

**North Carolina Board of Pharmacy and North Carolina Medical Board
Protocol for Testing and Initiation of Therapy for Suspected Influenza Infection
1-23-2026**

Pharmacists who perform assessment and testing for treatment of influenza under this protocol shall:

- Complete an ACPE accredited CLIA-waived point-of-care education and training program.
- Remain up to date with current Centers for Disease Control (CDC) recommendations regarding the use of antiviral medications for the treatment of influenza.
- Ensure that all individuals, under the supervision of the pharmacists (including registered pharmacists' interns and pharmacy technicians) who are involved in patient specimen collection receive documented hands-on training in specimen collection procedures, including appropriate infection control practices.
- Exercise clinical judgment in assessing patients pursuant to this protocol outside of the standard influenza season (approximately October 1 - April 30).

Acute Influenza Infection Antiviral Therapy Protocol	
Eligible Candidates for Influenza POC Testing and Subsequent Treatment (Inclusion Criteria)	<ul style="list-style-type: none"> • Any individual who presents to the pharmacy is eligible for influenza POC testing and subsequent treatment if they meet ALL three of the criteria listed below: <ol style="list-style-type: none"> 1. Age five (5) years or older (with consent of a parent/guardian if < 18 years old) AND 2. Complains of ANY sign or symptom consistent with influenza that began within the past 48 hours (e.g., fever, myalgia, headache, malaise, cough, sore throat), AND 3. Testing is deemed clinically appropriate based on pharmacist's professional judgment and current influenza activity in the community (based on CDC and local public health surveillance data.) • Additionally, any individual who meets ALL the above three criteria and belongs to one or more of the following high-risk groups listed below should be prioritized for influenza testing and subsequent treatment <ul style="list-style-type: none"> - Pregnant or breastfeeding - Adults 50 years and older (especially those ≥ 65 years) - Immunocompromised – Defined as individuals: <ul style="list-style-type: none"> o Receiving active cancer treatment for tumor or cancers of the blood (e.g. leukemia, lymphoma, multiple myeloma) o With a history of solid organ or stem cell transplant receiving immunosuppressive therapy o With primary immunodeficiency (e.g. DiGeorge syndrome, Wiskott-Aldrich syndrome, Bruton disease) o Receiving immunosuppressive drug therapy including corticosteroids for greater than 2 weeks o Diagnosed with sickle cell disease, o Living with HIV/AIDS o With any other conditions which significantly affect immune system function as reported by the individual or determined by the pharmacist - With any condition requiring supplemental oxygen therapy - Under 19 years old and on long-term aspirin therapy - Diagnosed with chronic kidney disease (CKD) NOT currently receiving hemodialysis or peritoneal dialysis - Diagnosed with chronic pulmonary disease (e.g. asthma, COPD or cystic fibrosis) - Diagnosed with cardiovascular disease - Diagnosed with diabetes - Persons of American Indian or Alaska Native descent - People with severe obesity (BMI ≥40)
Ineligible Candidates for Influenza Treatment (Exclusion Criteria)	<ul style="list-style-type: none"> • Any individual who presents to the pharmacy and meets ANY of the following criteria: <ul style="list-style-type: none"> - Under 5 years of age - Complaints of ANY sign or symptom consistent with influenza (e.g., fever, myalgia, headache, malaise, cough, sore throat) for more than 48 hours - Currently taking or has taken an antiviral agent for influenza within the past 4 weeks. - End stage renal disease (ESRD) on hemodialysis or peritoneal dialysis - Clinically unstable based on the clinical judgment of the pharmacist for ANY of the following criteria: <ul style="list-style-type: none"> o Altered mental status o For adults 18 years and older: BP < 90/60 mmHg o For ages 10-17: Systolic blood pressure < 90mmHg o For ages 5-9 years: Systolic blood pressure < 70mmHg + (age in years x 2) o Respiratory rate > 25 breaths/min for adults OR > 20 breaths/min for age <18 years o Oxygen saturation (SpO₂): < 92 via pulse oximetry o Temperature: > 102°F (temporal), > 103 °F (oral), or > 104 °F (tympanic)

