

## PATIENT GROUP DIRECTION (PGD)

### Supply/Administration of Trimethoprim For the treatment of lower UTI

#### Documentation details

Reference no:	CommPharm Trimethoprim UTI PGD
Version no:	V1.3
Valid from:	December 2021
Review date:	October 2023
Expiry date:	December 2023




#### Change history

Version number	Change details	Date
1.0	Written by Elizabeth Jonas and checked by Michelle Jones & Helen Wilkinson	November 2019
1.1	Updated to make clearer the age range treatable under the PGD	July 2020
1.2	Written by BNSSG CCG, adapted for BSW CCG and checked by Marco Yeung and Paul Clarke	December 2021
1.3	Target UTI leaflet link fixed	January 2022

#### Glossary

Abbreviation	Definition

## 1. PGD template development

Developed by:	Name	Signature	Date
<b>Pharmacist</b>	Elizabeth Jonas, Senior Medicines Optimisation Pharmacist, BNSSG CCG		20.02.2020
<b>Doctor</b>	Dr Shaba Nabi, GP Prescribing lead, BNSSG CCG		13.02.2020
<b>Registered Professional representing users of the PGD</b>	Helen Wilkinson, Principal Medicines Optimisation Pharmacist, BNSSG CCG		12.02.2020

## PGD Working Group Membership

Name	Designation
Helen Wilkinson	Principal Medicines Optimisation Pharmacist, BNSSG CCG
Elizabeth Jonas	Senior Medicines Optimisation Pharmacist, BNSSG CCG
Michelle Jones	Senior Medicines Optimisation Pharmacist , BNSSG CCG
Judith Poulton	Pharmacist, Avon Local Pharmaceutical Committee
Dr Shaba Nabi	GP Prescribing Lead, BNSSG CCG
Richard Brown	Pharmacist, Avon Local Pharmaceutical Committee


**2. Organisational authorisations** (may require amendment depending on how the service using the PGD is being commissioned/the organisation who is responsible for authorising the PGD – not all fields may be applicable)


The PGD is not legally valid until it has had the relevant organisational authorisation.


It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

**Bath and North East Somerset, Swindon and Wiltshire CCG** authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
Community pharmacies contracted to provide the BSW CCG Community Pharmacy PGD Service for Minor Ailments
Limitations to authorisation
None

Senior Doctor			
Role	Name	Sign	Date
Medical Director BSW CCG	Dr Ruth Grabham		08.12.21

Senior Pharmacist			
Role	Name	Sign	Date
Associate Director (Medicines Optimisation), BSW CCG	Paul Clarke		02.12.21

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Director (Medicines Optimisation), BSW CCG	Nadine Fox		02.12.21

Local enquiries regarding the use of this PGD may be directed to [bswccg.prescribing@nhs.net](mailto:bswccg.prescribing@nhs.net)

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD. Alternative authorisation sheets/templates may be used where appropriate in accordance with local policy.

### 3. Characteristics of staff

<b>Qualifications and professional registration</b>	<ul style="list-style-type: none"> <li>Pharmacists registered with the General Pharmaceutical Council (GPhC)</li> </ul>
<b>Initial training</b>	<ul style="list-style-type: none"> <li>must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it</li> <li>Has undertaken appropriate training and declared themselves assessed competent to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD</li> <li>must have undertaken appropriate training for working under PGDs for supply/administration of medicines</li> <li>must be competent in the use of PGDs (see <a href="#">NICE Competency framework</a> for health professionals using patient group directions)</li> <li>must have access to the Patient Group Direction and associated online resource</li> <li>should fulfil any additional requirements defined by local policy</li> </ul> <p><b><i>The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate training and successfully completed the declaration of competence to undertake clinical assessment of patient leading to diagnosis of the conditions listed.</i></b></p>
<b>Competency assessment</b>	<p>Complete the self-declaration for this PGD on PharmOutcomes</p> <p>Staff operating under this PGD are encouraged to review their competency using the <a href="#">NICE Competency Framework for health professionals using patient group directions</a></p> <p><b><i>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.</i></b></p>
<b>Ongoing training and competency</b>	<p>Practitioners must ensure they are up to date with relevant issues and clinical skills relating to this PGD and 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 (CPD).</p>
<p><b><i>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.</i></b></p>	

