Treatment of Urinary Tract Infections (UTIs):

Optimizing Antimicrobial Therapy and Assessing New Antibiotics for UTI

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Disclosure

- I have no financial interests/arrangements to disclose that would be considered a conflict of interest.

Objectives

- Compare clinical presentation and diagnostic criteria for uncomplicated UTI (uUTI) versus complicated UTI (cUTI)
- Interpret evidence based treatment recommendations for antimicrobial management of uUTI versus cUTI
- Identify newer antibiotics approved for the treatment of UTIs and their role in clinical practice

IDSA Evidence Based Guidelines

Urinary Tract Infections

- **Current guidelines published by IDSA**
  - 2010: Acute Uncomplicated Cystitis and Pyelonephritis in Women*
  - 2019: Clinical Practice Guideline Update for the Management of Asymptomatic Bacteriuria
  - 2025: Guideline Update on Complicated Urinary Tract Infections

- **Knowledge gaps without evidence based treatment guidelines**
  - Uncomplicated cystitis management in males and females not addressed in 2010 guideline
  - Acute Bacterial Prostatitis

*premenopausal, non-pregnant women with no known urological abnormalities or co-morbidities

Gupta K, *et al*. *Clin Infect Dis* 2011;52(5):e103–e120.
Trautner BW, *et al*. *Clin Infect Dis* 2025. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

Urinary Tract Infections (UTIs)

- **As of 2021, UTIs accounted for:**
  - 404.61 million cases and 236,790 deaths
  - An estimated 7.7 million visits to US emergency departments for genitourinary issues (majority of those visits presumably for UTI)

- **UTIs are also the leading cause of gram-negative bacteremia**
  - A study published in 2021 showed 48% of gram negative bacteremias reported by 24 US hospitals

Trautner BW, *et al*. *Clin Infect Dis* 2025. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

Most Common Bacterial Pathogens – UTI

- ***Escherichia coli*** ★

- **Other gram negative species (*Enterobacterales sp.*)**
  - *Proteus mirabilis*
  - *Klebsiella pneumoniae*

- **Gram positive organisms (less common overall)**
  - *Staphylococcus saprophyticus*
  - *Streptococcus* species
  - *Enterococcus* species

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Trautner BW, *et al*. *Clin Infect Dis* 2025. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

Clinical Presentation and Diagnostic Criteria for Uncomplicated UTI versus Complicated UTI

How to Differentiate Uncomplicated vs Complicated UTI

New classifications of uUTI and cUTI

Old Classifications

Uncomplicated UTI:
Acute cystitis in afebrile nonpregnant premenopausal women with no diabetes and no urologic abnormalities

Acute Pyelonephritis: Acute kidney infection in women otherwise meeting the definition of uncomplicated UTI above

Complicated UTI: All other UTIs

New Classifications

Uncomplicated UTI: Infection confined to the bladder in afebrile women or men

Complicated UTI: infection beyond the bladder in women or men

- Pyelonephritis
- Febrile or bacteremic UTI
- Catheter-associated (CAUTI)
- Prostatitis* (*not covered by these guidelines)

Trautner BW, *et al. Clin Infect Dis* 2025. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

uUTI versus cUTI Patient Characteristics

	uUTI	cUTI
Local bladder signs/symptoms: dysuria, urgency, frequency, or suprapubic pain	**YES**	**YES**
Symptoms which suggest an infection extending beyond the bladder: fever/chills, rigors, hemodynamic instability, flank pain, CVA tenderness	NO	**YES**
Males	**YES**	**YES**
Females	**YES**	**YES**
Immunocompromised or Diabetic	**YES**	**YES**
Indwelling urinary catheter or stent/nephrostomy tube	NO	**YES**
Neurogenic bladder, urinary obstruction, urinary retention	NO	**YES**

Trautner BW, *et al*. *Clin Infect Dis* 2025. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

Diagnostic Criteria/Workup

- **NOTE:** All patients diagnosed with UTI need to have signs or symptoms related to the organisms in the bladder (or spreading beyond the bladder)

- **Role of Urinalysis in Diagnosis of UTI**
  - Sensitivity and specificity is inconsistent, diagnostic value is limited in UTI
  - Cannot be used as sole criteria for UTI diagnosis – clinical signs/symptoms must be present
  - A "positive UA" with lack of urinary symptoms likely = asymptomatic bacteruiuria (ASB) and does not need antibiotic treatment routinely

- **Urine culture indicated for all patients with cUTI diagnosis**
  - Can be considered for uUTI also (depending on patient specific risk factors)

Advani SD, *et al. Antimicrob Steward Healthc Epidemiol*. 2021;1(1):e6.
Simerville JA, *et al. Am Fam Physician*. 2005;71(6):1153-1162.
Trautner BW, *et al. Clin Infect Dis* 2025. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

Urinalysis Diagnostic Testing Performance for UTIs

Table 3. Diagnostic Testing Performance for Urinary Tract Infections[a]

Test results	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Dipstick				
Positive leukocyte esterase	72-97	41-86	43-56	82-91
Positive nitrite	19-48	92-100	50-83	70-88
Positive leukocyte esterase or nitrite	46-100	42-98	52-68	78-98
Microscopy, WBC/μL				
>5[b]	90-96	47-50	56-59	83-95
10	100	36	NA	NA
50	98	66	NA	NA
100	93	71	NA	NA
200	89	86	NA	NA
300	84	88	NA	NA
400	77	92	NA	NA

Nelson Z, *et al. JAMA Netw Open* 2024;7(11):e2444495.

Assessment: Patient Case #1

- 72 year old male presents to the emergency department with dehydration and generally not feeling well for a few days; patient does not report any urinary symptoms or systemic signs of illness, afebrile
- **PMH:** CHF, CKD, COPD
- **Allergies:** none
- **Relevant lab results:** Urinalysis – negative for leukocyte esterase and normal WBC, positive for nitrites and bacteria; urine culture pending; serum WBC = 6.4 k/uL

What should be done with the urinalysis result while the urine culture is pending?

A. Nothing
B. Start Ceftriaxone 1g IV q24h while waiting for the urine culture result
C. Start Nitrofurantoin 100mg PO q12h x 5 days
D. Nothing right now, but if the urine culture has > 100,000 cfu/ml bacterial growth, then start oral antibiotics targeted towards the organism isolated

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Evidence Based Treatment Recommendations for Antimicrobial Management of uUTI versus cUTI

General Principles of UTI Treatment

- Fluoroquinolones should be avoided for routine use in uUTI unless no other available options
- Duration of therapy is not necessarily disease state specific, can be variable depending on antimicrobial drug/class chosen
- Try to use the most targeted antimicrobial at the right dose/route/frequency/duration
    - Use facility or health system antibiogram to help guide empiric treatment
    - Use patient specific factors to help choose optimal agent
- Longer is not always better (see table below)

Condition	Duration	Literature Summary
Uncomplicated UTIs	3-5 days	Short courses of most antibiotics are as effective as longer regimens for cystitis in women
Complicated UTIs & Pyelonephritis	5-7 days	As effective as 10-14 day courses, including patients with bacteremia, when appropriate antibiotics are used

US Food and Drug Administration. 7-26-16. FDA updates warnings for fluoroquinolone antibiotics [Press Release]. https://www.fda.gov/drugs/information-drug-class/fda-approves-safety-labeling-changes-fluoroquinolones
Gupta K, *et al. Clin Infect Dis* 2011;52(5):e103–e120.
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Spelberg, B. JAMA Intern Med. 2016 September 01; 176(9): 1254–1255.

