Hertfordshire and West Essex Integrated Care Board

This Patient Group Direction (PGD) must only be used by registered healthcare professionals 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)

Supply of nitrofurantoin capsules/tablets for the treatment of Urinary Tract Infection (UTI) as part of the Hertfordshire and West Essex ICB Community Pharmacy Infection Management Service

Version Number 1.0

Change History	
Version and Date	**Change details**
Version 1.0 February 2023	National PGD template reviewed and updated by HWE ICB organisational review group. Approved for use by PGD organisational group and decision ratified by HWE ICB Primary Care Commissioning Committee 21st Feb 2023

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	16th May 2023
Review date	1st July 2025
Expiry date:	31st December 2025

This PGD template has been peer reviewed by the national UTI antimicrobial PGD Short Life Working Group in accordance with their Terms of Reference. It has been approved by The Advisory Committee on Antimicrobial Prescribing, Resistance and Healthcare Associated Infection (APRHAI) to the Department of Health and Social Care (England) in January 2023.

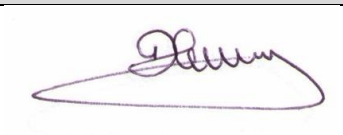
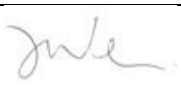
This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation
Dr Diane Ashiru-Oredope	Lead Pharmacist for UKHSA HCAI & AMR Division
Dr Imran Jawaid	GP and RCGP AMR representative
Dr Kiren Collison	GP Oxford, Deputy Medical Director for Primary Care, NHSE&I
Dr Naomi Fleming*	Regional AMS Lead East of England
Mandy Slatter	Southwest Regional UTI Improvement Collaborative Lead NHS England
Jackie Lamberty	Lead Pharmacist for Medicines Governance and PGD approvals UKHSA
Jo Jenkins (SLWG co-ordinator)	Lead Pharmacist Patient Group Directions and Medicines Mechanisms, Medicines Use and Safety Division, Specialist Pharmacy Service
Liz Cross*	Advanced Nurse Practitioner QN Manor View Practice

Professor Bhaskar Somani	Consultant Urologist, University Hospital Southampton
Professor Peter Wilson*	Consultant Medical Microbiologist, UCH
Temitope Odetunde	Head of Meds Management, First and Community Health and Care, Redhill, Surrey
Tracy Rogers	Director, Medicines Use and Safety Division, Specialist Pharmacy Service

*Core group members

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor	Daniel Carlton-Conway GP Prescribing Lead, HWE ICB		16.5.23
Senior pharmacist	Janet Weir, Lead Pharmacist, HWE ICB		10.5.23
Anti-microbial Specialist	David Ladenheim, Lead Pharmaceutical Advisor and Antimicrobial Medicines Lead, HWE ICB		10.5.23
Person signing on behalf of authorising body	Rachel Joyce, Medical Director, HWE ICB		15.5.23

Local organisational review group members:

Chris Harvey	Assistant Director of Nursing and Quality, HWE ICB
Asif Faizy	GP Prescribing Lead South West Herts, HWE ICB
Stacey Golding	Lead Pharmacist, Medication Governance, Safety and Quality, HWE ICB
Huda Siddiq	Pharmaceutical Advisor, HWE ICB
Farhan Moulana	Deputy Chief Officer, Community Pharmacy Hertfordshire

