COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor **(804) 367-4456 (Tel)**
Henrico, Virginia 23233 **(804) 527-4472(Fax)**

Tentative Agenda of Statewide Protocol Work Group Meeting
August 11, 2023
9AM

TOPIC	**PAGES**

Call to Order: Dale St. Clair, PharmD, Chairman
- Welcome & Introductions

Call for Public Comment: The work group will receive public comment at this time. The work group will not receive comment on any Board regulation process for which a public comment period has closed or any pending disciplinary matters.

Agenda Items:

• List of work group members	**2**
• Review SB948 and HB 2274	**3-6**
• Recommend statewide protocols for Board of Pharmacy review and implementation for pharmacists to initiate treatment with controlled substances or devices for the initiation of treatment of the following diseases or conditions for which clinical decision making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988:	
○ Group A Streptococcus bacteria infection,	**7-37**
○ Influenza virus infection,	**38-65**
○ COVID-19 virus infection,	**66-67**
○ Urinary tract infection	**68-84**

Adjourn

****The work group will have a working lunch at approximately 12pm.****

2023 Statewide Protocol Work Group Members

- R. Dale St. Clair, Jr., PharmD, Board of Pharmacy, Chairman
- Kristopher S. Ratliff, DPh, Board of Pharmacy, Member
- Ling Yuan, PharmD, Board of Pharmacy, Member
- L. Blanton Marchese, Board of Medicine, Member
- William T. Hutchens, MD, Board of Medicine, Member
- Krishna P. Madiraju, MD, Board of Medicine, Member
- Shaina Bernard, PharmD, Virginia Department of Health, Antibiotic Resistance Coordinator

CHAPTER 172

An Act to amend and reenact § 54.1-3303.1 of the Code of Virginia, relating to pharmacist scope of practice; initiation of treatment for certain diseases and conditions.

[S 948]

Approved March 22, 2023

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3303.1 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3303.1. Initiating of treatment with and dispensing and administering of controlled substances by pharmacists.

A. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs, devices, controlled paraphernalia, and other supplies and equipment to persons 18 years of age or older with whom the pharmacist has a bona fide pharmacist-patient relationship and in accordance with a statewide protocol developed by the Board in collaboration with the Board of Medicine and the Department of Health and set forth in regulations of the Board:

1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist;

2. Epinephrine;

3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;

4. Prenatal vitamins for which a prescription is required;

5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services;

6. Drugs as defined in § 54.1-3401, devices as defined in § 54.1-3401, controlled paraphernalia as defined in § 54.1-3466, and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment;

7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19;

8. Tuberculin purified protein derivative for tuberculosis testing;

9. Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention;

10. Nicotine replacement and other tobacco cessation therapies, including controlled substances as defined in the Drug Control Act (§ 54.1-3400 et seq.), together with providing appropriate patient counseling; ~~and~~

11. *Controlled substances or devices for the initiation of treatment of the following diseases or conditions for which clinical decision making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988: group A Streptococcus bacteria infection, influenza virus infection, COVID-19 virus infection, and urinary tract infection; and*

12. Tests for COVID-19 and other coronaviruses.

B. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons three years of age or older in accordance with a statewide protocol as set forth in regulations of the Board:

1. (Contingent Effective Date) Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and

2. (Contingent Effective Date) Tests for COVID-19 and other coronaviruses.

C. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. No pharmacist shall limit the ability of notification to be sent to the patient's primary care provider by requiring use of electronic mail that is secure or compliant with the federal Health Insurance Portability and Accountability Act (42 U.S.C. § 1320d et seq.). If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If

the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

D. A pharmacist who administers a vaccination pursuant to subdivisions A 7 and B 1 shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

E. A pharmacist who initiates treatment with, dispenses, or administers drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section shall obtain a history from the patient, including questioning the patient for any known allergies, adverse reactions, contraindications, or health diagnoses or conditions that would be adverse to the initiation of treatment, dispensing, or administration.

F. A pharmacist may initiate treatment with, dispense, or administer drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section through telemedicine services, as defined in § 38.2-3418.16, in compliance with all requirements of § 54.1-3303 and consistent with the applicable standard of care.

G. A pharmacist who administers a vaccination to a minor pursuant to subdivision B 1 shall provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.

2. That the Board of Pharmacy shall adopt a statewide protocol for the initiation of treatment with and dispensing and administering of drugs and devices by pharmacists in accordance with § 54.1-3303.1 of the Code of Virginia, as amended by this act, by November 1, 2023. Such protocol shall be developed by a work group consisting of representatives from the Board of Pharmacy, the Board of Medicine, and the Department of Health. The work group shall have an equal number of members who are representatives of the Board of Pharmacy and the Board of Medicine.

3. That the Board of Pharmacy shall promulgate regulations to implement the provisions of the first enactment of this act to be effective within 280 days of its enactment. Such regulations shall include provisions for ensuring that physical settings in which treatment is provided pursuant to this act shall be in compliance with the federal Health Insurance Portability and Accountability Act, 42 U.S.C. § 1302d et seq., as amended.

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

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[H 2274]

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provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

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Agenda Topic: Recommend statewide protocols for Group A Streptococcus (GAS) bacteria infection for patients 18 and over

Included in Agenda Packet:

- Arkansas Statewide Protocol
- Iowa Statewide Protocol
- Kansas Protocol

Action Needed:

- Motion to recommend that the Board of Pharmacy adopt a Group A Streptococcus Bacteria statewide protocol for patients 18yyears of age and older that models one of the protocols included in the agenda packet or includes specific elements of the various protocols as presented or amended.

Group A Streptococcal Pharyngitis Treatment Protocol

I. Purpose

The purpose of this standing order is to reduce morbidity and mortality in Arkansas by allowing Arkansas-licensed pharmacists to initiate therapy including ordering and/or dispensing treatment medications, along with any necessary supplies for administration, to eligible persons who are GAS pharyngitis positive.

II. Authority

This standing order is issued pursuant to Act 503 of 2021 (HB 1246) (Arkansas Code § 17-92-101) to authorize licensed pharmacists in Arkansas to order and/or dispense GAS treatment medications according to the provisions of Arkansas Code § 17-92-101 and the requirements of this standing order.

III. Screening and Assessment

The Board of Pharmacy will adopt screening assessment and questionnaire (Appendix A) to be used by pharmacists throughout the state. When a patient requests point-of-care testing services, or when a pharmacist, in his or her professional judgement, decides to initiate point-of-care testing and treatment, the patient will be assessed for presenting signs and symptoms that warrant GAS testing, parental consent for individuals under the age of 18, and if appropriate, administer a rapid GAS point-of-care test.

IV. Dispensing Guidelines

A. Eligibility Criteria

Inclusion:

- Age 3 years and older
- Centor Score ≥ 2
- Positive GAS result via CLIA-waived point-of-care RADT

Exclusion:

- Immunocompromised as defined
    - Been receiving active cancer treatment for tumors or cancers of the blood
    - Received an organ transplant and are taking medicine to suppress the immune system
    - Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
    - Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
    - Advanced or untreated HIV infection

    - Active treatment with high-dose corticosteroids (20mg prednisone daily for >2 weeks) or other drugs that may suppress your immune response
- Pregnant
- Antibiotic therapy prescribed for sore throat or upper respiratory infection with in previous 30 days
- Clinically unstable based on the clinical judgement of the pharmacist or any of the following criteria:
    - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
        - For age 3-9 years: Systolic blood pressure <70 + (age in years × 2)
    - Tachypnea (>25 breaths/min adult or >20 breaths/min <18 y/o)
    - Oxygen saturation (SpO_2) <90% via pulse oximetry

B. Contraindications

Do not administer amoxicillin to an individual with a known hypersensitivity to penicillin or any component of the formulation

Do not administer cephalexin to an individual with a known hypersensitivity to cephalexin, other cephalosporins, or any component of the formulation

Do not administer azithromycin to an individual with a known hypersensitivity to azithromycin, erythromycin, other macrolide (e.g., azalide or ketolide) antibiotics, or any component of the formulation.

Do not administer azithromycin to an individual with a history of cholestatic jaundice/hepatic dysfunction associated with prior azithromycin use

C. Product Availability

Streptococcal pharyngitis treatment products that may be dispensed/provided under this standing order. Following dosing below, pharmacist can dispense any commercially available product form (tablet, capsule, suspension) based on availability and patient preference.

1st line Treatment

- Amoxicillin
    - Adults: 1000mg by mouth once daily for 10 days
    - Children <20kg: 50mg/kg by mouth once daily for 10 days
- Penicillin V, oral
    - Adults: 500mg twice daily for 10 days
    - Children: 250 mg twice daily for 10 days

2nd Line Treatment or PCN allergy alternative

- Cephalexin
    - Adults: 500 mg by mouth twice daily for 10 days
    - Children <25kg: 20mg/kg/dose twice daily for 10 days

3rd Line Treatment if PCN allergy or equivalent exclusions to first or second line treatment options

- Azithromycin 500 mg by mouth Day 1 and 250 mg by mouth Days 2-5
- Children <40kg: Azithromycin 12mg/kg per day for 5 days

Over-the-Counter Adjunctive Treatment

- Recommend adjunctive treatment as needed for symptom relief and use of weight-based dosing for children.
    - Acetaminophen 650 mg Q4-6H PRN (MAX 3250 mg/day)
    - Ibuprofen 200 mg Q4-6H PRN X10D for pain or X3D for fever
      Can titrate to 400 mg if needed (MAX 1200 mg/day)

D. Warnings/Precautions

1. Amoxicillin
    - *Concerns related to adverse effects:*
        - Anaphylactic/hypersensitivity reactions: Serious and occasionally severe or fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy, including amoxicillin, especially with a history of beta-lactam hypersensitivity (including severe reactions with cephalosporins) and/or a history of sensitivity to multiple allergens.
        - Superinfection: Prolonged use may result in fungal or bacterial superinfection, including *C. difficile*-associated diarrhea (CDAD) and pseudomembranous colitis; CDAD has been observed >2 months post antibiotic treatment.
    - *Disease-related concerns:*
        - Infectious mononucleosis: A high percentage of patients with infectious mononucleosis develop an erythematous rash during amoxicillin therapy; avoid use in these patients.
        - Renal impairment: Use with caution in patients with renal impairment; dosage adjustment recommended in patients with GFR <30 mL/minute. Avoid extended release 775 mg tablet and immediate release 875 mg tablet in patients with GFR <30 mL/minute or patients requiring hemodialysis.
    - *Dosage form specific issues:*
        - Benzyl alcohol and derivatives: Some dosage forms may contain sodium benzoate/benzoic acid; benzoic acid (benzoate) is a metabolite of benzyl

alcohol; large amounts of benzyl alcohol (≥99 mg/kg/day) have been associated with a potentially fatal toxicity ("gasping syndrome") in neonates; the "gasping syndrome" consists of metabolic acidosis, respiratory distress, gasping respirations, CNS dysfunction (including convulsions, intracranial hemorrhage), hypotension, and cardiovascular collapse (AAP ["Inactive" 1997]; CDC 1982); some data suggests that benzoate displaces bilirubin from protein binding sites (Ahlfors 2001); avoid or use dosage forms containing benzyl alcohol derivative with caution in neonates. See manufacturer's labeling.

- Chewable tablets: May contain phenylalanine; see manufacturer's labeling.

2. Penicillin V
   - *Concerns related to adverse effects:*
     - Anaphylactic/hypersensitivity reactions: Serious and occasionally severe or fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy, especially with a history of beta-lactam hypersensitivity or history of sensitivity to multiple allergens.). Use with caution in asthmatic patients. If a serious reaction occurs, treatment with supportive care measures and airway protection should be instituted immediately.
     - Superinfection: Prolonged use may result in fungal or bacterial superinfection, including C. difficile-associated diarrhea (CDAD) and pseudomembranous colitis; CDAD has been observed >2 months postantibiotic treatment.
   - *Disease-related concerns:*
     - Renal impairment: Use with caution in patients with severe renal impairment.
     - Seizure disorders: Use with caution in patients with a history of seizure disorder; high levels, particularly in the presence of renal impairment, may increase risk of seizures.
   - *Other warnings/precautions*
     - Prolonged use: Extended duration of therapy or use associated with high serum concentrations (eg, in renal insufficiency) may be associated with an increased risk for some adverse reactions (neutropenia, hemolytic anemia, serum sickness).
3. Cephalexin
   - *Concerns related to adverse effects:*
     - Hypersensitivity: Allergic reactions (e.g., rash, urticaria, angioedema, anaphylaxis, erythema multiforme, Stevens-Johnson syndrome, toxic

epidermal necrolysis [TEN]) have been reported. If an allergic reaction occurs, discontinue immediately and institute appropriate treatment.

- Elevated INR: May be associated with increased INR, especially in nutritionally deficient patients, prolonged treatment, hepatic, or renal disease.
- Penicillin allergy: Use with caution in patients with a history of penicillin allergy, especially IgE-mediated reactions (e.g., anaphylaxis, angioedema, urticaria).
- Seizure disorder: Use with caution in patients with a history of seizure disorder; high levels, particularly in the presence of renal impairment, may increase risk of seizures.
- Superinfection: Prolonged use may result in fungal or bacterial superinfection, including *C. difficile*-associated diarrhea (CDAD) and pseudomembranous colitis; CDAD has been observed >2 months post antibiotic treatment.

- *Disease-related concerns:*
  - Renal impairment: Use with caution in patients with renal impairment; modify dosage in severe impairment.
- *Other warnings/precautions:*
  - Direct Coombs tests: Positive direct Coombs tests and acute intravascular hemolysis has been reported. If anemia develops during or after therapy, discontinue use and work up for drug-induced hemolytic anemia.

