Australian Capital Territory

Medicines, Poisons and Therapeutic goods (Pharmacist Extended Scope of Practice – Urinary Tract Infection) Authorisation 2025 (No 1)

Notifiable instrument NI2025–612

made under the

Medicines, Poisons and Therapeutic Goods Regulation 2008, Section 490A, Authorisations for health practitioners to deal with medicines with CHO approval—Act, s 20 (1) (c)

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1 Name of instrument

This instrument is the Medicines, Poisons and Therapeutic Goods (Pharmacist Extended Scope of Practice- Urinary Tract Infection) Authorisation 2025 (No 1).

2 Commencement

This instrument commences the day after notification.

3 Authorisation

A pharmacist is authorised to supply a medicine or a class of medicines to a person without a prescription if the supply is performed in accordance with the ACT Pharmacist Extended Scope of Practice Urinary Tract Infection Authorisation as set out in Schedule 1 of this document.

Dr Kerryn Coleman
Chief Health Officer
30 October 2025

ACT Pharmacist Extended Scope of Practice Urinary Tract Infection Authorisation

Introduction

This Pharmacist Extended Scope of Practice Urinary Tract Infection Authorisation (UTI Authorisation) is made under section 490A of the Medicines, Poisons and Therapeutic Goods Regulation 2008 for the purposes of establishing conditions and criteria under which a registered pharmacist may initiate the supply of the particular medicine or class of medicine to which the authorisation relates in the absence of a supply authority (prescription).

This UTI Authorisation should be read in conjunction with the *Medicines, Poisons and Therapeutic Goods Act 2008*, the Medicines, Poisons and Therapeutic Goods Regulation 2008 (from www.legislation.act.gov.au) to ensure pharmacists are fully aware of their obligations when providing services.

Authorisation for pharmacists to supply medicines

A registered pharmacist[#] may deal with a medicine or a class of medicine to which the authorisation relates to under their own authority (without a prescription) to a person under the following conditions:

- The medicine is listed under Part A – Medicines Authorisations;
- The patient is eligible under the patient eligibility criteria under the relevant section of Part A - Medicines Authorisations;
- Any other conditions listed under the relevant section of Part A – Medicines Authorisations;
- The prescribed training requirements listed under the appropriate section of Part B – Pharmacist Training Requirements are met;
- The patient and the pharmacist must both be physically present at a pharmacy that meets the listed requirements of Part C – Premises Standard, for consultation with the patient to occur prior to supply.
- The prescribed record keeping requirements listed under Part D – Record Keeping Requirements are met;
- Pharmacists must follow all clinical protocols, if any clinical protocols are approved, under the appropriate section of Part E – Clinical Protocols; and
- Pharmacists are required to comply with Australian Health Practitioner Regulation Agency (AHPRA) and the Pharmacy Board of Australia Code of Conduct, and the expected standards of ethical behaviour of pharmacists towards individuals, the community and society. Breaches will be dealt with in accordance with Part F-Governance and Complaints.

[#] A Pharmacist is a person who holds registration under the Health Practitioner Regulation National Law (ACT) and is employed or engaged in a pharmacy that meets the requirements in Part C.

For further information about this authorisation please contact the Health Protection Service on 5124 9700 or at HPS@act.gov.au

Contents

Part A - Medicines Authorisations

i. Approved Medicines

Eligible pharmacists may supply the following medicines for UTI services*:

- nitrofurantoin,
- fosfomycin, if nitrofurantoin is unavailable or inappropriate for treatment of the particular patient,
- trimethoprim, if both nitrofurantoin and fosfomycin are unavailable or inappropriate for treatment of the particular patient,
- cefalexin, if nitrofurantoin, fosfomycin and trimethoprim are unavailable or inappropriate for treatment of the particular patient.

