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 Dumfries and Galloway Community Pharmacies. This document authorises the supply 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 Dumfries & Galloway by registered pharmacists within Community Pharmacies.

NHS Dumfries and Galloway

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 Dumfries and Galloway Community Pharmacies.

Date direction comes into force	June 2016	**Date direction expires (review date)**	June 2018
Staff group	Community Pharmacists working in NHS Dumfries & Galloway who; • have received training to undertake supply of medicines under Patient Group Directions • have undertaken specified local and national training, including *National Education Scotland (NES) training on the supply of Trimethoprim for Uncomplicated UTIs via PGD*, and are competent in all aspects of this medication, including contra-indications and the recognition and treatment of adverse effects • agree to be professionally accountable for their work • are 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. • are aware of current treatment recommendations and are competent to discuss issues about the drug with the patient • agree to maintain their skills, knowledge and their own professional level of competence in this area according to their individual code of professional conduct • agree to work within the terms of this NHS Dumfries & Galloway PGD. may supply, without medical prescription, the preparation specified in, and in accordance with, this Patient Group Direction		
Clinical condition to be treated	Acute uncomplicated urinary tract infection (UTI) in non-pregnant females 16 years and over and under 65 years of age		
Client group: criteria for inclusion	Females aged 16-65 years presenting with three or more of the following symptoms OR if **BOTH** dysuria and frequency are present • Dysuria • Frequency • Urgency • Polyuria • Suprapubic tenderness Follow flow chart guidance see **Appendix 1.** Females meeting the criteria above where they, their parent/guardian or person with parental responsibility do not wish specifically to consult with a doctor and are happy for the supply to be given by the pharmacist.		
Criteria for exclusion	• 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) • Haematuria • Confused or dehydrated • Patients already taking antibiotic prophylaxis for recurrent UTI e.g. Trimethoprim • Pregnancy • Patients with known moderate/severe 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 • A catheter is in situ • Patients have known hyperkalaemia, diabetes, severe hepatic insufficiency,		

	megaloblastic anaemia, the Lapp lactose deficiency or glucose-galactose malabsorption or are immunosupressed • 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.
Action if excluded	Refer for medical advice and document
Action for patients declining treatment	Patient should be advised of self management options and advised to see their GP if symptoms fail to resolve within 3 days. Where patient needs cannot be met in the pharmacy, refer to GP, out of hours service, Accident and Emergency Dept. or Genitourinary Medicine clinic (GUM) as appropriate. If urgent referral is required, refer to GP or use direct referral process during out of hours period (See **Appendix 2**)
Name of medicines which may be administered under this protocol	Trimethoprim 200mg tablets
Legal status of medicines	Prescription Only Medicine (POM)
Storage Requirements	(as per manufacturer's instructions)
Dose to be given	200mg
Frequency of administration	Twice a day (12 hourly) for 3 days
Total dose Quantity (Maximum/Minimum)	Total daily dose: 400mg in divided doses Total supply: 6 Tablets
Route/method of administration	Oral tablet
Advice to be given to patient	• Provide appropriate 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, ensuring adequate fluid intake • 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). • 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
Adverse reactions	Possible adverse effects include gastrointestinal disturbances including nausea and vomiting and glossitis, pruritis, rashes hyperkalaemia, depression of haematopoesis, photosensitivity. Monilial overgrowth, headache, urticaria. 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).
Additional Information including interaction	Patients are excluded from receiving medication that may interact with Trimethoprim. Consult current BNF, Appendix 1 for full information. Examples of interactions are; ▪ 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 , therefore, 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, Eplenerone, Repaglinide, Lamivudine.
Documentation to be completed	**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 supply ▪ 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 D&G Consent to Treatment policy ▪ 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 pharmacist 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 in accordance with NHS Dumfries & Galloway policy: **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, where this is greater than above.
Responsibility of professional managers	Professional managers will be responsible for ensuring that: ▪ a current PGD is available to staff providing care under this direction ▪ staff have access to all relevant Scottish Government Health Directorate advice, including relevant CMO letters ▪ staff have received adequate training in all areas relevant to this PGD and meet all requirements ▪ a current record of trained staff authorised to supply the medicine specified in this PGD is maintained

