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.

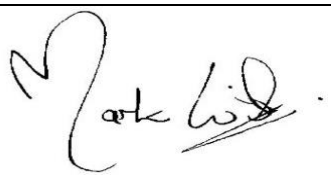
PATIENT GROUP DIRECTION (PGD)

Supply of nitrofurantoin capsules/tablets for the treatment of Urinary Tract Infection (UTI) under the NHS England commissioned Pharmacy First service

Version Number 1.2

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
Version 1.2 January 2024	• Content aligned with PGDs in Pharmacy First suite. • Expansion of the definition of immunosuppressed • Addition of abnormal vaginal discharge, suspected STI and urethritis as exclusions • Addition of hepatoxicity warning from MHRA • Addition of caution re: rare metabolic conditions and certain excipients • Addition of self-care advice • Removal of nitrofurantoin 100g M/R tablets: no longer commercially available

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor ***Professor Sir Stephen Powis***	National Medical Director, NHS England		11.12.23
Senior pharmacist ***David Webb***	Chief Pharmaceutical Officer, NHS England		08.12.23
Specialist in microbiology ***Professor Mark Wilcox***	National Clinical Director for AMR & IPC, NHS England		11.12.23
Person signing on behalf of authorising body ***David Webb***	Chief Pharmaceutical Officer, NHS England		08.12.23

PGD DEVELOPMENT GROUP

Date PGD comes into effect:	31/01/2024
Review date	30/07/2026
Expiry date:	30/01/2027

This PGD has been peer reviewed by the national UTI antimicrobial PGD Short Life Working Group in accordance with their Terms of Reference. It has been reviewed 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.

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	NHS England Regional Antimicrobial Stewardship lead for the East of England region
Mandy Slatter	Southwest Regional UTI Improvement Collaborative Lead NHS England
Jackie Lamberty	Lead Pharmacist for Medicines Governance and PGD approvals UKHSA
Jo Jenkins	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

Characteristics of staff

Qualifications and professional registration	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 education and training and be competent to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with the specification. • To deliver this service, the registered healthcare professional should have evidence of competence in the clinical skills and knowledge covered in the Centre for Pharmacy Postgraduate Education (CPPE) Pharmacy First Service self-assessment framework. • Before commencement of the service, the pharmacy contractor must ensure that pharmacists and pharmacy staff providing the service are competent to do so and be familiar with the clinical pathways, clinical protocol and PGDs. This may involve completion of training.
Competency assessment	• Individuals operating under this PGD must be assessed as competent or complete a self-declaration of competence to operate under this PGD (see an example authorisation record sheet in Appendix A). • Individuals operating under this PGD are advised 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 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.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

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)
Criteria for inclusion	• Informed consent • Non-pregnant females aged 16 years to 64 years • Signs and symptoms of UTI using the appropriate Urinary tract infection: diagnostic tools for primary care • Diagnosis of lower UTI using Urinary tract infection: diagnostic tools for primary care • No nitrofurantoin use in the past 3 months
Criteria for exclusion	• Consent refused and documented in the individual's clinical notes • Individuals aged 15 years or under or 65 years of age and over • Males • Pregnancy or suspected pregnancy • Current breastfeeding • Severely immunosuppressed individuals as defined in Chapter 28a Green book): ***Individuals with primary or acquired immunodeficiency states due to conditions including:*** • *acute and chronic leukaemias, and clinically aggressive lymphomas (including Hodgkin's lymphoma) who are less than 12 months since achieving cure* • *individuals under follow up for a chronic lymphoproliferative disorders including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma, Waldenstrom's macroglobulinemia and other plasma cell dyscrasias (N.B: this list not exhaustive)* • *immunosuppression due to HIV/AIDS with a current CD4 count of below 200 cells/µl.* • *primary or acquired cellular and combined immune deficiencies – those with lymphopaenia (<1,000 lymphocytes/ul) or with a functional lymphocyte disorder* • *those who have received an allogeneic (cells from a donor) or an autologous (using their own cells) stem cell transplant in the previous 24 months* • *those who have received a stem cell transplant more than 24 months ago but have ongoing immunosuppression or graft versus host disease (GVHD)* ***Individuals on immunosuppressive or immunomodulating therapy including:*** • *those who are receiving or have received in the past 6 months immunosuppressive chemotherapy or radiotherapy for any indication* • *those who are receiving or have received in the previous 6 months immunosuppressive therapy for a solid organ transplant* • *those who are receiving or have received in the previous 3 months targeted therapy for autoimmune disease, such as JAK inhibitors or biologic immune modulators including B-cell targeted therapies (including rituximab but for which a 6 month period should be considered immunosuppressive), monoclonal tumor necrosis factor inhibitors (TNFi), T-cell co-stimulation modulators, soluble TNF*

