

**ACUTE INFLUENZA INFECTION: ANTIVIRAL THERAPY PROTOCOL
FOR USE DURING THE COVID-19 (SARS-CoV-2) PANDEMIC v4
Approved 9/30/2020**

***UPDATE* to Protocol Requirements During the COVID-19 (SARS-CoV-2) Pandemic**

Due to the similarities in clinical presentation of influenza and COVID-19 viruses, persons with influenza symptoms must also be tested for SARS-Cov-2. Accordingly, pharmacists using this protocol to test for influenza and initiate the dispensing of antiviral therapy must be able to test for SARS-CoV-2. Pharmacists unable to conduct a rapid SARS-CoV-2 test, or collect a sample for send-off testing, are not authorized to use this or any previously approved versions of the acute influenza infection protocols unless US Department of Health and Human Services or US Centers for Disease Control and Prevention release guidelines that allow for acute influenza testing in the absence of SARS-CoV-2 testing during the COVID-19 Pandemic.

To provide point-of-care COVID-19 testing pharmacists must:

- 1) Meet the requirements established by the Kentucky Board of Pharmacy and in accordance with the Governor's Executive Order to Prevent the spread of COVID-19 in the Commonwealth.
- 2) Follow all criteria and procedures for point-of-care COVID-19 testing as outlined in the current [Kentucky Statewide Physician Protocol for Point of Care COVID-19 Testing](#) (except for reimbursement, unless applicable).
- 3) Comply with all current reporting requirements per the Kentucky Department of Public Health.

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 Rapid Influenza Diagnostic Test (RIDT) or CLIA-waived real-time Polymerase Chain Reaction (PCR) test.

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 (RIDT and/or PCR) 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.¹

Provider of Training: _____

Date of Training: _____

CRITERIA

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

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

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 or 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 taken orally

All individuals who request influenza testing but 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.

¹ <https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm>

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:

- **Adults:** 75 mg twice a day x 5 days
- **Children** (current weight determined using pharmacy's scale) x 5 days:
 - **15 kg or less:** 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 12 and older:**
 - **40 to less than 80kg:** single dose of 40 mg
 - **80 kg or more:** single dose of 80mg

Inhaled Zanamivir dosing:

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

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 as identified through assessment and screening.

Relevant Medical and Social History

- Past medical history
- Current medications
- Allergies and hypersensitivities
- Onset and duration of flu-like symptoms
- Positive RIDT or PCR

Contraindications and Precautions

- Know 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)
- Weight under 40kg (baloxavir)
- Under 7 years of age(zanamavir)
- Under 12 years of age(baloxavir)
- Under five years of age

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

No additional follow-up monitoring or laboratory tests will be required. Pharmacist will follow-up within 36-72 hours for evaluation of therapy, adverse effects, and need for referral for additional medical intervention.

EDUCATION REQUIREMENTS

All individuals tested under this protocol will receive counseling on influenza vaccination and education on appropriate self-care, including symptom control, hygiene, and infection control measures.

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
- Telephone follow-up by a pharmacist within 36 to 72 hours of dispensing to assess the need for additional medical intervention. Follow-up will assess for clinical stability, onset of new symptoms, 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
 - Onset of symptoms inconsistent with influenza or indicative of serious complications from influenza
 - Medication adverse effects severe enough to warrant discontinuation of therapy

Individuals who test negative for influenza via point-of-care testing will be counseled on the risk of a false-negative test result and will be counseled on selfcare or referred to a primary care provider or urgent/emergent treatment facility as clinically appropriate. Referral will be made when the pharmacist has high suspicion of a false-negative result (i.e. when influenza activity in the community is high and person has clear signs and symptoms of influenza infection), determines that the individual is at high risk for complications, or otherwise considers additional care to be in the best interest of the individual.

DOCUMENTATION

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

- Documentation of the presenting signs and symptoms that warranted influenza testing
- Documentation of parental consent for individuals under age 18
- Documentation of the manufacturer, lot, expiration date, and result of the point-of-care RIDT or PCR used to determine influenza status
- Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication
- Documentation that the individual received and expressed understanding of the education required by this protocol

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 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

Pharmacist Name

Date

Pharmacist Signature