**Pharmacists may only supply a medicine for the treatment of urinary tract infection in accordance with the Clinical Protocols approved in Part E. Pharmacists must not supply a medicine in a quantity that exceeds the duration of treatment specified in Part E. If the smallest available size of the manufacturer's pack of a medicine exceeds the quantity listed in Part E, the pharmacist may supply the medicine in the smallest available size, but for no longer than 12 weeks.*

ii. Eligible Patients

Eligible pharmacists can supply UTI services to people who are assigned female at birth, aged 18 to 65 years. In determining eligibility, pharmacists must comply with the clinical protocol, provided in Appendix 1.

iii. Adverse Events

If a treating pharmacist becomes aware of an uncommon, unexpected or serious adverse event following treatment with an Approved Medicine, this must be reported to the Therapeutic Goods Association. This must be conducted via the usual processes, by reporting online at https://aems.tga.gov.au/

Part B - Pharmacist Training Requirements

Pharmacists are considered to have appropriate training and competence to administer extended scope of practice services in the ACT, as outlined in this instrument, if they hold current registration with the Pharmacy Board of Australia under the Australian Health Practitioner Regulation Agency (AHPRA), and have completed an Accredited clinical training course as described below:

- Pharmaceutical Society of Australia – Managing Uncomplicated Cystitis, **OR**
- Australasian College of Pharmacy – Uncomplicated Cystitis Treatment – Pharmacist Training
- Any other Accredited training advised or required by the Chief Health Officer

Part C - Premises Standards

For a pharmacist to supply extended scope of practice services, the services must be provided in a pharmacy that meets the following requirements:

- Maintains up-to-date service availability listings on Health Direct;
- Has a consulting room consistent with the following:
    - is not to be used for any other purpose (such as a dispensary, storeroom, staff room or retail area),
    - is fully enclosed and provides adequate privacy for confidential conversations and any required examination (a divider or curtain in a dispensary, storeroom, staff room or retail area is not acceptable),
    - has adequate lighting,
    - is maintained at a comfortable ambient temperature,
    - has hand sanitisation facilities, and
    - has sufficient floor area, clear of equipment and furniture, to accommodate the applicable patient receiving the consultation and an accompanying person, and to allow the pharmacist adequate space to manoeuvre.

Part D - Record Keeping Requirements

After providing a service under this authorisation, pharmacists are required to complete a full clinical record and should share a record of the consultation with the patient's usual treating medical practitioner, with the client's consent.

Full Clinical Record

Pharmacists are required to make a full clinical record of the consultation using secure digital software. Records must be stored securely for a minimum of seven years and must contain:

- Sufficient information to identify the patient;
- The date of the consultation;
- The name of the pharmacist who undertook the consultation and their Healthcare Provider Identifier – Individual;
- Any information known to the pharmacist that is relevant to the patient's diagnosis or treatment (for example, information concerning the patient's medical history);
- Any clinical opinion reached by the pharmacist;
- Actions and management plan taken by the pharmacist;
- Particulars of any medication supplied for the patient (such as form, strength and amount);
- Notes or advice given to the patient in relation to any treatment proposed by the pharmacist who is treating the patient;
- Any consent given by a patient to the consultation, supply of medication and treatment proposed; and
- Any referrals made to a medical practitioner or other healthcare professional.

Sharing Clinical Record

The pharmacist must seek the patient's consent to share a record of the consultation and any subsequent consultations (including adverse events) with the patient's usual treating medical practitioner or medical practice, where the patient has one, following consent by the patient. If the patient **does** consent to the disclosure, the record must be shared within seven (7) days following the consultation.

Communication with the patient's usual treating medical practitioner or medical practice should ensure patient confidentiality is maintained. Use of a secure digital messaging platform is considered best practice.

Part E - Clinical Protocols

All pharmacists must act in accordance with the approved UTI Clinical Protocol as included in **Appendix 1**.

