Pharmacy Name: _____

Pharmacy Permit Number: _____

ACUTE INFLUENZA INFECTION: CHEMOPROPHYLAXIS PROTOCOL

Approved
07/24/2024
V4

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]

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]

<u>Ambulatory Settings</u>

Inclusion criteria:

Any individual who presents to the pharmacy and meets **ALL** the following criteria:

- Close contact to person(s) with known or suspected influenza infection within the past 48 hours
- 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
    - morbidly obese

Exclusion criteria:

- Age < 5 years (should be referred to pediatrician)
- Pregnant (should be referred to OBGYN or PCP)
- Receipt of live influenza vaccine within past 2 weeks

Healthcare Institutional Settings

Inclusion criteria:

- Resident of long-term care facility where a case of acute influenza has been identified
  Or
- Employee of a long-term care facility where a case of acute influenza has been identified

Exclusion criteria:

- Pregnant (should be referred to OBGYN or PCP)
- Receipt of live influenza vaccine within past 2 weeks

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 x 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 (≥7 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 (≥7 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 and children 5 and older**
  - **<20 kg:** 2mg/kg once as single dose
  - **≥20 kg to <80 kg:** single dose of 40mg
  - **≥80 kg:** single dose of 80mg

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.

Assess for Relevant Medical and Social History

- Patient demographics and weight if <18y/o using scale in pharmacy
- Past medical history
- Relevant social history
- Current medications
- Allergies and hypersensitivities

Medication Specific 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)
- Under 12 years of age with underlying medical conditions (baloxavir)

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

Pharmacist will follow-up within 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
- Appropriate hygiene and infection control measures

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 2:171 for the dispensing of prescription medication, and
- 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.]

[1] *Influenza Antiviral Medications: Summary for Clinicians.* Available at https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm

TERMS

This protocol is authorized pursuant to 201 KAR 2:380 and is effective when it is submitted to the registry. Any termination shall require prior notice to all parties no later than 30 days after discontinuing the protocol.

SIGNATURES

_____ _____

Prescriber Name Date

_____

Prescriber Kentucky License Number

_____

Prescriber Signature

_____ _____

Pharmacist Name Date

_____

Pharmacist Kentucky License Number

_____

Pharmacist Signature

Course Taken for Training: _____

Provider of Training: _____

Date Training Completed: _____

Any pharmacist not party to the protocol will be subject to discipline should they utilize the protocol. A pharmacist utilizing the protocol must be employed by or contracted with the permit listed in the executed protocol.

For additional pharmacists party to this protocol, the pharmacy should keep a list of the additional pharmacists and their training at the pharmacy.

ADDITIONAL SIGNATURE PAGE

By signing below, I attest that I read and understand the Board-authorized protocol, entitled : _____
and that I will follow all guidelines and requirements included in the Board-authorized protocol.

_____ _____
Pharmacist Name Date

_____
Pharmacist Kentucky License Number

_____
Pharmacist Signature

Course Taken for Training: _____

Provider of Training: _____

Date Training Completed: _____