	<p><i>NOTE: Meeting exclusion criteria under this protocol only prohibits the pharmacist from initiating antiviral treatment. It does not prohibit pharmacists from conducting point-of-care testing, nor from providing counseling on prevention strategies, symptom management, emergency warning signs, and guidance on when to seek further medical attention. Pharmacists' ability to test and educate, even when treatment is not an option, helps protect both the individual and the broader public.</i></p>		
Assessment of Influenza Treatment	<ul style="list-style-type: none"> Pharmacists shall assess an individual's eligibility for influenza treatment based on the inclusion and exclusion criteria outlined in this protocol. The assessment should be documented using the <i>Pharmacist Assessment, Evaluation, and Prescribing Form</i> for Influenza Treatment provided or an equivalent form incorporating the included elements. All individuals deemed ineligible for treatment should be referred by the pharmacist to their medical provider or to an urgent/emergency care facility, as clinically appropriate 		
Evaluation of CLIA-Waived POC Test Results	<ul style="list-style-type: none"> Pharmacists—or appropriately trained personnel authorized to collect specimens under the pharmacist's supervision—may offer point-of-care testing to determine the individual's influenza status. If the test result is positive, the pharmacist shall: <ul style="list-style-type: none"> Review the test result with the individual and discuss the benefits and harms of antiviral treatment, if clinically appropriate Assess the individual for any contraindications, warnings, or precautions related to available antiviral agents Select the appropriate antiviral medication and dosage form based on clinical assessment If the test result is negative, the pharmacist shall: <ul style="list-style-type: none"> Counsel the individual or caregiver on the possibility of a false-negative result Provide recommendations on appropriate supportive care, including: <ul style="list-style-type: none"> staying home for at least 24 hours after the fever subsides without the use fever-reducing medicine drinking plenty of fluids treating symptoms as needed considering influenza vaccination, if not already immunized Refer the individual to their medical provider or urgent/emergency care facility if, based on clinical judgment, further evaluation is warranted 		
	Antiviral Therapy		
Medication	Oral Oseltamivir (Tamiflu®)	Inhaled Zanamivir (Relenza®)	Oral Baloxavir Marboxil (Xofluza®)
Influenza Treatment (18 years and older)	75mg bid x 5 days Renal Impairment* 30mg bid x 5 days (CrCl > 30-60ml/min) 30mg qd x 5 days (CrCl > 10-30ml/min) <p>*Renal Impairment: Requires a lab value from the past 6 months, obtained from a physician's office, lab, patient EHR, or reported by the patient—if, in the pharmacist's clinical judgment, the patient's report is deemed reliable</p>	1 inhaler – 2 inhalations by mouth bid x 5 days	Weight-based dosing 40kg to <80kg: 40mg (single dose) 80kg or more: 80mg (single dose)
Influenza Treatment (5 to 17 years)	Weight-based dosing 15kg or less: 30mg bid x 5 days >15kg to 23kg: 45mg bid x 5 days >23kg to 40kg: 60mg bid x 5 days >40kg: 75mg bid x 5 days	For 7 Years and Older 1 inhaler – 2 inhalations by mouth bid x 5 days	Weight-based dosing < 20kg: 2mg/kg by suspension (single dose) 20kg to < 80kg: 40mg (single dose) 40kg to <80kg: 40mg (single dose) 80kg or more: 80mg (single dose)
Refills	No Refills		
Antiviral Contraindications Warnings & Precautions	Oral Oseltamivir (Tamiflu®)	Inhaled Zanamivir (Relenza®)	Oral Baloxavir Marboxil (Xofluza®)
	DO NOT USE Oseltamivir In: <ul style="list-style-type: none"> Individuals with known hypersensitivity to Oseltamivir or any of its ingredients Individuals under 18 years with renal impairment Individuals 18 years or older with CrCl <10ml/min 	DO NOT USE Zanamivir In: <ul style="list-style-type: none"> Individuals with a known hypersensitivity to Zanamivir or any of its ingredients Individuals with underlying respiratory disease, including asthma or COPD or cystic fibrosis Individuals under 7 years for treatment Individuals with known allergies to lactose or milk proteins 	DO NOT USE Baloxavir In <ul style="list-style-type: none"> Individuals with a known hypersensitivity to Baloxavir or any of its ingredients Individuals under 5 years for treatment

Patient Counseling	<ul style="list-style-type: none"> • The pharmacist shall provide appropriate counseling to all individuals receiving services under this protocol, whether they are assessed, tested, or treated, including but not limited to the following topics: <ul style="list-style-type: none"> - Influenza vaccination - The benefits and harms of antiviral therapy for influenza, if clinically appropriate - The need for referral to a medical provider, urgent/emergent care facility, if clinically appropriate - Appropriate self-care, including symptom control, hygiene and infection control measures - CDC guidelines that an individual with a confirmed diagnosis of influenza should stay home from work, school, or daycare until they are afebrile ($\leq 100^{\circ}\text{F}$) for at least 24 hours without the use of a fever-reducing medication and at least 24 hours after starting antiviral therapy. For individuals without fever, the CDC recommends staying out of work or school for at least 5 days from symptom onset. - Medication counseling - Signs and symptoms that warrant emergency medical care
Notification of Medical Provider	<ul style="list-style-type: none"> ▪ Pharmacists shall ask ALL individuals assessed under this protocol to provide the name and contact information of their medical provider. ▪ If an individual (or parent/guardian) identifies a medical provider: <ul style="list-style-type: none"> - For positive test results where medication is dispensed, the pharmacist shall provide the individual's medical provider a summary of the encounter within 72 hours. - At a minimum, the summary should include the individual's name & date of birth, influenza test result and medication dispensed. - For positive test results where no medication is dispensed, the pharmacist shall provide the individual's medical provider with a summary of the encounter within 72 hours - At a minimum, the summary must include the individuals' name and date of birth, Influenza test result and reason antiviral therapy was not dispensed (e.g., ineligibility, therapy contraindication or individual declined treatment) ▪ If an individual (or parent/guardian) does NOT identify a medical provider: <ul style="list-style-type: none"> - The pharmacist shall counsel on the benefits of establishing care with a medical provider, AND - Provide information on accessible care options, such as private practices, federally qualified health centers (FQHCs), free clinics, and local health departments serving the patient's area.
Documentation	<ul style="list-style-type: none"> ▪ The pharmacist shall document the encounter for any individual who is assessed, tested, or treated under this protocol. Documentation must include the following elements, as applicable: <ul style="list-style-type: none"> - Documentation of parental or guardian consent for patients under 18 years of age - Attestation by the individual or parent/guardian confirming receipt and understanding of the counseling and educational materials provided - A description of the presenting signs and symptoms that prompted clinical assessment. - Relevant medical history collected by the pharmacist during the patient assessment. - The outcomes of POC testing, if performed - The manufacturer, lot, expiration date, and result of the CLIA-waived test used to determine influenza status. - The treatment provided, if the individual met the eligibility criteria, or documentation of why treatment was not initiated (i.e. ineligible, therapy contraindication, declined treatment, etc.)
Records Retention:	<ul style="list-style-type: none"> ▪ Records for antivirals dispensed, delivered or administered pursuant to this protocol shall be maintained in accordance with applicable state and federal law.