Using an Antibiogram

An antibiogram is a summary of antimicrobial susceptibilities of bacterial isolates over a defined time period

- A vital tool for clinicians to ensure selection of the most appropriate antimicrobial therapy
- Facility-specific antibiograms monitor susceptibility and resistance patterns within an institution
- Nebraska Department of Health and Human Services provides an annual statewide gram-negative antibiogram, as well as local health department gram-negative antibiograms

https://dhhs.ne.gov/Reports/Gram-Negative%20Antibiograms%20Annual%20Report%20-%202024.pdf

Douglas County Health Department

Includes Inpatient and Outpatient isolates, first isolate per patient
Data Displayed as: % Susceptible (Number of Available Isolates)

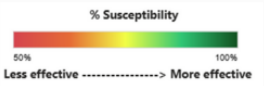
	Total_Isolates	Ampicillin	Ampicillin_Sulbactam	Amoxicillin_Clavulanate	Piperacillin_Tazobactam	Cefazolin	Cefuroxime	Cefoxitin	Ceftriaxone	Ceftazidime	Cefepime	Ceftolozane_Tazobactam	Ertapenem	Meropenem	Gentamicin	Tobramycin	Levofloxacin	Trimethoprim_Sulfa	Nitrofurantoin	Tetracycline
Acinetobacter baumannii	17	R	94.1% (17)^	R		R	R	R		100% (10)^	100% (11)^		R	100% (9)^	91.7% (12)^	100% (15)^	83.3% (12)^	100% (17)^	R	88.9% (9)^
Citrobacter freundii	166	R	R	R	86.6% (164)	R	R	R	77.4% (124)	91.9% (123)	98.2% (165)		96.8% (126)	99.2% (124)	93.4% (166)	92.1% (126)	90.9% (165)	86.1% (166)	91.4% (152)	84.6% (123)
Citrobacter koseri	180	R	97.2% (109)	100% (119)	100% (175)	96.8% (125)	91% (122)	96.3% (108)	100% (179)	100% (109)	99.2% (122)	98.1% (54)	100% (118)	100% (118)	100% (178)	100% (119)	100% (174)	99.4% (180)	69.7% (155)	96.6% (116)
Escherichia coli	7884	56.4% (7871)	50.1% (4091)	82.8% (3380)	91.6% (5065)	88.4% (3637)	83.1% (3585)	89.8% (3105)	92.5% (7841)	99.8% (3130)	86.8% (3945)	99.4% (3103)	99.8% (3439)	99.9% (3120)	92.2% (7584)	85.4% (3754)	81.2% (7363)	77.9% (7849)	97% (7024)	77% (3110)
Haemophilus influenzae	17	70.6% (17)*		100% (4)*					100% (12)^	100% (2)^				100% (9)^			100% (1)^	33.3% (9)^		100% (1)^
Klebsiella aerogenes	331	R	R	R	85.2% (325)	R	39.5% (215)	7.6% (118)	79.4% (223)	91.9% (209)	97.5% (326)	100% (9)^	95.6% (228)	100% (209)	98.5% (328)	97.6% (211)	98.4% (323)	97.3% (331)	25.2% (270)	94.2% (205)
Klebsiella oxytoca	362	R	67.6% (339)	90.1% (242)	93.6% (343)	50% (326)	83.3% (240)	92.8% (235)	93.7% (351)	98.3% (239)	92.9% (255)	99.2% (131)	99.6% (246)	100% (239)	97.4% (350)	96.3% (240)	96.5% (347)	91.8% (354)	89.2% (277)	88.9% (234)
Enterobacter cloacae complex	347	R	R	R	81.6% (316)	R	R	R	69.4% (219)	75.1% (217)	93.9% (346)	R	89.2% (231)	100% (227)	97.4% (340)	95.5% (247)	95% (338)	91.6% (347)	27.3% (260)	88.6% (236)
Klebsiella pneumoniae	1802	R	85.8% (1692)	92.6% (1081)	93.1% (1728)	87.7% (1106)	86.8% (1092)	90.9% (1062)	92.9% (1777)	96.7% (1071)	89.2% (1156)	99.2% (529)	99.6% (1120)	99.9% (1071)	96.3% (1769)	93.8% (1114)	90.3% (1758)	89.6% (1788)	39.9% (1611)	85.7% (1063)
Morganella morganii	26	R	100% (1)^		96% (25)^				100% (3)^		100% (23)^		100% (2)^	100% (1)^	80.8% (26)^	25% (4)^	69.2% (26)^	69.2% (26)^	R	R
Proteus mirabilis	994	85.5% (989)	90.5% (640)	97.3% (585)	98.6% (660)	53.6% (586)	97.1% (581)	97.3% (584)	97% (974)	100% (586)	95.9% (607)	99.7% (327)	100% (604)	100% (332)	94.4% (983)	91.7% (605)	85.5% (983)	86% (984)	R	R
Providencia spp.	26		100% (1)*		100% (26)*				50% (2)*		96% (25)*		100% (2)*		69.2% (26)*		69.2% (26)*	80.8% (26)*		
Pseudomonas aeruginosa	947	R	R	R	94.4% (913)	R	R	R	R	97.9% (607)	95.4% (909)	99.7% (364)	R	92.1% (635)		97.5% (685)	82.6% (868)	R		R
Serratia marcescens	152	R	R	R	85.1% (101)	R	R	R	77.2% (101)	97% (101)	100% (148)	98.6% (74)	98% (98)	100% (97)	98.7% (150)	94.1% (101)	93.4% (151)	96.7% (150)	R	30.6% (85)

Percent Susceptible Key: 100-90 | 89.9-70 | <70 | Not enough data to interpret, <70% of susceptibility data available

Blanks = Indicate drug not routinely tested
R = Intrinsically resistant
^ = Use caution interpreting results with < 30 isolates reported

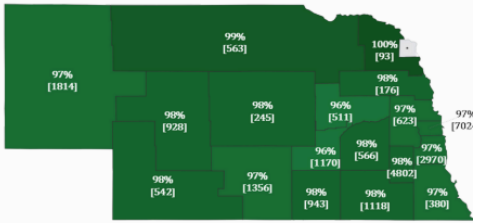
Escherichia coli

The maps below display the percent susceptibility and the number of isolates included by local health department jurisdiction. Red indicates less effective drug-bug combinations, and darker green indicates more effective combinations.
* indicates insufficient data to report (<15 isolates or <50% of susceptibility data available for the drug-bug combination)

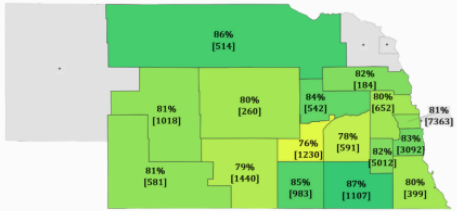


Nitrofurantoin

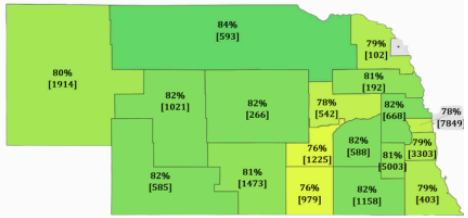
Please note: Nitrofurantoin is for treatment of lower urinary tract infections.



