



PSNE Ltd

# UTI PGD service – NENC ICS

Valid from 1 October 2023

## PGD - Treatment of Simple UTI in Females (from 16 years to under 65 years of age)

### Service Specification Service

<b>Service</b>	PGD for treatment of Simple UTI in females aged 16 years to under 65 years
<b>Commissioner Lead</b>	PSNE Ltd
<b>Period</b>	

#### 1. Population Needs

##### 1.1 National Context & Evidence Base

Each year the NHS provides around 110 million urgent same-day patient contacts. Around 85 million of these are urgent GP appointments and the rest are A&E or minor injuries-type visits. Estimates are that 6% of GP appointments are potentially avoidable through better use of self-care and community pharmacy. The NHS England “Transforming urgent and emergency care’ report stated that community pharmacy services can play an important role in enabling self-care, particularly amongst patients with minor ailments. Pharmacy teams provide professional advice and patients may choose to purchase over the counter (OTC) medicines. However pharmacies are only able to allow the purchase of an OTC medicine within its licensed indications for sale. Community pharmacists commonly report frustration at not being able to treat patients due to licensing restrictions, resulting in referrals to another part of the system for a Prescription Only Medicine (POM). This service is therefore to commission Community Pharmacy Patient Group Directions (PGDs) to enable supplies of POMs and mean that episodes of care can be completed in the pharmacy and referrals to GP practices or out of hours providers are avoided.

#### 2. Outcomes

##### 2.1 NHS Outcomes Framework Domains & Indicators

<b>Domain 1</b>	<b>Preventing people from dying prematurely</b>	
<b>Domain 2</b>	<b>Enhancing quality of life for people with long-term conditions</b>	
<b>Domain 3</b>	<b>Helping people to recover from episodes of ill-health or following injury</b>	✓
<b>Domain 4</b>	<b>Ensuring people have a positive experience of care</b>	✓
<b>Domain 5</b>	<b>Treating and caring for people in safe environment and protecting them from avoidable harm</b>	

#### 3. Scope

##### 3.1 Purpose

The service aims to provide any eligible patient, females from 16 years to under 65 years of age, access to medication for the treatment of simple urinary tract infection (UTI) via Community Pharmacy. The service will be provided through Community Pharmacies contracted to PSNE as the lead provider commissioned by NG CCG on behalf of NENC Integrated Care System/Board (ICB).

##### 3.2 Aims and Intended Service Outcomes

**3.2.1** To improve access and choice for people with some minor ailments normally requiring an FP10 prescription.

**3.2.2** Increase the scope of minor illness that community pharmacists can treat.

**3.2.3** Make use of the 7 day and out of hours' services provided by some community pharmacies.

**3.2.4** Ensure that patients are treated to the same clinical pathway in a consistent way regardless of which healthcare professional the patient consults with across NENC ICS/B

**3.2.5** Ensure that patients have a positive experience of care in a community pharmacy setting and can be treated in a single episode of care.

**3.2.6** Move care closer to home for patients

**3.2.7** Reduce pressure on other parts of the healthcare system, including urgent and emergency care.

**3.2.8** Reduce referrals to prescribing services purely because of OTC medicine licensing restrictions.

### **3.3 This service should benefit patients when:**

**3.3.1** The patient meets the clinical criteria within the PGD.

**3.3.2** The patient would otherwise need to seek a prescription for treatment.

### **3.4 Scope of Service**

**3.4.1** The following medicines are made available through the PGD service. The PGD has specific inclusion and exclusion criteria:

- Nitrofurantoin MR 100mg capsules
- Nitrofurantoin 50mg tablets

**3.4.2** Treatment must be provided by an accredited pharmacist following the standardised pathways and protocols. This will ensure that patients are treated to the same clinical pathway in a consistent way regardless of which healthcare professional the patient consults with, in the system (i.e. the patient will receive the same advice and treatment whether they see their GP, an OOH prescriber or a community pharmacist). After every consultation the pharmacist must give appropriate counselling and safety-netting advice in both written and verbal format.

**3.4.3** Urine dipstick tests are NOT diagnostic when used alone but for a female, who does not have a catheter and who presents with less than three indicative symptoms of lower UTI then the dipstick may be used to check for the presence of nitrites to aid diagnosis for these women (Appendix 1).

**3.4.4** Recording should be done at the time of the consultation using the online PharmOutcomes platform. In exceptional circumstances, where no live connection is available, a paper Proforma may be used (Appendix 2). Where a paper based proforma is completed during the consultation, the information must be uploaded onto PharmOutcomes.

