevention) OR the treatment of influenza A or B viral infection.

# **Quantity Limits Apply**

The post limit below approves for additional quantities above the initial quantity limit.

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### Post Limit Quantity

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Reference number(s) 111-J

Medication	Indication	Strength	Limit
Xofluza	Treatment or Post-	80 mg per tablet (1	1 tablets / 90 days
(baloxavir marboxil)	exposure Prophylaxis	tablet per blister card)	
Xofluza	<b>Treatment or Post-</b>	40 mg/20mL (2	40 mL / 90 days
(baloxavir marboxil)	exposure Prophylaxis	mg/mL) suspension	
Xofluza	Treatment or Post-	30 mg per packet	1 packet / 90 days
(baloxavir marboxil)	exposure Prophylaxis		
Xofluza	Treatment or Post-	40 mg per packet	2 packets / 90 days
(baloxavir marboxil)	exposure Prophylaxis		

## **Duration of Approval (DOA)**

• 111-J: DOA: 3 months

### References

- 1. Relenza [package insert]. Durham, NC: GlaxoSmithKline; October 2023.
- 2. Tamiflu [package insert]. South San Francisco, CA: Genentech, Inc.; August 2019.
- 3. Xofluza [package insert]. South San Francisco, CA: Genentech USA, Inc. May 2025.
- 4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed June5, 2025.
- 5. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/\_(cited: 06/05/2025).
- 6. Centers for Disease Control and Prevention Influenza (Flu) Health Professionals Influenza Antiviral Medications: Summary for Clinicians. Available at:

https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm. Accessed August 19, 2024.
7. American Academy of Pediatrics Committee on Infectious Diseases. Recommendations for Prevention and Control of Influenza in Children, 2022–2023. *Pediatrics*. 2022;150(4).

8. Uyeki TM, Bernstein HH, Bradley JS, et al. Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenza. *Clin Infect Dis*. 2019;68(6):e1–e47.

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