Pharmacy Name: _____

Pharmacy Permit Number: _____

ACUTE, UNCOMPLICATED URINARY TRACT INFECTION TREATMENT PROTOCOL
V3
Approved 09/17/2025

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]

CRITERIA

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

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. Clinical Practice Guidelines for the Treatment of Acute Uncomplicated Cystitis and Pyelonephritis in Women: A 2010 Update by IDSA. *Clinical Infectious Diseases.* 2011; 52(5):e103– e120. https://www.idsociety.org/practice-guideline/uncomplicated-cystitis-and-pyelonephritis-uti/. Accessed July 2025.

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 or urinary analgesic therapy dispensing under this protocol will be referred to a primary care provider or urgent or 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 or 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

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

Telephone follow-up within 72 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, urgent or 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 2:171 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 authorized pursuant to 201 KAR 2:380 and is effective when it is submitted to the registry. Any termination shall require prior notice to all parties no later than 30 days after discontinuing the protocol.

SIGNATURES

_____ _____

Prescriber Name Date

_____

Prescriber Kentucky License Number

_____

Prescriber Signature

_____ _____

Pharmacist Name Date

_____

Pharmacist Kentucky License Number

_____

Pharmacist Signature

Course Taken for Training: _____

Provider of Training: _____

Date Training Completed: _____

Any pharmacist not party to the protocol will be subject to discipline should they utilize the protocol. A pharmacist utilizing the protocol must be employed by or contracted with the permit listed in the executed protocol.

For additional pharmacists party to this protocol, the pharmacy should keep a list of the additional pharmacists and their training at the pharmacy.

ADDITIONAL SIGNATURE PAGE

By signing below, I attest that I read and understand the Board-authorized protocol, entitled: _____

and that I will follow all guidelines and requirements included in the Board-authorized protocol.

_____ _____

Pharmacist Name Date

_____

Pharmacist Kentucky License Number

_____

Pharmacist Signature

Course Taken for Training: _____

Provider of Training: _____

Date Training Completed: _____