



Patient Group Direction for the supply of Trimethoprim 200mg tablets for the treatment of women with uncomplicated urinary tract infections by Pharmacists working within NHS Borders Community Pharmacies.

This document authorises the supply and/or administration of Trimethoprim 200mg tablets by registered pharmacists to patients who meet the criteria for inclusion under the terms of the document.

The registered pharmacist seeking to supply Trimethoprim 200mg tablets must ensure that all clients have been screened and meet the criteria before supply takes place.

The purpose of this Patient Group Direction is to allow management of acute uncomplicated urinary tract infection (UTI) in non-pregnant females over 16 years and under 65 years of age in NHS Borders by registered pharmacists within Community Pharmacies.

New PGD

This direction was authorised on: Oct 2015

The direction will be reviewed by: Oct 2017

Author of PGD: Anne Duguid, Antimicrobial Pharmacist

Clinician Responsible for Training and Audit: Anne Duguid, Antimicrobial Pharmacist

Specialist clinical review by: Dr Ed James, Consultant Microbiologist



Patient Group Direction for the supply of Trimethoprim 200mg tablets for the treatment of women with uncomplicated urinary tract infections by Pharmacists working within NHS Borders Community Pharmacies.

1. This Patient Group Direction relates to the following specific preparation:

Name of medicine, strength, formulation	Trimethoprim 200mg tablets
Legal status	POM Prescription Only Medicine
Storage	(as per manufacturer's instructions)
Dose	200mg
Route/method	Oral Tablets
Frequency	Twice a day (12 hourly) for 3 days
Total dose Quantity (Maximum/Minimum)	Total daily dose: 400mg in divided doses Total supply: 6 Tablets
Advice to Patients	<ul style="list-style-type: none">• Provide cystitis information leaflet and discuss contents with patient• The patient information leaflet contained in the medicine should be made accessible to the patient. Where this is unsuitable, sufficient information should be given to the patient in a language that they can understand., explaining the importance of regular administration and course completion• Give advice on what to expect and what to do for major and minor reactions.• Explain treatment and course of action.• Explain the benefits and risks of taking antibiotics for this condition.• Advise to take at regular intervals and complete the course.• Advise if condition worsens, or symptoms persist for longer than 3 days, to seek further medical advice• If on combined oral contraception, no additional contraceptive precautions are required unless vomiting or diarrhoea occur. (See reference section for Faculty of Reproductive and sexual healthcare guidance - Jan 2011).

	<ul style="list-style-type: none"> • Drink adequate fluid • Paracetamol may relieve dysuric pain but if flank pain develops contact GP • Consider sexual history and possible STD and advise attendance at GUM clinic if appropriate.
Relevant Warnings	<p>Possible adverse effects include gastrointestinal disturbances including nausea and vomiting and glossitis, pruritis, rashes hyperkalaemia, depression of haematopoiesis, photosensitivity. Monilial overgrowth, headache, urticaria.</p> <p>Trimethoprim may be used for a short-term in lactating mothers, although the drug is excreted in breast milk. However, consideration should be given to referral of the mother for medical consultation if the baby is newborn (less than 4 weeks old).</p>
Follow up Arrangements	Not applicable

2. Clinical condition:

Clinical Condition to be treated	Acute uncomplicated urinary tract infection (UTI) in non-pregnant females over 16 years and under 65 years of age
Criteria for inclusion	<p>Females aged 16-64 years presenting with three or more of the following symptoms OR if BOTH dysuria and frequency are present</p> <ul style="list-style-type: none"> • Dysuria • Frequency • Urgency • Polyuria • Suprapubic tenderness <p>Follow flow chart guidance see Appendix 1.</p> <p>Females meeting the criteria above where they, their parent guardian or person with parental responsibility does not want specifically to consult with a doctor and are happy for the supply to be given by the pharmacist or Practice Nurse.</p>
Criteria for exclusion	<ul style="list-style-type: none"> • Males • Girls under 16 • Women aged 65 or over • Diabetics • Symptoms are suggestive of upper urinary tract infection (rapid onset, fever, rigors, nausea, vomiting, diarrhea, loin pain, flank tenderness, or systemically unwell)