	receptors, interleukin (IL)-6 receptor inhibitors., IL-17 inhibitors, IL 12/23 inhibitors, IL 23 inhibitors (N.B: this list is not exhaustive) ***Individuals with chronic immune mediated inflammatory disease who are receiving or have received immunosuppressive therapy*** • *moderate to high dose corticosteroids (equivalent ≥20mg prednisolone per day) for more than 10 days in the previous month* • *long term moderate dose corticosteroids (equivalent to ≥10mg prednisolone per day for more than 4 weeks) in the previous 3 months* • *any non-biological oral immune modulating drugs e.g. methotrexate >20mg per week (oral and subcutaneous), azathioprine >3.0mg/kg/day; 6-mercaptopurine >1.5mg/kg/day, mycophenolate >1g/day) in the previous 3 months* • *certain combination therapies at individual doses lower than stated above, including those on ≥7.5mg prednisolone per day in combination with other immunosuppressants (other than hydroxychloroquine or sulfasalazine) and those receiving methotrexate (any dose) with leflunomide in the previous 3 months* ***Individuals who have received a short course of high dose steroids (equivalent >40mg prednisolone per day for more than a week) for any reason in the previous month.*** • Immunosuppressed individuals: individuals who are immunosuppressed or are currently taking immunosuppressants (including systemic corticosteroids*) or immune modulators, but who do not meet the definition of severe immunosuppression (see above). [For equivalent doses in children, see Chapter 6 Green Book] * does not include: ○ replacement corticosteroids for individuals with adrenal insufficiency ○ corticosteroid inhalers or corticosteroids applied topically (e.g. to the skin, ears, eyes, nasal cavity) ○ intra-articular, -bursal or -tendon corticosteroid injections. • Known hypersensitivity to nitrofurantoin or any of the components within the formulation - see Summary of Product Characteristics **Acceptable sources of allergy information include individual/carer or National Care Record** • Inability to absorb oral medications and/or inability to swallow oral dosage formulations (i.e. tablets or capsules) • Individuals already taking prophylactic antibiotics for UTI • Recurrent UTI (2 episodes in last 6 months, 3 episodes in last 12 months) – requires urine culture • Failed previous antibiotic for this episode of UTI • Treatment for UTI with any antimicrobial in the past 3 months. • Abnormal vaginal discharge • Urethritis (inflammation post sexual intercourse, irritants) • Genitourinary symptoms of menopause (e.g. vulvovaginal atrophy) • Suspected sexually transmitted infection • 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 • Any individual identified with symptoms of severe/life-threatening infection or systemic sepsis should be referred urgently via ambulance. • 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) • Known previous nitrofurantoin resistant UTI (recorded in accessible information e.g. National Care Record, 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 • Hospitalisation in a foreign country within last 3 months • Care home resident • UK hospitalisation for > 7 days in last 6 months • 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 • Known Chronic Kidney Disease (CKD) stages 3b, 4 or 5 (eGFR <45ml/min/1.73m²) • Less than 3 days before receiving, or within 3 days after receiving, oral typhoid vaccine
Cautions including any relevant action to be taken	• Visible haematuria: treat for UTI but inform individual/carer/parent/guardian to seek medical attention 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 individual/carer/parent/guardian of relevant adverse effects and to seek medical advice if adverse reactions occur. For further detail refer to MHRA Nitrofurantoin Drug Safety Update. • Caution should be exercised when supplying nitrofurantoin capsules or tablets to individuals who should avoid the following excipients: ○ **Lactose, sucrose, fructose and sorbitol:** Individuals with rare hereditary problems of galactosaemia, galactose intolerance, total lactase deficiency, glucose-galactose malabsorption, sucrase-isomaltase deficiency, fructose-1,6-bisphosphatase deficiency (also known as hereditary fructose intolerance): check the individual list of excipients