Levofloxacin



Trimethoprim-Sulfamethoxazole



https://dhhs.ne.gov/Reports/Gram-Negative%20Antibiograms%20Annual%20Report%20-%202024.pdf

Uncomplicated UTI (uUTI) Treatment Recommendations

Uncomplicated UTI Treatment Recommendations

2010 IDSA Guidelines

1st Line

- Nitrofurantoin macrocystals[a] 100mg PO BID x **5 days**
- Trimethoprim/sulfamethoxazole[b] 160-800mg PO BID x **3 days**

2nd Line

- Beta lactams[b] (ex. Cephalexin, Cefpodoxime, Amox/Clav) PO x **5 days**
- Fluoroquinolones[b] (Ciprofloxacin, Levofloxacin) PO x **3 days**

Alternatives

- Fosfomycin[a] 3g PO x 1

Notes

- **a.** If concerned for complicated UTI/pyelonephritis - avoid Nitrofurantoin and Fosfomycin
- **b.** If choosing TMP/SMX, Cipro/Levo, or beta lactams – assess for local resistance rates to uropathogens < 20%

Gupta K, *et al*. *Clin Infect Dis* 2011;52(5):e103–e120.
Trautner BW, *et al*. *Clin Infect Dis* 2025. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

Complicated UTI (cUTI) Treatment Recommendations

Complicated UTI – 2025 IDSA Guidelines

- Strong focus on inpatient management of complicated UTI presentation and empiric intravenous antibiotic therapy recommendations

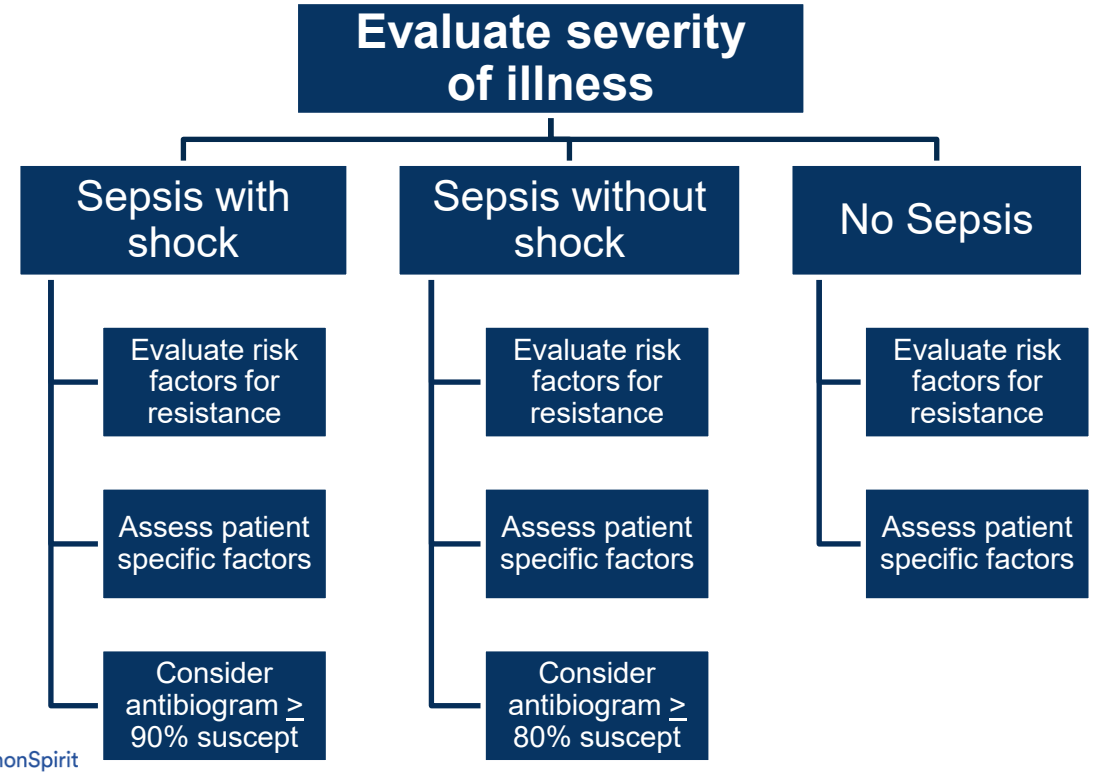
- Empiric therapy choice incorporates assessment of clinical presentation, acute severity of illness (i.e. sepsis), local/facility antibiogram, and risk factors for resistance

- Patients who present without sepsis, oral route of therapy is preferred (applicable to outpatient setting)

Trautner BW, *et al*. *Clin Infect Dis* 2025. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

Complicated UTI – 2025 IDSA Guidelines

Empiric Therapy Four Step Approach



Trautner BW, *et al*. *Clin Infect Dis* 2025. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

Complicated UTI – Empiric Therapy Guidance

2025 IDSA Guidelines

- **Risk Factors for Resistance**
  - Avoid antibiotics which patient has had resistant pathogen isolated from urine
  - More recent urine cultures are better guide (median in studies 3-6 months)
  - Consider avoiding fluoroquinolones if exposed in past 12 months

- **Patient Specific Risk Factors**
  - Risk of allergic reaction
  - Contraindications
  - Drug-drug interactions

Trautner BW, *et al*. *Clin Infect Dis* 2025. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

Complicated UTI Empiric Treatment Recommendations

2025 IDSA Guidelines

Sepsis with or without shock	• 3rd/4th generation Cephalosporins • Piperacillin/tazobactam • Carbapenems* • Fluoroquinolones*
Without sepsis – IV route	• 3rd/4th generation Cephalosporins • Piperacillin/tazobactam • Fluoroquinolones*
Without sepsis – oral route	• Fluoroquinolones • Trimethoprim/sulfamethoxazole • **Alternatives*:** Amox/Clav, Cephalexin, Cefpodoxime

***Considerations:**

- Carbapenems should not be used routinely unless risk factors for resistance/allergies
- Fluoroquinolones have a higher resistance rate than other IV agents recommended in sepsis
- **Cefdinir is not recommended due to poor bioavailability**
- Avoid Nitrofurantoin and Fosfomycin (do not concentrate outside of bladder)

