NHS
South Yorkshire
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

Trimethoprim 100mg or 200mg Tablets

for the Treatment of

Uncomplicated Urinary Tract Infections in Women

by Registered Pharmacists, as part of the

Doncaster Minor Ailments Service

Version Number 2.0

Change History	
Version and Date	**Change details**
1.0 April 2021	New PGD
2.0 Mar 2023	**PGD Review** **Section 2. Clinical Condition or Situation to which this PGD Applies** • Clinical condition or situation to which this PGD applies - updated • Criteria for inclusion – updated • Cautions including any relevant action to be taken – updated • Action to be taken if the patient is excluded – updated • Action to be taken if the patient or carer declines treatment – updated • Arrangements for referral for medical advice - updated **Section 3. Description of Treatment** • Identification &management of adverse reactions – updated • Management of and reporting procedure for adverse reactions – updated • Written information to be given to patient or carer – updated • Records – updated **Section 4. Key References** • Key references - updated

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

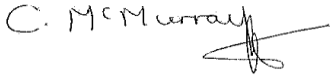
PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	01/04/2024
Review date	01/01/2026
Expiry date:	01/01/2026

This PGD has been developed / reviewed by the individuals named below. This PGD has been approved by the authorised signatories detailed in the Organisational Authorisations section of this document, on behalf of Doncaster Place.

Name	Designation
Chioma NNamdi	Locality Lead Pharmacist, Medicines Optimisation Team
Faiza Ali	Locality Lead Pharmacist, Medicines Optimisation Team
Ning Wong	Locality Lead Pharmacist, Medicines Optimisation Team

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor Dr V V S Rao Kolusu	Locality lead GP and Prescribing lead Doncaster Place		28/03/2024
Senior pharmacist Charlotte McMurray	Chief Pharmacist Doncaster Place		28/03/2024
Senior representative of professional group using the PGD			
Person signing on behalf of authorising body Dr V V S Rao Kolusu	Locality lead GP and Prescribing lead Doncaster Place		28/03/2024

GLOSSARY

PGD	Patient Group Direction
GPhC	General Pharmaceutical Council
UTI	Urinary Tract Infection
DMARD	Disease-modifying anti-rheumatic drug
OOH	Out of Hours Clinic

1. Characteristics of Staff

Qualifications and professional registration	Qualified pharmacist registered with the General Pharmaceutical Council (GPhC)
Initial training	Competent to work under Patient Group Directions, including satisfactory completion of training to assess patients and supply in accordance with this Patient Group Direction. Working as a community pharmacist and accredited to provide the Minor Ailments Service.
Competency assessment	CPPE Declaration of Competence Documents (DoCs). See Minor ailments (cppe.ac.uk) Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines 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.
Ongoing training and competency	Commitment to undertake training updates and revalidation according to the accreditation requirements of the commissioning organisation. Commitment to keep up to date with clinical developments in this area or changes to the recommendations for the medicine listed, as part of their Continuing Professional Development (CPD). Commitment to keep up to date Safeguarding training at a minimum of Level 2. The pharmacist must keep up to date with current legislation, including the Equality Act and Mental Capacity Act.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation 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 use is not appropriate e.g. due to allergy or intolerance.
Criteria for inclusion	Note – PGD to be used only where the risk of resistance is low based on NICE guidance. A lower risk of resistance may be more likely if: • not used in the past 3 months • previous urine culture suggests susceptibility but trimethoprim was not used • in younger people in areas where local epidemiology data suggest resistance is low • Informed consent • Non-pregnant women aged 16 to 64 years of age with severe symptoms or the presence of three or more of the following symptoms: • Dysuria • New nocturia • Urine cloudy to the naked eye • Urinary frequency • Urgency • Suprapubic tenderness • The patient agrees to treatment under this PGD • No trimethoprim use in the past 3 months Note that vaginal discharge reduces the likelihood of a woman having a bacterial UTI. 80% do not have UTI. Nitrofurantoin is first line for this indication. Trimethoprim must only be used if nitrofurantoin is contraindicated, unsuitable, or unavailable.