1. Characteristics of staff

Qualifications and professional registration	Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation. Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	The registered healthcare professional authorised to operate under this PGD must have: • undertaken appropriate training and successfully completed the competencies to undertake clinical assessment of individuals leading to diagnosis of the conditions listed. Minimum recommended training is completion of the RCGP eLearning Urinary Tract Infections (webinar, presentation, quiz and podcast are free to access) • undertaken appropriate training and successfully completed the competencies for the identification of sepsis • undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme completed required training (including updates) in safeguarding vulnerable adults HEE elfh Hub (e-lfh.org.uk)
Competency assessment	• Individuals operating under this PGD must be assessed as competent or complete a self-declaration of competence to operate under this PGD • Staff operating under this PGD should review their competency using the NICE Competency Framework for health professionals using patient group directions • Individuals operating under this PGD should follow the national guidance for diagnostic (UKHSA) and management (NICE) of 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). Individuals operating under this PGD must have access to the PGD and associated online resources.
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring 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 and further training provided as required. • It is the responsibility of the individual to keep up-to-date with continued professional development (CPD) • Organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to supply any medication rests with the individual registered health professional 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	Lower urinary tract infection (UTI) in non-pregnant women aged 16 years to 64 years **in the absence of current or recent fever (within past 48 hours)** **Where nitrofurantoin 100mg MR capsules are unavailable nitrofurantoin 50mg tablets may be offered using this PGD as an alternative first line choice.**
Criteria for inclusion	• Informed consent • Non pregnant females aged 16 years to 64 years • Signs and symptoms and diagnosis of UTI using the appropriate Public Health England Urinary tract infection: diagnostic tools for primary care including the use of dipsticks where this is identified in the guidance • No nitrofurantoin use in the past 3 months
Criteria for exclusion	• Consent refused or unable to consent and documented in the individual's medical notes • Individuals aged 65 years or over or 15 years and younger • Patients assigned male at birth • Pregnancy or suspected pregnancy • Current breastfeeding • Immunocompromised individuals • Known hypersensitivity to nitrofurantoin or any of the components within the formulation - see Summary of Product Characteristics • Any individual identified with symptoms of severe/life-threatening infection or systemic sepsis using NEWS2 should be referred urgently via ambulance • Any individual identified with symptoms of pyelonephritis but not systemically unwell should be referred to a prescriber urgently for same day assessment and management. Signs of pyelonephritis include: ○ kidney pain/tenderness in back under ribs

	○ new/different myalgia, flu like illness ○ shaking chills (rigors) or temperature 37.9°C or above ○ nausea/vomiting • History of raised temperature, fever or chills within past 48 hours • Abnormal vaginal discharge • 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) • Individuals already taking prophylactic antibiotics for UTI • Failed previous antibiotic for this episode of UTI • Recurrent UTI (>2 in 6 months, >3 in 12 months) – requires urine culture • Treatment for UTI with any antimicrobial in the past 3 months. • Known previous nitrofurantoin resistant UTI (recorded in accessible information e.g. SCR, clinical record if available) **OR** known previously resistant UTI to **any** antibiotic self-reported by the individual where records not available. • Individuals currently using urinary catheter devices including indwelling urethral catheters, supra-pubic catheters or intermittent self-catheterisation • Known Chronic Kidney Disease (CKD) stages 3b, 4 or 5 (eGFR <45ml/min/1.73m²) • Known porphyria • Known G6PD deficiency • Known anaemia • Known diabetes mellitus (Type 1 or 2) • Known folate deficiency • Known vitamin B deficiency • Known peripheral neuropathy

	• Known electrolyte imbalance • Hospitalisation in a foreign country within last 3 months • Care home resident • UK hospitalisation for > 7 days in last 6 months • Less than 3 days before receiving, or within 3 days after receiving, oral typhoid vaccine • Concurrent use of any interacting medicine as listed in 'Interactions' section of this PGD • 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
Cautions including any relevant action to be taken	• Visible haematuria – treat for UTI but inform individual/their carer to see clinician if haematuria continues after treatment • Nitrofurantoin should be used with caution in individuals with pulmonary disease, hepatic dysfunction, neurological disorders, and allergic conditions as these may be adverse effects of nitrofurantoin. Advise of relevant adverse effects and to seek medical advice if adverse reactions occur.
Specific information for suspected infection to be provided	Provide TARGET leaflet
Action to be taken if the individual is excluded or declines treatment	• Record reasons for exclusion in the PharmOutcomes consultation proforma, including advice given and any action taken. • Patients who do not meet the inclusion criteria due to severity of symptoms should be advised that cystitis is usually self-limiting and will resolve without antibiotics. Give self-care and safety netting advice as contained in the Target UTI leaflets. (Leaflets to discuss with patients: UTI Leaflet - Women Under 65 Years (rcgp.org.uk) Target UTI leaflets in languages other than English are available • Patients who meet the inclusion criteria for severity or number of symptoms but who are excluded from treatment with nitrofurantoin may be considered for treatment with trimethoprim. • Advise individual/their carer on alternative non antibiotic treatment if antibiotic not indicated and provide TARGET

