



RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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



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(zanamivir)

(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>.