Part F - Governance and complaints

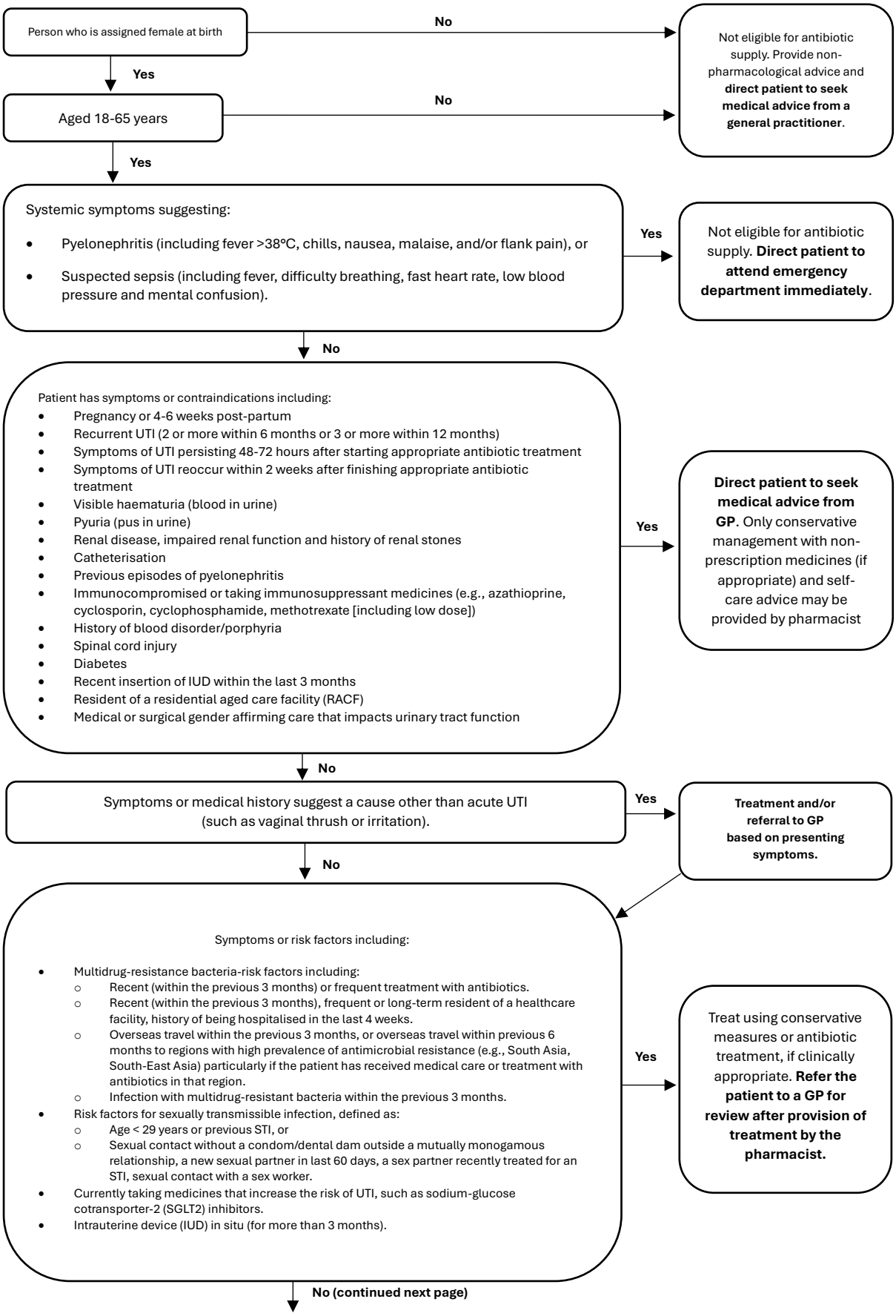
The Health and Community Services Directorate takes an educate and engage approach to regulation including for activities under the *Medicines, Poisons and Therapeutic Goods Act 2008*. This approach focuses on providing education directly to community pharmacists choosing to offer extended scope of practice services to ensure they understand their roles and responsibilities. Pharmacists are expected to follow the AHPRA Code of Conduct.

Contravening any condition of this authorisation is grounds for disciplinary action under Section 140 of the *Medicines, Poisons and Therapeutic Goods Act 2008 - Grounds for disciplinary action against authorisation holders*. A contravention of Section 140 of the Act may result in disciplinary action under *Section 141 - Disciplinary action against authorisation holders*.