3rd generation Cephalosporins: Ceftriaxone, Ceftazidime; **4th generation Cephalosporins:** Cefepime;
Carbapenems: Ertapenem, Meropenem, Imipenem-cilastatin; **Fluoroquinolones:** Ciprofloxacin, Levofloxacin

Trautner BW, *et al*. *Clin Infect Dis* 2025. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

IV Antibiotic Dosing Recommendations for cUTI

2025 IDSA Guidelines

Antibiotic	Dosing in normal renal function
Ceftriaxone	2g IV daily
Cefepime	2g IV q8-12h
Ceftazidime	2g IV q8h
Piperacillin-tazobactam	4.5g IV q8h
Ertapenem	1g IV daily
Imipenem-cilastatin	500mg IV q6h or 1g q8h
Meropenem	1g IV q8h

Trautner BW, *et al*. *Clin Infect Dis* 2025. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

Complicated UTI – Assessment for IV to Oral Switch

2025 IDSA Guidelines

In patients who are being treated parenterally for cUTI, are clinically improving, can take an oral medication and for whom an oral option is available, should parenteral therapy be transitioned to oral rather than continued for the complete duration of therapy?

YES!

- Recommendation is applicable to patients with cUTI (including acute pyelo) +/- gram negative bacteremia
- **Effective antimicrobial agent** = achieves therapeutic levels in the bloodstream, urine, and relevant tissue
- High value placed on reducing avoidable IV related adverse events, costs, resources

Trautner BW, *et al*. *Clin Infect Dis* 2025. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

Oral Antibiotic Dosing Recommendations for cUTI

2025 IDSA Guidelines

Antibiotic	Dosing in normal renal function
Ciprofloxacin	500-750mg PO q12h
Levofloxacin	500-750mg PO q24h
Trimethoprim/sulfamethoxazole	160-800 mg PO q12h
Cephalexin*	500-1000mg PO q6h
Cefuroxime*	500mg PO q12h
Cefpodoxime*	200-400mg PO q12h
Amoxicillin-clavulanate*	875-125mg PO q8-12h

***NOTE:** higher doses of oral beta lactams recommended to ensure adequate kidney/serum drug levels

Trautner BW, *et al*. *Clin Infect Dis* 2025. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

Complicated UTI – Duration of Therapy
2025 IDSA Guidelines

Summary of Evidence (January 2000 through September 2023)

- 10 randomized, controlled trials comparing treatment with shorter (5-7d) vs. longer duration (> 7 days)
- **Setting:** varied (outpatient, ED, hospitalized)
- **Patients enrolled:** both adult males and females (2,681 patients analyzed, overall females > males)
- **Most common pathogen:** *Escherichia coli* (median 84.2%)
- **Exclusion criteria:** varied greatly (indwelling urinary catheters, sepsis/septic shock, immunocompromised, severe renal insufficiency, functional or structure abnormalities of urinary tract, pregnancy/lactation)
- **Antibiotics studied:** majority addressed duration of fluoroquinolones (other agents: TMP/SMX, beta lactams)
- **Study design:** non-inferiority (all but one)
- **Relevant study outcomes:** clinical cure at end of therapy (EOT) or at first follow-up after EOT and recurrence of infection
- **Conclusions:** Overall, a shorter course of treatment likely does not reduce clinical efficacy or increase recurrence of infection, but a shorter course may not reduce adverse events.

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Complicated UTI – Duration of Therapy
2025 IDSA Guidelines

In patients presenting with complicated UTI (cUTI) with a clinical response to therapy, should total duration of antibiotics be prolonged to >7 days rather than shorter (<=7 days)?

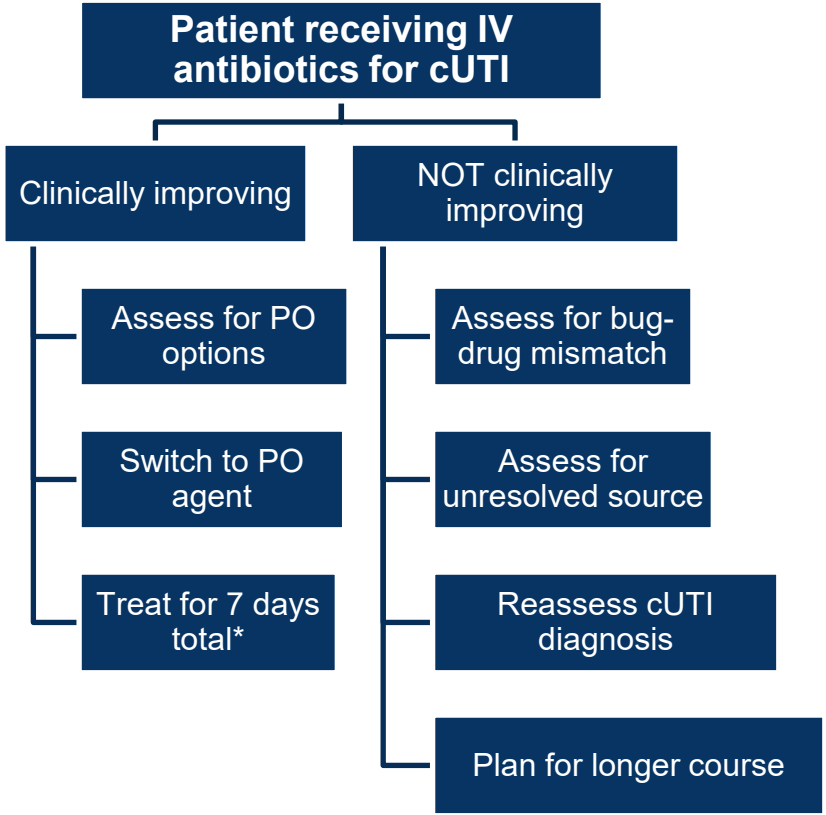
Clinically improving on effective therapy – shorter course is appropriate!

- **Effective antimicrobial agent** = achieves therapeutic levels in the bloodstream, urine, and relevant tissue
- Duration of therapy is counted from the first day of effective antibiotic therapy
- Men with febrile UTI in whom acute bacterial prostatitis is suspected may benefit from a longer treatment duration (14 days or more)
- Consider evaluation for an ongoing nidus of infection requiring source control in patients who do not have prompt clinical improvement
- Places a high value on antibiotic stewardship considerations

Trautner BW, *et al. Clin Infect Dis* 2025. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

Complicated UTI – Assessment of IV to PO and Duration

2025 IDSA Guidelines



*for cUTI without bacteremia – FQN duration could be 5-7d total

Trautner BW, *et al. Clin Infect Dis* 2025. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

Assessment: Patient Case #2

- 45 year old female presents with dysuria and increased frequency, no fever or flank pain
- **PMH:** DM2, Rheumatoid Arthritis, Anxiety, Obesity
- **Allergies:** sulfa (hives)
- **Relevant lab results:** urine dipstick positive for leukocyte esterase, nitrite negative
- **No recent reported antibiotic use**

What is the most appropriate empiric regimen for treatment of this patient?

