PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**INFLUENZA TREATMENT & PREVENTION**
BRAND NAME (generic)	**RELENZA (zanamivir)** **TAMIFLU (oseltamivir)** **XOFLUZA (baloxavir marboxil)**

Status: CVS Caremark® Criteria
Type: Post Limit Prior Authorization

POLICY

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.

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[6,7]

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[6,7]

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[4,6]

Xofluza

Treatment of Influenza

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

- otherwise healthy adults and pediatric patients 5 years of age and older,
  OR
- adults and pediatric patients 12 years of age and older who are 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

The requested drug will be covered with prior authorization when the following criteria are met:

- The request is for Xofluza (baloxavir marboxil) for any of the following: A) treatment of acute uncomplicated influenza in an otherwise healthy patient 5 years of age or older, B) treatment of acute uncomplicated influenza for a patient 12 years of age or older who is at high risk of developing influenza-related complications, C) post-exposure prophylaxis of influenza in a patient 5 years of age or older

OR

- The request is for Tamiflu (oseltamivir) for the prophylaxis of influenza A or B viral infection in a patient 3 months of age or older during a community outbreak

OR

- The request is for Relenza (zanamivir) for the prophylaxis of influenza A or B viral infection in a patient 5 years of age or older during a community outbreak

OR

- 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.

POST LIMIT QUANTITY			
Medication	**Indication**	**Strength**	**Limit**
Relenza (zanamivir)	Treatment or Household Prophylaxis	5 mg blister per inhalation	20 blisters / 90 days
	Community Outbreak Prophylaxis		60 blisters / 90 days
Tamiflu (oseltamivir)	Treatment or Household Prophylaxis	360 mg/60mL (6 mg/mL) suspension	180 mL / 90 days
		30 mg per capsule	20 capsules / 90 days
		45 mg per capsule	10 capsules / 90 days
		75 mg per capsule	10 capsules / 90 days
	Community Outbreak Prophylaxis	360 mg/60mL (6 mg/mL) suspension	540 mL / 90 days
		30 mg per capsule	90 capsules / 90 days
		45 mg per capsule	50 capsules / 90 days
		75 mg per capsule	50 capsules / 90 days
	Community Outbreak Prophylaxis – Immunocompromised patient	360 mg/60mL (6 mg/mL) suspension	1080 mL / 90 days
		30 mg per capsule	170 capsules / 90 days
		45 mg per capsule	90 capsules / 90 days
		75 mg per capsule	90 capsules / 90 days
Xofluza (baloxavir marboxil)	Treatment or Post-exposure Prophylaxis	20 mg per tablet (2 tablets per blister card)	2 tablets / 90 days
		40 mg per tablet (1 tablet per blister card)	1 tablets / 90 days
		40 mg per tablet (2 tablets per blister card)	2 tablets / 90 days
		80 mg per tablet (1 tablet per blister card)	1 tablets / 90 days
		40 mg/20mL (2 mg/mL) suspension	40 mL / 90 days

Duration of Approval (DOA):

- 111-J: DOA: 3 months

REFERENCES

1. Relenza [package insert]. Research Triangle Park, NC: GlaxoSmithKline; October 2021.
2. Tamiflu [package insert]. South San Francisco, CA: Genentech, Inc.; August 2019.
3. Xofluza [package insert]. South San Francisco, CA: Genentech USA, Inc. August 2022.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed June 27, 2023.
5. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 06/27/2023).
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 June 27, 2023.
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.