Reports of unsafe practices, poor clinical practice or failure to adhere to the Code of Conduct may be reported to AHPRA and/or the ACT Health Services Commissioner.

Appendix 1 - UTI Clinical Protocol

This clinical protocol has been adapted from the NSW Pharmacist Practice Standards for Use of Antibiotics to Treat Urinary Tract Infection created by NSW Health used in the ACT with permission.



The details of all consultations and outcomes must be recorded using secure digital software.
Records must be stored securely for minimum seven (7) years.

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Symptoms of uncomplicated UTI include dysuria, urinary frequency, urinary urgency, and/or suprapubic pain or discomfort.

Patient has **two or more** of the above symptoms

No

Patient has only **one** of the above symptoms (one symptom is not sufficient to indicate presence of a UTI)

Yes

Not eligible for antibiotic supply. **Provide conservative treatment only. Direct patient to attend seek medical advice if symptoms**

Yes

Provisional diagnosis of uncomplicated UTI can be made. Consultation must then include:

- Obtain informed consent from the patient for: participation, financial consent and pharmacist communication with other health practitioners. Document evidence of consent made by the pharmacist in the patient's clinical record.

AND

Initial therapy: review the Therapeutic Guidelines approach to management of acute cystitis. As per the Therapeutic Guidelines, discuss option of nonantibiotic therapy (analgesia with nonsteroidal anti-inflammatory drugs [NSAIDs]). Explain benefits and risks to types of therapy. Note patients on non-antibiotic therapy are less likely to need antibiotics; however, without antibiotics, 1-5% are expected to progress to pyelonephritis or sepsis.

AND

Provide education on non-pharmacological management and self-care including symptom management and when to seek medical care:

- Educate patients prone to developing UTIs about prophylaxis
- Urinary alkalinising agents: efficacy of these agents for the symptomatic treatment of UTI have not been established however some patients find them useful. These agents significantly reduce the antimicrobial effect of nitrofurantoin.

AND

If empirical antibiotic therapy is recommended with an Approved Medicine, check first that the patient does not have any allergies or contraindications (refer to medical practitioner for treatment if so):

- First Line: Nitrofurantoin 100mg orally, every 6 hours for 5 days, or
- Second Line: Fosfomycin 3g orally, as a single dose, or
- Third Line: Trimethoprim 300mg orally, daily at night for 3 nights

If nitrofurantoin, fosfomycin or trimethoprim cannot be used for empirical therapy for acute cystitis in nonpregnant adult females, use: Cefalexin 500mg orally, every 12 hours for 5 days

Note: the hierarchical order above must be followed for all consultations

Where a patient has a My Health Record, the pharmacist must ensure the details of supply are uploaded to My Health Record, unless requested otherwise by the patient.

Always consider drug allergies and interactions when selecting treatment

Provide follow-up advice and expectations about symptom resolution:

- Advise the patient that symptoms should respond to appropriate antibiotic treatment within 48 hours.
- Advise the patient to seek medical care if symptoms worsen (e.g. fever 38°C or higher, rigors, loin or back pain, vomiting) or do not improve within 48 hours.
- Advise on what to do if side effects of medication occur (e.g. when to seek emergency care, medical review or return to pharmacy)
- Review the Therapeutic Guidelines indications for urinalysis.
- Advise the patient to seek care from a GP if symptoms reoccur within 2 weeks after finishing antibiotic treatment, or symptoms develop that are not symptoms of an acute UTI.
- Where patient has a regular GP or general practice service share a record of the consultation, within a week, with the patient's consent.

Where GP referral or follow-up is required but the patient does not have a regular GP or that GP is unavailable (within an appropriate timeframe), contact **Healthdirect** on 1800 022 222 for advice on patient disposition.

The details of all consultations and outcomes must be recorded using secure digital software.
Records must be stored securely for minimum seven (7) years.