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Section:	Prescription Drugs	**Effective Date:**	July 1, 2023
Subsection:	Anti-infective Agents	**Original Policy Date:**	September 8, 2011
Subject:	Relenza	**Page:**	1 of 6

Last Review Date: June 15, 2023

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 indications: 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 may be considered **medically necessary** if the conditions indicated below are met.

Relenza may be considered **investigational** 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
    b. Patient has **ONE** of the following:
        i. High risk for complications
        ii. Immunocompromised
        iii. 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
    b. Patient has **ONE** of the following:
        i. Immunocompromised
        ii. Patient resides in an institutional setting (e.g., long term care facilities)

Policy Guidelines

Pre - PA Allowance

Age 5 years of age or older

Quantity

Strength	Quantity
10 mg	40 inhalations

Duration 12 months

Prior - Approval Limits

Treatment of influenza:

Quantity

Strength	Quantity per 30 days
10 mg	20 inhalations

Duration 1 month

Prophylaxis of influenza for high risk patients:

Quantity

Strength	Quantity per 30 days
10 mg	20 inhalations

Duration 1 month

Prophylaxis of influenza for immunocompromised or institutionalized patients:

Quantity

Strength	Quantity per 180 days
10 mg	360 inhalations per 180 days

Duration 6 months

Prior – Approval *Renewal* Limits

Prophylaxis of influenza for immunocompromised or institutionalized patients:

Quantity

Strength	Quantity per 180 days
10 mg	360 inhalations per 180 days

Duration: 6 months

Rationale

Summary

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

1. Relenza [package insert]. Research Triangle Park, NC: GlaxoSmithKline; October 2021.
2. IDSA Seasonal Influenza in Adults and Children – Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management: Clinical Practice Guidelines

of the Infectious Diseases Society of America. Clin Infect Dis. (2009) 48 (8): 1003-1032.http://cid.oxfordjournals.org/content/48/8/1003.1/F3.expansion.html.

3. Influenza Antiviral Medications: Summary for Clinicians (2018-2019 influenza season). Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases (NCIRD). https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm#dosage.

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.
March 2008	Addition of criteria requiring treatment to be started within 48 hours of symptoms to reflect FDA indications
April 2009	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
December 2012	Annual review and update
March 2014	Annual review and reference update Duration for immunocompromised patients changed to 6 months
March 2015	Annual review and reference update
March 2016	Annual editorial review Policy number changed from 5.03.17 to 5.01.17
December 2017	Annual editorial review and reference update Addition of the flu season verbiage defining the start of the new flu season
February 2018	Addition of renewal for prophylaxis of influenza in immunocompromised patients and patients in an institutional setting and the clarification of prophylaxis types to initiation
June 2018	Annual review
March 2019	Annual review and reference update
December 2020	Annual review and reference update
September 2021	Annual editorial review
September 2022	Annual review and reference update
June 2023	Annual editorial review. Rearranged requirements for clarity

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 15, 2023 and is effective on July 1, 2023.