ACUTE INFLUENZA INFECTION: CHEMOPROPHYLAXIS PROTOCOL

Approved
07/27/2021 V3

PURPOSE
This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of antiviral therapies to prevent influenza infection. The purpose of this protocol is to ensure appropriate and timely antiviral therapy for individuals at risk for influenza infection after exposure to a person with known or suspected influenza infection.

PHARMACIST EDUCATION AND TRAINING
Prior to initiating the dispensing of antiviral therapy under this protocol, pharmacist(s) must have received education and training in influenza chemoprophylaxis from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy. Additionally, pharmacist(s) must maintain knowledge of the Centers for Disease Control and Prevention (CDC)'s current recommendations for the use of antiviral drugs in the chemoprophylaxis of influenza.1

Provider of Training: ________________________________

Date Training Completed: ____________________________

CRITERIA
Pharmacists authorized to initiate the dispensing of antiviral therapy to prevent acute influenza infection will treat individuals according to guidance from the CDC.1

Ambulatory Settings
Inclusion criteria:
Any individual who presents to the pharmacy and meets ALL the following criteria:

- Family or close contact of person(s) with known or suspected influenza infection
- Exposed to person(s) with known or suspected influenza infection within the past 48 hours
- Unvaccinated against the influenza virus strains circulating at the time of exposure
- At high risk for influenza complications as evidenced by one or more of the following:
  - aged 65 or older
  - chronic pulmonary disease
  - immunosuppression
  - aged <19 years who are receiving long term aspirin therapy

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1 Influenza Antiviral Medications: Summary for Clinicians. Available at https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm
Exclusion criteria:
- Age < 5 years (should be referred to pediatrician)
- Pregnant (should be referred to OBGYN or PCP)

Healthcare Institutional Settings
Inclusion criteria:
- Resident of long-term care facility where a case of acute influenza has been identified
- Unvaccinated employee of a long-term care facility where a case of acute influenza has been identified
- Employee of a long-term care facility, regardless of influenza vaccination status, if the outbreak is caused by a strain of influenza virus that is not well-matched by the vaccine

MEDICATIONS
This protocol authorizes pharmacists to initiate the dispensing of the following antiviral agents. The pharmacist may dispense any dosage form deemed appropriate for the individual.

Oral oseltamivir dosing in ambulatory settings:
- **Adults:** 75 mg once a day for 7 days following last exposure
- **Children (≥5 years):** (current weight determined using pharmacy’s scale) for 7 days following last exposure
  - 15 kg or less: 30 mg once a day
  - >15 to 23 kg: 45 mg once a day
  - >23 to 40 kg: 60 mg once a day
  - > 40 kg: 75 mg once a day

Oral oseltamivir dosing in institutional settings:
- **Adults:** 75 mg once a day for a minimum of 14 days, continuing up to 1 week after last known identified case
- **Children (≥5 years):** (current weight) for a minimum of 14 days, continuing up to 1 week after last known identified case
  - 15 kg or less: 30 mg once a day
  - >15 to 23 kg: 45 mg once a day
  - >23 to 40 kg: 60 mg once a day
  - > 40 kg: 75 mg once a day

Inhaled zanamivir dosing in ambulatory settings:
- **Adults:** 10mg (two 5mg inhalations) once a day x 7 days following last exposure
- **Children (≥5 years):** 10mg (two 5mg inhalations) once a day x 7 days following last exposure
Inhaled zanamivir dosing in institutional settings:
- **Adults:** 10mg (two 5mg inhalations) once a day x 14 days for up to 1 week after last known identified case
- **Children (≥5 years):** 10mg (two 5mg inhalations) once a day x 14 days for up to 1 week after last known identified case

Oral baloxavir dosing in ambulatory settings:
- **Adults:**
  - <80 kg: 40mg once as single dose
  - ≥80 kg: 80mg once single dose
- **Children (≥12 years):**
  - <80 kg: 40mg once as single dose
  - ≥80 kg: 80mg once as single dose

**PROCEDURES FOR INITIATION OF THERAPY**
Antiviral therapy will be initiated only in carefully selected individuals based on relevant medical and social history and considerations of contraindications and precautions.

**Relevant Medical and Social History**
- Past medical history
- Current medications
- Allergies and hypersensitivities

**Contraindications and Precautions**
- Known hypersensitivity to oseltamivir, zanamivir, or baloxavir
- Underlying respiratory disease or asthma (zanamivir)
- Severe renal dysfunction (est. CrCl < 30 ml/min, oseltamivir)
- Fructose/sorbitol intolerance (oseltamivir)
- Patients allergic to milk proteins (zanamivir)

**PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES**
Pharmacist will follow-up within 36-72 hours for evaluation of therapy, adverse effects, and possible need of referral in case of onset of symptoms consistent with influenza or medication adverse effects severe enough to warrant discontinuation of therapy.

**EDUCATION REQUIREMENTS**
Individuals receiving antiviral therapies under this protocol will receive the following education:
- Medication counseling consistent with state and federal requirements for prescription drug products
- That prophylaxis lowers but does not eliminate the risk for influenza
- That susceptibility to influenza returns once the antiviral medication is stopped
• That the influenza vaccine is recommended if eligible
• Instructions to seek medical care as soon as they develop signs and symptoms of the flu
• Instructions on signs or symptoms that warrant emergent medical care

DOCUMENTATION
Pharmacist(s) will document via prescription record each individual eligible for influenza chemoprophylaxis under this protocol, including:
• Documentation of parental consent for individuals under age 18
• Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication
• Documentation that the individual received the education required by this protocol

NOTIFICATION
Pharmacist(s) shall ask all persons receiving antiviral therapies under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the medications dispensed under the protocol to the identified primary care provider within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still have antiviral therapies under this protocol provided all other applicable requirements of the protocol are met.

[If directed by the authorizing physician, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing physician of persons receiving antiviral therapy under this protocol within 7 days of initiating dispensing.]

TERMS
This protocol is effective as of the date all parties execute this document. It shall remain in effect for a period of one year and shall automatically renew for successive one-year periods unless otherwise terminated by any party, with or without cause. Any termination without cause shall require prior notice to all parties of no less than 60 days.

SIGNATURES

Prescriber Name ________________________________ Date __________________

Prescriber Signature ________________________________