	available in the SPC before supplying. ○ **Aspartame:** Individuals with phenylketonuria (PKU) must not use medicines containing aspartame. Check the individual list of excipients available in the SPC before supplying.
Specific information for suspected infection to be provided	Provide TARGET Treating Your Infection Urinary Tract Infection (TYI-UTI) patient information leaflet (TARGET UTI leaflet) Provide self-care advice including: • Paracetamol (or if preferred and suitable, ibuprofen) (over the counter) can be used for pain relief. (For further information see: Mild to moderate pain and NSAIDs-prescribing issues). • Drink plenty of fluids during the day so urine is pale in colour.
Action to be taken if the individual is excluded	• Record reasons for exclusion in the appropriate clinical record. **Individuals where treatment is not indicated:** • Advise individual/carer/parent/guardian of alternative non antibiotic treatment if antibiotic not indicated and provide TARGET UTI leaflet and safety netting advice. • Supporting resources available via TARGET community pharmacy toolkit **Refer to a prescriber for further assessment if:** • Abnormal vaginal discharge (80% do not have UTI) • Urethritis (inflammation post sexual intercourse, irritants) • Genitourinary symptoms of menopause (e.g. vulvovaginal atrophy) • Individuals where treatment under this PGD is not indicated/permitted but urinary symptoms are present and require further assessment **Refer urgently to a prescriber (e.g. General Practice or sexual health service, as appropriate) for further assessment if:** • Known or suspected pregnancy • Individual is severely immunosuppressed or immunosuppressed • Suspected sexually transmitted infection **Refer urgently to General Practice or out of hours service for same day assessment if:** • Systemically unwell, but not showing signs or symptoms of sepsis • New signs/symptoms of upper UTI or pyelonephritis (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) **If sepsis is suspected refer the individual urgently to A&E**
Action to be taken if the individual/carer/parent/ guardian declines treatment	• Document advice given • Provide safety netting advice and advise individual/carer/parent/guardian of alternative treatment available using TARGET UTI leaflet • Refer to a prescriber if appropriate.

Arrangements for referral for medical advice	Refer to a prescriber if antibiotic appropriate but falls outside of this PGD.

Description of treatment

Name, strength & formulation of drug	Nitrofurantoin 50mg immediate release tablets or capsules Nitrofurantoin 100mg modified release capsules
Legal category	POM
Route / method of administration	Orally, swallowed whole taken with food or milk.
Off-label use	**Temperature variations** 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 licence.
Dose and frequency of administration	**Adults:** 100mg modified release capsules twice a day (every 12 hours) **OR if 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 3 days of treatment completed.**
Quantity to be supplied	In line with the Pharmacy First service specification the best value product to meet the clinical need should be supplied from those listed within this PGD. **Adults:** Appropriately labelled pack of 6 x 100mg modified release 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	Where it is known an individual is concurrently taking the following medicine, treatment should not be undertaken under this PGD and the individual referred to a prescriber: • Typhoid vaccine (oral): see Criteria for exclusion No other clinically significant interactions identified. 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 The following side effects are listed in the product SPC/BNF as **common** with nitrofurantoin (but may not reflect all reported side effects): • Nausea • Vomiting • Diarrhoea • Loss of appetite • Headaches • Dizziness • Drowsiness • Discoloured dark yellow or brown urine The following side effects are listed in the product SPC/BNF as **rare but serious** with nitrofurantoin: • **Respiratory reactions** (including trouble breathing, shortness of breath, a lingering cough, coughing up blood or mucus, or pain or discomfort when breathing): advise to seek urgent medical advice if new or worsening breathing difficulties develop. 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. • **Hepatic reactions** (including yellowing of the skin or eyes, upper right abdominal pain, dark urine and pale or grey coloured stools, itching or joint pain and swelling)**:** advise to seek urgent medical advice if signs or symptoms of liver dysfunction develop. • **Neurological disorders:** advise to seek urgent medical advice if peripheral neuropathy develops.