Criteria for exclusion	• Consent refused and documented • Males • Vaginal Discharge or irritation • Known hypersensitivity/allergy to trimethoprim or any excipient in the product • Treatment with trimethoprim/nitrofurantoin in the last three months and any additional risk factors for resistance to trimethoprim • Treatment for any UTI with any antimicrobial in the past 3 months • Patients aged 15 years of age and younger • Patients aged 65 years of age and over • Pregnant or breastfeeding • Hypersensitivity to trimethoprim/nitrofurantoin • Known renal impairment • Known blood dyscrasias • Known hepatic insufficiency • Haematuria • Fever or systemically unwell (e.g. nausea, vomiting, tachycardia, fatigue, feeling generally unwell, temperature of 37.9°C or more), as this may indicate severe illness or sepsis • Previous failed antibiotic treatment • Persistent symptoms • Recurrent UTI (>2 episodes in 6 months, >3 episodes in 12 months) – requires urine culture • Abnormalities or pathology of genito-urinary tract • Patients with indwelling catheters • Patients known or expected to be immunocompromised (due to disease or treatment) • Previous failed antibiotic treatment (for same episode) • Significant loin pain • Signs of confusion • Signs of dehydration • Inability to absorb oral medications and/or inability to swallow oral dosage formulations (i.e. tablets) • Current prophylactic treatment with trimethoprim or any other anti-infective agent for recurrent UTI • Suspected STI • Hospitalisation in a foreign country within last 3 months • Care home resident • UK hospitalisation for > 7 days in last 6 months • Known blood dyscrasias • Known porphyria • Known anaemia • Known diabetes mellitus (Type 1 or 2) • Severe hepatic insufficiency • Known folate deficiency • Known chronic kidney disease (CKD) stages 4 or 5 (eGFR < 30ml/min) • Individuals concurrently taking methotrexate, dapsone, pyrimethamine or colistimethate or concurrent use of any interacting medicine as listed in 'Interactions' section of this PGD Less than 3 days before receiving, or within 3 days after receiving, oral typhoid vaccine
	• Patients taking any interacting medication (see current BNF or SPC) e.g. DMARD **methotrexate is a serious interaction** • Predisposition to folate insufficiency

Cautions including any relevant action to be taken	**Visible haematuria:** treat for UTI but inform individual/ action to be taken carer/parent/guardian to seek medical attention if haematuria continues after treatment. ********** Caution should be exercised when supplying trimethoprim to individuals taking the following medicine(s): **Coumarin anticoagulants** (e.g. warfarin, acenocoumarol, phenindione): Individual must be advised to contact the provider of their anticoagulant service to discuss the timing of their next monitoring. ********** Caution should be exercised when supplying trimethoprim 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. Refer to the Summary of Product Characteristics for the treatment to be supplied http://www.medicines.org.uk/emc/
Action to be taken if the patient 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. **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** 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.
Action to be taken if the patient or carer declines treatment	You must: • Document advice given • Provide safety netting advice and advise/ individual/carer/parent/guardian on 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.

3. Description of Treatment

Name, strength & formulation of drug	Trimethoprim 200mg Tablets
Legal category	POM
Route / method of administration	Oral
Indicate any off-label use (if relevant)	The product must be supplied for use within its licenced posology and method of administration for the purpose of this PGD.
Dose and frequency of administration	200mg twice a day for 3 days
Duration of treatment	3 days
Quantity to be supplied	Supply: 6 trimethoprim 200mg tablets or 12 trimethoprim 100mg tablets
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 &	The following side effects may be seen with trimethoprim:

management of adverse reactions	• Gastrointestinal disturbances including nausea and vomiting. • Rashes, pruritus and rarely hypersensitivity reactions (especially involving the skin) have been reported. • Headaches • Electrolyte imbalance • Fungal overgrowth Advise the patient that if they notice any adverse reactions, they must contact a pharmacist or their GP. A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/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 patient's medical record • Report via the pharmacy's policy for reporting adverse reactions • It is considered good practice to notify the individual's GP in the event of an adverse reaction.
Written information to be given to patient or carer	Give the marketing authorisation holder's patient information leaflet (PIL) with the product supplied every time. Provide the TARGET Treating your infection – urinary tract infection (UTI) leaflet Utilise TARGET antibiotic checklist for counselling individuals/carers/parents/guardians.
Patient advice / follow up treatment	• Discuss side effects and administration with the patient and provide a manufacturers patient information leaflet • Advise the patient to complete the course • Advise patient on self-care regarding adequate fluid intake and other self-management strategies such as wearing loose fitting clothes/underwear, wearing cotton underwear and avoidance of vaginal douches/deodorants • Paracetamol or ibuprofen may be useful to relieve pain/discomfort • Consult your GP if symptoms do not resolve after 3 days (**This instruction must be included on the label**) • Risk of possible STDs should be raised if appropriate • Advise patient on oral vitamin K antagonists that antibiotic treatment may affect their INR and to inform the anticoagulant clinic • If symptoms worsen during treatment, the patient experiences significant flank pain, becomes systemically unwell or develops a fever then the patient should seek further medical advice • Consider the risk of sepsis The patient must contact their GP (or NHS 111 if no GP accessible) if no improvement within 48 hours, if symptoms worsen, or any new symptoms occur.

Records	Record: • That valid informed consent was given • Name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • Name of registered health professional • 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 of medication supplied/administered • Date of supply/administration • Dose, form and route of supply/administration • Quantity supplied/administered • Batch number and expiry date (if applicable) • Advice given, including advice given if excluded or declines treatment • Details of any adverse drug reactions and actions taken • That the medicine is supplied via a PGD 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.

4. Key References

Key references	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2 • 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://elearning.rcgp.org.uk/mod/book/view.php?id=12647&chapterid=441

5. Registered Pharmacist Authorisation Sheet

Before signing this PGD, check that the document has had the necessary authorisations in Section 1. 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**