**3.4.5** Pharmacists must complete fully the PharmOutcomes template for each supply made. A copy will be sent to the patient's registered GP. Patient will be advised that a follow up phone call will take place on day 3 to check patient's wellbeing.

**3.4.6** Any patient that is not exempt from prescription charges must be charged for each medicine that is supplied at the same rate as the current NHS prescription charge.

**3.4.7** Any patient that is exempt from NHS prescription charges must be asked for proof of their exemption. Proof of exemption is not mandatory but it must be requested. A record of the patient's declaration of exemption from prescription charges will be kept in PharmOutcomes.

**3.4.8** Pharmacy staff will submit a claim to the commissioner via PharmOutcomes monthly so that we can reimburse medication costs and provide remuneration for the service.

**3.4.9** If pharmacists are unable to treat the patient in community pharmacy then they should refer the patient to another part of the system and support the patient to make an appropriate appointment.

**3.4.10** Pharmacists should highlight patients repeatedly accessing the service to their general practice for review.

**3.4.11** Pharmacists are reminded that they should access the National Care Record Service to confirm the current prescription, allergies, etc. for a patient.

### **3.5 Pharmacy & Pharmacist Accreditation**

**3.5.1** If a pharmacy provider agrees to provide this service, they must ensure that all the staff working in the pharmacy (including locums) are aware that they will be participating and how to participate.

**3.5.2** A pharmacist representative from the pharmacy must attend all relevant and appropriate training and cascade to the other staff (including locums) within the pharmacy.

**3.5.3** All pharmacies and pharmacists delivering the service (including locums) are required to complete the Declaration of Competence (DoC) on PharmOutcomes. Once this has been approved by the commissioner, the pharmacy will then be able to deliver the service.

The DoC will require pharmacists to complete defined learning:

- e-learning on Consultation skills from CPPE  
<https://www.cppe.ac.uk/programmes/l/consult-p-02>
- e-learning on Sepsis from CPPE  
<https://www.cppe.ac.uk/gateway/sepsis>
- e-learning on Safeguarding Level 2 from CPPE  
<https://www.cppe.ac.uk/programmes/l/safegrding-e-02>
- e-learning on Antimicrobial Stewardship  
<https://www.e-lfh.org.uk/programmes/antimicrobial-resistance-and-infections/>

**3.5.4** Pharmacists must ensure they are up to date with relevant issues and clinical skills relating to the PGD and should be aware of any change to the recommendations for the medicines listed. It is the responsibility of the individual to keep up to date with Continued Professional Development (CPD). Patient group directions do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and professional code of conduct.

### **3.6 Population covered**

**3.6.1** This is an open access scheme open to all patients that meet the PGD criteria, registered with a GP in England.

### **3.7 Any acceptance and exclusion criteria and thresholds**

**3.7.1** Clinical criteria for inclusion and exclusion are included within the individual PGD.

### **3.8 Interdependence with other services/providers**

**3.8.1** The service is not intended to replace the NHS England commissioned Community Pharmacy Consultation Service but offers an alternative or additional option where clinically appropriate.

## **4. Applicable Service Standards**

### **4. Applicable Service Standards**

#### **4.1 Applicable national standards (e.g. NICE)**

NICE guidance MPG2 Patient Group Directions  
<https://www.nice.org.uk/guidance/MPG2>

#### **4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)**

NENC ICS Primary Care Antimicrobial Guidelines & NENC ICS Lower UTI Guidelines <https://www.nice.org.uk/guidance/ng109>

General Pharmaceutical Council. Standards for Pharmacy Professionals  
<https://www.pharmacyregulation.org/standards-for-pharmacy-professionals>

#### **4.3 Additional reading / further learning options**

CPPE Common Clinical Conditions and Minor Ailments  
<https://www.cppe.ac.uk/gateway/cpcs>

See also the references on the individual PGDs

#### **4.4 Other Local Policies to Note**

NG CCG safeguarding policies for children and adults:  
Safeguarding Children policy  
Safeguarding Adults policy

Mental Capacity Act and Deprivation of Liberty Safeguards information  
<https://www.scie.org.uk/mca/dols>

## **5. Applicable quality requirements and CQUIN goals**

### **5. Applicable quality requirements**

#### **5.1 Applicable Quality Requirements**

**5.1.1** All pharmacists providing the service have completed a declaration of competence (this must be completed before the service can be provided by the pharmacist).

