

## **ACUTE INFLUENZA INFECTION: ANTIVIRAL THERAPY PROTOCOL v2**

### **Approved 12-12-18**

#### **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).

#### **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 RIDT testing techniques 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.<sup>1</sup>

Provider of Training: \_\_\_\_\_

Date Training Completed: \_\_\_\_\_

#### **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.<sup>1</sup>

##### 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

##### 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)

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

- Long-term aspirin therapy in individuals younger than 19 years of age
- Antiviral agent prescribed currently or within the previous 2 weeks
- Any condition requiring home oxygen therapy
- Known hypersensitivity to oseltamivir or other antiviral therapy or any 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 physician or urgent/emergent treatment facility if clinically appropriate.

## 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

### Contraindications and Precautions

- Know hypersensitivity to oseltamivir, zanamivir or baloxavir
- Underlying respiratory disease or asthma (zanamivir)
- Sever renal dysfunction (est. CrCl < 30 ml/min, oseltamavir)
- Fructose/sorbitol intolerance (oseltamivir)
- Weight under 40kg (baloxavir)
- Under 7 years of age (oseltamavir)
- 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 physician 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 physician 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 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 physician, the pharmacist will provide that physician 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 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

\_\_\_\_\_  
Pharmacist Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Pharmacist Signature