4. Azithromycin
   - *Concerns related to adverse effects:*
     - Superinfection: Prolonged use may result in fungal superinfection.
   - *Disease-related concerns:*
     - Bronchiolitis obliterans: When studied to prevent bronchiolitis obliterans syndrome in patients with hematologic malignancy who underwent allogeneic hematopoietic cell transplantation, rates of cancer relapse and mortality were increased among patients receiving long-term azithromycin, leading to early trial termination (Bergeron 2017; FDA Drug Safety Communication 2018).
     - Gonorrhea/syphilis: May mask or delay symptoms of incubating gonorrhea or syphilis, so appropriate culture and susceptibility tests should be performed prior to initiating a treatment regimen.
     - Myasthenia gravis: Use with caution in patients with myasthenia gravis; exacerbation and new onset of symptoms have occurred.

- *Special populations:*
    - Infants: Use of azithromycin in neonates and infants <6 weeks of age has been associated with infantile hypertrophic pyloric stenosis (IHPS); the strongest association occurred with exposure during the first 2 weeks of life; observe for nonbilious vomiting or irritability with feeding (Eberly 2015). The risks and benefits of azithromycin use should be carefully considered in neonates; some experts recommend avoidance except for in the treatment of pertussis or *C. trachomatis* pneumonia; specific risk-benefit ratio should be considered before use for *Ureaplasma* spp. eradication (Meyers 2020).
- *Dosage form specific issues:*
    - Oral suspensions: Immediate release and extended-release suspensions are not interchangeable.

E. Documentation

Patient records must be furnished to a health care practitioner designated by the patient upon the request of the patient. Documentation may include, but is not limited to presenting signs and symptoms that warrant strep testing, parental consent for individuals under the age of 18, and results of rapid diagnostic test(s). Maintain records of all patients receiving services for two (2) years.

APPENDIX A.

Pharmacist Assessment, Evaluation and Prescribing Protocol Form: *Strep Throat*

PATIENT INFORMATION		
Name:	Date of Birth:	Age:
Address:	City/State/Zip:	
Email Address:	Phone:	
Primary Care Provider:		
Medication allergies?		
Current medications? (prescription, over-the-counter, herbals, topical medications, pain or allergy medication, and any supplements/vitamins)		
Treatments tried for the current condition (if none please indicate N/A):		

PATIENT ELIGIBILITY		
1. Are you 3 years of age and older?	❑ Yes	❑ No
2. Have you received antibiotics for sore throat or upper respiratory infection within the past 30 days?	❑ Yes	❑ No
3. Are you pregnant?	❑ Yes	❑ No
4. Have you ever been diagnosed with a weakened immune system? (e.g. cancer, transplant, or long term steroids)	❑ Yes* *Pharmacists refer to page 2, #4 for criteria	❑ No

When complete, please return the form to pharmacy staff along with insurance information

-- FOR PHARMACY STAFF ONLY--

Physical Assessment	**REFER TO PCP** if determined clinically unstable or any of the following criteria
❑ Blood pressure:_____ ❑ RR:_____ ❑ %Oxygen:_____ ❑ Temperature:_____	❑ Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg ❑ For age 3-9 years: Systolic blood pressure <70 + (age in years × 2) ❑ Tachypnea >25 breaths/min adult or >20 breaths/min <18 y/o ❑ Low oxygen <90% oxygen via pulse oximetry

Centor Score Assessment		**Interpretation**
Age	❑ 3-14 years: +1 ❑ 15-44: 0 ❑ ≥ 45 year: -1	Total Points: _____ ❑ If Score ≥ 2, proceed in using protocol ❑ If Score < 2, excluded from protocol
Exudate or swelling on tonsils	❑ No: 0 ❑ Yes: +1	
Tender/swollen anterior cervical lymph nodes	❑ No: 0 ❑ Yes: +1	
Temperature > 100.4°F	❑ No: 0 ❑ Yes: +1	
Cough	❑ Present: 0 ❑ Absent: +1	
CLIA-waived POCT Result		❑ Positive for GAS – continue ❑ Negative for GAS – refer to PCP + Symptomatic Treatment

Pharmacist Interpretation of qualifying questions and physical assessment; refer to PCP as appropriate. Exclusion criteria does not preclude from testing services. **Refer to PCP for treatment if:**

1. If younger than 3 years old **REFER TO PCP**
2. If patient has taken antibiotics for sore throat or URI in the last 30 days **REFER TO PCP**
3. If patient is pregnant **REFER TO PCP**
4. If patient is immunocompromised **REFER TO PCP**
    a. Been receiving active cancer treatment for tumors or cancers of the blood
    b. Received an organ transplant and are taking medicine to suppress the immune system
    c. Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
    d. Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
    e. Advanced or untreated HIV infection
    f. Active treatment with high-dose corticosteroids (20mg prednisone daily for >2 weeks) or other drugs that may suppress your immune response
5. CLIA-waived POCT result is negative for GAS **REFER TO PCP**

Treat using protocol if:

1. Age 3 years and older
2. Centor Score ≥ 2
3. Positive GAS result via CLIA-waived point-of-care RADT

Diagnosis of Patient:		
❑ Strep ADULT ≥18 year	❑ Strep CHILD/ADOLESCENT	❑ Refer to PCP

*the following can act as the prescription

Treatment Options		
Streptococcal pharyngitis ADULT >18		
Strep first line treatment options:		
❑ Amoxicillin	Dispense: ❑ 500mg #20 ❑ 1000mg #10 No refills	Sig: 500mg by mouth twice daily for 10 days OR Sig: 1000mg by mouth daily for 10 days
❑ Penicillin VK	Dispense: ❑ 500mg #20 No refills	Sig: 500mg by mouth twice daily for 10 days
2nd Line Treatment or Penicillin allergy alternative		
❑ Cephalexin	Dispense ❑ 500mg #20 No refills	Sig: 500mg by mouth BID for 10 days
3rd Line Treatment for Penicillin allergy or equivalent		
❑ Azithromycin	Dispense ❑ 250mg #6 No refills	Sig: (500mg) by mouth on day 1, then (250 mg) po days 2-5
Symptomatic treatments (over the counter)		
❑ Acetaminophen regular strength (325mg) → 650 mg q4-6hr prn (MAX 3250 mg/day) ❑ Ibuprofen → 200mg q4-6h prn (400mg if no response to 200mg) (MAX 1200mg/day x10 days for pain or x 3 days for fever) ❑ Lozenges/drops containing menthol, dyclonine, benzocaine, or hexylresorcinol ❑ Throat spray containing phenol or benzocaine ❑ Hot/cold liquids or foods→ cold food provide hydration and numbing, hot foods feel good on sore throat. SOFT FOODS preferable to rough or hard foods ❑ Tea/honey → coats throat to provide relief of pain and irritation.		

Patient:_____ DOB:_____

Prescribed by:_____

Signature:_____Date:_____

*the following can act as the prescription

Treatment Options		
Streptococcal pharyngitis CHILDREN AND ADOLESCENTS age 3-17 **Patient weight in kg:_____**		
First line treatment option		
❑ Amoxicillin	Dispense: ❑ _____mg (50mg/kg) #10 doses No refills	***MAX daily dose 1,000mg/day*** Sig: 50mg/kg by mouth Daily x10 days
❑ Penicillin VK	Dispense ❑ 250mg #20 doses No refills	Sig: 250mg by mouth twice daily for 10 days
2nd Line Treatment or Penicillin allergy alternative		
❑ Cephalexin	Dispense ❑ _____mg (20mg/kg) #20 doses No refills	***MAX 500mg per dose*** Sig: 20mg/kg/dose by mouth twice daily for 10 days
3rd Line Treatment		
❑ Azithromycin	Dispense ❑ _____mg (12mg/kg) #5 doses No refills	***MAX 500mg per dose*** Sig: 12mg/kg/dose by mouth daily for 5 days
Symptomatic treatments (over the counter)		
❑ Acetaminophen regular strength (325mg) → 325 mg q4-6hr prn (MAX 1,625 mg/day) OR _____mg q4-6h prn 10-15 mg/kg/dose MAX 75 mg/kg/day not to exceed 4,000 mg/day ❑ Ibuprofen → for pain _____ mg q6-8hr if <50kg 4-10 mg/kg/dose (MAX single dose 400mg MAX daily 40mg/kg/day) For fever: _____mg q6-8h (MAX daily dose is 40mg/kg/day up to 1,200mg. MAX single dose 400mg) ❑ Lozenges/drops containing menthol, dyclonine, benzocaine, or hexylresorcinol ❑ Throat spray containing phenol or benzocaine ❑ Hot/cold liquids or foods→ cold food provide hydration and numbing, hot foods feel good on sore throat. SOFT FOODS preferable to rough or hard foods ❑ Tea/honey → coats throat to provide relief of pain and irritation		

Patient:_____ DOB:_____

Prescribed by:_____

Signature:_____Date:_____

References:

1. Infectious Diseases Society of America. Influenza Guidelines. http://www.idsociety.org
2. LexiComp. Wolters Kluwer Clinical Drug Information. http://online.lexi.com

Pediatric Vital Signs Reference Chart

Heart Rate (beats/min)		
Age	**Awake**	**Asleep**
Neonate (<28 d)	100-205	90-160
Infant (1-12 mos)	100-190	
Toddler (1-2 y)	98-140	80-120
Preschool (3-5 y)	80-120	65-100
School-age (6-11 y)	75-118	58-90
Adolescent (12-15 y)	60-100	50-90

Respiratory Rate (breaths/min)	
Age	**Normal**
Infant (<1 y)	30-53
Toddler (1-2 y)	22-37
Preschool (3-5 y)	20-28
School-age (6-11 y)	18-25
Adolescent (12-15 y)	12-20

Reference: PALS Guidelines, 2015

Blood Pressure (mmHg)

Age		Systolic	Diastolic	Systolic Hypotension
Birth (12 h)	<1 kg	39-59	16-36	<40-50
	3 kg	60-76	31-45	<50
Neonate (96 h)		67-84	35-53	<60
Infant (1-12 mos)		72-104	37-56	<70
Toddler (1-2 y)		86-106	42-63	<70 + (age in years × 2)
Preschool (3-5 y)		89-112	46-72	
School-age (6-9 y)		97-115	57-76	
Preadolescent (10-11 y)		102-120	61-80	<90
Adolescent (12-15 y)		110-131	64-83	

Reference: PALS Guidelines, 2015
For diagnosis of hypertension, refer to the 2017 AAP guidelines Table 4 & 5:
http://pediatrics.aappublications.org/content/early/2017/08/21/peds.2017-1904

Temperature (°C)

Method	Normal
Rectal	36.6-38.0
Tympanic	35.8-38.0
Oral	35.5-37.5
Axillary	36.5-37.5

Ranges do not vary with age.
Screening: axillary, temporal, tympanic (↓ accuracy)
Definitive: rectal & oral (↑ reflection of core temp.)
Reference: CPS Position Statement on Temperature Measurement in Pediatrics (2015)

Oxygen Saturation (SpO_2)

SpO_2 is lower in the immediate newborn period. Beyond this period, a SpO_2 of **<90-92%** may suggest a **respiratory condition** or **cyanotic heart disease**.

Dr. Chris Novak & Dr. Peter Gill for www.pedscases.com
(Edited March 2020 by Richard He)

ACUTE GROUP A STREPTOCOCCAL (GAS) PHARYNGITIS 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 antibiotic therapies to treat acute Group A streptococcal (GAS) pharyngitis infection. The purpose of this protocol is to ensure appropriate and timely antibiotic therapy for individuals with GAS pharyngitis following diagnostic confirmation via a CLIA-waived point-of-care 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 GAS pharyngitis testing and dispensing of antibiotic therapy under this protocol, all individuals who will be involved in testing shall document successful completion of education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the pharmacy.

Individuals who will be involved with patient specimen collection shall have documented hands-on training for specimen collection which includes infection control measures. Required training shall be successfully completed via a program accredited by the Accreditation Council for Pharmacy Education (ACPE) or pre-approved by the Board. A registered nurse who is licensed pursuant to Iowa Code 152 or 152E is deemed to have met the training requirement for patient specimen collection.

Additionally, a pharmacist shall document successful completion of at least one (1) hour of ACPE-approved continuing education related to streptococcal infection during the

pharmacist's license renewal period during which the pharmacist is engaged in point-of-care testing and treatment for GAS pharyngitis.

The pharmacist shall be familiar with the current Clinical Practice Guideline for the Diagnosis and Management of Group A Streptococcal Pharyngitis by the Infectious Disease Society of America (IDSA).

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 parent/guardian if < 18 years old), and
2. Complaint of ANY sign or symptom consistent with GAS pharyngitis (sore throat, pain on swallowing, fever, headache, swollen or tender cervical lymph nodes, inflamed or swollen tonsils or uvula).

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 and social history*. The pharmacist shall collect and evaluate the following medical and social 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. Relevant social history,
   e. For females of child-bearing potential, pregnancy or breastfeeding status
   f. Current medication use, and
   g. Allergies and hypersensitivities (pharmacist shall assess reported allergies for validity by reviewing the patient's pharmacy record, if applicable, and documenting the reported reaction).

B. *Exclusion criteria*. Upon evaluation of the medical and social history in paragraph A, the pharmacist shall not dispense antibiotic 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 treatment 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. History of rheumatic fever, rheumatic heart disease, scarlet fever, or GAS-induced glomerulonephritis,
d. Antibiotic therapy prescribed for sore throat or upper respiratory infection within the previous 30 days,
e. Clinical instability based on the pharmacist's clinical judgment or any of the following conditions:
    i. Acute altered mental status,
    ii. Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg,
    iii. Pulse > 125 beats/minute,
    iv. Respiratory rate > 30 breaths/minute, or
    v. Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit, or
f. Presenting with overt viral features (rhinorrhea, cough, oral ulcers, and/or hoarseness).