**5.1.2** The pharmacy agrees to liaise with the commissioner to audit the service so that informed decisions can be made about how to improve it.

**5.1.3** Patient feedback will be collected via information given to the patient and follow up phone call(s) or text message(s). Outcome measures will be part of service evaluation and will be gathered using the PharmOutcomes module.

**5.1.4** The commissioner will monitor supplies made through the service monthly and may raise queries with the supplying pharmacy.

**5.1.5** If a pharmacy fails to provide the service on three consecutive occasions (unless there are extremely exceptional circumstances), the commissioner reserves the right to remove the service from that pharmacy. If a pharmacy is unable to provide the service, they must inform the commissioner and ensure that the DOS team is made aware on the day (or in advance) so that referrals from NHS111 can be temporarily suspended until usual service provision resumes. Pharmacies must inform the DOS team when normal service resumes.

**5.1.6** The pharmacy will arrange clinical waste collection in line with their IPC protocols and the dipsticks recommended for use is MULTISTIX GP.

#### **5.2 Clinical Incident Reporting**

**5.2.1** Pharmacies must feedback any serious incidents that occur to the commissioner within 48 hours of being notified of such an incident by a patient or other healthcare provider. The email address for SI's is [helpdesk@psne.co.uk](mailto:helpdesk@psne.co.uk)

**5.2.2** Any serious incidents will be dealt with in accordance with the relevant provider/commissioner policies

**5.2.3** In the event of a clinical incident/adverse event, the patient's GP should be informed.

#### **5.3 Complaints Procedure**

**5.3.1** Any complaints from patients should be dealt with via the provider's own standard complaints procedure in the first instance. If the complaint is not resolved, the patient should direct their complaint to the NENC Customer Services Team: [neccsu.complaints@nhs.net](mailto:neccsu.complaints@nhs.net)

## 6. Location of Provider Premises

Pharmacies located with the NENC ICS.

### Payment Schedule

- a. £300 set up fee
- b. £14 per consultation
- c. Undertaking dipstick test £3
- d. Where medication is needed
  - i. The cost of the medicines (using dm+d) + VAT
  - ii. Minus any prescription charges collected (if applicable)
- e. Completion of patient follow up research criteria
  - i. £5 day 3 follow up phone call and related data entry
- f. Any additional OTC / P medicines supplied outside of the PGD will need to be paid for by the patient

### Invoicing

Pharmacies must complete a PharmOutcomes 'Confirmation of Readiness' to confirm all service criteria are met. Completion will generate an invoice for the £300 set up fee.

Pharmacies must complete a PharmOutcomes PGD Service template for each supply. A monthly invoice will be generated automatically and sent to the commissioner each calendar month (in arrears), checked and then submitted for payment. Claims for payment will only be processed through PharmOutcomes unless otherwise advised.

## Appendix 1.

Healthy, non-pregnant women aged 16-64 years, presenting with:

- two or more of the 5 key diagnostic signs or other severe urinary symptoms below:
  - dysuria (burning pain when passing urine)
  - nocturia (passing urine more often than usual at night)
  - Urgency
  - Frequency
  - Visible haematuria
- And a positive dipstick test

Note: Use dipstick tests for women presenting for treatment in line with updated SIGN guideline [sign- 160-qrg-uti\\_web-version.pdf](#)

**You are reminded that dipsticks should only be used as an aid to diagnosis in symptomatic, non- catheterised females.**

1. Collect fresh urine specimen in a clean, dry container. Mix well immediately before testing. All samples should be midstream:
  - a. The patient washes hands and opens the collection cup without touching the inside of the cup
  - b. Clean the urethral area with an antiseptic
  - c. Patient should be advised not to touch the cup to the urethra or any skin when collecting the sample
  - d. If the container/sample becomes contaminated with faeces, pubic hair or other substances, then a new collection cup/sample needs to be used.
  - e. The patient must then urinate for 5 seconds, move the collection cup into the urine stream, fill the collection cup, remove the cup and continue urinating, making sure that that no skin aside from the urethra touches the urine.
  - f. Place the lid on the collection cup.
2. Remove one strip from the bottle of strips and replace the cap. Completely immerse reagent areas of the strip in the urine and remove immediately to avoid dissolving out of reagents.
3. While removing, run the edge of the strip against the rim of the urine container to remove excess urine. Hold the strip in a horizontal position to prevent possible mixing of chemicals from adjacent reagent areas and/or contaminating the hands with urine.
4. Compare reagent areas to corresponding colour chart on the bottle label at the time specified. Hold strip close to colour blocks and match carefully. Avoid laying the strip directly on the colour chart, as this will result in the urine soiling the chart.





