Relenza

Description

Relenza (zanamivir)

Background
Relenza (zanamivir), an antiviral drug, is an inhibitor of influenza virus neuraminidase, affecting release of viral particles. The efficacy of zanamivir in preventing naturally occurring influenza illness has been demonstrated in 2 post exposure prophylaxis studies in households and 2 seasonal prophylaxis studies during community outbreaks of influenza (1).

Regulatory Status
FDA-approved indication: Relenza, an influenza neuraminidase inhibitor (NAI), is indicated for (1):
1. Treatment of influenza in patients aged 7 years and older who have been symptomatic for no more than 2 days.
2. Prophylaxis of influenza in patients aged 5 years and older.

Limitations of Use (1):
- 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.

Persons at high risk of complications from influenza should be considered for antiviral therapy. There is data to suggest that the highest risk of both mortality and serious morbidity (e.g.
hospitalization) occurs for severely immunocompromised patients (e.g. hematopoietic stem cell transplant patients) and very elderly (age >85 years). Residents of nursing homes and infants aged <24 months also have high hospitalization rates but lower case-fatality rates than do the other 2 groups (2).

Examples of persons at high risk of complications would be (2):
- Unvaccinated infants aged 12-24 months
- Persons with asthma or other chronic pulmonary diseases, such as cystic fibrosis in children or chronic obstructive pulmonary disease in adults.
- Persons with hemodynamically significant cardiac disease
- Persons who have immunosuppressive disorders or who are receiving immunosuppressive therapy
- HIV-infected persons
- Persons with sickle cell anemia and other hemoglobinopathies
- Persons with diseases that require long-term aspirin therapy, such as rheumatoid arthritis or Kawasaki disease
- Persons with chronic renal dysfunction
- Persons with cancer
- Persons with chronic metabolic disease, such as diabetes mellitus
- Persons with neuromuscular disorders, seizure disorders, or cognitive dysfunction that may compromise the handling of respiratory secretions
- Adults aged >65 years
- Residents of any age of nursing homes or other long-term care institutions

Not a substitute for annual influenza vaccination (1).

Consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use Relenza (1).

Per the CDC, chemoprophylaxis is recommended for control of outbreaks in institutional settings (e.g. long-term care facilities for elderly persons and children) and hospitals. CDC recommends antiviral chemoprophylaxis for a minimum of 2 weeks, and continuing up to 1 week after the last known case was identified. Antiviral chemoprophylaxis is recommended for all residents, including those who have received the influenza vaccination (3).

**Related policies**
Tamiflu, Xofluza
Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Relenza is medically necessary for the treatment of influenza in patients 7 years of age and older, and for prophylaxis of influenza in patients 5 years of age and older and if the conditions indicated below are met.

Relenza may be considered investigational in all other patients and for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have ONE of the following:

1. Treatment of Influenza with
   a. Onset of symptoms within the previous 48 hours
   b. 7 years of age or older

2. Prophylaxis of Influenza
   a. 5 years of age or older

   AND ONE of the following:
   a. High risk for complications
   b. Immunocompromised
   c. Resides in an institutional setting (e.g. long term care facilities)

Prior – Approval Renewal Requirements

Diagnosis

Patient must have the following:

1. Prophylaxis of Influenza
   a. 5 years of age or older
AND ONE of the following:
   a. Immunocompromised
   b. Patient resides in an institutional setting (e.g. long term care facilities)

Policy Guidelines

Pre - PA Allowance

Age 5 years of age or older

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>10 mg</td>
<td>40 inhalations</td>
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</table>

Duration 12 months

Prior - Approval Limits

Treatment of influenza

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mg</td>
<td>20 inhalations</td>
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</table>

Duration 1 month

Prophylaxis of influenza

For high risk patients

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity per 30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mg</td>
<td>20 inhalations</td>
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</tbody>
</table>

Duration 1 month

For immunocompromised or institutionalized patients

Quantity
Relenza (zanamivir), an antiviral drug, is an inhibitor of influenza virus neuraminidase, affecting release of viral particles (1). Persons at high risk of complications from influenza should be considered for antiviral therapy. There is data to suggest that the highest risk of both mortality and serious morbidity (e.g. hospitalization) occurs for severely immunocompromised patients (e.g. hematopoietic stem cell transplant patients) and very elderly (age >85 years). Residents of nursing homes and infants aged <24 months also have high hospitalization rates but lower case-fatality rates than do the other 2 groups (2).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Relenza while maintaining optimal therapeutic outcomes.

References
January 2019.


<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>March 2006</td>
<td>Addition of prophylaxis treatment to reflect FDA approved package labeling. Age limit on Pre-PA Allowance added to bring criteria in line with FDA approved package labeling.</td>
</tr>
<tr>
<td>March 2008</td>
<td>Addition of criteria requiring treatment to be started within 48 hours of symptoms to reflect FDA indications</td>
</tr>
<tr>
<td>April 2009</td>
<td>Standard allowance increased due to the introduction of H1N1 flu and the possibility of contracting several different strains of flu during a 12 month period</td>
</tr>
<tr>
<td>December 2012</td>
<td>Annual review and update</td>
</tr>
<tr>
<td>March 2014</td>
<td>Annual review and reference update Duration for immunocompromised patients changed to 6 months</td>
</tr>
<tr>
<td>March 2015</td>
<td>Annual review and reference update</td>
</tr>
<tr>
<td>March 2016</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td>December 2017</td>
<td>Policy number changed from 5.03.17 to 5.01.17</td>
</tr>
<tr>
<td>February 2018</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>June 2018</td>
<td>Addition of the flu season verbiage defining the start of the new flu season</td>
</tr>
<tr>
<td>March 2019</td>
<td>Addition of renewal for prophylaxis of influenza in immunocompromised patients and patients in an institutional setting and the clarification of prophylaxis types to initiation</td>
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</table>

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.