	<ul style="list-style-type: none"> • Haematuria • Confused or dehydrated • Patients already taking antibiotic prophylaxis for recurrent UTI, e.g. Trimethoprim • Pregnancy • Patients with known renal impairment • Patients with known haematological abnormalities. • Patients with porphyria/folate deficiency • Patients with vaginal itch/discharge • Patients have allergy/previous adverse effect from co-trimoxazole, trimethoprim or to any other components of the medication • A prior episode of UTI in last 28 days was treated with an antibiotic. • There have been 2 or more UTI episodes in the last 6 months or 3 or more episodes in the last 12 months. • There is a catheter in situ. • Patients have known hyperkalaemia, diabetes, severe hepatic insufficiency, megaloblastic anaemia, the Lapp lactose deficiency or glucose-galactose malabsorption or are immunosuppressed. • Patients taking any medicines which interact – see current BNF Appendix 1, e.g. Amiodarone, Azathioprine, Ciclosporin, Digoxin, Eplenerone, Mercaptopurine, Methotrexate, Phenytoin, Pyrimethamine (anti-malarial), Rifampicin, Repaglinide, Lamivudine, Warfarin. • There is known abnormality to the urinary tract.
Action if excluded	Refer for medical advice and document
Action if declines	<p>Patient should be advised of self management options and advised to see their GP if symptoms fail to resolve within 3 days.</p> <p>Where patient needs cannot be met in the pharmacy, refer to GP, out of hours service, Accident and Emergency Dept. or genitor urinary medicine clinic (GUM) as appropriate.</p> <p>If urgent referral is required, refer to GP or use direct referral process during out of hours period (See appendix 2)</p>

<p>Interactions with other medicaments and other forms of interaction</p>	<p>Patients are excluded from receiving medication with which there is an interaction under the remit of this PGD. Consult current BNF, Appendix 1 for full information. Trimethoprim may increase the potential for bone marrow aplasia with bone marrow depressants eg. Azathioprine, Mercaptopurine and Methotrexate. Trimethoprim may increase the plasma concentration of phenytoin and digoxin – patients should be carefully monitored. Increased risk of nephrotoxicity with trimethoprim in patients taking Ciclosporin. Increased anti-folate effect in patients receiving pyrimethamine (anti-malarial) in addition to trimethoprim. Rifampicin may reduce the plasma concentration of trimethoprim. Trimethoprim may potentiate the anticoagulant effect of warfarin. Other interacting medications include Amiodarone, Eplerenone, Repaglinide, Lamivudine.</p>
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3. Documentation/Record keeping.

a) The following records should be kept (either paper or computer based)-

Name and address of patient/parent/guardian/person with parental responsibility

CHI number

Date of birth

GP details

Symptoms reported

Exclusion criteria, record why drug not supplied

Reason for giving

Consent to the supply: prior to supply of the drug, consent must be obtained, preferably written, either from the patient, parent, guardian or person with parental responsibility and documented on the supply form. Consent must be in line with current NHS Borders Consent to Treatment policy

(<http://intranet/resource.asp?uid=23913>).

The medicine name, dose, route, time of dose(s), and where appropriate, start date, number of doses and or period of time, for which the medicine is to be supplied or administered

The signature and printed name of the healthcare professional who supplied or administered the medicine

The patient group direction title and/or number

The patient's GP should be advised of the supply of trimethoprim on the same, or next available working day.

These records should be retained:

For young people older than 16 years, retain until the patient's 25th birthday or 26th if the young person was 17 at the conclusion of treatment

For 17 years and over, retain for 6 years after date of supply.

Or for 3 years after death, or in accordance with local policy, where this is greater than above.

b) Preparation, audit trail, data collection and reconciliation-

Stock balances should be reconcilable with Receipts, Administration, Records and Disposals on a patient by patient basis.

All records of supply of the drug specified in this PGD will be filed with the normal records of medicines supply in each service. A designated person within each service will be responsible for auditing completion of drug forms and collation of data.

c) Storage- As per manufacturers' instructions

4. Professional Responsibility.

- The Health Professional will ensure he/she has the relevant training and is competent in all aspects of medication, including contra-indications and the recognition and treatment of adverse effects.
- He/she will have been trained and assessed as being competent in the supply of the drug. All staff will have access to the current PGD. Training updates should be attended as appropriate.
- He/she must agree to be professionally accountable for their work (appendix 3)
- He/she must be competent to assess the patient's capacity to understand the nature and purpose of the supply in order for the patient to give or refuse consent.
- He/she must be aware of current treatment recommendations and be competent to discuss issues about the drug with the patient
- He/she will maintain their skills, knowledge and their own professional level of competence in this area according to their individual code of professional conduct.
- He/she agrees to work within the terms of the NHS Borders PGD.
- He/she should ensure that the following are available at sites where the drug is to be supplied:
 - Access to medical support (this may be via telephone)
 - Safe storage areas for medicines and equipment
 - Approved equipment for the disposal of used materials
 - Clean and tidy work areas
 - Copies of the current PGD for the drug specified in the PGD