	leaflet and safety netting advice. • Refer to a prescriber if antibiotic appropriate but falls outside of this PGD. • The clinician may advise deferred antibiotic treatment. If the individual agrees to defer treatment the clinician should determine that they could be treated under the service PGDs if they do return. If they are excluded from a PGD supply, they should be advised to see an appropriate prescriber if they need treatment after waiting the agreed timescale agreed in the deferment conversation. If the individual could be treated via the service PGD and returns after waiting the appropriate amount of time the clinician can then supply the medication once an appropriate assessment under the PGD is undertaken. The clinician making the assessment may refer to the original consultation notes but must fully reassess the individual for suitability for treatment as this clinician is responsible for the assessment and decision to supply. The supply should be recorded using PharmOutcomes in the Deferred Treatment Module which then forms part of the PharmOutcomes clinical record. This ensures that the number of individuals returning for deferred treatment can be monitored. • **Refer urgently** to GP practice or out of hours via NHS 111 as appropriate **if:** • individual immunocompromised • fever present or systemically unwell and/or symptoms of upper UTI or pyelonephritis • **If sepsis is suspected refer the individual urgently to A&E**
Action to be taken if the individual/their carer declines treatment	• Document advice given • Provide safety netting advice and advise individual/their carer on alternative treatment available using TARGET leaflet • Refer to an alternative provider if appropriate.
Arrangements for referral for medical advice	**Refer urgently to GP Practice or out of hours via NHS 111 as appropriate if:** • individual immunocompromised • fever present or systemically unwell and/or symptoms

	of upper UTI or pyelonephritis • Refer to a prescriber if antibiotic appropriate but falls outside of this PGD .

3. Description of treatment

Name, strength & formulation of drug	Nitrofurantoin 100mg modified release tablets or capsules or 50 mg immediate release tablets or capsules
Legal category	POM
Route / method of administration	Orally, swallowed whole taken with food or milk.
Indicate any off-label use (if relevant)	Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions a pharmacist must ensure the medicine remains pharmaceutically stable and appropriate for use if it is to be issued. Where medicines have been assessed by a pharmacist in accordance with national or specific product recommendations/manufacturer advice as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with the pharmacist. Where a drug is recommended off-label consider, as part of the consent process, informing the individual/carer that the drug is being offered in accordance with national guidance but that this is outside the product license.
Dose and frequency of administration	**First choice** -100mg modified release tablets or capsules twice a day (every 12 hours) **OR**

	Second choice where capsules are unsuitable or unavailable 50 mg immediate release tablets or capsules four times a day (every 6 hours)
Duration of treatment	3 days **Treatment should be started immediately and all supplied doses taken.**
Quantity to be supplied	Appropriately labelled pack of 6 x 100mg modified release tablets or capsules **OR** Appropriately labelled pack of 12 x 50mg immediate release tablets or capsules.
Storage	Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
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 (e.g. EMLA®) A thorough medication history must be taken to identify concurrent medication use. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org **Common side effects include:** • nausea • vomiting • diarrhoea • loss of appetite

	• headaches • dizziness • drowsiness • discoloured dark yellow or brown urine **Rare but serious side effects:** **Respiratory disorders –** advise to seek urgent medical advice if breathing difficulties develop. BNF advises that acute pulmonary reactions usually occur within the first week of treatment and are reversible with cessation of therapy. Chronic pulmonary reactions can develop insidiously. Discontinue treatment with nitrofurantoin if pulmonary reactions occur. **Neurological disorders –** advise to seek urgent medical advice if peripheral neuropathy develops.
Management of and reporting procedure for adverse reactions	• Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the individual's clinical record. • Report via organisation incident policy. • It is considered good practice to notify the individual's GP in the event of an adverse reaction.
Written or other information to be given to individual or carer	• Provide marketing authorisation holder's information leaflet (PIL) provided with the product. • Provide the TARGET Treating your infection – urinary tract infection (UTI) leaflet • Give any additional information in accordance with the local service specification.