#### 4. Clinical condition or situation to which this PGD applies

<p><b>Clinical condition or situation to which this PGD applies</b></p>	<p><b>Treatment of acute uncomplicated urinary tract infections, in non-pregnant females aged between 16 and 64 years old</b></p>
<p><b>Criteria for inclusion</b></p>	<ul style="list-style-type: none"> <li>• Female with an uncomplicated urinary tract infection</li> <li>• Aged between 16 and 64 years (inclusive)</li> <li>• Valid informed consent</li>   <li>• Two or three of the three key diagnosis signs / symptoms <ul style="list-style-type: none"> <li>- Dysuria</li> <li>- New nocturia</li> <li>- Urine cloudy to the naked eye</li> </ul> </li> </ul> <p>First line treatment</p>
<p><b>Criteria for exclusion</b></p>	<ul style="list-style-type: none"> <li>• No valid informed consent</li> <li>• Age under 16 years</li> <li>• Patients 65 years old or over</li> <li>• Male patients</li> <li>• <b>Red flags</b></li> <li>• Signs of sepsis</li> <li>• Patient with symptoms of pyelonephritis (signs include kidney pain/ tenderness in the back under the ribs, new/different myalgia, flu like illness, shaking chills (rigors) or temperature 37.9oC or above, nausea/vomiting)</li> <li>• Visible haematuria (blood in urine)</li> <li>• Pregnancy</li> <li>• Breast-feeding</li> <li>• Patients who are immuno-compromised</li> <li>• Patient with vaginal and/ or urethral causes of urinary symptoms:</li> <li>• Vaginal discharge (80% do not have a UTI),</li> <li>• Urethritis</li> <li>• Sexually transmitted infections</li> <li>• Genitourinary syndrome of menopause</li> <li>• Thrush</li> <li>• Patients with known renal impairment</li> <li>• Have any urological abnormalities (for example renal calculus, vesicoureteric reflux, reflux nephropathy, neurogenic bladder, urinary obstruction or recent instrumentation) or who have had surgery involving the lower urinary tract, urinary catheter</li> <li>• Presenting with a recent UTI treated with antibiotics in the last two weeks</li> <li>• Women with drug induced cystitis (allopurinol, danazol, cyclophosphamide, tiaprofenic acid and possibly other NSAIDs)</li> <li>• Acute porphyria</li> <li>• Patients with only one of the key diagnosis signs/ symptoms (dysuria, new nocturia, urine cloudy to the naked eye) – refer to GP practice or out of hours for a urine dipstick to be performed to aid diagnosis</li> <li>• Patients with none of the key diagnosis signs/ symptoms (dysuria, new nocturia, urine cloudy to the naked eye). Review if there are any other urinary symptoms:</li> </ul>

	<ul style="list-style-type: none"> <li>• Urgency</li> <li>• Frequency</li> <li>• Visible haematuria</li> <li>• Suprapubic tenderness <ul style="list-style-type: none"> <li>• If there are refer to GP practice or out of hours for a urine dipstick to be performed to aid diagnosis. If not reassure UTI unlikely.</li> </ul> </li> <li>• Have risk factors for increased resistance (see Nitrofurantoin PGD): <ul style="list-style-type: none"> <li>• Care home resident</li> <li>• Recurrent UTI (2 episodes in last 6 months or 3 episodes in last 12 months)</li> <li>• Hospitalisation &gt;7 days in last 6 months</li> <li>• Unresolving urinary symptoms</li> <li>• Recent travel to a country with increased antimicrobial resistance (outside Northern Europe and Australasia),</li> <li>• previous known UTI resistant to trimethoprim, cephalosporin or quinolones</li> <li>• Hypersensitivity to trimethoprim or co-trimoxazole (Septrin®) or any of the excipients contained within the tablet.</li> <li>• Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.</li> <li>• Blood dyscrasias and clotting problems including patients with megaloblastic anaemia e.g. vitamin B<sub>12</sub> or folate Deficiency or other blood dyscrasias.</li> <li>• Patients taking Methotrexate</li> <li>• Patients taking prophylactic trimethoprim</li> </ul> </li> </ul>
<p><b>Cautions including any relevant action to be taken</b></p>	<ul style="list-style-type: none"> <li>• For women under 65 years with mild symptoms who have normal immunity, normal renal function, and a normal renal tract, treatment can be delayed if she wishes to see if symptoms will resolve without treatment</li> <li>• Diabetic patients – UTI could be a symptom of poor control and so current medication should be discussed/ reviewed.</li> <li>• Patients with a predisposition to folate deficiency (such as those receiving concomitant folate antagonists or anticonvulsants) as treatment with trimethoprim may induce folate deficiency (note diagnosed folate deficiency is an exclusion)</li> <li>• If there are any concerns that a young person is being abused or exploited, the UTI can still be treated, and the appropriate Safeguarding SOP followed.</li> </ul>
<p><b>Action to be taken if the patient is excluded</b></p>	<ul style="list-style-type: none"> <li>• Record reasons for exclusion and any action(s) taken in patient notes</li> <li>• Document advice given and the decision reached</li> <li>• Advise patient on alternative treatment.</li> <li>• Refer to a prescriber if appropriate</li> </ul>
<p><b>Action to be taken if the patient or carer declines treatment</b></p>	<ul style="list-style-type: none"> <li>• Record reasons for decline and any action(s) taken in patient notes</li> <li>• Advise patient on alternative treatment.</li> <li>• Document advice given and the decision reached</li> </ul>