	• For further information refer to MHRA Nitrofurantoin Drug Safety Update. Severe adverse reactions are rare, but anaphylaxis (delayed or immediate) has been reported and requires immediate medical treatment. In the event of a severe adverse reaction, the individual must be advised to stop treatment immediately and seek urgent medical advice.
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/carer/parent/ guardian	• Provide marketing authorisation holder's information leaflet (PIL) provided with the product. • Provide the TARGET Treating your infection – urinary tract infection (UTI) leaflet. • Utilise TARGET antibiotic checklist for counselling individuals/carers/parents/guardians. • Give any additional information in accordance with the service specification.
Individual advice / follow up treatment	• Explain the dose, frequency and method of administration. • The individual/carer/parent/guardian should be advised to read PIL • Advise individual/carer/parent/guardian to take the medication at regular intervals with food or milk and to finish the course. • Symptoms should start to improve within 48 hours of taking nitrofurantoin – advise individual/carer/parent/guardian to seek medical advice if no improvement within this time. • Inform individual/carer/parent/guardian 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 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/parent/guardian should be advised to seek medical advice in the event of an adverse reaction or if any other

	new symptoms develop. • If dose is missed advise to refer to PIL supplied with the product • Advise individual/carer/parent/guardian to complete the full course even if symptoms improve. • Advise individual/carer/parent/guardian to seek medical attention if symptoms worsen rapidly or significantly at any time. • Advise individual/carer/parent/guardian to seek medical attention if symptoms do not improve after completion of antibiotic treatment course. • Advise individual/carer/parent/guardian to seek immediate medical attention (by calling 999 or going to A&E) if the individual develops signs or symptoms of sepsis. • Advise individual/carer/parent/guardian to return any used medicines to a pharmacy for disposal: do not dispose of medicines in the bin, down the sink or toilet.
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 or record where an individual is not registered with a GP • Name and registration number of registered healthcare professional operating under this PGD • Specify how the individual has/has not met the criteria of the PGD • Relevant past and present medical history and medication history • Any known allergies and nature of reaction(s) • Name/dose/form/quantity of medicine supplied • Date and time of supply • Documentation of cautions as appropriate • Advice given, including advice given if individual excluded or declines treatment • Details of any adverse drug reactions and actions taken • Advice given about the medication including side effects, benefits, and when and what to do if any concerns. • Any follow up and/or referral arrangements made. • Any supply outside the terms of the product marketing authorisation • 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: • The pharmacy contractor will ensure that a notification of the provision of the service is sent to the patient's general practice on the day of provision or on the following working day. Where possible, this should be sent as a structured message in real-time via the NHS assured Pharmacy First IT system. In the absence of an automated digital solution or if there is a temporary problem with the system, this should be sent via

	NHSmail or hard copy. • Where an action is required by the General Practice team (such as booking the patient in for a follow up or appointment) an action message or alternative form of an URGENT ACTION communication (rather than the standard post event message) must be sent to the practice. • 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 must be signed and dated (or a password controlled e-records).** **All records must be clear, legible and contemporaneous.** **A record of all individuals receiving treatment under this PGD must also be kept for audit purposes in accordance with the service specification.**

Key references

Key references (last accessed November 2023)	• 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 • 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

Appendix A – example registered health professional authorisation sheet (example – local versions/electronic systems may be used)

PGD Name/Version **Valid from:** **Expiry:**

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 insert name of organisation 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.

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