Pharmacy Name: _____

Pharmacy Permit Number: _____

ACUTE INFLUENZA INFECTION: ANTIVIRAL THERAPY PROTOCOL
v6
Approved 01/24/2024

PURPOSE
This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of antiviral therapies to treat acute influenza infection. The purpose of this protocol is to ensure appropriate and timely antiviral therapy for individuals with influenza following diagnostic confirmation via CLIA-waived point-of-care testing.[1]

PHARMACIST EDUCATION AND TRAINING
Prior to initiating influenza testing and dispensing of antiviral therapy under this protocol, pharmacist(s) must have received education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the pharmacy 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 treatment of influenza.[2]

CRITERIA
Pharmacist(s) authorized to initiate the dispensing of antiviral therapy to treat acute influenza infection will treat individuals according to annual guidance from the CDC.[2]

Inclusion criteria:
Any individual who presents to the pharmacy during influenza season, when known influenza viruses are circulating in the community, and meets **ALL** of the following criteria:

- Age 5 years or older (with consent of a parent/guardian if < 18 years old)
- Complaint of **ANY** sign/symptom consistent with influenza (fever, myalgia, headache, malaise, nonproductive cough, sore throat, rhinitis)
- Reported symptom onset < 48 hours before time of presentation
- Positive influenza virus result via CLIA-waived point-of-care RIDT or PCR

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[1] https://www.cdc.gov/flu/professionals/diagnosis/table-nucleic-acid-detection.html
[2] https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm
Influenza Antiviral Medications: Summary for Clinicians | CDC

Exclusion criteria:
Any individual who meets **any** of the following criteria:

- Age < 5 years
- Pregnant or breastfeeding
- Renal dysfunction (based on individual's report or pharmacy records)
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS)
- Long-term aspirin therapy in individuals younger than 19 years of age
- Antiviral agent for influenza prescribed currently or within the previous 2 weeks
- Any condition requiring home oxygen therapy
- Known hypersensitivity to all antiviral therapies for influenza and to any common component of the products.
- Receipt of FluMist within past 2 weeks
- Clinically unstable based on the clinical judgment of the pharmacist for any of the following criteria:
    - Acutely altered mental status
    - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
    - Pulse >125 beats/min
    - Respiratory rate >30 breaths/min
    - Temperature ≥103 °F

All individuals who do not qualify for antiviral therapy dispensing under this protocol will be referred to a primary care provider or urgent/emergent treatment facility if clinically appropriate and in cases of high suspicion of false-negative result.

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

Oral **Oseltamivir** dosing:

- Adults: 75 mg twice a day x 5 days
- Children (current weight determined using pharmacy's scale) x 5 days**:**
    - **≤15 kg:** 30 mg twice a day
    - **>15 to 23 kg**: 45 mg twice a day
    - **>23 to 40 kg**: 60 mg twice a day
    - **> 40 kg**: 75 mg twice a day

Oral **Baloxavir** dosing:

- Adults and children 5 and older:
    - **<20 kg:** 2 mg/kg single dose
    - **≥20 kg to <80 kg:** single dose of 40 mg
    - **≥80 kg:** single dose of 80 mg

Inhaled **Zanamivir** dosing:

- Adults: 10 mg (two 5 mg inhalations) twice a day x 5 days
- Children 7 or older: 10 mg (two 5 mg inhalations) twice a day x 5 days

Adjunctive therapy may be useful for treatment of moderate to severe symptoms or control of high fever associated and should be considered as an adjunct to an appropriate antivirals.

- **Acetaminophen** PO; follow over the counter (OTC) dosing recommendations
- **Ibuprofen** PO; follow over the counter (OTC) dosing recommendations

PROCEDURES FOR INITIATION OF THERAPY

Perform CLIA-waived point-of-care test to determine presence of influenza virus:

- If positive: continue to evaluate with protocol
- If negative: refer patient to urgent care

Antiviral therapy will be initiated only in carefully selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening.

Assess for Relevant Medical and Social History

- Patient demographics and weight if <18 y/o using scale in pharmacy
- Medical history
- Relevant social history
- Current medications
- Allergies and hypersensitivities
- Onset and duration of flu-like symptoms

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, oseltamavir)
- Fructose/sorbitol intolerance (oseltamivir)
- Patients allergic to milk protein (zanamivir)
- Under 12 years of age with underlying medical conditions (baloxavir)

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

Telephone follow-up within 72 hours of dispensing to assess the need for additional medical intervention. Follow-up will assess for clinical stability, symptom burden, and medication adverse effects. Referral to a primary care provider or urgent/emergent treatment facility will occur if any of the following are reported:

- Significant deterioration in condition or new evidence of clinical instability

- Lack of improvement in symptoms or onset of symptoms indicative of serious complications
- Medication adverse effects severe enough to warrant discontinuation

EDUCATION REQUIREMENTS

All individuals tested under this protocol will receive counseling on:

- Influenza vaccination
- Appropriate self-care, including symptom control, hygiene, and infection control measures.
- Per CDC guidelines, people with acute influenza should stay home from work, school, or daycare until they are afebrile for 24 hours

Individuals receiving antiviral therapies under this protocol will also receive the following:

- Medication counseling consistent with state and federal requirements for prescription drug products
- Instructions on signs or symptoms that warrant emergent medical care
- Follow-up details
- Upon request, documentation for work/school absence

DOCUMENTATION

Pharmacist(s) will document via prescription record each person who is tested for influenza under this protocol, including:

- Documentation as required in 201 KAR 2:171 for the dispensing of prescription medication
- Documentation of the presenting signs and symptoms that warranted testing
- Documentation of parental consent for individuals under age 18
- Documentation of the manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used to determine influenza status
- Documentation that the individual (or caregiver) received the education required by this protocol
- Documentation of clinical follow up as appropriate

NOTIFICATION

Pharmacist(s) shall ask all persons tested under this protocol for the name and contact information of a primary care provider. If an individual or parent/guardian identifies a primary care provider, the pharmacist will provide that provider with a summary of the encounter, including at least the individual's name, date of birth, influenza test results, medication dispensed, and follow-up plan, within 2 business days.

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

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.