This Patient Group Direction (PGD) must only be used by registered pharmacists who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

For use in the community pharmacy extended care service

Supply of Nitrofurantoin for uncomplicated Urinary Tract Infections in non-pregnant women aged 16 years and over but under 65 years in NHS England Midlands Region

Version Number 6.0 / 2023

Change History	
Version and Date	**Change details**
2.0 / 2022	Existing PGD incorporated into national template
3.0 / 2022	Draft following NHSEI clinical review
4.0 / 2022	FINAL PGD following system review.
5.0 / 2023	Annual review
6.0 / 2023	FINAL PGD following system review

This Patient Group Direction (PGD) must only be used by pharmacists who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

PGD DEVELOPMENT GROUP

Date PGD comes into effect:	31st March 2023
Review date	January 2024
Expiry date:	31st March 2024

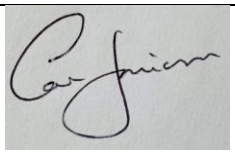
The template for this PGD has been peer reviewed by the Antimicrobial PGDs Short Life Working Group in accordance with their Terms of Reference and approved by the NHSE AMR Programme Board.

This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation

The PGD is not legally valid until it has had the relevant organisational approval - see below.

CLINICAL AUTHORISATION OF PGD

Name	Job title and organisation	Signature	Date
Dr Jessica Sokolov	Medical Director, NHSE Midlands		14/03/2023
Richard Seal	Regional Chief Pharmacist, NHSE Midlands		10/03/2023
Andrew Pickard (*Lead Author*)	Regional Pharmacy Advisor, NHSE Midlands		09/03/2023
Dr Conor Jamieson	Regional Antimicrobial Stewardship Lead, NHSE Midlands		10/03/2023

ORGANISATIONAL AUTHORISATION OF PGD

Name	Job title and organisation	Signature	Date
Rebecca Woods	Head of Primary Care Commissioning, NHSE Midlands		**14.03.23**

1. Characteristics of staff

Qualifications and professional registration	• The community pharmacist must be registered with the General Pharmaceutical Council. • The community pharmacist must be accredited by NHS England Midlands to provide the Pharmacy Extended Care (Tier1) Service.
Training requirements	• The community pharmacist authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patient leading to diagnosis of the conditions listed in this PGD in accordance with local policy. • Undertaken appropriate training and successfully completed the competencies for the identification of sepsis • Undertaken appropriate training and successfully completed the competencies for safeguarding vulnerable adults • Individuals operating under this PGD should follow the national guidance for diagnostic (UKHSA) and management (NICE) of simple urinary tract infections in the UK. • Individuals operating under this PGD must be familiar with the product and alert to changes in the Summary of Product Characteristics (SPC) • The community pharmacist must provide the service in accordance with the requirements of the associated Service Specification – Pharmacy Extended Care (Tier1) Service
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for the recognition and management of simple urinary tract infections. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD (eg superintendent pharmacist or line manager), and further training provided as required.
The decision to supply any medication rests with the individual pharmacist who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Treatment of uncomplicated lower urinary tract infection in non-pregnant women aged 16 years and over but under 65 years of age.
First Line Treatment	Nitrofurantoin MR 100mg capsules twice daily for 3 days with food
Second Line Treatment	Nitrofurantoin 50mg tablets or capsules four times a day for 3 days with food.
Criteria for inclusion	Informed consent must be obtained prior to continuing with the consultation. Absence of current or recent fever (within the past 48 hours) Healthy, non-pregnant women presenting with any of the 3 key diagnostic signs or other severe urinary symptoms below; • dysuria (burning pain when passing urine) • new nocturia (passing urine more often than usual at night) • urine cloudy to the naked eye And /or severe urinary symptoms; • Visible haematuria • Urgency • Frequency • Suprapubic tenderness **Note:** **Use dipstick tests only if there is only one of the 3 key diagnostic signs/symptoms present or one of the four additional urinary symptoms which are severe (as per PHE guidance for women under 65 with suspected UTI) Follow the advice in the flow chart to determine what the recommended action is following interpretation of the urine dipstick test.** Urinary tract infection: diagnostic tools for primary care - GOV.UK (www.gov.uk)
Criteria for exclusion	• Informed consent not given • Male • Under 16 years of age • Patients aged 65 years and over • The individual has a complicated UTI (associated with a structural or functional abnormality, which increases the risk of a more serious outcome or treatment failure – individual reports being under the care of a Urologist) • Current or recent fever within the past 48 hours • Pregnancy or suspected pregnancy • Breast feeding • Immunocompromised complex multiple morbidities