Patients who do not qualify for antibiotic therapy in response to testing under this protocol shall be referred to a primary care or urgent/emergency treatment facility as clinically appropriate for additional evaluation when the pharmacist has a high suspicion of a false-negative result, determines that the patient is at high risk for complications, or otherwise considers additional care to be in the best interest of the patient.

VI. Evaluation of CLIA-waived Rapid Antigen Detection Test (RADT) result

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

A. *Negative test result.*
    a. For patients aged 18 years and older, no back-up throat culture is needed. The pharmacist shall counsel the patient or caregiver on the risk of a false-negative test result and on appropriate self-care (get plenty of rest, drink plenty of fluids, treat symptoms as needed, etc.) 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, 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. For patients aged six (6) to <18 years, back-up throat culture is required and the patient shall be referred to a primary care provider or urgent/emergency treatment facility as clinically appropriate.

B. *Positive test result*. The pharmacist may proceed to consideration for antibiotic therapy treatment.

VII. Medications authorized

The pharmacist is authorized to order and dispense the following antibiotic 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. If the pharmacist has a recent patient creatinine level and current weight, the pharmacist may adjust the medication dose per the manufacturer package insert for patients with CrCl < 30.

A. First-line treatment
    a. Amoxicillin
        i. Contraindication
            1. Penicillin allergy
        ii. Dosing
            1. 25 mg/kg (max 500 mg) PO twice daily x 10 days, or
            2. 50 mg/kg (max 1,000 mg) PO once daily x 10 days
B. Second-line treatment (for patients with mild allergic reactions, e.g. rash, to penicillin)
    a. Cephalexin
        i. Contraindications
            1. Cephalosporin allergy
            2. Severe penicillin allergy
        ii. Dosing
            1. 20 mg/kg/dose (max 500 mg/dose) PO twice daily x 10 days
C. Third-line treatment (for patients with mild allergic reactions, e.g. rash, to penicillin or cephalosporins or severe reactions, e.g. anaphylaxis, to penicillin)
    a. Azithromycin
        i. Contraindication
            1. Macrolide allergy
        ii. Dosing
            1. 12 mg/kg (max 500 mg) PO once daily x 5 days
    b. Clindamycin
        i. Contraindication
            1. Clindamycin allergy
        ii. Dosing

1. 7 mg/kg/dose (max 300 mg/dose) PO three times daily x 10 days

c. Clarithromycin
   i. Contraindication
      1. Macrolide allergy
   ii. Dosing
      1. 7.5 mg/kg/dose (max 250 mg/dose) PO twice daily x 10 days

D. The pharmacist may recommend the following adjunctive therapy for treatment of moderate to severe symptoms or control of high fever associated with acute GAS pharyngitis, unless contraindicated:
   a. Acetaminophen PO according to OTC dosing recommendations, and
   b. Ibuprofen PO according to OTC dosing recommendations.

VIII. Labeling

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

IX. Patient education required

The pharmacist shall counsel and educate the patient on appropriate self-care, including symptom control, hygiene, and infection control measures, and IDSA guidelines which recommend the patient stay home from work, school, or daycare until they are afebrile and until 24 hours after initiation of appropriate antibiotic therapy. A pharmacist ordering and dispensing antibiotic 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 24 to 48 hours of dispensing for evaluation of therapy, the need for additional medical intervention, clinical stability, symptom burden, 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. Lack of improvement in symptoms or onset of symptoms indicative of serious complications, or
c. Medication adverse effects severe enough to warrant discontinuation of therapy.

XI. Protocol, facility and equipment

A pharmacist who orders and administers GAS pharyngitis CLIA-waived diagnostic testing and dispenses antibiotic 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 GAS pharyngitis under this protocol:

1. The presenting signs and symptoms that warranted GAS pharyngitis testing,
2. The parental/guardian consent for patients under the age of 18 years,
3. The patient's medical and social history collected by the pharmacist,
4. The manufacturer, lot, expiration date, and result of the test used to determine GAS pharyngitis status,
5. Required elements for the dispensing of prescription medication, if dispensed, pursuant to board rule 657—6.8(155A),
6. The patient's attestation that they received and expressed understanding of the required counseling and education, and
7. The rationale for the antibiotic selected.

XIII. Notification

A. *Medication dispensed*. For patients who were dispensed antibiotic 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. GAS pharyngitis test result,
3. Medication dispensed, and
4. Follow-up plan.

B. *Positive test result with no medication dispensed*. For patient who received a positive test result, but who were ineligible for or declined antibiotic 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:
   1. The patient's name and date of birth,
   2. GAS pharyngitis test result, and
   3. Contraindication or reason that antibiotic 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.

XIV. Effective date

This protocol is effective August 24, 2022, 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.

Protocol for Testing and Initiation of Therapy for Suspected Acute Group A Streptococcal Pharyngitis in Adult Patients

1. Authorization

This protocol is issued pursuant to K.S.A. 65-16,131, which allows a pharmacist to initiate therapy for streptococcal pharyngitis pursuant to a statewide protocol adopted by the Kansas Collaborative Drug Therapy Management Advisory Committee. The intent of the Protocol is to provide testing and treatment for acute patients, not chronic carriers. A pharmacist shall engage in this Protocol only when the pharmacist has complied with the Kansas Pharmacy Practice Act and all rules and regulations promulgated thereunder.

This authorizes the Kansas-licensed pharmacist who has signed and dated this Protocol to initiate CLIA-waived point-of-care testing for acute Group A streptococcal (GAS) pharyngitis and, when diagnostically confirmed, initiate the dispensing of antibiotics to treat the infection.

A pharmacist may not initiate assessment or testing unless sufficient antibiotics are readily available to treat acute GAS pharyngitis infection pursuant to this Protocol.

A pharmacist shall ensure that sufficient space is available in or around the pharmacy for safe and confidential assessment and treatment of patients under this Protocol.

Terms identified in this Protocol shall have the meaning set forth in K.S.A. 65-1626, and amendments thereto.

2. Evaluation Criteria

Pharmacist(s) authorized to initiate the dispensing of antibiotic therapy to treat acute GAS pharyngitis infection shall treat patients according to current IDSA guidelines.

Pharmacists shall assess a patient based on the inclusion and exclusion criteria below based on the sample Pharmacist Assessment, Evaluation, and Prescribing Form in Appendix A.

Inclusion criteria:

Any patient who presents to the pharmacy and meets **all** the following criteria:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with acute GAS pharyngitis (sore throat, pain on swallowing, fever, swollen or tender cervical lymph nodes, or inflamed or swollen tonsils or uvula);
- Reported symptom onset < 96 hours before time of presentation; and
- If testing positive, the patient must be willing to wait at the pharmacy until antibiotics are dispensed.

Exclusion criteria:

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

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS);
- History of rheumatic fever, rheumatic heart disease, scarlet fever, or acute GAS pharyngitis induced glomerulonephritis;

- Presenting with overt viral features, such as conjunctivitis, rhinorrhea, cough, oral ulcers, and/or hoarseness;
- Known hypersensitivity to all antibiotic therapies available for treatment in this Protocol;
- Resident of a nursing home or long-term care facility;
- A patient being treated in a medical care facility or emergency department;
- A patient receiving hospice or home health services;
- History of tonsillectomy within the past 30 days;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms;
- Severe symptoms of respiratory distress, including:
    - Muffled voice;
    - Drooling;
    - Stridor;
    - Respiratory distress;
    - "Sniffing" or "tripod" positions;
    - Fever and rigors;
    - Severe unilateral sore throat;
    - Bulging of the pharyngeal wall/floor or soft palate;
    - Trismus;
    - Crepitus;
    - Stiff neck; or
    - History of penetrating trauma to oropharynx; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or
        - Temperature > 100.4 degrees Fahrenheit; or
    - Any one of the following criteria:
        - Acute altered mental status;
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >125 beats/min;
        - Respiratory rate >30 breaths/min;
        - Oxygen saturation (SpO_2) < 90% via pulse oximetry; or
        - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

The pharmacist shall provide counseling to any patient being assessed, tested, and/or treated pursuant to this Protocol on all the following:

- Appropriate self-care, including symptom control, hygiene, and infection control measures;

- CDC guidelines and KDHE guidelines (see pg 53) that a patient with a confirmed diagnosis of acute GAS pharyngitis should stay home from work or school until they are afebrile for at least 24 hours after starting antibiotic therapy;
- Medication counseling pursuant to K.A.R. 68-2-20; and
- Signs and symptoms that warrant emergency medical care.

3. Initiation of Therapy and Procedures

The pharmacist shall assess the patient's relevant medical and social history:

- Patient demographics
- Medical history
- Relevant social history
- Current clinical comorbidities or disease states, including current mental status
- Current blood pressure, pulse, oxygen saturation, respiratory rate, temperature, and weight
- For females of child-bearing potential, pregnancy, or breastfeeding status
- Current Medications
- Medication allergies and hypersensitivities (pharmacist shall assess reported allergies for validity by reviewing the patient's pharmacy record, if applicable, and documenting the reported reaction)
- Onset and duration of signs and symptoms

If the patient qualifies for CLIA-waived testing under this Protocol, then the pharmacist shall perform a CLIA-waived point-of-care test to determine the patient's acute GAS pharyngitis status.

- If positive, the pharmacist may proceed to consideration for immediate antibiotic therapy treatment.
- If negative, 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, etc.) or shall refer the patient to a primary care provider or urgent/emergency treatment facility as clinically appropriate.

The pharmacist shall evaluate for contraindications and precautions:

- Mild allergic reactions to penicillin (amoxicillin)
- Mild allergic reactions to cephalosporins (cephalexin)
- Severe allergic reactions to penicillin (amoxicillin and cephalexin)
- Allergic reactions to macrolides (azithromycin and clarithromycin)
- Allergic reactions to clindamycin
- History of chronic kidney disease (i.e., creatinine clearance (CrCl) < 60 ml/min, reduced kidney function, etc.)

The pharmacist may initiate antibiotic therapy only in carefully selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening.

Antibiotic Therapy

The pharmacist is authorized to order and dispense one of the following medication regimens to a patient that meets the evaluation inclusion criteria unless an identified contraindication applies for the patient.

Selection of antibiotic regimen will follow the ordered preference listed below. A lower-ranked regimen will only be prescribed if the patient or pharmacy record indicates a drug allergy or other contraindication to a higher-ranked regimen, or if the drug is not commercially available or appears on the FDA drug shortages list. If the patient is currently receiving another antibiotic, the pharmacist may utilize a lower-ranked regimen. However, a change to the dosage of the patient's current medication or the treatment selected by the pharmacist to treat the acute GAS pharyngitis shall not be considered. The pharmacist shall assess reported drug allergies for validity by reviewing the patient's pharmacy record and documenting the reported reaction.

If the pharmacist has a recent patient creatinine level and current weight, the pharmacist may adjust the medication dose per the manufacturer package insert for patients with CrCl < 30.

A. First-line treatment
    a. Amoxicillin
        i. Contraindication: Penicillin allergy
        ii. Dosing: 500 mg PO twice daily x 10 days, or
    b. Penicillin
        i. Contraindication: Penicillin allergy
        ii. Dosing
            1. Penicillin V, oral – 500mg PO twice daily x 10 days
            2. Penicillin G benzathine – 1.2million units IM, single dose, to be administered by the pharmacist
B. Second-line treatment
    a. Cephalexin
        i. Contraindications
            1. Cephalosporin allergy
            2. Severe penicillin allergy
        ii. Dosing: 500 mg PO twice daily x 10 days
    b. Cefadroxil
        i. Contraindications
            1. Cephalosporin allergy
            2. Severe penicillin allergy
        ii. Dosing: 1g PO daily x 10 days
C. Third-line treatment
    a. Azithromycin
        i. Contraindication: Macrolide allergy
        ii. Dosing: 500 mg PO once daily x 5 days
    b. Clindamycin
        i. Contraindication: Clindamycin allergy
        ii. Dosing: 300 mg PO three times daily x 10 days

D. Fourth-line treatment
    a. Clarithromycin
        i. Contraindication: Macrolide allergy
        ii. Dosing: 250 mg PO twice daily x 10 days
E. The pharmacist may recommend the following adjunctive therapy for treatment of moderate to severe symptoms or control of high fever associated with acute GAS pharyngitis, unless contraindicated:
    a. Acetaminophen PO according to OTC dosing recommendations; and
    b. Ibuprofen PO according to OTC dosing recommendations.

In any case where amoxicillin is not the selected regimen, the pharmacist shall document the rationale for selecting the antibiotic dispensed. Documentation may include medication sensitivity, cost, and shared clinical decision-making.

The pharmacy shall ensure that a pharmacist that has entered the Protocol shall monitor the patient for continuation or adjustment of therapy, including the following:

- As clinically appropriate, initiate telephone follow-up within 72 hours of dispensing to assess the clinical stability, onset of new symptoms, and medication adverse effects.
- If the patient is 65 years of age or older, telephone follow-up is mandatory within 72 hours of dispensing to assess the above patient status. If an initial follow-up does not result in direct patient contact, a second telephone follow-up attempt shall be made. Follow-up attempts must be documented by the pharmacist.
- Refer to a primary care provider or urgent/emergent treatment facility if any of the following are reported:
    - Significant deterioration in condition or new evidence of clinical instability;
    - Onset of symptoms inconsistent with acute GAS pharyngitis infection or indicative of serious complications; or
    - Medication adverse effects severe enough to warrant discontinuation.

4. Documentation and Recordkeeping

The pharmacist shall create a medication profile record for each patient who is assessed, tested, and/or treated for acute GAS pharyngitis pursuant to this Protocol and shall document the results and dispensing of any antibiotic therapy in the prescription record, including documentation of the following:

- Elements required by K.S.A. 65-1642 and K.A.R.68-7-14;
- Presenting signs and symptoms of the patient that warranted testing;
- The manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used;
- Patient informed consent and counseling provided, including any patient referral;
- Rationale for the antibiotic therapy selected, if any, and/or OTC medications recommended for symptom management;
- Appropriate clinical follow-up, if any; and
- Notifications to other healthcare providers.