References

- 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/CEUguidancedruginteractionshormonal.pdf7
- British National Formulary (BNF) current edition https://www.medicinescomplete.com/mc/
- British National Formulary (BNF) Children edition https://www.medicinescomplete.com/mc/
- NHS Dumfries & Galloway Joint Formulary http://www.dgprescribingmatters.co.uk
- Trimethoprim SPC found at: www.medicines.org.uk

This PGD was devised by	**Consultant Microbiologist** Name Dr Linsey Batchelor Signature ..... Date 31/5/16..... **Specialist Antimicrobial Pharmacist** Name Susan Roberts Signature ..... Date 16/5/16..... **Service Development Pharmacist** Name Catherine Smith Signature ..... Date 9/5/16.....
This PGD has been approved by	Name Dr Grecy Bell Associate Medical Director Signature ..... Date 8/6/16..... Name Michael Pratt Chief Pharmacist Signature ..... Date 10/5/16..... For NHS Dumfries and Galloway
Approved by NHS Dumfries & Galloway Area Drug and Therapeutics Committee on 28/04/2016	

NHS Dumfries and Galloway

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 Dumfries and Galloway Community Pharmacies.

Individual Authorisation

This PGD does 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. It is also your responsibility to ensure that all consultations with patients occur within a private and confidential area of the pharmacy where a copy of the PGD is available. All records of consultations must be stored securely and in accordance with this document.

I confirm that;

- I have received training to undertake supply of medicines under Patient Group Directions
- I have undertaken specified local and national training, including *National Education Scotland (NES) training on the supply of Trimethoprim for Uncomplicated UTIs via PGD (**proof of training is required)***, and I am competent in all aspects of this medication, including contra-indications and the recognition and treatment of adverse effects
- I agree to be professionally accountable for my work
- I am 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
- I am aware of current treatment recommendations and I am competent to discuss issues about the drug with the patient
- I agree to maintain my skills, knowledge and my own professional level of competence in this area
- I agree to work within the terms of this NHS Dumfries & Galloway PGD.

I have read and understood the Patient Group Direction and agree to supply Trimethoprim in accordance with this PGD.

Name of pharmacist _____

GPhC Number _____

Normal Pharmacy Locations _____
(If pharmacy locum not linked
to a specific pharmacy or pharmacy group
please provide contact details)

Signature _____

Date _____

The above named person has satisfied the training requirements and 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: _____