	• Consider pyelonephritis and refer immediately to Primary Care Clinician or Urgent Care Centre if suspected; - Kidney pain/ tenderness in back under the ribs - New / different myalgia, flu-like illness - Shaking chills (rigors) or temperature 37.9°C or above - Nausea and vomiting • Elderly patients with confusion suggestive of UTI • Known hypersensitivity to nitrofurantoin or any of the components within the formulation • Exclude vaginal and urethral causes of urinary symptoms. - Vaginal discharge - Urethritis - Exclude STIs - Genitourinary syndrome of menopause (vulvo-vaginal atrophy) • Treatment for UTI with any antimicrobial in the past 3 months • Individuals already taking prophylactic antibiotics for UTI • Recurrent UTI (>2 episodes in 6 months, >3 episodes in 12 months) • More than two episodes of UTI treated under this PGD within previous 12 months • Known previous nitrofurantoin resistant UTI (recorded in accessible information eg. SCR) **OR** known previously resistant UTI to any antibiotic self-reported by the individual where records not available. • Catheterised patients • Known blood dyscrasias (G6PD deficiency specifically) • Known acute porphyria • Known anaemia • Known diabetes mellitus (Type 1 or 2) • Known folate deficiency • Known vitamin B deficiency • Known electrolyte imbalance • Suspected malignancy (gynaecological or urological cancers may result in urinary symptoms) - suspect if weight loss, unexplained bleeding, persistent or frequent abdominal pain, new lumps – refer to primary care clinician • Known moderate to severe renal impairment eGFR <45ml/min/1.73m^2 • Known pulmonary disease • Known peripheral neuropathy • History of kidney stones/renal colic • Patients who cannot swallow tablets or capsules • Hospitalisation in a foreign country within the last 3 months • UK hospitalisation for >7days in the last 6 months • Less than 3 days before receiving, or within 3 days after receiving, oral typhoid vaccine • Concomitant use of medication that has a clinically significant interaction with nitrofurantoin.

	THINK SEPSIS – check for signs/ symptoms using local / national tool e.g. National Early Warning Score (NEWS) 2 | RCP London Please refer to SPC Home - electronic medicines compendium (emc) or BNF British National Formulary - NICE for full details.
Deferred treatment	If clinically appropriate, and the individual agrees to defer treatment, the pharmacist should determine that they could be treated under the service PGDs if they do return. If the individual then returns after waiting the appropriate amount of time, the pharmacist can then supply the medication once an appropriate follow-up assessment under the PGD is undertaken. The pharmacist making the assessment may refer to the original consultation notes, but must fully reassess the individual for suitability for treatment. The supply should be recorded in the Deferred Treatment Module within PharmOutcomes.
Cautions including any relevant action to be taken	Patients with an underlying condition that may reduce renal function. This includes patients with the following conditions; • Hypertension • Heart disease • Known hepatic dysfunction Visible haematuria – treat for UTI but inform individual/their carer to see a clinician if haematuria continues after treatment. Concomitant use of medication that can adversely affect renal function, such as ACE inhibitors and diuretics, or medication that can cause urinary tract symptoms (e.g., cyclophosphamide, opioids, nifedipine) For these groups of patients, the pharmacist should establish if the patient has had a recent renal function test. If the most recent test indicates that the eGFR level is equal to, or above 45ml/min/1.73m^2, then a supply can be made. If this information is not available, the patient should be excluded under this service and referred to their Primary Care Clinician. Please refer to SPC Home - electronic medicines compendium (emc) or BNF British National Formulary - NICE for full details.
Specific information for suspected infection to be provided	• Advise that in 50% of cases, symptoms clear up within 3 days without treatment • If symptoms worsen rapidly or significantly, or have not improved after 48 hours, advise patient to contact their Primary Care Clinician. • If the condition becomes recurrent, contact Primary Care Clinician for further investigation • Paracetamol or ibuprofen can be taken to alleviate symptomatic pain or discomfort