Each pharmacist dispensing medication pursuant to this Protocol shall record themselves as the prescriber. The record shall be maintained such that the required information is readily retrievable and shall be securely stored within the pharmacy or electronic pharmacy management system for a period of 10 years from the date of assessment, testing, and/or dispensing. Records may be required to be stored (and may be off-site) for longer periods to comply with other state and federal laws.

5. Training and Counseling

Prior to initiating testing and dispensing antibiotic therapies under this Protocol, a pharmacist shall receive and document 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 (ACPE). Additionally, the pharmacist shall maintain knowledge of the Infectious Disease Society of America (IDSA)'s current guidelines for the treatment of acute GAS pharyngitis. Individuals who will be involved with patient specimen collection shall have documented hands-on training for specimen collection which includes infection control measures.

6. Notification

The pharmacist shall ask the patient tested under this Protocol for the name and contact information of a primary care provider. If the patient identifies a primary care provider, the pharmacist shall provide a summary of the patient encounter to the provider within seven days, including at least the patient's name, date of birth, acute GAS pharyngitis test results, any medication dispensed, and follow-up plan.

Each pharmacist that conducts a CLIA-waived point-of-care test shall provide the patient with a copy of the test result.

7. Signed Protocol

Each pharmacist utilizing this Protocol shall maintain a copy of the signed and dated Protocol for ten years from the date of last assessment, testing, or dispensing at each Kansas Board of Pharmacy registered facility where the pharmacist has provided services.

PHARMACIST AUTHORIZATION*

Printed Name	Kansas License Number

SIGNATURE

DATE SIGNED

Kansas	**STATE BOARD OF PHARMACY** 800 SW Jackson, Suite 1414 Topeka, Kansas 66612-1244 www.pharmacy.ks.gov (785)296-4056 pharmacy@ks.gov Fax (785) 296-8420	**STATEWIDE PROTOCOL:** **Acute GAS Pharyngitis - Adult** Appendix A

Pharmacist Assessment, Evaluation and Prescribing Protocol Form: Acute Group A Streptococcal Pharyngitis, Adult

PATIENT INFORMATION

Name		Date of Birth	Age
		Phone	Email
Address			
City	State	Zip	County
Primary Care Provider			
Medication Allergies			
Current Medications (Rx, OTC, herbal, topical, pain or allergy, supplements, vitamins, etc.):			
Treatments tried for current condition (if none, indicate N/A):			

PATIENT ELIGIBILITY

☐ Yes ☐ No Are you 18 years of age or older?
☐ Yes ☐ No Are you pregnant or breastfeeding?
☐ Yes ☐ No Have you ever been diagnosed with a weakened immune system (e.g., cancer, HIV/AIDS, transplant, long-term steroids, etc.)? If yes, explain:
☐ Yes ☐ No Do you have a history of rheumatic fever, rheumatic heart disease, scarlet fever, or acute GAS pharyngitis induced glomerulonephritis?
☐ Yes ☐ No Do you have a history of allergic reactions to antibiotics, such as penicillin, amoxycillin, cephalexin, clarithromycin, or clindamycin?
☐ Yes ☐ No Are you a resident of a nursing home or long-term care facility, in hospice, or receiving home health services?
☐ Yes ☐ No Do you have a pending test for your symptoms (COVID, strep, flu)?
☐ Yes ☐ No Have you had a tonsillectomy in the previous 30 days?
When did your symptoms start? ☐ More than four days ago. ☐ Fewer than four days ago
Do you have any of the following symptoms (check all that apply)? ☐ Fever ☐ Sore throat ☐ Pain swallowing ☐ Swollen/tender cervical lymph nodes ☐ Inflamed or swollen tonsils or uvula ☐ Other:

– PHARMACY STAFF ONLY –

PATIENT ASSESSMENT

Physical Assessment (please record values)	**Refer to PCP** if determined clinically unstable in pharmacist professional judgment or **any** of the following criteria:
Blood Pressure	Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
Respiratory Rate	Respiratory rate >30 breaths/min (single criteria); Respiratory rate >20 breaths/min (dual criteria)
Oxygen Saturation	Oxygen saturation (SpO_2) < 90% via pulse oximetry
Pulse	Pulse >125 beats/min (single criteria); Pulse >90 beats/min (dual criteria)
Temperature	Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit (single criteria); Temperature < 96.8 degrees Fahrenheit (single criteria); Temperature > 100.4 degrees Fahrenheit (dual criteria)
☐ Yes ☐ No Acute altered mental status	Yes
Severe Symptoms of Respiratory Distress	Muffled voice; Drooling; Stridor; Respiratory distress; "Sniffing" or "tripod" positions; Fever and rigors; Severe unilateral sore throat; Bulging of the pharyngeal wall/floor or soft palate; Trismus; Crepitus; Stiff neck; or History of penetrating trauma to oropharynx.
Overt Viral Features	Conjunctivitis, rhinorrhea, cough, oral ulcers, and/or hoarseness

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

Treat using protocol if:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with acute GAS pharyngitis (sore throat, pain on swallowing, fever, swollen or tender cervical lymph nodes, or inflamed or swollen tonsils or uvula);
- Reported symptom onset < 96 hours before time of presentation; and
- If testing positive, the patient must be willing to wait at the pharmacy until antibiotics are dispensed.

Refer to PCP and exclude from testing if:

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS);
- History of rheumatic fever, rheumatic heart disease, scarlet fever, or acute GAS pharyngitis induced glomerulonephritis;
- Presenting with overt viral features, such as conjunctivitis, rhinorrhea, cough, oral ulcers, and/or hoarseness;
- Known hypersensitivity to all antibiotic therapies available for treatment in this Protocol;
- Residents of a nursing home or long-term care facility;
- A patient being treated in a medical care facility or emergency department;
- A patient receiving hospice or home health services;
- History of tonsillectomy within the past 30 days;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms;

- Severe symptoms of respiratory distress, including:
  - Muffled voice;
  - Drooling;
  - Stridor;
  - Respiratory distress;
  - "Sniffing" or "tripod" positions;
  - Fever and rigors;
  - Severe unilateral sore throat;
  - Bulging of the pharyngeal wall/floor or soft palate;
  - Trismus;
  - Crepitus;
  - Stiff neck; or
  - History of penetrating trauma to oropharynx; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
  - Two or more of the following criteria:
    - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
    - Pulse >90 beats/min;
    - Respiratory rate >20 breaths/min;
    - Temperature < 96.8 degrees Fahrenheit; or
    - Temperature > 100.4 degrees Fahrenheit; or
  - Any one of the following criteria:
    - Acute altered mental status;
    - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
    - Pulse >125 beats/min;
    - Respiratory rate >30 breaths/min;
    - Oxygen saturation (SpO_2) < 90% via pulse oximetry; or
    - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

CLIA-WAIVED POC TEST RESULT

☐ Positive for acute GAS pharyngitis (continue)

☐ Negative for acute GAS pharyngitis (refer to PCP + symptomatic treatment)

PATIENT ACTION

☐ Yes ☐ No Acute GAS pharyngitis Diagnosed

☐ Yes ☐ No Antibiotic Treatment Prescribed

☐ Yes ☐ No Refer to PCP

Therapy Options		
Acute GAS Pharyngitis Adult **Treatment**		
Documentation of Rationale for Treatment Selection (if required):		
❑ Oral Amoxicillin	Dispense: ❑ 500mg #20 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 10 days; or
❑ Oral Penicillin V	Dispense: ❑ 500mg #20 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 10 days
❑ IM Penicillin G benzathine	Dispense: ❑ 1.2million units IM, single dose No refills	To be administered by the pharmacist
❑ Oral Cephalexin	Dispense: ❑ 500mg #20 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 10 days
❑ Oral Cefadroxil	Dispense: ❑ 1g #10 No refills	Sig: Take 1 (one) (1g) by mouth daily for 10 days
❑ Oral Azithromycin	Dispense: ❑ 500mg #5 No refills	Sig: Take 1 (one) (500mg) by mouth daily for 5 days
❑ Oral Clindamycin	Dispense: ❑ 300mg #30 No refills	Sig: Take 1 (one) (300mg) by mouth three times daily for 10 days
❑ Oral Clarithromycin	Dispense: ❑ 250mg #20 No refills	Sig: Take 1 (one) (250mg) by mouth twice daily for 10 days

PHARMACIST PRESCRIBER CERTIFICATION

Printed Name	License Number

SIGNATURE

DATE

PATIENT FOLLOW-UP

Assessment	**Refer to PCP (**if symptoms persist) ☐ Yes ☐ No

PHARMACIST FOLLOW-UP CERTIFICATION

Printed Name	License Number

SIGNATURE

DATE

Agenda Topic: Recommend statewide protocols for Influenza virus infection for patients 18 and over

Included in Agenda Packet:

- Arkansas Statewide Protocol
- Iowa Statewide Protocol
- Kansas Protocol

Action Needed:

- Motion to recommend that the Board of Pharmacy adopt an influenza virus protocol for patients 18 years of age and older that models one of the protocols included in the agenda packet or includes specific elements of the various protocols as presented or amended.

Influenza Treatment Protocol

I. Purpose

The purpose of this standing order is to reduce morbidity and mortality of influenza infection in Arkansas by allowing Arkansas-licensed pharmacists to initiate therapy including ordering and/or dispensing treatment medications, along with any necessary supplies for administration, to eligible persons who are influenza positive or who have household exposure.

II. Authority

This standing order is issued pursuant to Act 503 of 2021 (HB 1246) (Arkansas Code § 17-92-101) to authorize licensed pharmacists in Arkansas to order and/or dispense influenza treatment medications according to the provisions of Arkansas Code § 17-92-101 and the requirements of this standing order.

III. Screening and Assessment

The Board of Pharmacy will adopt screening assessment and questionnaire (Appendix A) to be used by pharmacists throughout the state. When a patient requests point-of-care testing services, or when a pharmacist, in his or her professional judgement, decides to initiate point-of-care testing and treatment, the patient will be assessed for presenting signs and symptoms that warrant influenza testing, parental consent for individuals under the age of 18, and if appropriate, administer a rapid influenza point-of-care test.

IV. Dispensing Guidelines

A. Eligibility Criteria

Inclusion:

- Age 3 years and older
- Reported symptoms or household exposure onset < 48 hours before time of presentation
- CLIA-waived point-of-care test for influenza virus is performed or household exposure

Exclusion:

- History of adverse reactions to any previous influenza treatment
- Pregnancy
- Use of antiviral therapy for influenza in the past **30 days**
- Flu-like symptoms for more than 48 hours
- Immunocompromised defined as:
    - Been receiving active cancer treatment for tumors or cancers of the blood

    - Received an organ transplant and are taking medicine to suppress the immune system
    - Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
    - Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
    - Advanced or untreated HIV infection
    - Active treatment with high-dose corticosteroids (20mg prednisone daily for >2 weeks) or other drugs that may suppress your immune response
- Clinically unstable based on the clinical judgement of the pharmacist or any of the following criteria:
    - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
        - For age 3-9 years: Systolic blood pressure <70 + (age in years × 2)
    - Tachypnea (>25 breaths/min adult or >20 breaths/min <18 y/o)
    - Oxygen saturation (SpO_2) <90% via pulse oximetry

B. Contraindications

Do not administer oseltamivir to an individual with a known hypersensitivity to oseltamivir or any component of the formulation

Do not administer zanamivir to an individual with a known hypersensitivity to zanamivir or any component of the formulation (contains milk proteins)

Do not administer baloxavir to an individual with a known hypersensitivity (e.g., anaphylaxis, angioedema, urticaria, erythema multiforme) to baloxavir or any component of the formulation

C. Product Availability

Influenza treatment products that may be dispensed/provided under this standing order. Following dosing below, pharmacist can dispense any commercial available product form (tablet, capsule, suspension) based on availability and patient preference.

1. Oral Oseltamivir dosing:
    - **Adults, treatment:** 75 mg twice a day x 5 days
    - **Adults, prophylaxis:** 75 mg once daily x 7 days if vaccinated, 14 days if unvaccinated
    - **Children, treatment** Weight-based dosing 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

- **Children, prophylaxis**: Weight-based dosing x 7 days
  - **15 kg or less:** 30 mg once a day
  - **>15 to 23 kg**: 45 mg once a day
  - **>23 to 40 kg**: 60 mg once a day
  - **> 40 kg**: 75 mg once a day

2. Inhaled Zanamivir dosing:
   - **Adults, treatment**: 10mg (two 5mg inhalations) twice a day x 5 days
   - **Adults, prophylaxis**: 10mg (two 5mg inhalations) once daily x 7 days
   - **Children, treatment** (7 years or older): 10mg (two 5mg inhalations) twice a day x 5 days
   - **Children, prophylaxis** (5 years or older): 10mg (two 5mg inhalations) once daily x 7 days
   -
3. Oral Baloxavir dosing:
   - **Adults and Children 12 and older, treatment:**
     - **40 kg to less than 80kg:** single dose of 40 mg
     - **80 kg or more:** single dose of 80mg
   - **Adults, children 12 and older, prophylaxis**
     - **40 kg to less than 80kg:** single dose of 40 mg
     - **80 kg or more:** single dose of 80mg

D. Warnings/Precautions

1. Oseltamivir
   - Disease-related concerns
     - Cardiovascular disease: Use with caution in patients with chronic cardiac disease
     - Hepatic impairment: Use with caution in patients with severe hepatic impairment
     - Renal impairment: Use with caution; dosage adjustment is required for patients with renal impairment. Not recommended for patients with end stage renal disease (ESRD) not undergoing dialysis
     - Respiratory disease: Use with caution in patients with respiratory disease
   - Dosage forms specific issues
     - Some dosage form may contain sodium benzoate/benzoic acid which are metabolites of benzyl alcohol and have been associated with a potentially fatal toxicity in neonate ("gasping syndrome")
     - Oral suspension contains sorbitol (delivers ~2 g sorbitol per 75 mg dose) which is greater than the maximum daily limit for patients with hereditary fructose intolerance; may cause diarrhea and dyspepsia; use with caution
   - Appropriate Use

- Oseltamivir is not a substitute for the influenza virus vaccine. It has not been shown to prevent primary or concomitant bacterial infections that may occur with influenza virus. Antiviral treatment should begin within 48 hours of symptom onset; however, the CDC recommends that treatment may still be beneficial and should be started in patients with severe, complicated, or progressive illness, and in hospitalized patients if >48 hours. Treatment should not be delayed while awaiting results of laboratory tests for influenza. Outpatients who are not at high risk for developing severe or complicated illness are not likely to benefit if treatment is started >48 hours after symptom onset (CDC 2020a).