Professional managers will be responsible for:

- Ensuring that the current PGD is available to staff providing care under this direction.
- Ensuring that staff have access to all relevant Scottish Government Health Directorate advice, including any relevant CMO letters (s)
- Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above
- Maintaining a current record of all staff authorised to supply the drug specified in this PGD

Pharmacists working within NHS Borders can be authorised to supply the drug specified in this PGD by the Director of Pharmacy.

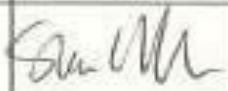

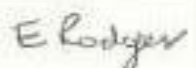
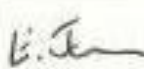
A certificate of competence (Appendix 4) signed by the authorising manager should be supplied. This should be held as agreed locally.

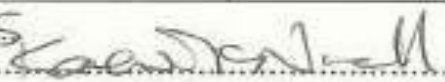
5. Sources of Evidence used for the PGD creation should be stated.

- ❖ Sign 88 – Management of suspected bacterial urinary tract infection in adults at:
<http://www.sign.ac.uk/pdf/sign88.pdf>
- ❖ Faculty of Reproductive and sexual healthcare guidance - Jan 2011
<http://www.fsrh.org/pdfs/CEUguidancedruginteractions hormonal.pdf#page=17>
- ❖ British National Formulary (BNF) current edition
<https://www.medicinescomplete.com/mc/>
- ❖ British National Formulary (BNF) Children edition
<https://www.medicinescomplete.com/mc/>
- ❖ Borders Joint Formulary (BJF)
http://intranet/new_intranet/microsites/index.asp?siteid=65&uid=1
- ❖ Trimethoprim SPC found at:
www.medicines.org.uk

Patient Group Direction for the supply of Trimethoprim 200mg Tablets by health professionals employed by NHS Borders

This Patient Group Direction is approved for use by the under-signed :

Job Title	Name	Signed	Date
Senior Doctor/Dentist for relevant clinical area	Sheena MacDonald		4/11/15
NHS Borders Director of Pharmacy	Alison Wilson		6/11/15
NHS Borders Senior Health Professional for Clinical Area	Evelyn Rodger		04/11/15
NHS Borders Consultant Microbiologist	Edward James		09/11/15

PGD AUTHORISED ON ...10/11/15
 Signed by ADTC CHAIRPERSON: 
 Name: ...Karen McNicoll.....

The Health Professionals named below, being employees of NHS Borders are authorised to supply this medication under this Patient Group Direction and agree to supply this medication in accordance with this Patient Group Direction