A. Nitrofurantoin 100mg PO BID x 7 days
B. Ciprofloxacin 500mg PO BID x 5 days
C. Nitrofurantoin 100mg PO BID x 5 days
D. Fosfomycin 3g PO x 1

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B. Ciprofloxacin 500mg PO BID x 5 days
C. Nitrofurantoin 100mg PO BID x 5 days
D. Fosfomycin 3g PO x 1

Trautner BW, *et al*. *Clin Infect Dis* 2025. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

Assessment: Patient Case #3

- 67 year old male presents with dysuria, fever (101F), and hypotension
- **PMH:** Obesity, gout, BPH; **Allergies:** None
- **Relevant lab results:**
  - Urinalysis positive for leukocyte esterase, nitrites, and WBC > 20; serum WBC = 22 k/uL
  - **Blood culture:** *Proteus mirabilis* (**Resistant:** Ampicillin, Ampicillin/Sulbactam, Cefazolin, and Trimethoprim/Sulfamethoxazole; **Susceptible:** Ceftriaxone, Ciprofloxacin, Levofloxacin, Piperacillin/Tazobactam, and Tobramycin)
  - **Urine culture:** > 100,000 cfu/ml *Proteus mirabilis* (**Resistant:** Ampicillin, Ampicillin/Sulbactam, Cefazolin, and Trimethoprim/Sulfamethoxazole; **Susceptible:** Ceftriaxone, Ciprofloxacin, Levofloxacin, Nitrofurantoin, Piperacillin/Tazobactam, and Tobramycin)

Patient was initially started on Ceftriaxone (has completed 3 days of therapy), has now been clinically improving and the provider would like to switch to an oral regimen – which is most optimal?

A. Cefdinir 300mg PO BID x 4 more days
B. Ciprofloxacin 500mg PO BID x 2 more days
C. Nitrofurantoin 100mg PO BID x 4 more days
D. Levofloxacin 750mg PO daily x 4 more days

Assessment: Patient Case #3

- 67 year old male presents with dysuria, fever (101F), and hypotension
- **PMH:** Obesity, gout, BPH; **Allergies:** None
- **Relevant lab results:**
  - Urinalysis positive for leukocyte esterase, nitrites, and WBC > 20; serum WBC = 22 k/uL
  - **Blood culture:** *Proteus mirabilis* (**Resistant:** Ampicillin, Ampicillin/Sulbactam, Cefazolin, and Trimethoprim/Sulfamethoxazole; **Susceptible:** Ceftriaxone, Ciprofloxacin, Levofloxacin, Piperacillin/Tazobactam, and Tobramycin)
  - **Urine culture:** > 100,000 cfu/ml *Proteus mirabilis* (**Resistant:** Ampicillin, Ampicillin/Sulbactam, Cefazolin, and Trimethoprim/Sulfamethoxazole; **Susceptible:** Ceftriaxone, Ciprofloxacin, Levofloxacin, Nitrofurantoin, Piperacillin/Tazobactam, and Tobramycin)

Patient was initially started on Ceftriaxone (has completed 3 days of therapy), has now been clinically improving and the provider would like to switch to an oral regimen – which is most optimal?

A. Cefdinir 300mg PO BID x 4 more days
B. Ciprofloxacin 500mg PO BID x 2 more days
C. Nitrofurantoin 100mg PO BID x 4 more days
D. Levofloxacin 750mg PO daily x 4 more days

Newer Antibiotics for the Treatment of Urinary Tract Infection

Newer Antibiotics FDA Approved for UTI

Antibiotic	FDA Approval Date	uUTI	cUTI	FDA Indication	ESBL* Coverage
Pivmecillinam (brand name: Pivya)	April 2024	**YES**	NO	Treatment of **female adults** with uUTI	**YES**
Sulopenem Etzadraoxil* (brand name: Orlynvah)	October 2024	**YES**	NO	Treatment of **female adults** with uUTI	**YES**
Gepotidacin (brand name: Blujepa)	March 2025	**YES**	NO	Treatment of uUTI in **females aged > 12 years old**	**YES**
Tebipenem Pivoxil (brand name: Utebzi)	June 2026	NO	**YES**	Treatment of **adults** with cUTI, including pyelonephritis	**YES**

*Sulopenem is sold as a tablet in combination with probenicid ; ESBL = Extended Spectrum Beta-Lactamase

Pivmecillinam, Sulopenem, Gepotidacin, Tebipenem Pivoxil. In: Lexi-Drugs Online. UpToDate Inc.; [2026]. Accessed [August 21, 2026]. https://online.lexi.com

Pivmecillinam

- **Recommended Dose:** One tablet (185mg) by mouth three times daily for 3-7 days
- **Drug class:** Penicillin
- **Common Side Effects:** GI related (upset stomach, diarrhea)
- **Warnings/Precautions:**
  - Avoid if prior history of penicillin allergy
  - Avoid if primary or secondary carnitine deficiency
- **Drug Interactions:** minimal
- **Cost (AWP):** $123.60 per tablet
  - $1100-$2600 per treatment course depending on duration of therapy

Pivmecillinam. In: Lexi-Drugs Online. UpToDate Inc.; [2026]. Accessed [August 21, 2026]. https://online.lexi.com

Pivmecillinam vs. Cephalexin for uUTI

- **Multi-center, randomized double-blinded safety and efficacy trial in the US comparing:**
  - Pivmecillinam 185mg 3x/day (n = 127) x 3 days
  - Cephalexin 250mg 4x/day (n = 132) x 7 days
- **Patient Population:** females aged ≥18 years with evidence of pyuria, a baseline urine culture, and symptoms with ≥2 of uUTI (dysuria, urinary frequency, urinary urgency, and suprapubic pain)
- **Outcomes assessed:** clinical response, microbiological response, and overall/composite response

Table 1. Results

Outcome	Pivmecillinam n = 127	Cephalexin n = 132	Difference (95% CI)
Overall Response, n (%)	91 (71.7)	100 (75.8)	-4.1 (-15.6 to 7.4)
Clinical Response, n (%)	105 (82.7)	112 (84.8)	-2.2 (-11.9 to 7.6)
Microbiological Response, n (%)	97 (76.4)	106 (80.3)	-3.9 (-14.7 to 6.9)

Conclusion: Results demonstrate efficacy of Pivmecillinam 185 mg three times daily for 3 days with similar overall outcomes/success rates in comparison to Cephalexin 250mg four times daily for 7 days for the treatment of uncomplicated UTI

Menday AP. *Int J Antimicrob Agents* 2000; 13:183-7.
Lodise TP *et al*. *Clin Infect Dis* 2025;81(5):e285-93 .

