Pharmaceutical Society of Australia

This document is designed to provide guidance to pharmacists on a range of issues including appropriate and effective processes, desired behaviour of good practice, how professional responsibilities may be best fulfilled, and expected outcomes. At all times, pharmacists must meet any legislative requirements and are expected to exercise professional judgment in adapting the guidance provided here to presenting circumstances.

Treatment guideline for pharmacists
Cystitis

2020

Consider professional obligations

A Professional standards
B Privacy
C Documentation

Assess patient needs

Consider:
D Presenting symptoms
E Age
F Patient history
G Pregnancy

Refer when

- Signs and symptoms of pyelonephritis:
  - fever >38 °C
  - chills or rigors
  - back or side (flank) pain
  - nausea or vomiting
- Symptoms of cystitis persist 48–72 hours after starting appropriate antibiotic treatment
- Symptoms of cystitis reoccur within 2 weeks after finishing appropriate antibiotic treatment
- Only one primary symptom of acute cystitis
- Symptoms or medical history suggest a cause other than acute cystitis, vulvovaginal candidiasis or bacterial vaginosis
- Age <18 years or >65 years
- Previous episodes of pyelonephritis
- Risk of complicated urinary tract infection (UTI) – also see *F. Patient history:*
  - pregnancy
  - postpartum
  - immunocompromised
  - diabetes
  - renal disease or impaired renal function
  - urinary tract abnormality or obstruction
  - urinary catheter within last 48 hours
  - antibiotics within last 3 months
  - inpatient/resident of a healthcare or other care facility within last 3 months
  - overseas travel within last 3 months
- Recurrent UTI:
  - Two or more UTIs within 6 months
  - Three or more UTIs within 12 months
- Intrauterine device (IUD) in situ
- Risk factors for sexually transmissible infection

Confirm recommendation is appropriate

Consider:
H Treatment options
I Contraindications and precautions
J Lactation
K Drug interactions

Supply and/or refer if necessary

- First time symptoms
- Symptoms not previously diagnosed by a medical practitioner
- Contraindications and precautions
- Concurrent medicines

Provide counselling (supported by written information)

Consider:
L Dose
M Additional dosing advice
N Treatment expectations
O Adverse effects
P Self-care strategies
Q Follow-up advice

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Explanatory notes

Note: In this guidance document, the term 'female' refers to a patient with anatomy characteristic of a biologic female.[1] This guidance document focuses on treatment of urinary tract infection (UTI) in a person with a biologic female urinary tract. Pharmacists may need to consider whether this guidance applies to a transgender person.

A. Professional standards

The *Professional Practice Standards* (PPS)[2] outline the appropriate actions to be taken by pharmacists and trained pharmacy staff in response to a direct product- or symptom-based request.

The *Code of Conduct for Pharmacists*[3] and the *Code of Ethics for Pharmacists*[4] provide guidance on the ethical framework through which effective health services should be delivered.

The *Guidelines for Advertising Regulated Health Services*[5] provides guidance about obligations of pharmacists under the National Law with respect to advertising. All advertisements for the service must comply with relevant Commonwealth, state and territory legislation.

B. Privacy

Pharmacists must meet their obligations in relation to respecting the patient's privacy and confidentiality in the provision of antibiotics for acute uncomplicated cystitis, and associated patient counselling.[2] This includes offering patients a private consultation area where conversations can occur at normal speaking volumes without being overheard.

All written communication, including electronic communication (e.g. email), that contains the patient's health information should be secure.[6]

C. Documentation

Pharmacists are advised to document the service provided according to the PPS. In addition, pharmacists should record the supply of antibiotics for acute uncomplicated cystitis in accordance with relevant legislation and professional responsibilities.[2] Documentation of referral, and any education or counselling provided to the patient is also advised.

If the patient provides consent, pharmacists are advised to inform the patient's preferred medical practitioner in writing of the supply of an antibiotic for acute uncomplicated cystitis.

