### FDA APPROVED INDICATIONS AND DOSAGE\(^1,2,4\)

<table>
<thead>
<tr>
<th>Agent</th>
<th>Indication</th>
<th>Dosage &amp; Administration</th>
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</thead>
</table>
| **Relenza®** (zanamivir) oral inhalation powder | Treatment of influenza in patients aged 7 years and older who have been symptomatic for no more than 2 days. Prophylaxis of influenza in patients aged 5 years and older. Important limitations on use of zanamivir:  
  - Not recommended for treatment or prophylaxis of influenza in:  
    - Individuals with underlying airways disease  
  - Not proven effective for:  
    - Treatment in individuals with underlying airways disease.  
    - Prophylaxis in nursing home residents. | Treatment of influenza:  
  - 10 mg twice daily for 5 days  
Prophylaxis of influenza:  
  - Household setting: 10 mg once daily for 10 days  
  - Community Outbreak: 10 mg once daily for 28 days  
The 10-mg dose is provided by 2 inhalations (one 5-mg blister per inhalation). |
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| Tamiflu® (oseltamivir)<sup>a</sup> capsules, oral suspension | Treatment of acute, uncomplicated influenza in patients 2 weeks of age and older who have been symptomatic for no more than 2 days. | Treatment of influenza:  
- Adults and adolescents (13 years and older): 75 mg twice daily for 5 days  
- Pediatric patients 1 to 12 years of age: Based on weight twice daily for 5 days  
- Pediatric patients 2 weeks to less than 1 year of age: 3mg/kg twice daily for 5 days  
- Renally impaired adult patients (creatinine clearance >30-60 mL/min): Reduce to 30 mg twice daily for 5 days  
- Renally impaired adult patients (creatinine clearance >10-30 mL/min): Reduce to 30 mg once daily for 5 days  
- ESRD patients on hemodialysis: Reduce to 30 mg after every hemodialysis cycle. Treatment duration not to exceed 5 days  
- ESRD patients on CAPD: Reduce to a single 30 mg dose administered immediately after a dialysis exchange  

Prophylaxis of influenza:  
- Adults and adolescents (13 years and older): 75 mg once daily for at least 10 days - Community outbreak: 75 mg once daily for up to 6 weeks  
- Pediatric patients 1 to 12 years of age: Based on weight once daily for 10 days - Community outbreak: Based on weight once daily for up to 6 weeks  
- Renally impaired adult patients (creatinine clearance >30-60 mL/min): Reduce to 30 mg once daily  
- Renally impaired adult patients (creatinine clearance >10-30 mL/min): Reduce to 30 mg once every other day  
- ESRD patients on hemodialysis: Reduce to 30 mg after alternate hemodialysis cycles for the recommended duration of prophylaxis  
- ESRD patients on CAPD: Reduce to 30 mg once weekly immediately after dialysis exchange for the recommended duration of prophylaxis |

Important limitations of use:  
- Efficacy not established in patients who begin therapy after 48 hours of symptoms.  
- Not a substitute for annual influenza vaccination.  
- No evidence of efficacy for illness from agents other than influenza viruses types A and B.  
- Consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use.

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**Agent** | **Indication** | **Dosage & Administration**
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**Xofluza™** (baloxavir marboxil) | Treatment of acute uncomplicated influenza in patients 12 years of age or 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 virus strains when deciding whether to use Xofluza | 40 kg to less than 80 kg: Single dose of 40 mg
At least 80 kg: Single dose of 80 mg

* – generic available

**CLINICAL RATIONALE**

**Guidelines**
The Center for Disease Control and Prevention (CDC) does not recommend widespread or routine use of antiviral medications for chemoprophylaxis so as to limit the possibilities that antiviral resistant viruses could emerge. Indiscriminate use of chemoprophylaxis might promote resistance to antiviral medications, or reduce antiviral medication availability for treatment of persons at higher risk for influenza complications or those who are severely ill. To be effective as chemoprophylaxis, an antiviral medication must be taken each day for the duration of potential exposure to a person with influenza and continued for 7 days after the last known exposure. For persons taking antiviral chemoprophylaxis after inactivated influenza vaccination, the recommended duration is until immunity after vaccination develops (antibody development after vaccination takes about two weeks in adults and can take longer in children depending on age and vaccination history).³

**Safety**
Zanamivir is contraindicated in patients with history of allergic reaction to any ingredient of Relenza, including milk proteins.¹

Oseltamivir is contraindicated in patients with known serious hypersensitivity to oseltamivir or any of the components of Tamiflu.²

**REFERENCES**
Anti-Influenza Agent Quantity Limit

OBJECTIVE
The intent of the Anti-Influenza Agent Quantity Limit is to help encourage appropriate dosage according to FDA label and/or guidelines. The program accommodates for two rounds of influenza treatment or 20 days of prophylaxis in a 120 day period. Requests for larger quantities will be evaluated through the Clinical Review process when the prescriber provides evidence that dosing with higher quantities is appropriate for the patient.

PROGRAM QUANTITY LIMITS

<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>GPI</th>
<th>Multisource Code</th>
<th>Quantity per 120 days</th>
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<tbody>
<tr>
<td>Relenza (zanamivir)</td>
<td>12504080008020</td>
<td>M, N, O, or Y</td>
<td>40 blisters</td>
</tr>
<tr>
<td>Tamiflu (oseltamivir)</td>
<td>12504060200110</td>
<td>M, N, O, or Y</td>
<td>20 capsules</td>
</tr>
<tr>
<td></td>
<td>12504060200115</td>
<td>M, N, O, or Y</td>
<td>20 capsules</td>
</tr>
<tr>
<td></td>
<td>12504060200120</td>
<td>M, N, O, or Y</td>
<td>20 capsules</td>
</tr>
<tr>
<td></td>
<td>12504060201910</td>
<td>M, N, O, or Y</td>
<td>360 ml</td>
</tr>
<tr>
<td></td>
<td>12504060201920</td>
<td>M, N, O, or Y</td>
<td>150 ml</td>
</tr>
<tr>
<td>Xofluza (baloxavir marboxil)</td>
<td>1250202020B720</td>
<td>M, N, O, or Y</td>
<td>4 tablets</td>
</tr>
<tr>
<td></td>
<td>1250202020B735</td>
<td>M, N, O, or Y</td>
<td>4 tablets</td>
</tr>
</tbody>
</table>

- generic available

QUANTITY LIMIT AUTHORIZATION CRITERIA FOR APPROVAL
Requests above the set quantity limit will be approved when BOTH of the following are met:

1. ONE of the following:
   a. The patient requires additional courses of therapy due to additional episodes of acute influenza infection
   
   OR

   b. The patient requires additional courses or increased duration of therapy for prophylaxis after exposure to an influenza infected person

   AND

2. If there is no shortage of the prescribed product:
   c. ONE of the following:
   d. BOTH of the following:
      i. The requested quantity (dose) is less than or equal to the FDA labeled dose
      
      AND

      ii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

   OR

   e. BOTH of the following:
      i. The requested quantity (dose) is greater than the FDA labeled dose
      
      AND

      ii. The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

3. If there is a shortage of the prescribed product
   a. The requested quantity (dose) is less than or equal to the FDA labeled dose
   
   OR

   a. BOTH of the following:
      i. The requested quantity (dose) is greater than the FDA labeled dose

      AND
ii. The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

**Length of Approval:** 4 months