Sulopenem Etzadroxil*

- **Recommended Dose:** One tablet (500mg/500mg) with food twice daily for 5 days
- **Drug class:** Thiopenem
- **Common Side Effects:** GI related (upset stomach, diarrhea), headache
- **Warnings/Precautions:**
  - Contraindicated if known uric acid kidney stones
  - Caution if known prior beta lactam allergy with anaphylaxis
  - Use is not recommended if CrCL < 15ml/min or on hemodialysis
- **Drug Interactions:**
  - Contraindicated with Ketorolac (Risk X – avoid use)
  - Many other interactions – mainly related to Probenicid
- **Cost (AWP):** $357 per tablet ($3570 for full treatment course)

*Oral tablet formulation includes both Sulopenem Etzadroxil and Probenicid)

Sulopenem. In: Lexi-Drugs Online. UpToDate Inc.; [2026]. Accessed [August 21, 2026]. https://online.lexi.com

Sulopenem vs. Ciprofloxacin for uUTI

- **Prospective, randomized, multicenter, double-blind, double-dummy study at 142 centers in 4 countries comparing:**
  - Sulopenem etzadroxil/Probenicid 500mg/500mg twice daily for 5 days
  - Ciprofloxacin 250mg twice daily for 3 days
- **Inclusion Criteria:** women aged ≥18 years with a positive urinalysis and ≥ 2 signs/symptoms of uUTI (urinary frequency, urgency, dysuria, or suprapubic pain)
- **Primary endpoint:** Overall success, defined as both clinical and microbiologic response at day 12
  - For Ciprofloxacin-nonsusceptible pathogens → Sulopenem was compared for superiority over Ciprofloxacin
  - For Ciprofloxacin-susceptible pathogens → Ciprofloxacin and Sulopenem were compared for non-inferiority (limit for non-inferiority was set at -10%)

Dunne MW, *et al*. *Clin Infect Dis* 2022 Sep 7;76(1):66–77.

Sulopenem vs. Ciprofloxacin for uUTI

Table 1. Results - Ciprofloxacin non-susceptible

Outcome	Sulopenem n = 147	Ciprofloxacin n = 139	Difference (95% CI)	p value
Overall Success at Day 12, n (%)	92 (62.6)	50 (36)	26.6 (15.1 to 37.4)	< 0.001

Table 2. Results - Ciprofloxacin susceptible

Outcome	Sulopenem n = 370	Ciprofloxacin n = 415	Difference (95% CI)
Overall Success at Day 12, n (%)	247 (66.8)	326 (78.6)	−11.8 (−18.0 to −5.6)

Table 3. Results - Combined Groups

Outcome	Sulopenem n = 517	Ciprofloxacin n = 554	Difference (95% CI)
Overall Success at Day 12, n (%)	339 (65.6)	376 (67.9)	−2.3 (−7.9 to 3.3)

Conclusions: Sulopenem overall was noninferior to ciprofloxacin in the treatment of uUTIs. Sulopenem was superior to ciprofloxacin in patients with uUTIs due to ciprofloxacin-nonsusceptible pathogens. Sulopenem was not noninferior in patients with ciprofloxacin-susceptible pathogens.

Dunne MW, *et al*. *Clin Infect Dis* 2022 Sep 7;76(1):66–77.

Gepotidacin

- **Recommended Dose:** Two tablets (1.5 grams) after meals twice daily for 5 days
  - Females ≥12 years old and weighing ≥ 40kg
- **Drug class:** Triazaacenaphthylene
- **Common Side Effects:** GI related (stomach pain, diarrhea, vomiting, gas), headache, muscle spasm, sweating, feeling tired, increased salivation
- **Warnings/Precautions:**
  - Risk of QTC prolongation
  - Acetylcholinesterase inhibition (adverse reactions, increased cholinergic effects when severe)
  - Avoid use if CrCL < 30ml/min, hemodialysis, or severe liver impairment (Child-Pugh Class C)
- **Drug Interactions:** Major substrate of CYP3A4 – many interactions
- **Cost (AWP):** $114 per 750mg tablet, cost per 1.5 g dose = $228 ($2280 per treatment course)

Gepotidacin. In: Lexi-Drugs Online. UpToDate Inc.; [2026]. Accessed [August 21, 2026]. https://online.lexi.com

Gepotidacin vs. Nitrofurantoin for uUTI

- **EAGLE-2 and EAGLE-3:** Phase 3, randomized, multicenter, double-blind, double-dummy, non-inferiority (10% margin) trials at 219 centers worldwide
  - Gepotidacin 1500mg twice daily x 5 days
  - Nitrofurantoin 100mg twice daily x 5 days
- **Inclusion Criteria:** Female, non-pregnant, aged 12 years or older, > 40kg, with evidence of positive urinalysis and 2 or more symptoms of uUTI (dysuria, frequency, urgency, or lower abdominal pain)
- **Primary Endpoint:** Therapeutic response (success or failure) at test-of-cure (day 10–13)
  - **Therapeutic success:** combined clinical success and microbiological success without other systemic antimicrobial use
  - After an interim analysis→ both studies were stopped for efficacy
  - Primary analysis population →adjusted to include only patients who, at the time of the interim analysis data cutoff, had the opportunity to reach the test-of-cure visit or were known to not have attained therapeutic success before the test-of-cure visit

Wagenlehner F, *et al.Lancet* 2024;43 (10428):741-55.

Gepotidacin vs. Nitrofurantoin for uUTI

Table 1. Results - EAGLE-2

Outcome	Gepotidacin n = 320	Nitrofurantoin n = 287	Adjusted Difference (95% CI)
Therapeutic Success, n (%)	162 (50.6)	135 (47)	4.3 (–3.6 to 12.1)

Table 2. Results - EAGLE-3

Outcome	Gepotidacin n = 277	Nitrofurantoin n = 264	Adjusted Difference (95% CI)
Therapeutic Success, n (%)	162 (58.5)	115 (43.6)	14.6 (6.4 to 22.8)

Conclusion: Gepotidacin was non-inferior to nitrofurantoin in both studies and superior to nitrofurantoin in EAGLE-3.

Wagenlehner F, *et al.Lancet* 2024;43(10428):741-55.