D. Presenting symptoms

Most UTIs occur when bacteria from the bowel spread into and up the urethra to the bladder. Sometimes the bacteria also spread up the ureters to the kidneys. Occasionally, bacteria or other micro-organisms spread into the kidney from the bloodstream.[7,8,9,10]

The female urinary tract is particularly susceptible to UTIs because the urethral meatus is close to the anus and the urethra (distance to the bladder) is short. In females, UTI most commonly causes inflammation of the urethra (urethritis) and bladder (cystitis), but UTI can also involve the ureters (ureteritis) and kidneys (pyelonephritis).[7,11,12,13]

The most common cause of UTIs is *Escherichia coli.* Other bacteria that cause UTI include Proteus, Klebsiella, Enterococci, group B Streptococci, Staphylococcus and Pseudomonas species.[14]

Symptoms of cystitis

The primary symptoms of acute cystitis are[7,9,14]:

- dysuria (pain, discomfort, stinging or burning when urinating)
- urinary urgency
- urinary frequency
- suprapubic (above the pubic bone) pain or discomfort.

Cystitis may also cause cloudy, bloody or strong-smelling urine. However, urine colour and odour are not reliable signs of UTI as they can be influenced by food intake, hydration status, and other conditions or factors.[7,11]

The symptoms of cystitis are often caused by UTI, but similar symptoms can be caused by a number of other conditions—see examples in Table 1.[7,8,15]

If the patient is a female with two or more primary symptoms of acute cystitis, and no other symptoms, consider providing an appropriate antibiotic. See *E. Age, F. Patient history* and *H. Treatment options*.

If the patient's symptoms are suggestive of vulvovaginal candidiasis or bacterial vaginosis, consider recommending treatment with an appropriate *Pharmacist Only* medicine. Refer the patient to a medical practitioner if symptoms suggestive of other conditions are present. See Table 1.

Table 1. Some conditions with symptoms similar to cystitis

Cause	Symptoms similar to cystitis	Other symptoms
Vulvovaginal candidiasis	• Dysuria (when urine is in contact with vulvar skin)	• Vulvovaginal itch (most common symptom) • Vulvovaginal soreness and burning • Vulvovaginal redness and swelling • Dyspareunia • Odourless vaginal discharge that may be thick and white, or watery
Bacterial vaginosis	• Dysuria	• Vaginal itching • Unpleasant fishy vaginal odour • Thin, grey or white vaginal discharge
Vulvovaginal atrophy	• Dysuria • Urethral discomfort • Urinary urgency and frequency	• Vulvovaginal dryness, burning, irritation, itching • Vulvar or vaginal bleeding • Milky or yellow vaginal discharge • Dyspareunia
Vulvar lichen sclerosus	• Dysuria	• Vulvar itching and discomfort • Vulvar white patches • Anal itch and painful defecation • Dyspareunia
Sexually transmissible infections • **chlamydia** • **gonorrhoea** • **trichomoniasis**	• Dysuria • Urinary frequency • Lower abdominal or pelvic pain	• Vaginal bleeding between periods • Dyspareunia • Abnormal vaginal discharge (e.g. mucopurulent, malodorous, thin and frothy) • Vulvar itch • Rectal pain, bleeding or discharge
Genital herpes	• Dysuria (when urine is in contact with ulcers) • Lower back pain	• Genital blisters/painful ulcers • Genital itch • Headache, malaise, myalgia • Fever

Table 1. Some conditions with symptoms similar to cystitis (continued)