2. Zanamivir
   - Concerns related to adverse effects
     - Allergic reactions: Allergic-like reactions, including anaphylaxis, oropharyngeal edema, and serious skin rashes have been reported. Discontinue use and institute appropriate treatment if an allergic reaction occurs.
     - Neuropsychiatric events: rare occurrences of neuropsychiatric events (including confusion, delirium, hallucinations, seizure, and/or self-injury) have been reported, primarily in pediatric patients; may be abrupt in onset. Direct causation is difficult to establish; influenza infection may also be associated with behavioral and neurologic changes.
     - Respiratory effects: Bronchospasm, including serious cases and some with fatal outcomes, and decreased lung function have been reported in patients with and without airway disease; discontinue with bronchospasm or decreased lung function. For a patient with an underlying airway disease where a medical decision has been made to use zanamivir, a fast-acting bronchodilator should be made available.
   - Respiratory disease
     - Not recommended for use in patients with underlying respiratory disease, such as asthma or COPD, due to lack of efficacy in influenza treatment and risk of serious bronchospasm. If zanamivir is prescribed in such patients, closely monitor respiratory function.
   - Nursing home patients
     - Nursing home patients: Effectiveness has not been established for prophylaxis of influenza in nursing home patients (per manufacturer); however, the CDC recommends zanamivir as an option to be used to control institutional outbreaks of influenza (refer to current guidelines) (CDC 2020a).
3. Baloxavir
   - Bacterial infection
     - There is no evidence of efficacy of baloxavir marboxil in illnesses (eg, bacterial infections) caused by pathogens other than influenza viruses. Serious bacterial infections may begin with influenza-like symptoms, may

coexist with, or occur as an influenza complication. Baloxavir marboxil has not been shown to prevent such complications. Monitor for potential secondary bacterial infections and manage appropriately.

- Hypersensitivity
  - Hypersensitivity reactions, including anaphylaxis, angioedema, urticaria, and erythema multiforme have been reported; evaluate and treat accordingly.

E. Documentation

Positive influenza cases that result in hospitalization or death are required to be reported to the Arkansas Department of Health (ADH) at https://flureport.adh.arkansas.gov. To aid in influenza surveillance, ADH also encourages providers to report other positive influenza test results to the same website. Patient records must be furnished to a health care practitioner designated by the patient upon the request of the patient. Documentation may include, but is not limited to, presenting signs and symptoms that warrant influenza testing, parental consent for individuals under the age of 18, and results of RIDT. Maintain records of all patients receiving services for two (2) years.

APPENDIX A

Pharmacist Assessment, Evaluation and Prescribing Protocol Form: *Influenza*

PATIENT INFORMATION		
Name:	Date of Birth:	Age:
Address:	City/State/Zip:	
Email Address:	Phone:	
Primary Care Provider:		
Medication allergies?		
Current medications? (prescription, over-the-counter, herbals, topical medications, pain or allergy medication, and any supplements/vitamins)		
Treatments tried for the current condition (if none please indicate N/A):		

PATIENT ELIGIBILITY		
1. Are you 3 years of age and older?	❑ Yes	❑ No
2. Are you pregnant?	❑ Yes	❑ No
3. Have you ever been diagnosed with a weakened immune system? (e.g. cancer, transplant, or long term steroids)	❑ Yes* *Pharmacists see page 2, #4 for criteria	❑ No
4. When did your flu-like symptoms **start**?	❑ More than 2 days ago	❑ 2 days ago, yesterday or today
5. Do you have any of the following flu-like symptoms? (check all that apply)	❑ Fever ❑ Nasal congestion ❑ Muscle/body aches ❑ Cough ❑ Sore throat ❑ Other:_____	
6. Do you have any of the following? (check all that apply)	❑ History of allergic reactions to influenza treatment ❑ History of physiologic side effects from any previous influenza treatment ❑ Use of antiviral therapy for influenza in the **past 30 days** ❑ Received influenza (flu) vaccine within the past 12 months	

When complete, please return the form to pharmacy staff along with insurance information

-- FOR PHARMACY STAFF ONLY--

Physical Assessment	**REFER TO PCP** if determined clinically unstable or any of the following criteria
❑ Blood pressure:_____ ❑ RR:_____ ❑ %Oxygen:_____ ❑ Temperature:_____	❑ Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg ❑ For age 3-9 years: Systolic blood pressure <70 + (age in years × 2) ❑ Tachypnea >25 breaths/min adult or >20 breaths/min <18 y/o ❑ Low oxygen <90% oxygen via pulse oximetry
CLIA-waived POCT Result	❑ Positive for influenza – continue ❑ Negative for influenza – refer to PCP + Symptomatic Treatment OR household post-exposure prophylaxis

Pharmacist Interpretation of qualifying questions and physical assessment; refer to PCP as appropriate. Exclusion criteria does not preclude from testing services. **Refer to PCP for treatment if:**

1. If patient is under 3 years of age **REFER TO PCP**
2. If patient is pregnant **REFER TO PCP**
3. If patient has had symptoms >48 hours **REFER TO PCP**
4. If patient is immunocompromised **REFER TO PCP**
    a. Been receiving active cancer treatment for tumors or cancers of the blood
    b. Received an organ transplant and are taking medicine to suppress the immune system
    c. Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
    d. Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
    e. Advanced or untreated HIV infection
    f. Active treatment with high-dose corticosteroids (20mg prednisone daily for >2 weeks) or other drugs that may suppress your immune response
5. If patient has history of adverse reactions to previous influenza treatment **REFER TO PCP**
6. If patient has used antiviral agents for influenza in the past 30 days **REFER TO PCP**

Treat using protocol if:

1. Age 3 years and older
2. Reported symptoms or household exposure onset < 48 hours before time of presentation
3. CLIA-waived point-of-care test for influenza virus is performed
    a. Symptomatic patient is positive for influenza virus via CLIA-waived point-of-care test
4. Household post-exposure prophylaxis

Diagnosis of Patient		
❑ Influenza ADULT ❑ Influenza Prophylaxis Adult	❑ Influenza CHILDREN and ADOLESCENTS ❑ Influenza Prophylaxis CHILDREN and ADOLESCENTS	❑ Refer to PCP

***the following can act as the prescription**

ADULT Therapy Options		
Influenza Adult **Treatment**		
❑ Oseltamivir	Dispense: ❑ 75mg #10 No refills	Sig: Take 1 (one) (75mg) by mouth twice daily for 5 days
❑ Zanamivir	Dispense: ❑ 1 inhaler No refills	2 inhalations by mouth twice daily for 5 days
❑ Baloxavir	Dispense: ❑ 40mg x 1 ❑ 80mg x 1 No refills	Take 1 tablet by mouth now
Influenza Adult **Prophylaxis**		
❑ Oseltamivir	Dispense: ❑ 75mg #7 ❑ 75mg #14 No refills	Sig: Take 1 (one) (75mg) by mouth once daily x 7 days Sig: Take 1 tablet by mouth once daily x 14 days
❑ Zanamivir	Dispense: ❑ 1 inhaler No refills	2 inhalations by mouth once daily x 7 days
❑ Baloxavir	Dispense: ❑ 40mg x 1 (if ≥40kg to 79kg) ❑ 80mg x 1 (if ≥ 80kg) No refills	Take 1 tablet by mouth now

Patient:_____.

Prescribed by:_____.

Signature:_____Date:_____.

Follow-Up in 48 hours	
Assessment:	❑ If symptoms persist, refer to PCP

*the following can act as the prescription

CHILDREN and ADOLESCENTS Therapy Options		
Influenza Children or Adolescent **Treatment** Weight (kg):_____		
❑ Oseltamivir	Dispense: Weight-based dosing ❑ ≤15kg: 30mg #10 ❑ 15-23kg: 45mg #10 ❑ 23-40kg: 60mg #10 ❑ >40kg: 75mg #10 No refills	Sigs: ❑ ≤15kg: 30mg by mouth BID x 5 days ❑ 15-23kg: 45 by mouth BID x 5 days ❑ 23-40kg: 60mg by mouth BID x 5 days ❑ >40kg: 75mg by mouth BID x 5 days
❑ Zanamivir	Dispense: ❑ 1 inhaler No refills	2 inhalations by mouth twice daily for 5 days
❑ Baloxavir	Dispense: ❑ 40mg x 1 ❑ 80mg x 1 No refills	Take 1 tablet by mouth now
Influenza Children or Adolescent **Prophylaxis** Weight (kg):_____		
❑ Oseltamivir	Dispense: Weight-based dosing ❑ ≤15kg: 30mg #7 ❑ 15-23kg: 45mg #7 ❑ 23-40kg: 60mg #7 ❑ >40kg: 75mg #7 No refills	Sigs: ❑ ≤15kg: 30mg by mouth daily x 7 days ❑ 15-23kg: 45 by mouth daily x 7 days ❑ 23-40kg: 60mg by mouth daily x 7 days ❑ >40kg: 75mg by mouth daily x 7 days
❑ Zanamivir	Dispense: ❑ 1 inhaler No refills	2 inhalations by mouth once daily x 7 days
❑ Baloxavir	Dispense: ❑ 40mg x 1 (if ≥40kg to 79kg) ❑ 80mg x 1 (if ≥ 80kg) No refills	Take 1 tablet by mouth now

Patient:_____.

Prescribed by:_____.

Signature:_____Date:_____.

Follow-Up in 48 hours	
Assessment:	❑ If symptoms persist, refer to PCP

References:

Infectious Diseases Society of America. Influenza Guidelines. http://www.idsociety.org

LexiComp. Wolters Kluwer Clinical Drug Information. http://online.lexi.com

Pediatric Vital Signs Reference Chart

Heart Rate (beats/min)		
Age	**Awake**	**Asleep**
Neonate (<28 d)	100-205	90-160
Infant (1-12 mos)	100-190	
Toddler (1-2 y)	98-140	80-120
Preschool (3-5 y)	80-120	65-100
School-age (6-11 y)	75-118	58-90
Adolescent (12-15 y)	60-100	50-90

Respiratory Rate (breaths/min)	
Age	**Normal**
Infant (<1 y)	30-53
Toddler (1-2 y)	22-37
Preschool (3-5 y)	20-28
School-age (6-11 y)	18-25
Adolescent (12-15 y)	12-20

Reference: PALS Guidelines, 2015

Blood Pressure (mmHg)				
Age		**Systolic**	**Diastolic**	**Systolic Hypotension**
Birth (12 h)	<1 kg	39-59	16-36	<40-50
	3 kg	60-76	31-45	<50
Neonate (96 h)		67-84	35-53	<60
Infant (1-12 mos)		72-104	37-56	<70
Toddler (1-2 y)		86-106	42-63	<70 + (age in years × 2)
Preschool (3-5 y)		89-112	46-72	
School-age (6-9 y)		97-115	57-76	
Preadolescent (10-11 y)		102-120	61-80	<90
Adolescent (12-15 y)		110-131	64-83	

Reference: PALS Guidelines, 2015
For diagnosis of hypertension, refer to the 2017 AAP guidelines Table 4 & 5:
http://pediatrics.aappublications.org/content/early/2017/08/21/peds.2017-1904

Temperature (°C)	
Method	**Normal**
Rectal	36.6-38.0
Tympanic	35.8-38.0
Oral	35.5-37.5
Axillary	36.5-37.5

Ranges do not vary with age.
Screening: axillary, temporal, tympanic (↓ accuracy)
Definitive: rectal & oral (↑ reflection of core temp.)
Reference: CPS Position Statement on Temperature Measurement in Pediatrics (2015)

Oxygen Saturation (SpO_2)

SpO_2 is lower in the immediate newborn period. Beyond this period, a SpO_2 of **<90-92%** may suggest a **respiratory condition** or **cyanotic heart disease**.

Dr. Chris Novak & Dr. Peter Gill for www.pedscases.com
(Edited March 2020 by Richard He)

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, all individuals who will be involved in testing shall document successful completion of education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the pharmacy.

Individuals who will be involved with patient specimen collection shall have documented hands-on training for specimen collection which includes infection control measures. Required training shall be successfully completed via a program accredited by the Accreditation Council for Pharmacy Education (ACPE) or pre-approved by the Board. A registered nurse who is licensed pursuant to Iowa Code 152 or 152E is deemed to have met the training requirement for patient specimen collection.

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 August 24, 2022, 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.

Protocol for Testing and Initiation of Therapy for Suspected Influenza in Adult Patients

1. Authorization

This protocol is issued pursuant to K.S.A. 65-16,131, which allows a pharmacist to initiate therapy for influenza pursuant to a statewide protocol adopted by the Kansas Collaborative Drug Therapy Management Advisory Committee. A pharmacist shall engage in this protocol only when the pharmacist has complied with the Kansas Pharmacy Practice Act and all rules and regulations promulgated thereunder.