Tebipenem Pivoxil

- **Recommended Dose:** 600mg by mouth every 6 hours for 5-7 days
  - Can be used in male and female adults with complicated UTI (including pyelonephritis)
- **Drug class:** Carbapenem
- **Common Side Effects:** GI related (stomach pain, diarrhea), headache
- **Warnings/Precautions:**
  - Caution if known prior beta lactam allergy with anaphylaxis
  - Avoid if primary or secondary carnitine deficiency
  - Avoid if known CNS disorders – increased risk of seizures/other CNS reactions
  - Avoid use if CrCL < 15ml/min
- **Drug Interactions:** Valproic Acid and derivatives, OAT 1/3 inhibitors
- **Cost (AWP):** not on the market yet

Tebipenem Pivoxil. In: Lexi-Drugs Online. UpToDate Inc.; [2026]. Accessed [August 21, 2026]. https://online.lexi.com

Tebipenem vs. IV Carbapenems for cUTI

	Study Design	Patient Population	Key Inclusion/Exclusion Criteria
Tebipenem vs. IV Ertapenem	Phase 3, international, double-blind, double-dummy, non-inferiority trial	hospitalized, adult patients with cUTI or pyelonephritis	**Inclusion:** ≥ 18 years of age, diagnosis of cUTI or acute pyelonephritis **Exclusion:** confirmed or suspected infection with a carbapenem-resistant pathogen, CrCL ≤ 30ml/min, receipt of more than one dose of a short-acting antibiotic within 72 hours before randomization, septic shock, severe hepatic impairment, pregnancy, immunocompromised, hypersensitivity to any beta-lactam antibiotic
Tebipenem vs. IV Imipenem-cilastatin	Randomized, international, double-blind, double-dummy, non-inferiority trial	hospitalized, adult patients with cUTI or pyelonephritis	**Inclusion:** ≥ 18 years of age, diagnosis of cUTI or acute pyelonephritis **Exclusion:** CrCL ≤ 30ml/min, receipt of potential effective antimicrobial within 72 hours before randomization, history of known seizure disorder, severe hepatic impairment, pregnancy, HIV, valproic acid derivatives

Eckburg PB, *et al*. *N Engl J Med* 2022;386:1327-1338.
Hong DK, *et al*. *Open Forum Infect Dis* 2026 Jan 11; 13(Suppl 1).

Tebipenem vs. IV Carbapenems for cUTI

	Treatment	Results	Conclusion
Tebipenem vs. IV Ertapenem	Tebipenem 600mg PO q8h vs. Ertapenem 1g IV q24h Duration: 7-10 days	**Overall Response*** • Tebipenem: 264/449 (58.8%) • Ertapenem: 258/419 (61.6%) • **Weighted Difference:** –3.3% • **95% CI:** –9.7 to 3.2	Oral Tebipenem pivoxil was noninferior to IV Ertapenem in the treatment of cUTI and acute pyelonephritis
Tebipenem vs. IV Imipenem–cilastatin	Tebipenem 600mg PO q6h vs. Imipenem-cilastatin 500mg IV q6h Duration: 7-10 days	**Overall Response*** • Tebipenem: 261/446 (58.5%) • Imipenem-cilastatin: 291/483 (60.2%) • **Adjusted Difference:** –1.3% • **95% CI:** –7.5 to 4.8 • **NOTE:** Treatment effects were comparable in participants with ESBL+ Enterobacterales	Oral Tebipenem pivoxil was non-inferior to IV Imipenem-cilastatin in the treatment of cUTI or acute pyelonephritis and showed comparable efficacy in participants with ESBL+ *Enterobacterales*

***Overall Response:** composite endpoint of clinical and microbiological cure

Eckburg PB, *et al*. *N Engl J Med* 2022;386:1327-1338.
Hong DK, *et al*. *Open Forum Infect Dis* 2026 Jan 11; 13(Suppl 1).

Assessment: Patient Case #4

- 80 year old female presents with dysuria and increased frequency, afebrile, no systemic signs of infection
- **PMH:** Hypertension, Hyperlipidemia, CHF, Osteoarthritis
- **Allergies:** Penicillin (hives – tolerates Cephalosporins)
- **Relevant lab results:** urinalysis > 50 WBC, leukocyte esterase positive
- **Urine culture:** > 100,000 cfu/ml ESBL *Klebsiella pneumoniae* (**Resistance:** Ampicillin, Ampicillin/Sulbactam, Cefazolin, Ceftriaxone, Cefepime, Ciprofloxacin, Levofloxacin, Nitrofurantoin, Piperacillin/Tazobactam, Tobramycin, Trimethoprim/Sulfamethoxazole; **Susceptible:** Ertapenem, Meropenem)

Which of the following newer antibiotics would NOT be FDA indicated for this patient?

A. Gepotidacin
B. Tebipenem pivoxil
C. Sulopenem etzadroxil
D. Pivmecillinam

Assessment: Patient Case #4

- 80 year old female presents with dysuria and increased frequency, afebrile, no systemic signs of infection
- **PMH:** Hypertension, Hyperlipidemia, CHF, Osteoarthritis
- **Allergies:** Penicillin (hives – tolerates Cephalosporins)
- **Relevant lab results:** urinalysis > 50 WBC, leukocyte esterase positive
- **Urine culture:** > 100,000 cfu/ml ESBL *Klebsiella pneumoniae* (**Resistance:** Ampicillin, Ampicillin/Sulbactam, Cefazolin, Ceftriaxone, Cefepime, Ciprofloxacin, Levofloxacin, Nitrofurantoin, Piperacillin/Tazobactam, Tobramycin, Trimethoprim/Sulfamethoxazole; **Susceptible:** Ertapenem, Meropenem)

Which of the following newer antibiotics would NOT be FDA indicated for this patient?

A. Gepotidacin

B. Tebipenem pivoxil

C. Sulopenem etzadroxil

D. Pivmecillinam

So when do we use these newer antibiotics?

- Place is therapy in still limited overall (cost, lack of necessity in hospital setting, many other alternatives for treatment of UTI)
- Susceptibility testing is not routinely available
- All showed non-inferiority to standard of care comparison agents
- Do not necessarily routinely provide any added benefit clinically for treatment of UTI over other available agents when pathogens causing infection are not multi-drug resistant
- **All 4 agents can provide coverage for ESBL producing organisms**

Extended Spectrum Beta Lactamase *Enterobacterales* (ESBL-E)

Infectious Diseases Society of America 2026 Guidance on the Treatment of Antimicrobial-Resistant Gram-Negative Infections

- Includes most up to date recommendations for ESBL-E (in addition to other multi-drug resistant gram negatives)
- **ESBLs are enzymes that inactivate most penicillins, cephalosporins, and aztreonam**
  - Remain susceptible to carbapenems
  - Do not inactivate non-beta lactam agents (ex. fluoroquinolones, trimethoprim/sulfamethoxazole, aminoglycosides, nitrofurantoin, fosfomycin*)
  - Most common ESBL gene in the US is CTX-M
- **Most prevalent gram negative ESBL-E organisms:** *Escherichia coli, Klebsiella pneumoniae, Klebsiella oxytoca,* and *Proteus mirabilis*

***Fosfomycin has activity for ESBL *E. coli* only**

Tamma PD, *et al. Clinical Infectious Diseases*, 2026; https://www.idsociety.org/globalassets/idsa/practice-guidelines/amr-guidance/5.0/amr-guidance-update.pdf

Treatment of UTIs Caused by ESBL-E

2026 IDSA Guidelines

Uncomplicated cystitis/uUTI

- **Preferred:** Nitrofurantoin and TMP/SMX
- **Second Line:** Ciprofloxacin, Levofloxacin, IV Carbapenems
- **Alternatives:** Aminoglycoside (single dose x 1), PO Fosfomycin*, Gepotidacin, Pivmecillinam, or Sulopenem