Individual advice / follow up treatment	• Explain dose and method of administration. • Symptoms should start to improve within 48 hours of taking nitrofurantoin – advise individual to seek medical advice if no improvement within this time. • Inform the individual/carer of possible side effects and their management, including that the urine may become discoloured (brown/yellow) while taking nitrofurantoin but that this is not of concern and urine will return to normal colour when the course is complete. • Advise the individual/carer to take the medication at regular intervals with food or milk and to finish the course. • Advise that nitrofurantoin is not a penicillin related antibiotic • Medicines which make the urine less acidic such as OTC cystitis preparations containing potassium citrate, sodium bicarbonate or sodium citrate decreases the antibacterial action of nitrofurantoin and should not be taken during the course of nitrofurantoin. • Antacids such as magnesium trisilicate can decrease the absorption of nitrofurantoin and should not be taken during the course of nitrofurantoin. • Risk of possible STDs should be raised if appropriate. Sexually active young women with urinary symptoms advise or offer Chlamydia screening. https://www.sexualhealthhertfordshire.clch.nhs.uk/sti-testing • If the individual is affected by dizziness or drowsiness advise them not to drive or operate machinery. • The individual/carer should be advised to seek medical advice in the event of an adverse reaction or if any other new symptoms develop. • The individual/carer should be advised to read PIL • If dose is missed advise to refer to PIL supplied with the product • Advise individual to complete the full course even if symptoms improve. • Individuals will be contacted 5 days after medication supply to ascertain success of treatment and arrange referral to appropriate practitioner if symptoms have not resolved. This can be done face to face or over the telephone ensuring

	outcome is documented including whether symptoms resolved, partially resolved, ongoing, any further healthcare contact already happened or recommended. • Advise the individual to return any used medicines to a pharmacy for disposal. • Advise patient that their GP will be informed within two working days that antibiotics have been supplied. • In the case of a deferred supply, contact should be made 5 days after supply • Ensure record of follow up consultation is entered into the PharmOutcomes service module as soon as possible and within two working days of follow up conversation.
Records	Appropriate records must be entered into the relevant module within PharmOutcomes on the day that the consultation takes place and must include the following: • That valid informed consent has been given • Individual's name, address and date of birth • Name of GP individual is registered with • Specify how the individual has/has not met the criteria of the PGD • Name/dose/form/quantity of medicine supplied • Date and time of supply • Relevant past and present medical history • Documentation of cautions as appropriate • Advice given if individual excluded or declines treatment • Details of any ADRs/allergy status and actions taken • The supply must be entered in the Patient Medication Record (PMR) • That supply was made under a PGD • Any safety incidents, such as medication errors, near misses and suspected adverse events • Any additional requirements in accordance with the service

	specification • GP to be notified within two working days of supply via PharmOutcomes or via secure email • All records should be kept in line with national guidance. This includes individual data, master copies of the PGD and lists of authorised practitioners. **Records should be signed and dated (or a password controlled e-records).** **All supplies of nitrofurantoin must be labelled in accordance with the labelling requirements for a dispensed medicine as stated within Schedule 25 of the Human Medicines Regulations 2012. Supplementary warning labels must be added as required.** **All records should be clear, legible and contemporaneous.** **A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.** Aspects of the service to be audited should include (but are not limited to): • The volume of individuals assessed using the PGD • The population demographics of patients using the service. • The volume supplied medication via PGD • The volume receiving TARGET information • Individual outcome at day 3-7 as per service specification • The number of escalations to other clinicians • Any reported clinical incidents and the findings from their subsequent investigation. • The types and effectiveness of secure digital referral routes deployed. • Impact on health inequalities (linking to post codes of those diagnosed)

	• Service user experience / satisfaction • Operational efficiency and identified issues with the running of the service, which may prompt changes to its design/future development • The cost of implementation including time and resource(s) required. • Impact on antibiotic use

4. Key references

Key references (accessed October 2022)	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • Reference guide to consent for examination or treatment https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • Urinary tract infection (lower): antimicrobial prescribing NG109 https://www.nice.org.uk/guidance/ng109 • Diagnosis of urinary tract infections Quick reference tool for primary care https://www.gov.uk/government/publications/urinary-tract-infection-diagnosis • Immunisation against infectious disease https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • TARGET Treating your infection - URINARY TRACT INFECTION (TYI-UTI) leaflet https://www.rcgp.org.uk/clinical-and-research/resources/toolkits/amr/target-antibiotics-toolkit/uti-resource-suite.aspx • Urinary tract infection (lower): antimicrobial prescribing NICE guideline [NG109] Published: 31 October 2018 https://www.nice.org.uk/guidance/ng109

Appendix A – Registered health professional authorisation sheet

PGD Name/Version: PGD CP UTI Nitrofurantoin v1.0

Valid from: 16th May 2023 **Expiry:** 31st Dec 2025

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

Registered health professional

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 health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of _____ for the above named health care professionals 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 health professionals to prevent additions post managerial authorisation.

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

This information must be available to HWE ICB on request.