This authorizes the Kansas-licensed pharmacist who has signed and dated this Protocol to initiate CLIA-waived point-of-care testing for influenza and, when diagnostically confirmed, initiate the dispensing of antiviral therapies to treat the infection.

A pharmacist may not initiate assessment or testing unless sufficient antiviral therapy is readily available to treat acute influenza infection pursuant to this Protocol.

A pharmacist shall ensure that sufficient space is available in or around the pharmacy for safe and confidential assessment and treatment of patients under this Protocol.

Terms identified in this Protocol shall have the meaning set forth in K.S.A. 65-1626, and amendments thereto.

A pharmacist shall exercise clinical judgement in assessing patients pursuant to this Protocol outside of the standard influenza season (approximately October 1 – April 30). Resource: https://www.cdc.gov/flu/weekly/

2. Evaluation Criteria

Pharmacist(s) authorized to initiate the dispensing of antiviral therapy to treat acute influenza infection shall treat patients according to current CDC guidelines.

Pharmacists shall assess a patient based on the inclusion and exclusion criteria below based on the sample Pharmacist Assessment, Evaluation, and Prescribing Form in Appendix A.

Inclusion criteria:

Any patient who presents to the pharmacy and meets **all** the following criteria:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with influenza (fever, myalgia, headache, malaise, nonproductive cough, sore throat, rhinitis);
- Reported symptom onset < 48 hours before time of presentation; and
- If testing positive, the patient must be willing to wait at the pharmacy until antiviral therapy is dispensed.

Exclusion criteria:

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

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS);

- A positive influenza test within the previous four weeks;
- Any condition requiring supplemental oxygen therapy;
- Known hypersensitivity to all antiviral therapies for influenza or to any common component of the products;
- Administration of FluMist or generic equivalent within the previous two weeks;
- Residents of a nursing home or long-term care facility;
- A patient being treated in a medical care facility or emergency department;
- A patient receiving hospice or home health services;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or
        - Temperature > 100.4 degrees Fahrenheit; or
    - Any one of the following criteria:
        - Acute altered mental status;
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >125 beats/min;
        - Respiratory rate >30 breaths/min;
        - Oxygen saturation (SpO_2) < 90% via pulse oximetry; or
        - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

The pharmacist shall provide counseling to any patient being assessed, tested, and/or treated pursuant to this Protocol on all the following:

- Influenza vaccination;
- Appropriate self-care, including symptom control, hygiene, and infection control measures;
- CDC guidelines that a patient with a confirmed diagnosis of influenza should stay home from work, school, or daycare until they are afebrile (100°F) for at least 24 hours without the use of a fever-reducing medication and at least 24 hours after starting antiviral therapy;
- Medication counseling pursuant to K.A.R. 68-2-20; and
- Signs and symptoms that warrant emergency medical care.

3. Initiation of Therapy and Procedures

The pharmacist shall assess the patient's relevant medical and social history:

- Patient demographics
- Medical history

- Relevant social history
- Current clinical comorbidities or disease states, including current mental status
- Current blood pressure, pulse, oxygen saturation, respiratory rate, temperature, and weight
- For females of child-bearing potential, pregnancy, or breastfeeding status
- Current Medications
- Medication allergies and hypersensitivities (pharmacist shall assess reported allergies for validity by reviewing the patient's pharmacy record, if applicable, and documenting the reported reaction)
- Onset and duration of flu-like signs and symptoms

If the patient qualifies for CLIA-waived testing under this Protocol, then the pharmacist shall perform a CLIA-waived point-of-care test to determine the patient's influenza status.

- If positive, the pharmacist may proceed to consideration for immediate antiviral therapy treatment.
- If negative, 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.

The pharmacist shall evaluate for contraindications and precautions.

The pharmacist may immediately initiate antiviral therapy only in carefully selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening.

Antiviral Therapy

The pharmacist is authorized to order and dispense the following antiviral agents to a patient that meets the evaluation inclusion criteria unless an identified contraindication applies for the patient.

A. Oral oseltamivir (Tamiflu)
    a. Contraindications
        i. Known hypersensitivity to oseltamivir or any component
        ii. Patients 18 years and older with CrCl < 10 ml/min. If the pharmacist is unable to obtain a current CrCl for a patient with a history of chronic kidney disease (i.e., creatinine clearance (CrCl) < 60 ml/min, reduced kidney function, etc.), then the patient should be excluded from receiving Tamiflu. For purposes of this Protocol, current CrCl means a lab value obtained within the past six months and documented by a physician's office, laboratory, or patient electronic health record, or reported by the patient and the pharmacist determines in their clinical judgment the patient report is accurate. The pharmacist shall document this information in the patient record.
    b. Dosing – all doses to be administered x 5 days
        i. Patients 18 years and older: 75 mg twice daily
        ii. 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
    b. Dosing – all doses to be administered as a single dose
        i. 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
    b. Dosing – all doses to be administered twice daily x 5 days
        i. 10 mg (two 5 mg inhalations)

If the patient qualifies for multiple therapies above, the pharmacist shall document the rationale for selecting the antiviral therapy dispensed. Documentation may include patient preference, cost, and shared clinical decision-making.

The pharmacy shall ensure that a pharmacist that has entered the Protocol shall monitor the patient for continuation or adjustment of therapy, including the following:

- As clinically appropriate, initiate telephone follow-up within 72 hours of dispensing to assess the clinical stability, onset of new symptoms, and medication adverse effects.
- If the patient is 65 years of age or older, telephone follow-up is mandatory within 72 hours of dispensing to assess the above patient status. If an initial follow-up does not result in direct patient contact, a second telephone follow-up attempt shall be made. Follow-up attempts must be documented by the pharmacist.
- Refer to a primary care provider or urgent/emergent treatment facility 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 of influenza; or
    - Medication adverse effects severe enough to warrant discontinuation.

4. Documentation and Recordkeeping

The pharmacist shall create a medication profile record for each patient who is assessed, tested, and/or treated for influenza pursuant to this Protocol and shall document the results and dispensing of any antiviral therapy in the prescription record, including documentation of the following:

- Elements required by K.S.A. 65-1642 and K.A.R.68-7-14;
- Presenting signs and symptoms of the patient that warranted testing;
- The manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used;
- Patient informed consent and counseling provided, including any patient referral;
- Rationale for the antiviral therapy selected, if any, and/or OTC medications recommended for symptom management;
- Appropriate clinical follow-up, if any; and
- Notifications to other healthcare providers.

Each pharmacist dispensing medication pursuant to this Protocol shall record themselves as the prescriber. The record shall be maintained such that the required information is readily retrievable and shall be securely stored within the pharmacy or electronic pharmacy management system for a period of 10 years from the date of assessment, testing, and/or dispensing. Records may be required to be stored (and may be off-site) for longer periods to comply with other state and federal laws.

5. Training and Counseling

Prior to initiating testing and dispensing antiviral therapies under this protocol, a pharmacist shall receive and document 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 (ACPE). Additionally, the pharmacist shall maintain knowledge of the Centers for Disease Control's (CDC) current recommendations for the use of antiviral drugs in the treatment of influenza. Individuals who will be involved with patient specimen collection shall have documented hands-on training for specimen collection which includes infection control measures.

6. Notification

The pharmacist shall ask the patient tested under this Protocol for the name and contact information of a primary care provider. If the patient identifies a primary care provider, the pharmacist shall provide a summary of the patient encounter to the provider within seven days, including at least the patient's name, date of birth, influenza test results, any medication dispensed, and follow-up plan.

Each pharmacist that conducts a CLIA-waived point-of-care test shall provide the patient with a copy of the test result.

7. Signed Protocol

Each pharmacist utilizing this Protocol shall maintain a copy of the signed and dated Protocol for ten years from the date of last assessment, testing, or dispensing at each Kansas Board of Pharmacy registered facility where the pharmacist has provided services.

PHARMACIST AUTHORIZATION*

Printed Name	Kansas License Number

SIGNATURE

DATE SIGNED

Kansas	**STATE BOARD OF PHARMACY** 800 SW Jackson, Suite 1414 Topeka, Kansas 66612-1244 www.pharmacy.ks.gov (785)296-4056 pharmacy@ks.gov Fax (785) 296-8420	**STATEWIDE PROTOCOL:** **Influenza - Adult** Appendix A

Pharmacist Assessment, Evaluation and Prescribing Protocol Form: Influenza, Adult

PATIENT INFORMATION

Name		Date of Birth	Age
		Phone	Email
Address			
City	State	Zip	County
Primary Care Provider			
Medication Allergies			
Current Medications (Rx, OTC, herbal, topical, pain or allergy, supplements, vitamins, etc.):			
Treatments tried for current condition (if none, indicate N/A):			

PATIENT ELIGIBILITY

☐ Yes ☐ No Are you 18 years of age or older?
☐ Yes ☐ No Are you pregnant or breastfeeding?
☐ Yes ☐ No Have you ever been diagnosed with a weakened immune system (e.g., cancer, HIV/AIDS, transplant, long-term steroids, etc.)? If yes, explain:
☐ Yes ☐ No Do you require supplemental oxygen therapy?
☐ Yes ☐ No Are you a resident of a nursing home or long-term care facility, in hospice, or receiving home health services?
☐ Yes ☐ No Do you have a pending test for your flu-like symptoms (COVID, strep, flu)?
☐ Yes ☐ No Have you tested positive for influenza in the previous four weeks?
When did your flu-like symptoms start? ☐ More than two days ago. ☐ 2 days ago, yesterday, or today.
Do you have any of the following symptoms (check all that apply)? ☐ Fever ☐ Nasal congestion ☐ Muscle/body aches ☐ Cough ☐ Sore Throat ☐ Other:
Do you have any of the following? ☐ History of allergic reactions to influenza treatment ☐ History of physiologic side effects from any previous influenza treatment ☐ Received FluMist or a generic equivalent within the past two weeks

– PHARMACY STAFF ONLY –

PATIENT ASSESSMENT

Physical Assessment (please record values)	**Refer to PCP** if determined clinically unstable in pharmacist professional judgment or **any** of the following criteria:
Blood Pressure	Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
Respiratory Rate	Respiratory rate >30 breaths/min (single criteria); Respiratory rate >20 breaths/min (dual criteria)
Oxygen Saturation	Oxygen saturation (SpO_2) < 90% via pulse oximetry
Pulse	Pulse >125 beats/min (single criteria); Pulse >90 beats/min (dual criteria)
Temperature	Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit (single criteria); Temperature < 96.8 degrees Fahrenheit (single criteria); Temperature > 100.4 degrees Fahrenheit (dual criteria)
☐ Yes ☐ No Acute altered mental status	Yes

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

Treat using protocol if:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with influenza (fever, myalgia, headache, malaise, nonproductive cough, sore throat, rhinitis);
- Reported symptom onset < 48 hours before time of presentation; and
- If testing positive, the patient must be willing to wait at the pharmacy until antiviral therapy is dispensed.

Refer to PCP and exclude from testing if:

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS);
- A positive influenza test within the previous four weeks;
- Any condition requiring supplemental oxygen therapy;
- Known hypersensitivity to all antiviral therapies for influenza or to any common component of the products;
- Administration of FluMist or generic equivalent within the previous two weeks;
- Residents of a nursing home or long-term care facility;
- A patient being treated in a medical care facility or emergency department;
- A patient receiving hospice or home health services;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or

- Temperature > 100.4 degrees Fahrenheit; or
- Any one of the following criteria:
  - Acute altered mental status;
  - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
  - Pulse >125 beats/min;
  - Respiratory rate >30 breaths/min;
  - Oxygen saturation (SpO_2) < 90% via pulse oximetry; or
  - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

CLIA-WAIVED POC TEST RESULT

☐ Positive for influenza (continue)

☐ Negative for influenza (refer to PCP + symptomatic treatment)

PATIENT ACTION

☐ Yes ☐ No Influenza Diagnosed

☐ Yes ☐ No Antiviral Treatment Prescribed

☐ Yes ☐ No Refer to PCP

Therapy Options		
Influenza Adult **Treatment**		
❑ Oral Oseltamivir (Tamiflu)	Dispense: ❑ 75mg #10 ❑ Renal impairment CrCl > 30 to 60 ml/min: 30mg twice daily CrCl > 10 to 30 ml/min: 30mg once daily No refills	Sig: Take 1 (one) (75mg) by mouth twice daily for 5 days
❑ Inhaled Zanamivir (Relenza Diskhaler)	Dispense: ❑ 1 inhaler No refills	2 inhalations by mouth twice daily for 5 days
❑ Oral Baloxavir Marboxil (Xofluza)	Dispense: ❑ 40mg x 1 ❑ 80mg x 1 No refills	Take 1 tablet by mouth now

PHARMACIST PRESCRIBER CERTIFICATION

Printed Name	License Number

SIGNATURE _____ DATE _____

PATIENT FOLLOW-UP

Assessment	**Refer to PCP (**if symptoms persist) ☐ Yes ☐ No

PHARMACIST FOLLOW-UP CERTIFICATION

Printed Name	License Number

SIGNATURE

DATE

Agenda Topic: Recommend statewide protocols for COVID-19 virus infection for patients 18 and over

Included in Agenda Packet:

- Statewide Protocol used in New Mexico

Action Needed:

- Motion to recommend that the Board of Pharmacy adopt a COVID-19 virus protocol for patients 18 years of age and older that models one of the protocols included in the agenda packet or includes specific elements of the various protocols as presented or amended.

Paxlovid Prescription Template for Pharmacist Prescribing

Patient Name: _____ Date:_____

Patient Address:_____ Patient Date of Birth:_____

Patient Telephone Number:_____

☐ Paxlovid Tablets (Standard Dose, eGFR ≥60mL/min): Take 2 pink (Nirmatrelvir 150 mg) tablets and 1 white (Ritonavir 100 mg) tablet by mouth together twice daily for five days. #30 Tablets.