Cause	Symptoms similar to cystitis	Other symptoms
Pelvic inflammatory disease	• Dysuria • Urinary frequency • Lower abdominal or pelvic pain	• Vaginal bleeding between periods • Dyspareunia • Malodorous, mucopurulent vaginal discharge • Fever (+/-chills)
Bladder cancer	• Dysuria • Urinary urgency and frequency • Back or pelvic pain • Haematuria	
Bladder calculi (stones)	• Dysuria • Urinary frequency • Lower abdominal pain • Haematuria	• Difficulty urinating or interrupted urine flow
Interstitial cystitis (bladder pain syndrome)	• Dysuria • Urinary urgency and frequency • Suprapubic pain	• Perineal pain • Pelvic pain • Bladder pain, pressure or spasms • Pubic pressure • Dyspareunia
Haemorrhagic cystitis (e.g. due to cyclophosphamide, ifosfamide, or radiation therapy)	• Dysuria • Urinary urgency and frequency • Suprapubic pain • Haematuria	
Appendicitis	• Dysuria • Urinary frequency • Lower abdominal pain	• Pain worsens with jarring movements • Nausea and vomiting • Loss of appetite • Abdominal bloating • Constipation or diarrhoea • Flatulence • Fever
Diverticulitis	• Dysuria • Urinary urgency and frequency • Suprapubic pain • Lower abdominal pain	• Nausea and vomiting • Constipation or diarrhoea • Fever
Transvaginal mesh implant	• Urinary urgency • Back or pelvic pain • Haematuria	• Urinary retention • Urinary incontinence • Poor urine flow • Vaginal bleeding between periods • Dyspareunia • Recurrent UTI or vaginal infection

References: Mayo Clinic[11]; Sobel[18]; Ross[19]; Hsu[20]; Ghanem[21]; Albrecht[22]; Murtagh[16]; Lotan[23]; Martin[24]; Bachman[25]; Cooper[26]; Clemens[27]; ACSQHC[28]; Trabuco[29]; Linder[30]; Pemberton[31]; ASHA[32]

Symptoms of pyelonephritis

Signs and symptoms of acute pyelonephritis include fever (≥38 °C), chills, rigors, back or side (flank) pain, and nausea/vomiting, with or without signs and symptoms of cystitis. Pyelonephritis can lead to sepsis or kidney damage.[8,10,14,11,16] Guidelines recommend urine culture and antimicrobial sensitivity testing before starting antibiotics.[14,17] Refer the patient to a medical practitioner if signs and symptoms of pyelonephritis are present, or if the patient has a history of previous episodes of pyelonephritis.

E. Age

The incidence of UTIs increases with older age. The elderly are at increased risk of UTI due to factors such as faecal impaction, incontinence, atrophy of the vaginal and perineal mucosa, impaired bladder emptying, chronic diseases (e.g. diabetes), catheters and medicines that cause urinary retention or constipation.[33,34]

In older people, UTI symptoms can be typical (see *D. Presenting symptoms*) and/or atypical, such as confusion or behavioural changes. Existing chronic urinary symptoms and cognitive impairment make it difficult to accurately assess symptoms of UTI.[14,33,34]

Refer patients >65 years to a medical practitioner for further investigation. See also *F. Patient history*

In children, the signs and symptoms of UTI vary with age. In addition, signs and symptoms can be non-specific, so a urine sample is needed for diagnosis.[35] Refer patients <18 years to a medical practitioner for further investigation.

F. Patient history

UTI can be classified as uncomplicated (simple) or complicated (complex). A UTI is usually considered uncomplicated when it occurs in a non-pregnant, pre-menopausal female with no relevant comorbidities or urinary tract abnormalities.[8,14,17]

Complicated UTI

UTIs are usually considered complicated when they occur in people with risk factors or medical conditions that increase the likelihood of complications or treatment failure.[8,14,17] Complicated UTI is caused by a wider range of bacteria than uncomplicated UTI, and the bacteria are more likely to be antibiotic resistant.[17] Refer patients with risk factors for complicated UTI to a medical practitioner. See Table 2.

Recurrent UTIs

Many females experience recurring UTIs. Recurrent UTI is defined as two or more UTIs within 6 months or three or more UTIs within 12 months.[14,12,17,38]

Recurrent infections can be due to reinfection, or to relapse caused by bacterial persistence. Most recurrences are thought to represent reinfection. UTI is considered to be a relapse if the recurrence occurs within 2 weeks of completion of treatment for the original infection and the infecting bacterial strain is the same.[8,38]

Factors that increase the risk of UTI (and recurrent UTI) in females include[8,12,17,38,39]:

- sexual intercourse
- use of spermicide
- a new sexual partner
- intrauterine device (IUD)
- mother with a history of UTI
- UTI during childhood
- UTI before menopause
- atrophic vaginitis due to oestrogen deficiency
- pregnancy
- diabetes
- immunosuppression
- urinary tract obstruction (e.g. pelvic organ prolapse, kidney stones)
- foreign objects (e.g. catheter, bladder calculi)
- abnormalities of the urinary tract (e.g. vesicoureteral reflux)
- urinary incontinence
- increased post-voiding residual urine
- ABH blood group antigens nonsecretor phenotype.

