ACUTE INFLUENZA INFECTION
STATEWIDE PROTOCOL
Iowa Board of Pharmacy

I. Purpose

This statewide protocol specifies the criteria and procedures for a pharmacist to initiate CLIA-waived point-of-care testing and, when indicated, 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 a CLIA-waived point-of-care influenza diagnostic test.

II. Authority

Pursuant to Iowa Code section 155A.46, a pharmacist may order and administer point-of-care testing and treatment pursuant to a protocol developed by the Iowa Board of Pharmacy ("board") in consultation with the Department of Public Health to individuals aged six (6) years and older, only in accordance with this protocol. For the purpose of this protocol, the pharmacist's order shall constitute a prescription. For the purpose of this protocol, "pharmacist" shall include a licensed pharmacist or registered pharmacist-intern who has completed the training requirements identified in Section III (Qualification). Pursuant to rule 657—3.21(155A), non-clinical, technical functions may be delegated to a pharmacy technician who has documented training in the function being delegated and who is under the supervision of a pharmacist.

III. Qualification

Prior to initiating influenza testing and dispensing of antiviral therapy under this protocol, a pharmacist shall document successful completion of education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the pharmacist from a provider accredited by the Accreditation Council for Pharmacy Education (ACPE). Individuals who will be involved with patient specimen collection shall have documented hands-on training for specimen collection which includes infection control measures.

Additionally, a pharmacist shall document successful completion of at least one (1) hour of ACPE-approved continuing education related to influenza during the pharmacist's license renewal period during which the pharmacist is engaged in point-of-care testing and treatment for acute influenza.

The pharmacist shall be familiar with the current recommendations for the use of antiviral drugs in the treatment of influenza by the Centers for Disease Control and Prevention (CDC).

IV. Criteria to initiate CLIA-waived diagnostic test

Any individual who meets ALL of the following criteria is eligible for CLIA-waived diagnostic testing:

1. Age six (6) years or older (with consent of a parent/guardian if < 18 years old),
2. Complaint of ANY sign or symptom consistent with influenza (fever, myalgia, headache, malaise, nonproductive cough, sore throat, rhinitis), and
3. Reported symptom onset < 48 hours before time of presentation.

If an individual does not qualify for testing under this protocol, the pharmacist shall refer the individual to a primary care provider or urgent/emergency treatment facility as clinically appropriate.

V. Patient evaluation

A. *Medical history*. The pharmacist shall collect and evaluate the following medical history:
   a. Past medical history
   b. Current clinical comorbidities or disease states, including current mental status
   c. Current blood pressure, pulse, respiratory rate, temperature, and weight
   d. For females of child-bearing potential, pregnancy or breastfeeding status
   e. Current medication use
   f. Allergies and hypersensitivities
   g. Onset and duration of flu-like signs and symptoms

B. *Exclusion criteria*. Upon evaluation of the medical history in paragraph A, the pharmacist shall not dispense antiviral therapy to a patient who meets ANY of the criteria listed herein and shall refer the patient to their primary care provider or other urgent/emergency care facility as clinically appropriate:
   a. Pregnant or breastfeeding,
   b. Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS),
   c. Long-term aspirin therapy in patients < 19 years of age,
   d. Antiviral agent for influenza prescribed currently or within the previous two (2) weeks,
   e. Any condition requiring supplemental oxygen therapy,
   f. Known hypersensitivity to all antiviral therapies for influenza or to any common component of the products,

g. Administration of FluMist or generic equivalent within the previous two (2) weeks,
h. Clinical instability based on the pharmacist's clinical judgment or any of the following conditions:
    i. Acute altered mental status,
    ii. Systolic blood pressure < 90mmHg or diastolic blood pressure < 60mmHg,
    iii. Pulse > 125 beats/minute,
    iv. Respiratory rate > 30 breaths/minute, or
    v. Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 (tympanic) Fahrenheit.

VI. Evaluation of CLIA-waived test result

The pharmacist shall evaluate the result of the test and provide the result to the patient or caregiver.

A. *Negative test result*. In the event that a patient's test produces a negative result for influenza, the pharmacist shall counsel the patient or caregiver on the risk of a false-negative test result and on appropriate self-care (stay home for at least 24 hours after fever subsides, drink plenty of fluids, treat symptoms as needed, and consider influenza immunization) or shall refer the patient to a primary care provider or urgent/emergency treatment facility as clinically appropriate. Such referral shall be made when the pharmacist has a high suspicion of a false-negative result (i.e., when influenza activity in the community is high and the patient has clear signs and symptoms of influenza infection), determines that the patient is at high risk for complications, or otherwise considers additional care to be in the best interest of the patient.
B. *Positive test result*. In the event that a patient's test produces a positive result for influenza, the pharmacist may proceed to consideration for antiviral therapy treatment.

VII. Medications authorized

The pharmacist is authorized to order and dispense the following antiviral agents, unless an identified contraindication applies for the patient, including selection of the product and dosage form deemed appropriate and in the best interest of the patient.

