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 228(S))

Supply of nitrofurantoin capsules/tablets for the treatment of Urinary Tract Infection (UTI) to patients between 13 and 65 years of age in Integrated Sexual Health Services (ISHS) Derbyshire Community Health Services

Version Number 1.1

Change History	
Version and Date	**Change details**
Version 1.0 January 2023	New template
Version 1.1 July 2023	Updated interaction information – removed dapsone and topical prilocaine as interacting drugs

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	November 2023
Review date	June 2025
Expiry date:	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

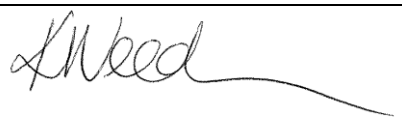
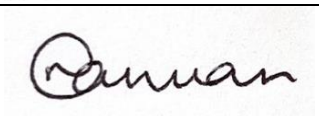
PATIENT GROUP DIRECTION DEVELOPMENT WORKING GROUP

This PGD has been agreed by doctors, and/or expert clinical practitioners, pharmacist and representative healthcare professionals from the trust stated below for use within Integrated Sexual Health Services (ISHS), University of Derby and Burton Teaching Hospitals Foundation Trust (UHDBFT) and Derbyshire Community Health Services Foundation Trust (DCHSFT)

PATIENT GROUP DIRECTION AUTHORISATION

PGD approved by PGD Working Group on *27th September 2023*

This PGD is authorised for use on behalf of DCHS by the following signatories:

Position of signatory	Name	Signature	Date
Director of Nursing, AHPs & Quality	Michelle Bateman		11/10/2023
Head of Medicines Management	Kate Needham		11/10/2023
Deputy Medical Director	Dr Seema Kumari		11/10/2023
Lead Clinician	Dr Ade Apoola		11/10/2023
Specialist in Antimicrobial Therapy	Cerina Nanuan		11/10/2023

REVIEWED FOR DCHS BY:		
Date	**Name**	**Position**
September 2023	Lisa Walton Dr Ade Apoola Cerina Nanuan	ISHS Specialist Nurse Practitioner ISHS Lead Clinician Advanced Pharmacist for IP&C

PGDs 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 in accordance with their own Code of Professional Conduct. Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medication(s) listed only in accordance with the PGD.

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 Urinary Tract Infections webinar, presentation, podcast and quiz • 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 locally required training (including updates) in safeguarding vulnerable adults • For advice on additional local training requirements see section 4: Characteristics of DCHS ISHS Staff.
Competency assessment	• Individuals operating under this PGD must be assessed as competent or complete a self-declaration of competence to operate under this PGD (Appendix A). • 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. • 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 13 years to 64 years **in the absence of current or recent fever (within past 48 hours)**
Criteria for inclusion	• Informed consent • Non pregnant females aged 13 years to 64 years • Signs and symptoms of UTI using the appropriate Urinary tract infection: diagnostic tools for primary care • No nitrofurantoin use in the past 3 months • Diagnosis of lower UTI using Diagnosis of urinary tract infections - Quick reference tool for primary care including the use of dipsticks where this is identified in the guidance.

Criteria for exclusion	• Consent refused and documented in the individual's medical notes
	• Individuals aged 65 years or over or 12 years and younger
	• Males
	• 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
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. Safeguarding: Where there are any safeguarding concerns refer to local policies for safeguarding adults and children and/or seek advice from the safeguarding lead/team in the organisation. Document the concern and outcome in the healthcare record. DCHS: Safeguarding adults and children policies on DCHS SharePoint. DCHS Safeguarding Team: 01773 850000. East Midland's Children and Young People's Sexual Assault Service (EMCYPSAS): 0800 183 0023 (24-hour service).
Specific information for suspected infection to be provided	Provide TARGET leaflet
Action to be taken if the individual is excluded	• Record reasons for exclusion in the appropriate clinical record. • 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 (if 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 a prescriber 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 a prescriber if appropriate.
Arrangements for referral for medical advice	**Refer urgently to a prescriber 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	100mg modified release tablets or capsules twice a day (every 12 hours) **OR** 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 modified release tablets or capsules **OR** Appropriately labelled pack of 12 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	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. • 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 at day 7 after medication supply if a mid-stream urine sample was taken to inform patient of a positive result • Advise the individual to return any used medicines to a pharmacy for disposal.
Records	Appropriate records 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 • All records should be clear, legible and contemporaneous. • Any safety incidents, such as medication errors, near misses and suspected adverse events • Any additional requirements in accordance with the service specification • 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 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. Characteristics of DCHS ISHS Staff

Qualifications	A registered nurse working within ISHS who is deemed competent by their clinical line manager and authorised by their professional lead to undertake the clinical assessment of a patients leading to the identification of those suitable for management under this PGD.
Additional Local Training	Has undertaken the local training programme on the process, responsibilities and scope of PGDs. Has undertaken local training based on the use of this PGD Has undertaken training in recognition of and treatment of anaphylaxis including basic life support in the 12 months. Has undertaken Safeguarding Children Level 3 training in the last 12 months. Has undertaken Safeguarding Adults Level 2 training in the last 3 years.
Continuing Training & Education	Evidence of Continuing Professional Development in ISHS nurse role. The nurse 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 and to work within the limitations of individual scope of practice.

5. 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: 228(S) Nitrofurantoin v1.1
Valid from: October 2023 **Expiry:** 31 December 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 Derbyshire Community Health Services 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.
PGD Authorisation Forms shall be maintained and retained by the Service Manager who is responsible for the safe storage of the records.