Arrangements for referral for medical advice	<ul style="list-style-type: none"> <li>Refer to a GP if appropriate</li> <li>Clinical information should be sent to the patient's GP in accordance with local protocols</li> </ul>
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## 5. Description of treatment

Name, strength & formulation of drug	TRIMETHOPRIM 200mg tablets
Legal category	Prescription-only medicine (POM)
Route / method of administration	ORAL
Dose and frequency of administration	200mg twice a day
Duration of treatment	THREE days
Quantity to be supplied	6 x Trimethoprim tablets
Storage	Stock must be stored in conditions in line with SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> Do not store above 25°C.
Drug interactions	<ul style="list-style-type: none"> <li>Trimethoprim increases the concentration of phenytoin and fosphenytoin</li> <li>There is an increased risk of side effects from pyrimethamine</li> <li>Trimethoprim may potentiate the anticoagulant effects of warfarin. Close monitoring is recommended.</li> <li>Increased exposure when given with Dapsone</li> <li>Increased concentration of digoxin</li> <li>Trimethoprim is predicted to increase the exposure to pramiexole and dose adjustment may be needed.</li> <li>Trimethoprim slightly increases the exposure to lamivudine</li> <li>Trimethoprim is predicted to increase the risk of side-effects when given with methotrexate and this combination should be avoided.</li> <li>Trimethoprim slightly increases the exposure to repaglinide – avoid or monitor blood glucose</li> <li>Rifampicin decreases the exposure to trimethoprim</li> <li>Trimethoprim is predicted to decrease the efficacy of sapropterin</li> </ul> <p><b><i>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></i></b></p>
Identification & management of adverse reactions	<ul style="list-style-type: none"> <li>Trimethoprim is generally well tolerated. Nausea, vomiting and skin rashes have been reported in rare instances. These effects are usually generally mild and quickly reversible on withdrawal of the drug.</li> <li>Pruritus and urticaria have been reported occasionally</li> <li>Hyperkalaemia</li> <li>Isolated cases of myalgia have occurred</li> <li>Trimethoprim may affect haematopoiesis</li> <li>Leucopenia, megaloblastic anaemia, thrombocytopenia,</li> </ul>