Pyelonephritis or cUTI

- **Preferred Oral:** TMP/SMX, Ciprofloxacin, Levofloxacin
- **Preferred IV or if unable to take oral:** IV Carbapenems or Cefepime-enmetazobactam
- **Alternative:** Aminoglycosides

Infections outside urinary tract
(including UTI with secondary bacteremia)

- **Preferred:** Meropenem, Imipenem-Cilastatin, or Ertapenem
- **Alternative:** Cefepime-enmetazobactam
- **Once clinical improvement and susceptibilities known:** consider oral TMP/SMX, Ciprofloxacin, Levofloxacin

*Fosfomycin has activity for ESBL *E. coli* only

Tamma PD, *et al. Clinical Infectious Diseases*, 2026; https://www.idsociety.org/globalassets/idsa/practice-guidelines/amr-guidance/5.0/amr-guidance-update.pdf

Newer UTI Antibiotics and ESBL-E uUTI

2026 IDSA Guidelines

- **Pivmecillinam**
  - Distinctive structure makes it a poor substrate for ESBL-E isolates
  - Shown activity for > 90% ESBL-E isolates
  - Observational studies have suggested increased failure risk for ESBL-E compared to non ESBL-E uUTIs; failure not shown when using higher dosing regimen (370mg q8h)
- **Sulopenem**
  - Shown activity for > 95% ESBL-E isolates
  - Similar response for ESBL-E uUTIs when compared to Ciprofloxacin
- **Gepotidacin**
  - Retains activity against some FQN resistant strains
  - Shown activity for > 90% of ESBL-E isolates in studies
  - Subgroup analysis in prior studies for women with ESBL *E. coli* uUTI showed numerically favorable results data from studies suggest at least as effective as Nitrofurantoin for ESBL-E uUTI

Tamma PD, *et al. Clinical Infectious Diseases*, 2026; https://www.idsociety.org/globalassets/idsa/practice-guidelines/amr-guidance/5.0/amr-guidance-update.pdf

Antibiotic Dosing Recommendations for ESBL-E

2026 IDSA Guidelines

Antibiotic	uUTI	cUTI/Pyelonephritis +/- Bacteremia
Amikacin	15mg/kg IV x 1 dose	15mg/kg IV x 1, subsequent dose/interval based on pharmacokinetics
Ciprofloxacin	400mg IV q12h, 500mg PO q12h	400mg IV q8h, 750mg PO q12h
Ertapenem	1g IV q24h	1g IV q24h
Fosfomycin	3g PO x 1	Not applicable
Gentamicin	5mg/kg IV x 1	7mg/kg IV x 1, subsequent dose/interval based on pharmacokinetics
Gepotidacin	1.5g PO q12h	Not applicable
Imipenem-cilastatin	500mg IV q6h	500mg IV q6h or 1,000mg IV q8h
Levofloxacin	750mg IV/PO q24h	750mg IV/PO q24h
Meropenem	1g IV q8h	2g IV q8h
Nitrofurantoin macrocystals	100mg PO q12h	Not applicable
Pivmecillinam	370mg PO q8h	Not applicable
Sulopenem etzadroxil-probenicid	500mg PO q12h	Not applicable
Tobramycin	5mg/kg IV x 1	7mg/kg IV x 1, subsequent dose/interval based on pharmacokinetics
Trimethoprim-sulfamethoxazole	160mg-800mg PO q12h	Consider increasing to weight-based dose (10-15mg/kg/day trimethoprim component IV/PO divided q8-12h)

Tamma PD, *et al. Clinical Infectious Diseases*, 2026; https://www.idsociety.org/globalassets/idsa/practice-guidelines/amr-guidance/5.0/amr-guidance-update.pdf

Assessment: Patient Case #5

- 50 year old female presents to clinic with increased frequency and urgency with urination, no fevers/chills/flank pain
- **PMH:** recurrent UTI, depression, DM2
- **Allergies:** FQN (tendon rupture)
- **Relevant lab results:** urine dipstick positive for leukocyte esterase and nitrite
- **Urine culture:** > 100,000 cfu/ml ESBL *E. coli* (**Resistance:** Ampicillin, Ampicillin/Sulbactam, Cefazolin, Ceftriaxone, Cefepime, Nitrofurantoin, Piperacillin/Tazobactam, Trimethoprim/Sulfamethoxazole, Tobramycin; **Susceptible:** Ciprofloxacin, Ertapenem, Fosfomycin, Levofloxacin)

What would be the most optimal antibiotic choice considering the IDSA guidelines for ESBL-E treatment, cost, and availability?

A. Ciprofloxacin 500mg PO q12h x 3 days
B. Gepotidacin 1.5g PO q12h x 5 days
C. Fosfomycin 3g PO x 1
D. Sulopenem 500mg/500mg PO q12h x 5 days

Assessment: Patient Case #5

- 50 year old female presents to clinic with increased frequency and urgency with urination, no fevers/chills/flank pain
- **PMH:** recurrent UTI, depression, DM2
- **Allergies:** FQN (tendon rupture)
- **Relevant lab results:** urine dipstick positive for leukocyte esterase and nitrite
- **Urine culture:** > 100,000 cfu/ml ESBL *E. coli* (**Resistance:** Ampicillin, Ampicillin/Sulbactam, Cefazolin, Ceftriaxone, Cefepime, Nitrofurantoin, Piperacillin/Tazobactam, Trimethoprim/Sulfamethoxazole, Tobramycin; **Susceptible:** Ciprofloxacin, Ertapenem, Fosfomycin, Levofloxacin)

What would be the most optimal antibiotic choice considering the IDSA guidelines for ESBL-E treatment, cost, and availability?

A. Ciprofloxacin 500mg PO q12h x 3 days
B. Gepotidacin 1.5g PO q12h x 5 days
C. Fosfomycin 3g PO x 1
D. Sulopenem 500mg/500mg PO q12h x 5 days

Summary

- Assessment of urinary symptoms and the presence of other systemic signs of illness can help differentiate between uUTI versus cUTI
- Differences in treatment duration for uUTI are dependent on drug class chosen with shorter duration typically being sufficient for most patients (3-5 days)
- Empiric therapy in cUTI is determined based on severity of illness at presentation, when clinical improvement is shown and susceptibilities reported – switching to an effective agent orally and treating for 7 days is sufficient for most patients
- Multiple newer antibiotics have been recently approved for the treatment of UTIs – however cost and lack of availability for susceptibility testing could make them overall less applicable in clinical practice
- Many treatment options are available for ESBL-E UTI – determination of optimal drug, route, and duration is dependent on uUTI versus cUTI versus concurrent bacteremia

Thank you

Treatment of Urinary Tract Infections (UTIs):

Optimizing Antimicrobial Therapy and Assessing New Antibiotics for UTI

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