## PRIOR AUTHORIZATION CRITERIA

<table>
<thead>
<tr>
<th>DRUG CLASS</th>
<th>INFLUENZA TREATMENT &amp; PREVENTION</th>
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</thead>
<tbody>
<tr>
<td>BRAND NAME (generic)</td>
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<tr>
<td>RELENZA (zanamivir)</td>
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<tr>
<td>TAMIFLU (oseltamivir)</td>
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<tr>
<td>XOFLUZA (baloxavir)</td>
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</table>

**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 on Use of Relenza**  
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 illness3-9

**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
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 influenza3-9

Xofluza
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.

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) for a patient 12 years of age or older who has acute uncomplicated influenza
  Post Quantity Limits For Approval:
  - 2 tablets of Xofluza (baloxavir) 20mg or 40mg
  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
  Post Quantity Limits For Approval:
  - 10 capsules of oseltamivir (Tamiflu) 45mg or
  - 10 capsules of oseltamivir (Tamiflu) 75mg or
  - 20 capsules of oseltamivir (Tamiflu) 30mg or
  - 3 bottles (180mL) of oseltamivir (Tamiflu) suspension
  - 20 blisters of Relenza (zanamivir)
  OR

• The request is for oseltamivir (Tamiflu) for the prophylaxis of influenza A or B viral infection in a patient 3 months of age or older who has been exposed to a community outbreak
  Post Quantity Limits For Approval:
  - 42 capsules of oseltamivir (Tamiflu) 75mg or
  - 42 capsules of oseltamivir (Tamiflu) 45mg or
  - 84 capsules of oseltamivir (Tamiflu) 30mg or
  - 9 bottles (540mL) of oseltamivir (Tamiflu) suspension
  For a patient with immune deficiencies, Post Quantity Limits For Approval:
  - 75mg: 84 Capsules or
  - 45mg: 84 Capsules or
  - 30mg: 168 Capsules or
  - Suspension: 1080mL
  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 who has been exposed to a community outbreak
  Post Quantity Limits For Approval:
  - 60 Blisters

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REFERENCES