A. Oral oseltamivir (Tamiflu)
    a. Contraindications
        i. Known hypersensitivity to oseltamivir or any component
        ii. Patients six (6) to < 18 years with renal impairment

iii. Patients 18 years and older with CrCl < 10 ml/min

b. Dosing – all doses to be administered x 5 days
   i. Patients 18 years and older: 75 mg twice daily
   ii. Patients six (6) years to < 18: weight-based
      1. 15 kg or less: 30 mg twice daily
      2. > 15 mg to 23 kg: 45 mg twice daily
      3. > 23 kg to 40 kg: 60 mg twice daily
      4. > 40 kg: 75 mg twice daily
   iii. Patients 18 years and older with renal impairment
      1. CrCl > 60 ml/min: no dosage adjustment necessary
      2. CrCl > 30 to 60 ml/min: 30mg twice daily
      3. CrCl > 10 to 30 ml/min: 30mg once daily

B. Oral baloxavir marboxil (Xofluza)
   a. Contraindications
      i. Known hypersensitivity to baloxavir or any component
      ii. Weight < 40 kg
      iii. Age less than 12 years old
   b. Dosing – all doses to be administered as a single dose
      i. Patients aged 12 and older: weight-based
         1. 40 kg to < 80 kg: 40 mg
         2. 80 kg and above: 80 mg
C. Inhaled zanamivir (Relenza Diskhaler)
   a. Contraindications
      i. Known hypersensitivity to zanamivir or any component
      ii. Underlying respiratory disease or asthma
      iii. Age less than seven (7) years old
   b. Dosing – all doses to be administered twice daily x 5 days
      i. Patients aged seven (7) years and older: 10 mg (two 5 mg inhalations)

VIII. Labeling

A prescription label shall be affixed to the antiviral product as required in rule 657—6.10(155A).

IX. Patient education required

The pharmacist shall counsel and educate the patient on influenza vaccination and appropriate self-care, including symptom control, hygiene, and infection control measures. A pharmacist ordering and dispensing antiviral therapy under this protocol shall provide the following:

1. Medication counseling consistent with state and federal requirements for prescription drug products and
2. Instructions on signs and symptoms that warrant emergency medical care.

X. Monitoring and follow-up

No additional follow-up laboratory test(s) shall be required. A pharmacist shall follow up with the patient or caregiver within 36 to 72 hours of dispensing for evaluation of therapy, the need for additional medical intervention, clinical stability, onset of new symptoms, and medication adverse effects. The pharmacist shall refer the patient to a primary care provider or urgent/emergency treatment facility if any of the following are reported:

a. Significant deterioration in condition or new evidence of clinical instability,
b. Onset of symptoms inconsistent with influenza or indicative of serious complications from influenza, or
c. Medication adverse effects severe enough to warrant discontinuation of therapy.

XI. Protocol, facility and equipment

A pharmacist who orders and administers CLIA-waived influenza testing and dispenses antiviral therapies pursuant to this protocol shall maintain a current copy of this protocol and an appropriately private area for patient testing and counseling at each location at which the pharmacist engages in the protocol activities. A pharmacist shall ensure that the following supplies are readily available when engaged in the activities identified in this protocol:

1. Testing equipment and associated supplies
2. Scale
3. Blood pressure cuff (appropriately sized for the patients treated)
4. Thermometer (oral, tympanic, or temporal)

XII. Documentation

The pharmacist shall maintain via patient record or electronic health record the following documentation for each patient who is tested for influenza under this protocol:

1. The presenting signs and symptoms that warranted influenza testing,
2. The parental/guardian consent for patients under the age of 18 years,
3. The patient's medical history collected by the pharmacist,

4. The manufacturer, lot, expiration date, and result of the CLIA-waived test used to determine influenza status,
5. Required elements for the dispensing of prescription medication, if dispensed, pursuant to board rule 657—6.8(155A), and
6. The patient's attestation that they received and expressed understanding of the required counseling and education.

XIII. Notification

A. *Positive test result with medication dispensed*. For patients who were dispensed antiviral therapy in response to a positive test result, the pharmacist shall provide the patient's primary care provider with a summary of the encounter within two (2) business days to include, at a minimum, the following:
    1. The patient's name and date of birth,
    2. Influenza test result,
    3. Medication dispensed, and
    4. Follow-up plan.

B. *Positive test result with no medication dispensed*. For patients who received a positive test result, but who were ineligible for or declined antiviral therapy, the pharmacist shall provide the patient's primary care provider with a summary of the encounter within two (2) business days to include, at a minimum, the following:
    a. The patient's name and date of birth,
    b. Influenza test result, and
    c. Contraindication or reason that antiviral therapy was not dispensed.

C. *Negative test result*. For patients who received a negative test result, the pharmacist may, but is not required to, provide the patient's primary care provider with a summary of the encounter with information as determined by the pharmacist's clinical judgment.

D. *No primary care provider*. In any of the situations in paragraphs A through C, if the patient or caregiver does not identify a primary care provider, the pharmacist shall provide the patient with a written record of the encounter and advise the patient to consult with an appropriate health care professional of the patient's choice.

E. *Iowa Influenza Surveillance Network*. While not currently subject to a mandatory reportable order, a pharmacy may report influenza test result data to the Iowa Influenza Surveillance Network.

XIV. Effective date

This protocol is effective September 1, 2021, and shall be in effect for a period of one year and shall automatically renew for subsequent one year periods unless otherwise amended or terminated by the board.