	• If pyelonephritis or sepsis is suspected, refer immediately to Primary Care Clinician or Urgent Care Centre. • Provide TARGET leaflet - UTI-Leaflet-V16.pdf (target-webinars.com)
Management of excluded clients	• If patient meets exclusion criteria, refer to a Primary Care Clinician. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. • If pyelonephritis or SEPSIS is suspected, **refer the individual urgently to A&E** • Record the reason for exclusion and any action taken on PharmOutcomes. • Advise individual/their carer on alternative non antibiotic treatment if an antibiotic is not indicated and provide TARGET leaflet and safety netting advice.
Management of patients requiring referral	If patient declines treatment or advice, ensure the following details are recorded on PharmOutcomes; • The advice given by the clinician • Details of any referral made • The intended actions of the patient (including parent or guardian). • Discuss potential consequences of not undertaking treatment and provide safety netting advice

3. Description of treatment

Name, strength & formulation of drug	• Nitrofurantoin MR 100mg capsules • Nitrofurantoin 50mg immediate release tablets • Nitrofurantoin 50mg immediate release capsules
Legal category	Prescription Only Medicine (POM)
Route of administration	Oral, swallowed whole taken with food or milk
Off label use	Not applicable
Dose and frequency of administration	First line treatment – • Nitrofurantoin MR 100mg capsules twice daily for 3 days with food or milk Second line treatment - • Nitrofurantoin 50mg tablets or capsules four times a day for 3 days with food or milk.
Duration of treatment	Duration of treatment is 3 days for all formulations. Treatment should be started immediately.
Quantity to be supplied	Appropriately labelled pack of 6 modified release capsules **OR** pack of 12 immediate release tablets or capsules.
Storage	Store in a dry place below 25°C or in accordance with the manufacturers Summary of Product Characteristics (SPC), which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF.
Drug interactions	The following interactions are identified as severe (red) interaction by the BNF. Where it is known an individual is concurrently taking one of the following medicines, treatment should not be undertaken under this PGD, and the individual referred to a prescriber; • Dapsone

	• Topical prilocaine (eg EMLA®) Additional interactions that also need to be taken into consideration prior to a supply being made; • Antacids for indigestion (e.g. magnesium trisilicate) decrease absorption of nitrofurantoin • Oral typhoid vaccine can be inactivated by nitrofurantoin (see exclusion criteria) • Probenecid and sulfinpyrazone decrease renal excretion • Medicines which slow the passage of food through the stomach (e.g. atropine, hyoscine) can lead to increased absorption of nitrofurantoin. • Carbonic anhydrase inhibitors (e.g. acetazolamide) can reduce the anti-bacterial activity of nitrofurantoin • Medicines which make the urine less acidic (e.g. potassium citrate mixture) can reduce anti-bacterial activity. • Quinolones can reduce anti-bacterial activity of nitrofurantoin Please refer to SPC Home - electronic medicines compendium (emc) or BNF British National Formulary - NICE for full details.
Identification & management of adverse reactions	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. The following side effects have occasionally been reported. These are generally mild and reversible when nitrofurantoin is withdrawn. • Nausea • Vomiting • Pruritus • Skin rashes • Abdominal pain and diarrhoea • Loss of appetite • Headache 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 (generally reversible on cessation of treatment) In the event of a severe adverse reaction, the patient must be advised to stop treatment immediately and seek urgent medical advice. Please refer to SPC for uncommon and rare side effects

Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse drug reactions (ADRs) to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all ADRs in the patient's medication record. • It is considered good practice to notify the individual's GP in the event of an adverse reaction
Further advice to be supplied to individuals	• Provide the patient with the manufacturer's Patient Information Leaflet and discuss as necessary. • Provide TARGET leaflet – Urinary Tract Infection TYI-UTI leaflet for women under 65 years. • Take the MR capsules regularly at 12 hourly intervals if possible, with food or milk, and complete the course • Advise that if a dose is missed, the patient should take it as soon as they remember, unless it's nearly time for the next dose. In this case, leave out the missed dose, and take the next dose at the usual time. • Immediate release tablets or capsules should be taken 6 hourly with food or milk to minimise GI reactions • Inform the individual/carer of possible side effects and their management • Drink plenty of fluids, but avoid caffeine containing, and alcoholic drinks • Try to empty the bladder when urinating • Passing water following intercourse may also prevent recurrent attacks • Attacks may be precipitated by the use of fragranced products. • If symptoms worsen rapidly or significantly, or have not improved after 48 hours, advise patient to contact their Primary Care Clinician. • If the condition becomes recurrent, contact Primary Care Clinician for further investigation • Advise that in 50% of cases, symptoms clear up within 3 days without treatment • Paracetamol or ibuprofen can be taken to alleviate symptomatic pain or discomfort • There is no evidence to support the use of either cranberry juice or urine alkalization products. • It is no longer necessary to use an extra method of contraception with the pill, patch or vaginal ring when taking nitrofurantoin unless the patient experiences diarrhoea and vomiting. This change in advice comes because to date there is no evidence to prove that antibiotics (other than rifampicin or rifabutin) affect these contraceptives. This is the latest guidance from the Faculty of Sexual & Reproductive Healthcare. • FOLLOW UP – Individuals must be contacted within 7 days of the initial consultation to ascertain success of treatment, and arrange referral to an appropriate clinician if symptoms have not resolved, and the individual has not already sought additional advice.

	Please refer to SPC Home - electronic medicines compendium (emc) or BNF British National Formulary - NICE for full details.
Records	• In discussion with the client enter consultation details onto the relevant module within PharmOutcomes at the time of the consultation. All consultations must be entered onto PharmOutcomes on the day that the consultation takes place. The record itself must include the following: - that valid informed consent was given where applicable - name of individual, address, date of birth and GP with whom the individual is registered (if relevant) - any known medication allergies - name of pharmacist operating under the PGD - name of medication supplied - batch number and expiry date - date of supply - dose, form and route of administration - quantity supplied - advice given, including advice given if excluded or declines treatment - details of any adverse drug reactions and actions taken - administered via Patient Group Direction (PGD) • Details of the supply must also be made in the patient's (PMR) record. • All supplies of nitrofurantoin must be labelled in accordance with the labelling requirements for a dispensed medicine as stated within Schedule 5 of The Medicines (Marketing Authorisations etc) Regulations 1994. No 3144 as amended. In addition to the above, the label must also state the words "Supplied under a PGD" to help with audit purposes. • Electronic patient records should be retained for adults for a period of 10 years after attendance and for children until the child is 25 years old. • If the client is excluded, a record of the reason for exclusion must be documented within PharmOutcomes, and any specific advice that has been given. In every case when a supply of nitrofurantoin is made in accordance with this PGD, the pharmacist must inform the patient's GP of the supply within two working days. This will be done through secure nhs.net email accounts via PharmOutcomes once the consultation data has been recorded within the specified module. Where no nhs.net account is available to PharmOutcomes, the pharmacist will be informed by the system and must make alternative

	arrangements to send the information (within two working days).

4. Key references

Key references	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF and BNFC https://bnf.nice.org.uk/ • NICE Urinary Tract Infection (lower): Antimicrobial Prescribing (NG109) • Clinical knowledge summaries – Uncomplicated UTI (lower) – women. September 2022 Urinary tract infection (lower) - women | Health topics A to Z | CKS | NICE • PHE Diagnosis of UTI – Algorithm 1 PHE UTI guideline | PHE/DH/DWP guideline | Guidelines • PHE -Diagnosis of UTI quick reference guide in primary care https://www.gov.uk/government/publications/urinary-tract-infection-diagnosis • NICE ANTIMICROBIAL SUMMARY GUIDANCE for UTI https://www.bnf.org/news/2021/07/29/bnf-hosts-antimicrobial-summary-guidance-on-behalf-of-nice-and-phe/ • Principles of Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use https://www.nice.org.uk/guidance/ng15

Appendix A – Registered pharmacist authorisation sheet

Supply of nitrofurantoin for the treatment of uncomplicated urinary tract infection in non-pregnant women aged 16 years and over and under 65 years

Version: 6.0/2023 Valid from: 31st March 2023 Expiry: 31st March 2024

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered pharmacist

By signing this patient group direction, you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered pharmacists named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of _____ (insert name of organisation) for the above named pharmacists who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered pharmacists to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered pharmacists authorised to work under this PGD.

Add details on how this information is to be retained according to organisation PGD policy.