Patients with recurrent UTI may require further investigation. In addition, recent or frequent antibiotic use for recurrent UTI is a risk factor for antibiotic resistance.[17,38] Refer patients presenting with symptoms of UTI to a medical practitioner if they have already had one UTI within the last 6 months or two UTIs within the last 12 months.

Residents of long-term care facilities

Many residents of long-term care facilities have risk factors for complicated UTI, such as comorbidities and age-related changes that affect genitourinary function. In addition, the presence of multidrug-resistant bacteria is common in long-term care facilities.[14,40,41] See Table 2. Refer patients in long-term care with genitourinary symptoms to a medical practitioner for further investigation.

Risk of sexually transmissible infection (STI)

In females, symptoms of cystitis and symptoms of certain STIs (e.g. chlamydia, gonorrhoea, trichomoniasis, genital herpes) can be similar. See *D. Presenting symptoms*. Relevant risk factors for STI in females include[42,43,44,45]:

- age ≤29 years
- previous STI
- sexual contact without a condom/dental dam outside a mutually monogamous relationship
- a new sex partner in last 60 days
- multiple sex partners
- a sex partner with multiple other sex partners
- a sex partner recently treated for an STI
- sexual contact with a sex worker.

Refer patients with relevant risk factors for STI to a medical practitioner for further investigation.

G. Pregnancy

Pregnancy-related effects on the bladder and ureters increase the risk that bacteriuria will progress to pyelonephritis. In addition, bacteriuria or UTI during pregnancy increases the risk of adverse pregnancy outcomes**.** [39,46] Refer pregnant patients presenting with symptoms of UTI to a medical practitioner.

Females can develop urinary tract complications, including infection, in the postpartum period after childbirth.[36] Refer patients presenting with symptoms of UTI who are in the postpartum period to a medical practitioner.

Table 2. Risk factors for complicated UTIs in females

Risk factor	Examples
Patient factors	• Age <18 years or >65 years • Pregnancy • Postpartum
Immunocompromised	• Diabetes • Immunosuppressant medicines
Anatomical or functional abnormalities of urinary tract	• Vesicoureteral reflux • Obstruction (e.g. kidney stones) • Neurogenic bladder (e.g. spinal cord injury, multiple sclerosis, stroke, Parkinson's disease) • Renal disease or impaired renal function
Instrumentation of urinary tract	• Urinary catheter within the previous 48 hours • Nephrostomy tube • Ureteral stent

Microbial	• Multidrug-resistant bacteria—risk factors include:
	  • recent (within the previous 3 months) or frequent treatment with antibiotics
	  • recent (within the previous 3 months), frequent or long-term resident of a healthcare facility
	  • lack of response to initial antibiotic treatment
	  • overseas travel within the previous 3 months
	  • infection with multidrug-resistant bacteria within the previous 3 months
	• Unusual microorganism—risk factors include recent travel to a country with high rates of multidrug resistance

References: Hooton[7]; eTG[14]; Chung[15]; Bonkat[17]; Berens[36]Dorsher[37]

H. Treatment options

In females with acute uncomplicated cystitis, the diagnosis can be reliably based on symptoms alone. When at least two primary symptoms of cystitis are present, with no vaginal discharge, the probability of cystitis is >90%. Guidelines recommend starting empirical antibiotic treatment to decrease the duration and severity of symptoms, and reduce the risk of progression to acute pyelonephritis or sepsis.[7,8,9,14,17]

The options for empirical antibiotic treatment of acute uncomplicated cystitis in non-pregnant females are as follows[14]:

1. Trimethoprim—first line treatment unless the patient has been treated with trimethoprim in the previous 3 months, or has a condition that contraindicates its use.
2. Nitrofurantoin—second line treatment when trimethoprim cannot be used, and there are no contraindications to use of nitrofurantoin.
3. Cefalexin—reserve for use when trimethoprim and nitrofurantoin cannot be used. Cefalexin oral suspension may be a suitable choice for patients with swallowing difficulties.