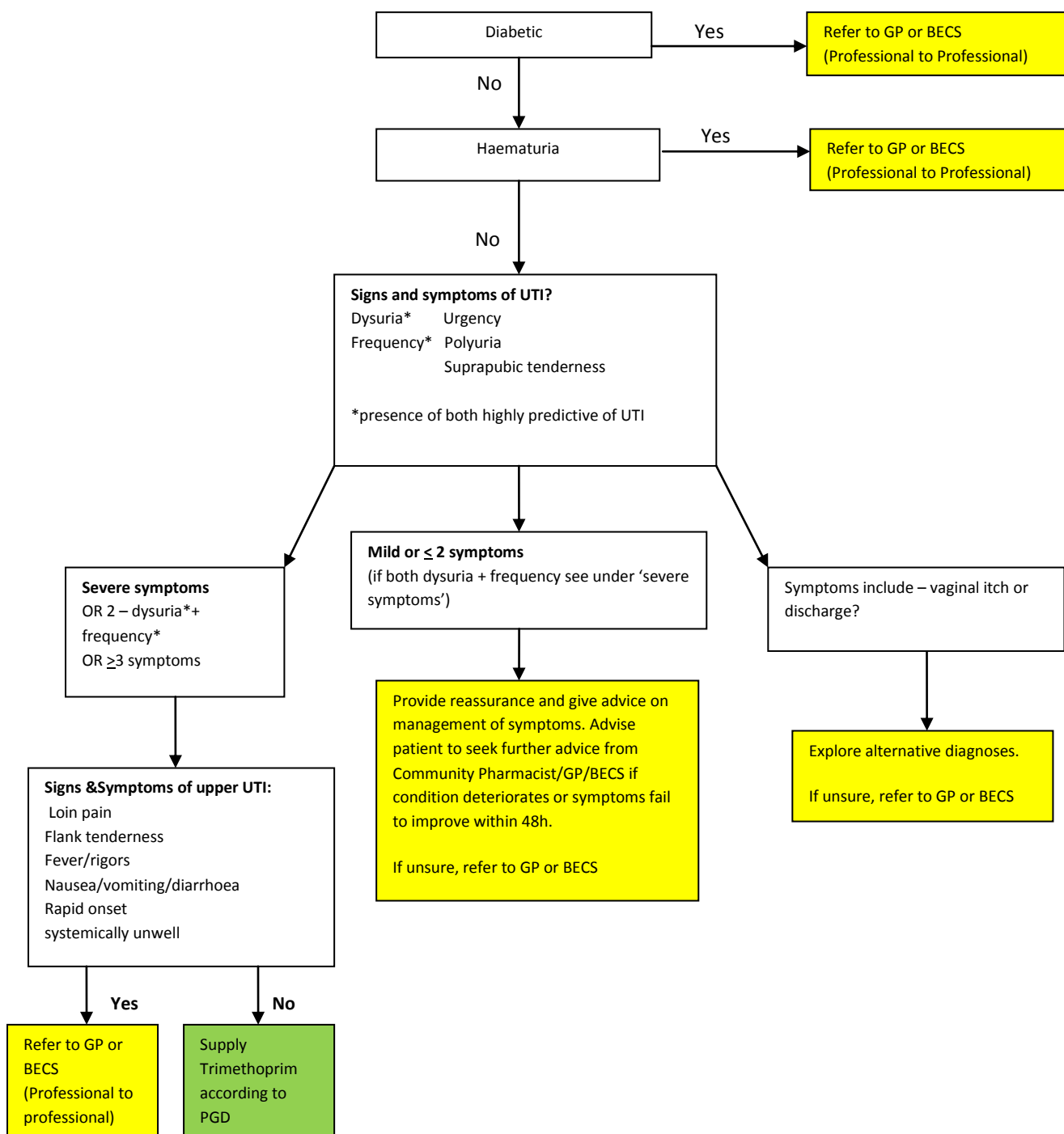
Name of Health Professional	Job Title	Signed	Date

Appendix 1

Patient Group Direction for the supply of trimethoprim for the treatment of Uncomplicated UTI by Pharmacists working within NHS Borders.

Management of suspected UTI in non-pregnant females aged 16-64 years

NB: Only proceed if patient has **no** exclusions under PGD



References:

- Sign88 Management of suspected bacterial urinary tract infection in adults July 2012
- HPA/RCGP Diagnosis of UTI quick reference guide for primary care April 2011

Appendix 2.

Direct professional to professional referral process.

During working hours: Pharmacist should telephone the GP practice to request patient review by GP at earliest opportunity. Copy of client assessment form should be faxed to GP practice at time of referral.

Out of Hours: Pharmacist should telephone the GP out of hour's service to request review by GP at earliest opportunity. Copy of client assessment form should be faxed to GP out of hour's service at time of referral.



Health Care Professional Agreement to Supply Medicines under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Pharmacy

Agree to supply medicines under the direction contained within the following Patient Group Direction

Patient Group Direction for the supply of Trimethoprim 200mg tablets for the treatment of women with uncomplicated urinary tract infections by Pharmacists working within NHS Borders Community Pharmacies.

I have completed the appropriate training to my professional standards enabling me to supply medicines under the above Patient Group Direction. I agree not to act beyond my professional competence nor out with the recommendations of the Patient Group Direction.

Signed: _____

Print Name: _____

Date: _____

Professional Registration No: _____



Certificate of Competence to Supply Medicines under Patient Group Direction

This authorises: _____(Insert name)

Working within: _____e.g. Pharmacy

To supply medicines under the following Patient Group Direction

Patient Group Direction for the supply of Trimethoprim 200mg tablets for the treatment of women with uncomplicated urinary tract infections by Pharmacists working within NHS Borders Community Pharmacies.

The above named person has satisfied the training requirements and is competent to supply medicines under the above Patient Group Direction. The above named person has agreed not to act beyond their professional competence nor out with the recommendations of the Patient Group Direction.

