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?

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☐ 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