## PROPER READ TIME IS CRITICAL FOR OPTIMAL RESULTS.

The following are specific readings and timings required for diagnosis of UTI.

- Read protein, blood, and nitrite at 60 seconds;
- Read leukocytes at 2 minutes.

Colour changes that occur after 2 minutes are of no diagnostic value.

### Reporting Results

Results are reported in the amounts expressed on the charts on the bottle label.

### Expected Values

#### Nitrite

This test relies on the breakdown of urinary nitrates to nitrites, which are not found in normal urine. Many Gram-negative and some Gram-positive bacteria are capable of producing this reaction and a positive test suggests their presence in significant numbers. A negative test does not rule out a UTI.

#### Blood

The significance of the trace reaction may vary among patients and clinical judgement is required for assessment in an individual case. Development of green spots or green colour on the reagent area within 60 seconds indicates the need for further investigation. False positive readings are most often due to contamination with menstrual blood; they are also seen with dehydration which concentrates the number of RBCs produced, and exercise. False negative readings: captopril, vitamin C, proteinuria, elevated SG, pH less than 5.1 and bacteriuria.

#### Protein

Normally no protein is detectable in urine, although a minute amount is excreted by the normal kidney. A colour matching any block greater than trace indicates significant proteinuria. For urine with a high specific gravity, the test area may most closely match the trace colour block even though only normal concentrations of protein are present. Clinical judgement is needed to evaluate the significance of trace results.