The appropriate antibiotic choice for a particular patient will depend on the patient's history of antibiotic use, medical conditions, and medicines. See *I. Contraindications and precautions, K. Drug interactions, M. Additional dosing advice and O. Adverse effects*.

I. Contraindications and precautions

Trimethoprim

Trimethoprim is contraindicated in patients with[47,48,49]:

- history of hypersensitivity to trimethoprim
- severe haematological disorders
- megaloblastic anaemia due to folate deficiency
- renal impairment (CrCl <10 mL/min); dose reduction is recommended in patients with CrCl <15 mL/min
- porphyria.

Trimethoprim should be used with caution in patients with[47,48]:

- hepatic impairment
- electrolyte disturbances—may worsen hyperkalaemia or hyponatraemia (low risk if treatment ≤3 days)
- folate deficiency—may worsen folate deficiency (low risk if treatment ≤3 days).

Nitrofurantoin

Nitrofurantoin is contraindicated in patients with[47,48]:

- history of hypersensitivity or severe adverse effects from nitrofurantoin
- renal impairment (CrCl <60 mL/min), anuria or oliguria
- G6PD, enolase or glutathione peroxidase deficiency.

There is an increased risk of peripheral polyneuropathy when nitrofurantoin is used in patients with renal failure, anaemia, diabetes mellitus, electrolyte disturbances or vitamin B deficiency.[48]

Cefalexin

- Cefalexin is contraindicated in patients with history of hypersensitivity to cephalosporins, or immediate or severe hypersensitivity to penicillins.[47,48]
- Dose reduction should be considered in patients with renal impairment (CrCl <20 mL/min).[47,48]

The patient's My Health Record (MHR) may provide information needed to choose the most appropriate antibiotic treatment for the patient. However, do not assume the information in the MHR is a current or complete record. It is good practice to advise the patient of the MHR access, and document relevant information from the MHR in the patient's profile in the pharmacy's documentation system.[50]

Consult relevant reference texts and product information monographs if use of the most appropriate antibiotic requires caution.

Refer the patient to a medical practitioner if:

- insufficient information, contraindications or precautions compromise the safe use of each antibiotic
- the patient has impaired renal function.

J. Lactation

Trimethoprim is considered safe to use during breastfeeding. Advise the mother to observe the breastfed infant for possible adverse effects (e.g. rash, vomiting, diarrhoea).[47,51]

Nitrofurantoin is considered safe to use during breastfeeding. However, use an alternative medicine in patients who are breastfeeding infants who are less than 1 month old, or who have glucose-6-phosphate dehydrogenase (G6PD) deficiency, as there is a risk of haemolysis in these infants.[47,51]

Cefalexin is safe to use during breastfeeding. Advise the mother to observe the breastfed infant for possible adverse effects (e.g. thrush, rash, vomiting, diarrhoea).[47,51]

K. Drug interactions

Consider choosing an antibiotic that does not put the patient at risk of drug interactions. Refer the patient to a medical practitioner if potential drug interactions compromise the safe use of each antibiotic.

Trimethoprim

Trimethoprim can[47,48,52]:

- increase the risk of hyperkalaemia if taken with medicines that increase serum potassium (e.g. ACE inhibitors)
- increase concentrations and risk of toxicity of phenytoin, digoxin, lamivudine and zidovudine
- increase the anticoagulant effect of warfarin
- have an additive myelosuppressive effect if taken with other medicines that have a myelosuppressive effect (e.g. methotrexate, pyrimethamine, clozapine).