Signed: _____Director of Pharmacy or Authorising Manager

Print Name: _____

Date: _____

**NHS Borders Treatment of uncomplicated Urinary Tract Infections (UTI's)
in non-pregnant adult females
Client Assessment Form and Notification of Supply through Community
Pharmacy**



Date:

Time:

CONFIDENTIAL WHEN COMPLETED:

Data protection confidentiality note: This message is intended only for the use of the individual or entity to whom it is addressed and may contain information that is privileged, confidential and exempt from disclosure under law. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited.

GP name:

GP practice address:

The following patient has attended this pharmacy for assessment and treatment of an uncomplicated urinary tract infection.

Patient name:

Date of Birth:

CHI: (If available)

Patient address:

Postcode:



(Tick as appropriate)

Following assessment your patient: Has been given a 3 day course of trimethoprim 200mg twice daily ☐

Has been referred for treatment to (state) ☐

Your patient has been advised to contact the practice if symptoms fail to resolve following treatment.
You may wish to include this information in your patient records.

Patient consent: I can confirm that the information provided is a true reflection of my individual circumstances and I give my consent to allow an NHS Borders Pharmacist to provide the most appropriate advice and/or treatment for me. I also give my permission to allow the pharmacist to pass, to my own GP, details of this consultation and any advice given or treatment provided. I have been advised that some of the information may be used to assess the uptake of the service but that this will be totally anonymous and not be attributable to any individual patient.

Patient signature:

Date:

This form should now be sent to the patient's GP

Appendix 5 (2/2)

Date of Assessment:	Time of Assessment:
Name of Patient:	Date of Birth:
Details of presenting symptoms are shown below:	
<p>Symptoms</p> <p>(circle as appropriate)</p> <p>Dysuria yes*/no</p> <p>Frequency yes*/no</p> <p>(*If both dysuria & frequency present, definitive of UTI)</p> <p>Urgency yes/no</p> <p>Polyuria yes/no</p> <p>Suprapubic tenderness yes/no</p> <p>Other _____</p> <p>Are symptoms related to UTI yes/no</p> <p>Dysuria & Frequency or ≥3 symptoms yes/no</p> <p>≤2 symptoms (not including Dysuria & Frequency) yes/no</p> <p>Suitable for Trimethoprim x 3 days yes/no</p> <p>Referred for treatment of UTI to: _____</p> <p>Treatment for UTI required yes/no</p>	<p>Contra-indications to treatment of UTI by Pharmacist: (circle as appropriate)</p> <p>Age <16 or ≥65 yes/no</p> <p>Allergy to/previous adverse effect from trimethoprim, co-trimoxazole or any of the components of the medication yes/no</p> <p>Haematuria yes/no</p> <p>Signs and Symptoms of upper UTI any of the following: Loin pain, flank tenderness, fever/rigor, nausea/vomiting/diarrhoea, rapid onset, systematically unwell yes/no</p> <p>Taking interacting medications: Check current BNF for interactions but including: Azathioprine, ciclosporin, mercaptopurine, methotrexate, phenytoin, warfarin, digoxin, pyrimethamine, rifampicin yes/no</p> <p>Medical conditions – any of the following: Renal impairment, hyperkalaemia, diabetes, severe hepatic insufficiency, megaloblastic anaemia, other blood dyscrasias, folate deficiency, porphyria, galactose intolerance, the Lapp lactose deficiency, glucose-galactose malabsorption, immunosuppressed, urinary tract abnormality, on antibiotic prophylaxis for recurrent UTI yes/no</p> <p>Confused/dehydrated yes/no</p> <p>Pregnant (confirmed or possible) yes/no</p> <p>Vaginal itch/discharge yes/no</p> <p>More than 2 episodes of UTI in 6 months or 3 episodes in 12 months yes/no</p> <p>Previous antibiotic treatment for UTI In last 28 days yes/no</p> <p>UTI Prophylaxis yes/no</p> <p>Catheter in situ yes/no</p> <p><u>Patients answering any questions Yes in this column are excluded from the PGD and must be managed as appropriate.</u></p>
<p>Are symptoms related to other condition yes*/no</p> <p>Treated by Pharmacy yes/no</p> <p>Referred for treatment to: _____</p>	
*Comments/Notes	
<p>(tick box if supplied)</p> <p>Cystitis information leaflet <input type="checkbox"/> Trimethoprim 200mg twice daily for 3 days (6 tablets) <input type="checkbox"/></p> <p>Pharmacist Name (print) _____</p> <p>Pharmacist signature _____ Date _____</p>	