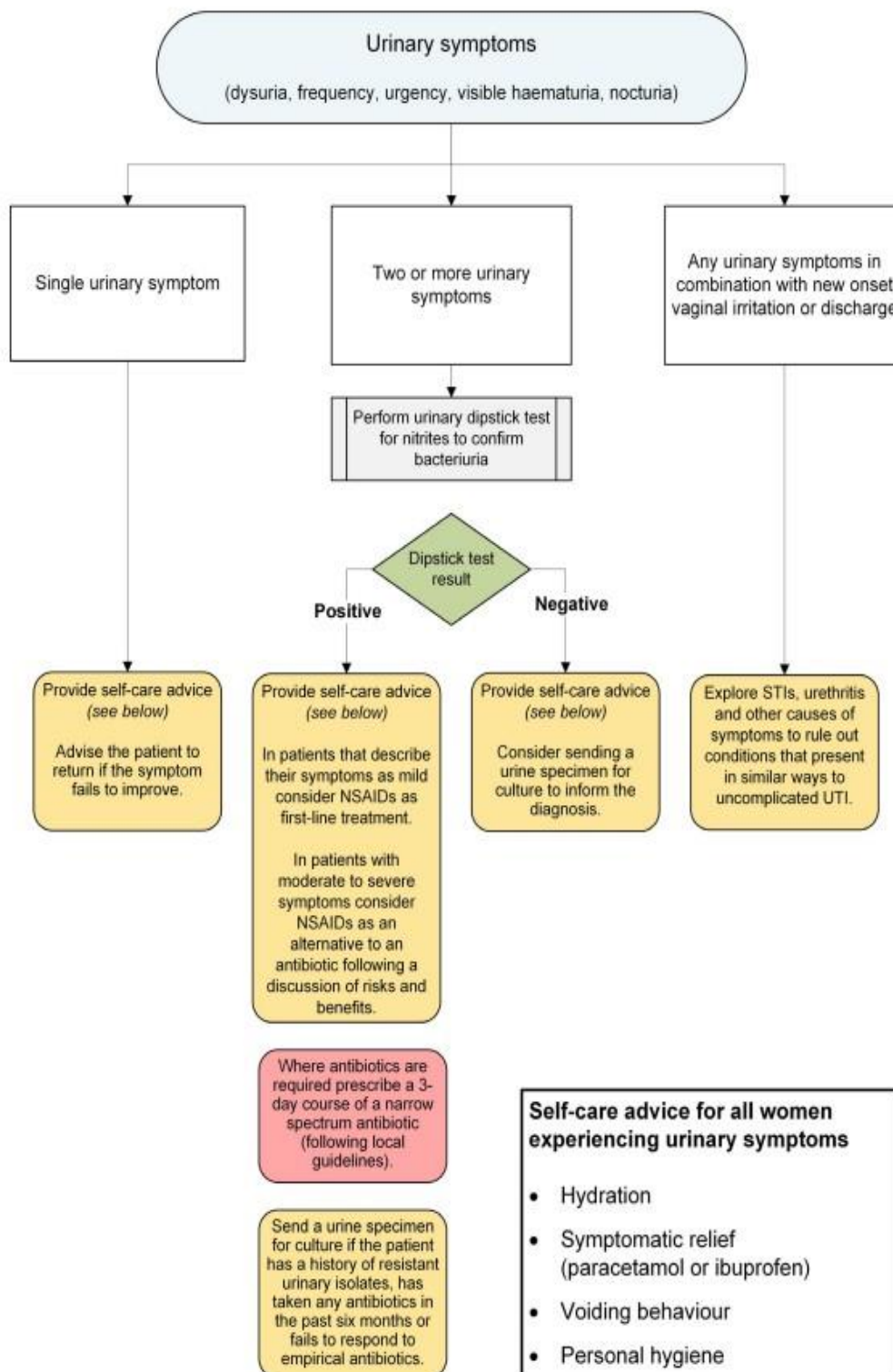
#### Leukocytes

Normal urine specimens generally yield negative results. Positive results (small or greater) are clinically significant. Trace results observed individually may be of questionable clinical significance. Trace results observed repeatedly may be clinically significant. Positive and repeated trace results indicate the need for further testing of the patient and/or urine specimen.

### Result of Dipstick Test

<b><u>Interpreting urine dipstick results:</u></b>	
Positive nitrite (+/- leucocyte +/- protein)	= <b>probable UTI</b>
Negative nitrite and positive leucocyte	= <b>possible UTI</b>
Negative nitrite and leucocyte, +ve blood or protein	= <b>consider other diagnosis</b>
All dipstick tests negative	= <b>UTI very unlikely</b>

**Algorithm for diagnostic and management options in non-pregnant women aged <65 years presenting with suspected LUTI**



## Appendix 2

### Proforma for use in case of IT failure



#### Appendix 2 – 2020 Proforma for use in case of IT Failure

#### Nitrofurantoin PGD to treat uncomplicated UTI (females from 16yrs up to 65yrs)

Date		Patient Name and DOB	
GP Practice		Address including Postcode	

Please note: The service is only available to females who are registered with a GP in the NHSE&I Midlands Region.

#### Inclusion Criteria

Women aged 16yrs and over with 3 of the listed symptoms:

Dysuria		Urinary frequency / urgency		Lower abdominal pain	
Blood in urine (haematuria)		Polyuria			

Patients may also have suprapubic pain, cloudy or foul smelling urine.

Vaginal discharge reduces the likelihood of the woman having a bacterial UTI.

**Use of Dipsticks – this is not a diagnostic indicator alone. Use dipstick only if necessary.**

Women aged 16yrs and over with 2 or less of the inclusion criteria symptoms:

If a female presents with one or two inclusion criteria symptoms they can only be treated if there is a strong possibility of UTI when tested with a dipstick. - **A nitrite and/or leucocytes dipstick must be positive.**

#### Dipstick Results (where used)

Positive nitrite (+/- leucocyte, +/- protein) = Probable UTI		Negative nitrite (+ leucocyte) = Possible UTI	
Negative nitrite and leucocyte (+ protein) = Unlikely UTI		All dipstick tests negative = UTI very unlikely	

#### General Advice on UTIs to be given to all females taking part in the service.

To support the worldwide drive to reduce antibiotic usage please inform clients that about half of women will be free from symptoms within 3 days even with no treatment <i>(If client decides to delay treatment, you will still be paid for completing the consultation)</i>	
Drink plenty of fluid – 3L per day.	
Avoid caffeine containing & alcoholic drinks	Try to empty bladder when urinating
May be precipitated by fragranced products	Importance of personal hygiene
Paracetamol / ibuprofen for pain/discomfort	Cranberry juice & alkalinizing prods – no evidence
To prevent the recurrence of UTI the following measures can help - Maintain an adequate fluid intake. Ensure the bladder is fully emptied. Empty bladder after sexual intercourse	

#### Exclusion Criteria (service for females age 16yrs + only)

Male	Elderly patients with confusion suggestive of UTI
Patients aged 65 years and over	Known hypersensitivity to Nitrofurantoin
Patients with back or loin pain and pyrexia, consider Pyelonephritis- refer to immediately (other possible symptoms include chills, nausea, vomiting, headache, rigors)	Concomitant use of medication that has a clinically significant interaction with Nitrofurantoin. For a comprehensive list of interactions, please refer to SPC or BNF
Recurrent UTI treated with antibiotics within previous 4 weeks	More than two episodes of UTI treated under this PGD within previous 12 months
Catheterised patients	Haematuria only
Blood dyscrasias (G6PD deficiency specifically)	Pregnancy or Breastfeeding
Renal Impairment (eGFR <45ml/min)	Pulmonary disease
Peripheral neuropathy	History of kidney stones / renal colic
Refused consent	Acute porphyria

#### Referral Information

If patient is excluded refer to GP for advice and treatment and also advise on support for self-care if appropriate.