The risk of clinically significant interactions is low if trimethoprim is used for ≤3 days.[47,52]

Nitrofurantoin

Antibacterial activity of nitrofurantoin is lost if urine pH is >8. Urinary alkalinisers should not be used in patients being treated with nitrofurantoin.[49,52]

Uricosuric drugs such as probenecid can inhibit renal tubular secretion of nitrofurantoin, resulting in increased serum levels and decreased urinary levels of nitrofurantoin. Consequently, the risk of nitrofurantoin toxicity may increase and its effectiveness in treating UTI may decrease.[48,52]

Cefalexin

Cefalexin is not associated with clinically important adverse drug interactions.

L. Dose

For treatment of acute uncomplicated cystitis in females use the following doses[14,47]:

- Trimethoprim 300 mg orally, daily at night for 3 nights.
- Nitrofurantoin 100 mg orally, every 6 hours for 5 days.
- Cefalexin 500 mg orally, every 12 hours for 5 days.

M. Additional dosing advice

Trimethoprim should be taken at night to maximise urinary concentrations. Trimethoprim can be taken with food to reduce gastrointestinal adverse effects.[48]

Nitrofurantoin should be taken with food or milk to increase absorption and decrease gastrointestinal adverse effects.[48]

N. Treatment expectations

Symptoms of acute uncomplicated cystitis should respond to appropriate antibiotic therapy within 48 hours. Dysuria usually improves within a few hours.[7]

O. Adverse effects

Trimethoprim

Common adverse effects of trimethoprim include rash, itch, nausea and vomiting, and fever. Electrolyte disturbances (hyperkalaemia, hyponatraemia) can occur, but are more likely in patients taking high doses or who have renal impairment. In rare cases, trimethoprim can cause haematological disorders (e.g. thrombocytopenia, leucopenia, megaloblastic anaemia) or severe hypersensitivity reactions (e.g. anaphylaxis, Stevens–Johnson syndrome or toxic epidermal necrolysis).[47,48]

Nitrofurantoin

Common adverse effects of nitrofurantoin include nausea, abdominal pain, diarrhoea and headaches. Nitrofurantoin can cause brown discolouration of urine. Rare but serious adverse effects of nitrofurantoin include peripheral polyneuropathy (including optic neuritis), hypersensitivity reactions (including Stevens–Johnson syndrome and anaphylaxis), hepatic toxicity, pulmonary toxicity and haematological disorders (e.g. haemolytic anaemia, leucopenia, thrombocytopenia, agranulocytosis, aplastic anaemia).[47,48]

Cefalexin

Adverse effects of cefalexin are rare. They include nausea, diarrhoea, abdominal pain, *Clostridium difficile*-associated disease (pseudomembranous colitis), hypersensitivity reactions, cholestatic jaundice and haematological disorders.[47,48]

Treatment with cefalexin can lead to superinfection with *Candida* spp., which may cause vulvovaginal candidiasis. A patient with dysuria may have vulvovaginal candidiasis secondary to use of cefalexin. See Table 1.[47,48]

P. Self-care strategies

Advise patients that paracetamol or nonsteroidal anti-inflammatory drugs (e.g. ibuprofen, naproxen) can reduce the pain and discomfort of UTI.[14]

Urinary alkalinising agents may relieve dysuria, however their safety and efficacy have not been established.[14] They are not effective if CrCl <30 mL/min, are contraindicated in hypernatraemia and renal failure, and should be used with caution in patients with sodium restriction.[34,48] In addition, they should not be used concurrently with nitrofurantoin. See *K. Drug interactions*.

Counsel female patients about self-care strategies that may reduce the risk of further UTIs. These include[14,17,38]:

- increase fluid intake to 2–3 L daily
- reduce or stop use of spermicides
- empty bladder soon after sexual intercourse
- wipe from front to back when toileting
- empty bladder completely when urinating (e.g. by double voiding).

Provide the patient with the relevant Consumer Medicines Information (CMI) leaflet, and a *Urinary tract infection* Self Care Fact Card or other consumer information.

Q. Follow-up advice

Advise the patient to consult a medical practitioner promptly if[7,38]:

- symptoms of cystitis persist 48–72 hours after starting antibiotic treatment
- symptoms of cystitis reoccur within 2 weeks after finishing antibiotic treatment
- symptoms develop that are not symptoms of acute cystitis.

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