Anti-Influenza Agents
Quantity Limit
Program Summary

This program applies to FlexRx Open, FlexRx Closed, GenRx Open, GenRx Closed, Health Insurance Marketplace, FocusRx and KeyRx formularies.

This is a FlexRx standard and GenRx standard quantity limit program.

**FDA APPROVED INDICATIONS AND DOSAGE**

<table>
<thead>
<tr>
<th>Agent</th>
<th>Indication</th>
<th>Dosage &amp; Administration</th>
</tr>
</thead>
</table>
| ReLenza® (zanamivir) oral inhalation powder | Treatment of acute, uncomplicated influenza type A and B infections 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 a substitute for annual influenza vaccination  
  - Consider available information on influenza susceptibility patterns and treatment effects when deciding whether to use  
  - Not recommended for treatment or prophylaxis of influenza in:  
    o Individuals with underlying airways disease  
  - Not proven effective for:  
    o Treatment in individuals with underlying airways disease.  
    o 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). |
<table>
<thead>
<tr>
<th><strong>Agent</strong></th>
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<th><strong>Dosage &amp; Administration</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Tamiflu® (oseltamivir)* capsules, oral suspension</td>
<td>Treatment of acute, uncomplicated influenza A and B in patients 2 weeks of age and older who have been symptomatic for no more than 48 hours. Prophylaxis of influenza A and B in patients 1 year and older. Important limitations of use: • Not a substitute for annual influenza vaccination • Consider available information on influenza susceptibility patterns and treatment effects when deciding whether to use • Not recommended for patients with end-stage renal disease not undergoing dialysis</td>
<td>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 &gt;30-60 mL/min): Reduce to 30 mg twice daily for 5 days • Renally impaired adult patients (creatinine clearance &gt;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 &gt;30-60 mL/min): Reduce to 30 mg once daily • Renally impaired adult patients (creatinine clearance &gt;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 • Community outbreak prophylaxis can be extended to up to 12 weeks in immunocompromised patients</td>
</tr>
<tr>
<td>Agent</td>
<td>Indication</td>
<td>Dosage &amp; Administration</td>
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<tr>
<td>Xofluza™ (baloxavir marboxil)</td>
<td>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</td>
<td>40 kg to less than 80 kg: Single dose of 40 mg At least 80 kg: Single dose of 80 mg</td>
</tr>
</tbody>
</table>

<sup>a</sup> – 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**
   [https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm](https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm)
Anti-Influenza Agent Quantity Limit

OBJECTIVE
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>
</tr>
</thead>
<tbody>
<tr>
<td>Relenza (zanamivir)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 mg blister</td>
<td>12504080008020</td>
<td>M, N, O, or Y</td>
<td>40 blisters</td>
</tr>
<tr>
<td>Tamiflu (oseltamivir)*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 mg capsule</td>
<td>12504060200110</td>
<td>M, N, O, or Y</td>
<td>40 capsules</td>
</tr>
<tr>
<td>45 mg capsule</td>
<td>12504060200115</td>
<td>M, N, O, or Y</td>
<td>20 capsules</td>
</tr>
<tr>
<td>75 mg capsule</td>
<td>12504060200120</td>
<td>M, N, O, or Y</td>
<td>20 capsules</td>
</tr>
<tr>
<td>6 mg/ml suspension</td>
<td>12504060201910</td>
<td>M, N, O, or Y</td>
<td>300 ml</td>
</tr>
<tr>
<td>Xofluza (baloxavir marboxil)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 mg tablets</td>
<td>1250202020B720</td>
<td>M, N, O, or Y</td>
<td>4 tablets</td>
</tr>
<tr>
<td>40 mg tablets</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. ONE of the following:
   a. There is no shortage of the requested agent and ONE of the following:
      i. ALL of the following:
         1. The requested quantity (dose) is greater than the program quantity limit
         AND
         2. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication
         AND
         3. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
      OR
      ii. ALL of the following:
         1. The requested quantity (dose) is greater than the program quantity limit
         AND
         2. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
         AND
         3. The prescriber has submitted documentation in support of therapy with a higher dose for the requested indication
      OR

b. There is a shortage of the requested agent and ONE of the following:
   i. ALL of the following:
      1. The requested quantity (dose) is greater than the program quantity limit
      **AND**
      2. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication
     **OR**
   ii. ALL of the following:
      1. The requested quantity (dose) is greater than the program quantity limit
      **AND**
      2. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
      **AND**
      3. The prescriber has submitted documentation in support of therapy with a higher dose for the requested indication

**Length of Approval:** 4 months