A copy of this form may be used as a referral form if the pharmacist wishes. If the patient has been referred to the pharmacy service via a Care Navigation Pathway and is symptomatic, but is excluded under the PGD, the pharmacist must make all reasonable attempts to contact the patients GP practice to arrange for an appointment.

## Medication Supply under PGD

In order for medication to be supplied the patient must give consent for information to be shared with their GP. The PharmOutcomes system will automatically inform the patients GP practice. If the practice cannot receive notifications the PharmOutcomes system will advise you to send info by another suitable method (consider GDPR)

**Nitrofurantoin MR 100mg capsules twice daily for 3 days OR Nitrofurantoin 50mg tablets four times a day for 3 days. Should be taken with food. Label must state "Supplied under PGD"**

Preparation supplied:	100mg S/R capsules (x 6) – FIRST LINE	
	50mg tablets (x12) – SECOND LINE	

*Nitrofurantoin suspension may NOT be supplied under this service*

**The following advice MUST be given on every supply.** (More comprehensive list of cautions + side effects in SPC)

Patient information leaflet given and discussed as necessary	
Nitrofurantoin may cause dizziness and drowsiness. Patients should be advised not to drive or operate machinery if affected until such symptoms stop.	
Discolouration of the urine to yellow or brown is common.	
Take all preparations with food to minimise GI effects and complete the course.	
Take the MR capsules regularly at 12 hourly intervals. Take the tablets regularly at approx. 6 hourly intervals	
Possible side effects GI disturbances (nausea, vomiting) Pruritis. Skin rashes. Abdominal pain + diarrhoea	
Severe adverse reactions are rare, but there have been reports of the following effects; Acute pulmonary reactions; Neurological effects including peripheral neuropathy; Severe allergic skin reactions including erythema multiforme; Haematological effects which are generally reversible on cessation of treatment.	
Report adverse reactions to pharmacy	
Advise clients to see GP if condition not improved after 3 days or if UTI becomes a recurring problem	
To prevent the recurrence of UTI the following measures can help - Maintain an adequate fluid intake. Ensure the bladder is fully emptied. Empty bladder after sexual intercourse	

## Final Checklist. Complete all sections.

### Consultation Outcome:

Patient excluded from PGD supply. Referred to GP	Consultation completed and patient has decided to defer antibiotic treatment	Supply made under PGD	
--	--	-----------------------	--

### Where a supply was made, the following must also be completed:

PMR entry completed	Nitrofurantoin labelled "Supplied under PGD"	Patient consent collected?	
Levy collected?	Exemption form signed?		

**Please note: Exemption forms should be retained in the pharmacy in case requested by NHS England & Improvement.**

For consultations carried out without a live PharmOutcomes connection the patient must sign the declaration. Otherwise consent is recorded electronically.

Client's Signature:	Date:
---------------------	-------

Pharmacists Name:	GPhC number:	Signature:	Date:
-------------------	--------------	------------	-------

### Appendix 3

#### Quality Requirements

<u>Quality Requirement</u>	<u>Threshold</u>	<u>Method of Measurement</u>	<u>Consequence of Breach</u>	<u>Timing of application of consequence</u>
Pharmacy has a completed Declaration of Competence	100%	PharmOutcomes	Pharmacy is not permitted to deliver the service	Immediate
All pharmacists delivering the service have completed a Declaration of Competence	100%	PharmOutcomes	Pharmacy is not permitted to deliver the service	6-week grace period for pharmacist to complete the DoC
The service provision is consistent i.e. able to offer the service on all relevant occasion			The commissioner will remove the service from the pharmacy	If a pharmacy fails to provide the service on three consecutive occasions (unless there are extremely exceptional circumstances), the commissioner reserves the right to remove the service from that pharmacy
The pharmacy agrees to participate in audit and collection of patient feedback as requested by the commissioner	100%	Template via PharmOutcomes	The commissioner will consider future commissioning of the service	
Additional data may be captured via PharmOutcomes, including patient feedback and antimicrobial stewardship				