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 postexposure 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, is indicated for:
- 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 (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).
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.

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

**Related policies**
Tamiflu

**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. Relenza may be considered **investigational** in all other patients.
Prior-Approval Requirements

Age
- 7 years of age or older for treatment of Influenza
- 5 years of age or older for prophylaxis of influenza

Diagnoses
- Patient must have **ONE** of the following:
  1. Treatment of Influenza with onset of symptoms within the previous 48 hours
  2. Prophylaxis of Influenza

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

Age
- 5 years of age or older

Quantity
- A total of **TWO** 5-day courses of Relenza therapy

Duration
- 12 months

Prior - Approval Limits

Quantity
- **For treatment of influenza**: 10mg twice daily for 5 days
- **For prophylaxis of influenza**: 10mg daily for 10 days for household setting; or 28 days for community outbreaks; or 6 months if patient is immunocompromised

Duration
- For influenza treatment and prophylaxis: 1 month duration
- For immunocompromised patients: 6 months
Prior – Approval Renewal Limits
None

Rationale

Summary
Relenza (zanamivir), an antiviral drug, is an inhibitor of influenza virus neuraminidase, affecting release of viral particles. 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.

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

References

Policy History
Date             Action
March 2006       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.
<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tr>
<td>March 2008</td>
<td>Addition of criteria requiring treatment to be started within 48 hours of symptoms to reflect FDA indications</td>
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<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>
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<tr>
<td>December 2012</td>
<td>Annual review and update</td>
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<tr>
<td>March 2014</td>
<td>Annual review and reference update</td>
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<td>Duration for immunocompromised patients changed to 6 months</td>
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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 13, 2014 and is effective April 1, 2014.

*Signature on File*

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