	<p>agranulocytosis, hyperkalaemia.</p> <ul style="list-style-type: none"> <li>• Gastro –intestinal disturbances including nausea and vomiting</li> <li>• Skin rashes, pruritus, depression of haematopoiesis</li> <li>• Rarely erythema multiforme; toxic epidermal necrolysis; photosensitivity and other allergic reactions including angioedema and anaphylaxis; aseptic meningitis and uveitis reported</li> </ul> <p>Use the Yellow Card System to report unexpected adverse drug reactions directly to the CSM. Guidance on the use of the Yellow Card System and Yellow Cards are available in the current BNF or via <a href="http://www.yellowcard.gov.uk">www.yellowcard.gov.uk</a></p> <p><b>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></b></p>
<p><b>Management of and reporting procedure for adverse reactions</b></p>	<ul style="list-style-type: none"> <li>• 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: <a href="https://yellowcard.mhra.gov.uk">https://yellowcard.mhra.gov.uk</a></li> <li>• Record all adverse drug reactions (ADRs) in the patient's medical record.</li> <li>• Report via organisation incident policy.</li> <li>• If anaphylaxis management may be required include this information here (e.g. adrenaline to be held/resuscitation team details)</li> </ul>
<p><b>Written information to be given to patient or carer</b></p>	<ul style="list-style-type: none"> <li>• Give marketing authorisation holder's patient information leaflet (PIL) provided with the product.</li> <li>• Provide copy of TARGET UTI leaflet <a href="https://elearning.rcgp.org.uk/mod/book/view.php?id=12647&amp;chapterid=441">https://elearning.rcgp.org.uk/mod/book/view.php?id=12647&amp;chapterid=441</a></li> </ul>
<p><b>Patient advice / follow up treatment</b></p>	<ul style="list-style-type: none"> <li>• Take the antibiotics at regular intervals and complete the course supplied</li> <li>• Advise patient to refer to their GP practice or contact NHS if: <ul style="list-style-type: none"> <li>- they have shivering, chills and muscle pain</li> <li>- feel confused or are very drowsy</li> <li>- have not passed urine all day</li> <li>- are vomiting</li> <li>- see blood in their urine</li> <li>- their temperature is above 38<sup>o</sup>c or less than 36<sup>o</sup>C</li> <li>- have kidney pain in their back just under the ribs</li> <li>- symptoms get worse</li> <li>- symptoms are not starting to improve within 48 hours of taking antibiotics.</li> </ul> </li> <li>• Discuss side effects and advise to come back if side effects occur</li> <li>• Advise on self-care including drinking enough fluids to stop you feeling thirsty – aiming for 6 to 8 glasses per day and 'over the counter' analgesia.</li> </ul> <p>If the patient has recurrent UTIs (three or more episodes of acute UTI in the last 12 months or two episodes within six months) discuss with them options to prevent UTIs – see the target UTI leaflet and recurrent UTI guidelines</p>

	<a href="https://prescribing.bswccg.nhs.uk/wpdm-package/wiltshire-swindon-banes-primary-care-antibiotic-guidance-jan-2019-nice-update">https://prescribing.bswccg.nhs.uk/wpdm-package/wiltshire-swindon-banes-primary-care-antibiotic-guidance-jan-2019-nice-update</a>
<b>Records</b>	<p>Record:</p> <ul style="list-style-type: none"> <li>• that valid informed consent was given</li> <li>• name/signature of individual, address, date of birth and GP with whom the individual is registered (if relevant)</li> <li>• History, examination, investigations, diagnosis</li> <li>• Drug history including any allergies</li> <li>• name of registered health professional</li> <li>• name and brand of medication supplied/administered</li> <li>• date and time of supply/administration</li> <li>• dose, form and route of supply/administration</li> <li>• quantity supplied/administered</li> <li>• batch number and expiry date (if applicable)</li> <li>• advice given, including advice given if excluded or declines treatment</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• supplied via Patient Group Direction (PGD)</li> <li>• Referral arrangements (including self-care)</li> <li>• Add patient name and date of supply to the pack before issuing. Liquid dose forms must include the expiry date of reconstituted suspension.</li> </ul> <p><b><i>Records should be signed and dated (or a password controlled e-records).</i></b>  <b><i>All records should be clear, legible and contemporaneous.</i></b>  <b><i>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</i></b></p>

## 6. Key references

<b>Key references</b>	<ul style="list-style-type: none"> <li>• Summary of Product Characteristics for Trimethoprim (available at <a href="http://www.emc.medicines.org.uk">www.emc.medicines.org.uk</a>)</li> <li>• British National Formulary (available online at <a href="http://www.medicinescomplete.com">www.medicinescomplete.com</a>)</li> <li>• BSW Antimicrobial Prescribing Guidelines available <a href="https://prescribing.bswccg.nhs.uk/wpdm-package/wiltshire-swindon-banes-primary-care-antibiotic-guidance-jan-2019-nice-update">https://prescribing.bswccg.nhs.uk/wpdm-package/wiltshire-swindon-banes-primary-care-antibiotic-guidance-jan-2019-nice-update</a></li> <li>• NICE Clinical Knowledge Summaries (available at <a href="https://cks.nice.org.uk/urinary-tract-infection-lower-women">https://cks.nice.org.uk/urinary-tract-infection-lower-women</a>)</li> <li>• Public Health England Urinary tract infection: diagnostic tool for primary care (available at <a href="https://www.gov.uk/government/publications/urinary-tract-infection-diagnosis">https://www.gov.uk/government/publications/urinary-tract-infection-diagnosis</a>)</li> </ul>
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## 7. Registered health professional authorisation sheet

**Comm Pharm Trimethoprim UTI Vs1.0      Valid from: Dec 2021      Expiry: Dec 2023**

Before signing this PGD, check that the document has had the necessary authorisations in section 2. 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 (if applicable)

**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.