☐ Paxlovid Tablets (Renal Dose, eGFR ≥30 to <60mL/min): Take 1 pink (Nirmatrelvir 150 mg) tablet and 1 white (Ritonavir 100 mg) tablet by mouth together twice daily for five days. #20 Tablets.

Refills: 0

Diagnosis: Covid-19

Prescriber Comments/Must Complete Below:

Meets limitations of authorized use: for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. ☐ YES

Date of Positive Test (Home Test Accepted) and Symptom Onset (must be within 5 days):_____

Renal Function (must be within 12 months): eGFR=_____

Hepatic Function normal (must be within 12 months, Child-Pugh Class C-Use NOT recommended): ☐ YES

Full Medication List Obtained (including OTCs/herbal supplements): ☐ YES

Reviewed for potential drug interactions and NO dose adjustments/medication modifications are needed: ☐ YES

- If modifications to other medications are needed, do not prescribe and refer for evaluation by a physician, CNP, or PA:

Paxlovid FDA EUA Fact Sheet given to patient at each time of prescribing: ☐ YES

Inform patient to AVOID going into the pharmacy for pick-up (use Drive-Thru, Curbside, Delivery): ☐ YES

Prescribing Pharmacist:_____

NPI or License # and Telephone:_____

Special Thanks to the Original Contributing Authors: New Mexico Pharmacists Association, University of New Mexico College of Pharmacy, University of New Mexico Poison Center & COVID Hotline, New Mexico Department of Health, New Mexico Board of Pharmacy, Walgreens Patient Care Center, Albuquerque, New Mexico.

Agenda Topic: Recommend statewide protocol for UTI for patients 18 and over

Included in Agenda Packet:

- Kansas Protocol
- Kentucky Protocol

Action Needed:

- Motion to recommend that the Board of Pharmacy adopt a UTI protocol for patients 18 years of age and older that is modeled after one of the protocols included in the agenda packet or includes specific elements of the various protocols as presented or amended.

Protocol for Testing and Initiation of Therapy for Suspected Acute Uncomplicated Lower Urinary Tract Infection in Women

1. Authorization

This protocol is issued pursuant to K.S.A. 65-16,131, which allows a pharmacist to initiate therapy for urinary tract infection pursuant to a statewide protocol adopted by the Kansas Collaborative Drug Therapy Management Advisory Committee. The intent of the Protocol is to provide testing and treatment for acute uncomplicated lower urinary tract infections in women. A pharmacist shall engage in this Protocol only when the pharmacist has complied with the Kansas Pharmacy Practice Act and all rules and regulations promulgated thereunder.

This authorizes the Kansas-licensed pharmacist who has signed and dated this Protocol to initiate CLIA-waived point-of-care testing for acute uncomplicated lower urinary tract infection (UTI) in women and, when diagnostically confirmed, initiate the dispensing of antibiotics to treat the infection.

A pharmacist may not initiate assessment or testing unless sufficient antibiotics are readily available to treat UTI pursuant to this Protocol.

A pharmacist shall ensure that sufficient space is available in or around the pharmacy for safe and confidential assessment and treatment of patients under this Protocol. In addition, a pharmacist shall ensure that a private restroom is available for collecting the patient specimen and appropriate procedures are in place to prevent contamination of the specimen and ensure proper cleaning of the restroom.

Terms identified in this Protocol shall have the meaning set forth in K.S.A. 65-1626, and amendments thereto.

Informed consent shall include ensuring that the patient understands that this Protocol does not include treating yeast infection, detecting drugs of abuse, detecting pregnancy, produce a urine culture, etc.

2. Evaluation Criteria

Pharmacist(s) authorized to initiate the dispensing of antibiotic therapy to treat UTI shall treat patients according to current IDSA guidelines.

Pharmacists shall assess a patient based on the inclusion and exclusion criteria below based on the sample Pharmacist Assessment, Evaluation, and Prescribing Form in Appendix A.

Inclusion criteria:

Any patient who presents to the pharmacy and meets **all** of the following criteria:

- Female patient ≥18 years of age but <65 years, and able to give informed consent;
- Prior history of UTI(s);
- One or more of the following symptoms: dysuria, increased frequency, and/or urgency; and
- Positive urine dipstick for nitrites and/or leukocytes via a CLIA-waived point-of-care detection test kit.

Exclusion criteria:

Any patient who meets **any** of the following criteria:

- Male;
- Pregnant or breastfeeding;
- Post-menopausal;
- Vaginitis symptoms (e.g., vaginal discharge or itching);
- Symptom onset >7 days prior;
- Immunocompromised state (e.g., hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS);
- Renal transplantation;
- Renal dysfunction (based on individual's report or pharmacy records);
- Diabetes mellitus;
- History of any urologic surgery, including but not limited to ureteral implantation, cystectomy, or urinary diversion;
- History of Clostridioides difficile (formerly Clostridium difficile) a.k.a. c.diff;
- Abnormal urinary tract function or structure (e.g., indwelling catheter, chronic intermittent catheterization, neurogenic bladder, renal stones, renal stents);
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms;
- Antibiotic therapy prescribed within the previous 30 days;
- Inpatient stay at a medical care facility within the previous 30 days;
- History of recurrent UTIs (>3 per year)
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or
        - Temperature > 100.4 degrees Fahrenheit; or
    - Any one of the following criteria:
        - Acute altered mental status;
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >125 beats/min;
        - Respiratory rate >30 breaths/min;
        - Oxygen saturation (SpO_2) < 90% via pulse oximetry; or
        - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit;
- Has or reports symptoms suggestive of pyelonephritis including:
    - Presence of fever (≥100.4 F; taken orally);
    - Nausea and vomiting; or
    - Flank pain;
- Resident of a nursing home or long-term care facility;
- A patient being treated in a medical care facility or emergency department; or
- A patient receiving hospice or home health services.

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate. Patients who do not qualify for antibiotic dispensing following testing will be referred for additional evaluation when the pharmacist has high suspicion of a false-negative result, determines that the patient is at high risk for complications, or otherwise considers additional care to be in the best interest of the patient.

The pharmacist shall provide counseling to any patient being assessed, tested, and/or treated pursuant to this Protocol on all the following:

- Instructions on when to seek medical attention, including:
  - Symptoms that do not resolve or worsen after three days;
  - Development of a fever (temperature ≥100.4 F, taken orally); or
  - Flank pain;
- Medication counseling pursuant to K.A.R. 68-2-20;
- Counseling on the importance of adherence to an antibiotic regimen and completion of the entire course; and
- Counseling regarding prevention of UTIs, including signs and symptoms that warrant emergency medical care.

3. Procedures for Testing and Initiation of Therapy

The pharmacist shall assess the patient's relevant medical and social history:

- Patient demographics
- Medical history
- Relevant social history
- Current clinical comorbidities or disease states, including current mental status
- Current blood pressure, pulse, oxygen saturation, respiratory rate, temperature, and weight
- For females of child-bearing potential: pregnancy and breastfeeding status
- Current medications
- Medication allergies and hypersensitivities (pharmacist shall assess reported allergies for validity by reviewing the patient's pharmacy record, if applicable, and documenting the reported reaction)
- Onset and duration of signs and symptoms

If the patient qualifies for CLIA-waived testing under this Protocol, then the pharmacist shall perform a CLIA-waived point-of-care test to determine the patient's UTI status.

- If positive, the pharmacist may proceed to consideration for antibiotic therapy treatment.
- If negative, the pharmacist shall counsel the patient on the risk of a false-negative test result and on appropriate self-care (get plenty of rest, drink plenty of fluids, treat symptoms as needed, etc.) or shall refer the patient to a primary care provider or urgent/emergency treatment facility as clinically appropriate.

The pharmacist shall evaluate for contraindications and precautions:

- Allergic reaction, hypersensitivity, or contraindication to a treatment listed in this Protocol
- Renal insufficiency (nitrofurantoin monohydrate/macrocrystals and phenazopyridine)
- Previous UTI treatment failure
- History of chronic kidney disease (i.e., creatinine clearance (CrCl) < 60 ml/min, reduced kidney function, etc.)

The pharmacist may initiate antibiotic therapy only in carefully selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening.

Antibiotic Therapy

The pharmacist is authorized to order and dispense one of the following medication regimens to a patient that meets the evaluation inclusion criteria unless an identified contraindication applies for the patient.

Selection of an antibiotic regimen from the list below. If the patient is currently receiving another antibiotic, the pharmacist shall not change the dosage of the patient's current medication. The pharmacist shall assess reported drug allergies for validity by reviewing the patient's pharmacy record and documenting the reported reaction. The choice between the antibiotic medication regimens should be individualized and based on patient allergy, contraindications/precautions, adherence history, local community resistance patterns, cost, and availability.

If prior authorization is needed for prescription insurance coverage, the Pharmacist may seek prior authorization or consider use of an alterative antibiotic therapy in the Protocol, if not contraindicated, and shall counsel the patient about cost options.

A. Antibiotic Treatment
    a. Nitrofurantoin monohydrate/macrocrystals
        i. Dosing: 100 mg PO BID for 5 days
    b. Trimethoprim-sulfamethoxazole
        i. Dosing: 160/800 mg PO BID for 3 days
    c. Fosfomycin trometamol
        i. Dosing: 3 gm PO single dose
B. This Protocol also authorizes pharmacists to initiate the dispensing of the following medication for the treatment of UTI related dysuria: Phenazopyridine 100-200 mg PO three times daily (TID) after meals for up to 2 days when used concomitantly with an antibiotic agent.

The pharmacy shall ensure that a pharmacist that has entered the Protocol shall monitor the patient for continuation or adjustment of therapy, including the following:

- As clinically appropriate, initiate telephone follow-up within 72 hours of dispensing to assess the clinical stability, onset of new symptoms, and medication adverse effects.
- Refer to a primary care provider or urgent/emergent treatment facility 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; or
    - Medication adverse effects severe enough to warrant discontinuation.

4. Documentation and Recordkeeping

The pharmacist shall create a medication profile record for each patient who is assessed, tested, and/or treated for UTI pursuant to this Protocol and shall document the results and dispensing of any antibiotic therapy in the prescription record, including documentation of the following:

- Elements required by K.S.A. 65-1642 and K.A.R.68-7-14;
- Presenting signs and symptoms of the patient that warranted testing;
- The manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used;
- Patient informed consent and counseling provided, including any patient referral;
- Rationale for the antibiotic therapy selected, if any, and/or OTC medications recommended for symptom management;
- Appropriate clinical follow-up, if any; and
- Notifications to other healthcare providers.

Each pharmacist dispensing medication pursuant to this Protocol shall record themselves as the prescriber. The record shall be maintained such that the required information is readily retrievable and shall be securely stored within the pharmacy or electronic pharmacy management system for a period of 10 years from the date of assessment, testing, and/or dispensing. Records may be required to be stored (and may be off-site) for longer periods to comply with other state and federal laws.

5. Training and Counseling

Prior to initiating testing and dispensing antibiotic therapies under this Protocol, a pharmacist shall receive and document 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 (ACPE). Additionally, the pharmacist shall maintain knowledge of the current Infectious Disease Society of America (IDSA)'s Guidelines for the treatment of Uncomplicated Cystitis and Pyelonephritis (UTI) and the American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin for the Treatment of Urinary Tract Infections in Nonpregnant Women. Individuals who will be involved with patient specimen collection shall have documented hands-on training for specimen collection which includes infection control measures.

6. Notification

The pharmacist shall ask the patient tested under this Protocol for the name and contact information of a primary care provider. If the patient identifies a primary care provider, the pharmacist shall provide a summary of the patient encounter to the provider within seven days, including at least the patient's name, date of birth, UTI test results, any medication dispensed, and follow-up plan.

Each pharmacist that conducts a CLIA-waived point-of-care test shall provide the patient with a copy of the test result.

7. Signed Protocol

Each pharmacist utilizing this Protocol shall maintain a copy of the signed and dated Protocol for ten years from the date of last assessment, testing, or dispensing at each Kansas Board of Pharmacy registered facility where the pharmacist has provided services.

PHARMACIST AUTHORIZATION*

Printed Name	Kansas License Number

SIGNATURE

DATE SIGNED

Kansas	**STATE BOARD OF PHARMACY** 800 SW Jackson, Suite 1414 Topeka, Kansas 66612-1244 www.pharmacy.ks.gov (785)296-4056 pharmacy@ks.gov Fax (785) 296-8420	**STATEWIDE PROTOCOL:** **Urinary Tract Infection** Appendix A

Pharmacist Assessment, Evaluation and Prescribing Protocol Form: Acute Uncomplicated Lower Urinary Tract Infection, Women

PATIENT INFORMATION

Name		Date of Birth	☐ Male ☐ Female
Email			Phone
Address			
City	State	Zip	
Primary Care Provider			
Medication Allergies			
Current Medications (Rx, OTC, herbal, topical, pain or allergy, supplements, vitamins, etc.):			
Treatments tried for current condition (if none, indicate N/A):			

PATIENT ELIGIBILITY

☐ Yes ☐ No Are you 18-64 years of age?
☐ Yes ☐ No Do you have a history of urinary tract infections? If yes, explain how many and over what time period:
☐ Yes ☐ No Are you pregnant or breastfeeding?
☐ Yes ☐ No Are you pre-menopausal?
☐ Yes ☐ No Are you diabetic?
☐ Yes ☐ No Have you ever been diagnosed with a weakened immune system (e.g., cancer, HIV/AIDS, transplant, long-term steroids, etc.)? If yes, explain:
☐ Yes ☐ No Have you ever been diagnosed with c.diff (Clostridioides difficile, formerly Clostridium difficile)?
☐ Yes ☐ No Do you have a history of renal transplant, dysfunction, urologic surgery (ureteral implantation, cystectomy, urinary diversion), or abnormal urinary tract function or structure (indwelling catheter, chronic intermittent catheterization, neurogenic bladder, renal stones, renal stents)?
☐ Yes ☐ No Do you have a history of allergic reactions to antibiotics, such as penicillin, amoxicillin, cephalexin, clarithromycin, or clindamycin?
☐ Yes ☐ No Are you a resident of a nursing home or long-term care facility, in hospice, or receiving home health services?
☐ Yes ☐ No Do you have a pending test for your symptoms?

☐ Yes ☐ No Have you been prescribed antibiotics in the previous 30 days?
☐ Yes ☐ No Have you had an inpatient or hospital stay in the previous 30 days?
When did your symptoms start? ☐ More than seven days ago. ☐ Fewer than seven days ago
Do you have any of the following symptoms (check all that apply)? ☐ Pain when urinating ☐ Increased urinary frequency or urgency ☐ Vaginal discharge or itching ☐ Nausea/vomiting ☐ Flank pain ☐ Other:

– PHARMACY STAFF ONLY –

PATIENT ASSESSMENT

Physical Assessment (please record values)	**Refer to PCP** if determined clinically unstable in pharmacist professional judgment or **any** of the following criteria:
Blood Pressure	Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
Respiratory Rate	Respiratory rate >30 breaths/min (single criteria); Respiratory rate >20 breaths/min (dual criteria)
Oxygen Saturation	Oxygen saturation (SpO_2) < 90% via pulse oximetry
Pulse	Pulse >125 beats/min (single criteria); Pulse >90 beats/min (dual criteria)
Temperature	Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit (single criteria); Temperature < 96.8 degrees Fahrenheit (dual criteria); Temperature > 100.4 degrees Fahrenheit (dual criteria, or pyelonephritis possibility in combination with nausea/vomiting or flank pain)
☐ Yes ☐ No Acute altered mental status	Yes

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

Treat using protocol if:

- Female patient ≥18 years of age but <65 years, and able to give informed consent;
- Prior history of UTI(s);
- One or more of the following symptoms: dysuria, increased frequency, and/or urgency; and
- Positive urine dipstick for nitrites and/or leukocytes via a CLIA-waived point-of-care detection test kit..

Refer to PCP and exclude from testing if:

- Male;
- Pregnant or breastfeeding;
- Post-menopausal;
- Vaginitis symptoms (e.g., vaginal discharge or itching);
- Symptom onset >7 days prior;

- Immunocompromised state (e.g., hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS);
- Renal transplantation;
- Renal dysfunction (based on individual's report or pharmacy records);
- Diabetes mellitus;
- History of any urologic surgery, including but not limited to ureteral implantation, cystectomy, or urinary diversion;
- History of Clostridioides difficile (formerly Clostridium difficile) a.k.a. c.diff;
- Abnormal urinary tract function or structure (e.g., indwelling catheter, chronic intermittent catheterization, neurogenic bladder, renal stones, renal stents);
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms;
- Antibiotic therapy prescribed within the previous 30 days;
- Inpatient stay at a medical care facility within the previous 30 days;
- History of recurrent UTIs (>3 per year)
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or
        - Temperature > 100.4 degrees Fahrenheit; or
    - Any one of the following criteria:
        - Acute altered mental status;
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >125 beats/min;
        - Respiratory rate >30 breaths/min;
        - Oxygen saturation (SpO2) < 90% via pulse oximetry; or
        - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit;
- Has or reports symptoms suggestive of pyelonephritis including:
    - Presence of fever (≥100.4 F; taken orally);
    - Nausea and vomiting; or
    - Flank pain;
- Resident of a nursing home or long-term care facility;
- A patient being treated in a medical care facility or emergency department; or
- A patient receiving hospice or home health services..

CLIA-WAIVED POC TEST RESULT

☐ Positive urine dipstick for nitrites and/or leukocytes indicating UTI

☐ Negative for UTI

PATIENT ACTION

☐ Yes ☐ No UTI Diagnosed

☐ Yes ☐ No Antibiotic Treatment Prescribed

☐ Yes ☐ No Refer to PCP

Therapy Options		
☐ UTI Antibiotic Treatment Prescribed as Marked Below ☐ No Treatment – Referred to PCP		
Documentation of Rationale for Treatment Selection (if required):		
❑ Oral Nitrofurantoin monohydrate/macrocrystals	Dispense: ❑ 100mg #10 No refills	Sig: Take 1 (one) (100mg) by mouth twice daily for 5 days
❑ Oral Trimethoprim-sulfamethoxazole	Dispense: ❑ 160/800mg #6 No refills	Sig: Take 1 (one) (160/800mg) by mouth twice daily for 3 days
❑ Oral Fosfomycin trometamol	Dispense: ❑ 3 gm, single dose No refills	Sig: Dissolve one packet (3 grams) in 4 ounces of water and drink as one dose.
❑ Phenazopyridine	Dispense: ❑ 100mg #6 ❑ 200mg #6 No refills	Sig: Take 1 tablet by mouth three times daily after meals for up to 2 days

PHARMACIST PRESCRIBER CERTIFICATION

Printed Name	License Number

SIGNATURE

DATE

PATIENT FOLLOW-UP

Assessment	**Refer to PCP (**if symptoms persist) ☐ Yes ☐ No

PHARMACIST FOLLOW-UP CERTIFICATION

Printed Name	License Number

SIGNATURE

DATE

ACUTE, UNCOMPLICATED URINARY TRACT INFECTION TREATMENT PROTOCOL
V2 Approved 12/11/2019

PURPOSE

This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of antibiotic and urinary analgesic therapies to treat acute, uncomplicated urinary tract infection (UTI) in adult females. The purpose of this protocol is to provide timely and accessible treatment for adult females with acute, uncomplicated UTI (also known as acute, uncomplicated cystitis) following diagnostic confirmation via CLIA-waived point-of-care urine dipstick rapid screening test.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating testing and dispensing of antibiotics under this protocol, pharmacist(s) must have received education and training in UTI and the supplies necessary to perform point-of-care urine dipstick testing 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 current Infectious Disease Society of America (IDSA)'s Guidelines for the treatment of Uncomplicated Cystitis and Pyelonephritis (UTI)[1] and the American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin for the Treatment of Urinary Tract Infections in Nonpregnant Women.[2]

Provider of Training: _____

Date Training Complete: _____

CRITERIA

Pharmacist(s) authorized to initiate the dispensing of antibiotics to treat acute uncomplicated UTI infection will treat individuals according to current IDSA/ACOG guidelines.[1,2]

Inclusion criteria:
Any individual who presents to the pharmacy and meets **ALL** of the following inclusion criteria:

- Female patient ≥18 years of age but <65 years
- Prior history of UTI(s)
- 1 or more of the following symptoms: dysuria, increased frequency, and/or urgency
- Positive urine dipstick for nitrites and leukocytes via a CLIA-waived point-of-care detection test kit

[1]Gupta K, Hooton TM, Naber KG, et al. International Clinical Practice Guidelines for the Treatment of Acute Uncomplicated Cystitis and Pyelonephritis in Women: A 2010 Update by the Infectious Diseases Society of America and the European Society for Microbiology and Infectious Diseases. *Clinical Infectious Diseases.* 2011; 52(5):e103–e120. https://www.idsociety.org/practice-guideline/uncomplicated-cystitis-and-pyelonephritis-uti/. Accessed March 2019. *(This guideline is currently being updated. Projected publication update: Summer 2022)*

[2]Treatment of urinary tract infections in nonpregnant women. ACOG Practice Bulletin No. 91 2008. American College of Obstetricians and Gynecologists. *Obstetrics & Gynecology*. 2008; 111:785-794. https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins-Gynecology/Treatment-of-Urinary-Tract-Infections-in-Nonpregnant-Women?IsMobileSet=false *(Reaffirmed 2016)*

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

- Male
- Pregnant
- Post-menopausal
- Vaginitis symptoms (e.g., vaginal discharge or itching)
- Symptom onset >7 days prior
- Immunocompromised state (e.g., hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS)
- Renal transplantation
- Abnormal urinary tract function or structure (e.g., indwelling catheter, neurogenic bladder, renal stones, renal stents)
- Has or reports symptoms suggestive of pyelonephritis including:
  - Presence of fever (≥100.4 F; taken orally)
  - Nausea and vomiting
  - Flank pain
- Diabetes mellitus
- Renal dysfunction (based on individual's report or pharmacy records)
- Antibiotic therapy prescribed for UTI within the previous 30 days
- Inpatient stay at a healthcare facility within the previous 30 days
- History of recurrent UTIs (>3 per year)

All individuals who request UTI testing but do not qualify for antibiotic/urinary analgesic therapy dispensing under this protocol will be referred to a primary care provider or urgent/emergent treatment facility if clinically appropriate. Individuals who do not qualify for antibiotic dispensing following point-of-care urine dipstick test will be referred for additional evaluation when the pharmacist has high suspicion of a false-negative result, determines that the individual is at high risk for complications, or otherwise considers additional care to be in the best interest of the individual.

MEDICATIONS

This protocol authorizes pharmacist(s) to initiate the dispensing of one of the following antibiotic medication regimens recommended by current IDSA guidelines for the treatment of acute, uncomplicated cystitis to an individual meeting the criteria:

Nitrofurantoin monohydrate/macrocrystals 100 mg PO BID for 5 days
OR
Trimethoprim-sulfamethoxazole 160/800 mg PO BID for 3 days
OR
Fosfomycin trometamol 3 gm PO single dose

The choice between the above antibiotic medication regimens should be individualized and based on patient allergy, contraindications/precautions, adherence history, local community resistance patterns, cost, and availability.

This protocol also authorizes pharmacists to initiate the dispensing of the following medication for the treatment of UTI related dysuria: Phenazopyridine 100-200 mg PO TID after meals for up to 2 days when used concomitantly with an antibiotic agent.

PROCEDURES FOR INITIATION OF THERAPY

Perform point-of-care urine dipstick test to determine if acute, uncomplicated UTI is present

- If positive, continue to evaluate with protocol
- If negative, refer to a primary care provider or urgent/emergent treatment facility if clinically appropriate

Antibiotic 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
- Medical history
- Relevant social history
- Current medications
- Medication allergies and hypersensitivities

Evaluate for Contraindications and Precautions:

- Allergic reaction to sulfa drugs (trimethoprim-sulfamethoxazole)
- Allergic reaction/hypersensitivity to nitrofurantoin monohydrate/macrocrystals, trimethoprim-sulfamethoxazole, or fosfomycin trometamol
- Renal insufficiency (nitrofurantoin monohydrate/macrocrystals and phenazopyridine)
- Previous UTI treatment failure

Selection of antibiotic regimen will be individualized and based on patient specific factors including drug allergies and contraindications to therapy. The pharmacist will assess reported drug allergies for validity by reviewing the individual's pharmacy record and documenting the reported reaction. The pharmacist will document the clinical reasoning for the antibiotic selection.

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

Telephone follow-up within 24 to 48 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
- Lack of improvement in symptoms or onset of symptoms indicative of serious complications
- Medication adverse effects severe enough to warrant discontinuation

EDUCATION REQUIREMENTS

Individuals receiving antibiotics under the protocol will also receive the following:

- Medication counseling consistent with state and federal requirements for prescription drug products
- Counseling on importance of adherence to antibiotic regimen and completion of entire course
- Instructions on when to seek medical attention:
    - Symptoms that do not resolve or worsen within 3 days
    - Development of fever (temperature ≥100.4 F; taken orally)
    - Presence of flank pain
- Counseling regarding prevention of UTIs
- Follow-up details

DOCUMENTATION

Pharmacist(s) will document via prescription record each individual who receives testing and medications to treat UTI under this protocol, including:

- Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication
- Documentation of the presenting signs and symptoms that warranted testing
- Documentation of the manufacturer, lot, expiration date, and result of the point-of-care urine dipstick test used to determine UTI status
- Documentation that the individual received the education required by this protocol
- Documentation of the history and assessment, the plan of care implemented, and follow-up monitoring and evaluation if warranted

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 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, urine dipstick test results, medication dispensed, and follow-up plan, within 2 business days. Any individual affirmatively stating that the individual does not have a primary care provider may still receive UTI treatment under this protocol provided all other applicable requirements of the protocol are met.

[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 UTI treatment under this protocol within 7 days of initiating dispensing.]

TERMS

This protocol is effective as of the date all parties execute the 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 sixty days.

SIGNATURES

Prescriber Name	Date
Prescriber Signature	
Pharmacist Name	Date
Pharmacist Signature	

References used to develop this protocol:

1. Gupta K, Hooton TM, Naber KG, et al. International Clinical Practice Guidelines for the Treatment of Acute Uncomplicated Cystitis and Pyelonephritis in Women: A 2010 Update by the Infectious Diseases Society of America and the European Society for Microbiology and Infectious Diseases. *Clinical Infectious Diseases.* 2011; 52(5):e103–e120. https://www.idsociety.org/practice-guideline/uncomplicated-cystitis-and-pyelonephritis-uti/ . Accessed March 2019. *(This guideline is currently being updated. Projected publication update: Summer 2022)*
2. Treatment of urinary tract infections in nonpregnant women. ACOG Practice Bulletin No. 91 2008. American College of Obstetricians and Gynecologists. *Obstetrics & Gynecology*. 2008; 111:785-794. https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins-Gynecology/Treatment-of-Urinary-Tract-Infections-in-Nonpregnant-Women?IsMobileSet=false . (Reaffirmed 2016)
3. Mazzulli T. Diagnosis and management of simple and complicated urinary tract infections (UTIs). *Canadian Journal of Urology*. 2012:19(supp1):42-48.
4. University of Michigan Clinical Care Guidelines: Urinary Tract Infection. http://www.med.umich.edu/1info/FHP/practiceguides/uti/uti.pdf. Published September 2016. Accessed March 2019.