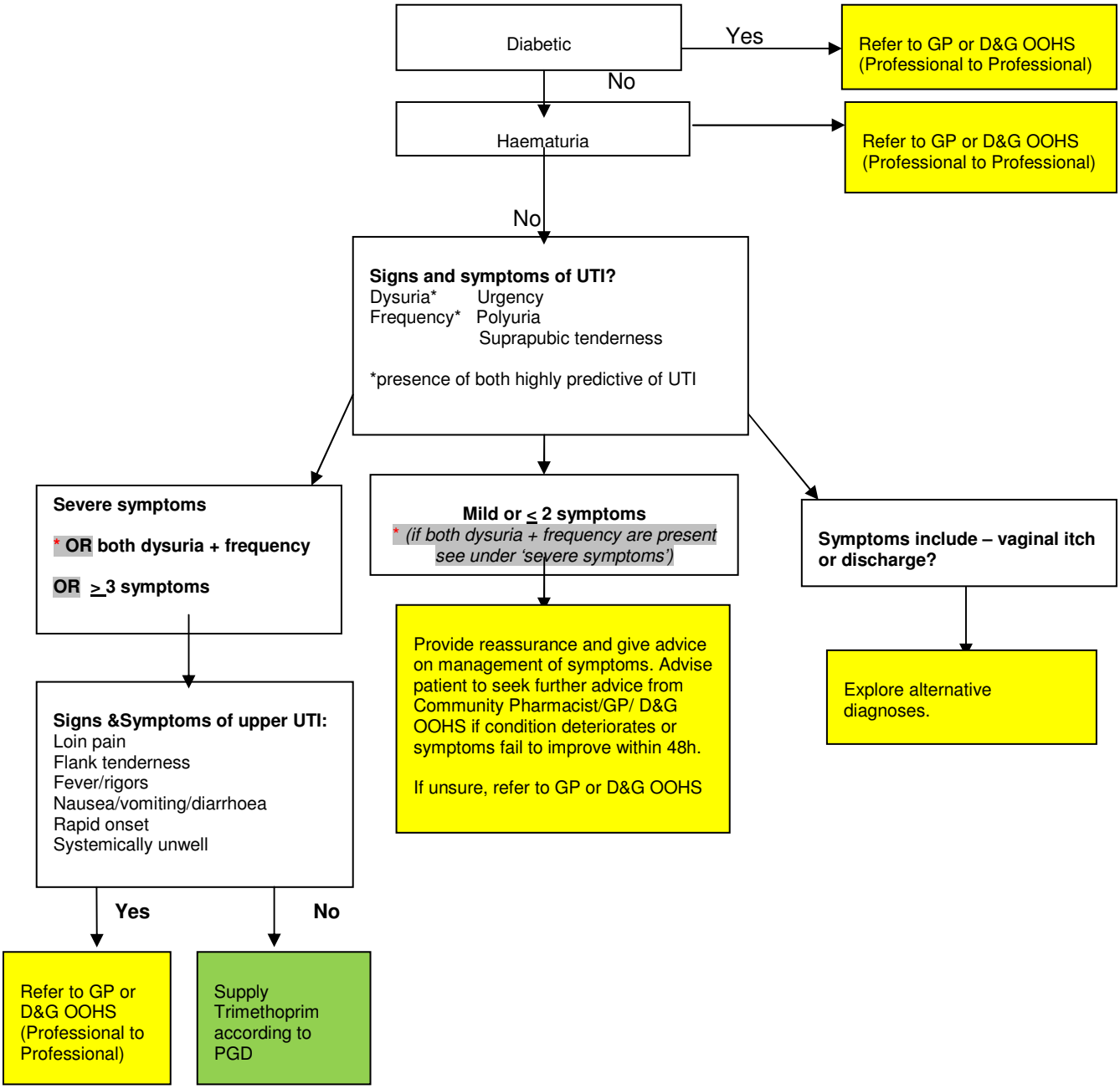
Date: _____

Appendix 1

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

Management of suspected UTI in non-pregnant females aged 16-65 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: The Pharmacist should telephone the GP practice to request a patient review by the GP at the earliest opportunity. A copy of the Client Assessment Form should be provided where possible *or should be discussed directly with the GP.*

Out of Hours: The Pharmacist should telephone the GP Out of Hour's Service to request a patient review at the earliest opportunity. A copy of the Client Assessment Form should be provided where possible *or should be discussed directly with the GP.*

Appendix 3 (1/2)

NHS Dumfries & Galloway Treatment of uncomplicated Urinary Tract Infections (UTI's) in non-pregnant adult females

Client Assessment Form and Notification of Supply through Community Pharmacy

Date: DD/ MM/ YYYY

Time:

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:

Pharmacy stamp

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:

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 Dumfries & Galloway 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.

DD/ MM/ YYYY

NHS Dumfries and Galloway

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 Dumfries and Galloway Community Pharmacies.

Appendix 3 (2/2)

Date of Assessment:	**Time of Assessment:**
Name of Patient:	**Date of Birth:**

Details of presenting symptoms are shown below:

Symptoms

(circle as appropriate)

Dysuria **yes*/no**
Frequency **yes*/no**

(*If both dysuria & frequency present, definitive of UTI)

Urgency yes/no
Polyuria yes/no
Suprapubic tenderness yes/no

Other _____

_____

Are symptoms related to UTI yes/no

Dysuria & Frequency or ≥3 symptoms yes/no

≤2 symptoms (not including Dysuria & Frequency) yes/no

Suitable for Trimethoprim x 3 days yes/no

Treatment for UTI required yes/no

Are symptoms related to other condition yes*/no

Treated by Pharmacy yes/no

Referred for treatment to: _____

Contra-indications to treatment of UTI by Pharmacist:
(circle as appropriate)

Age <16 or ≥65 yes/no

Allergy to trimethroprim, co-trimoxazole or any of the components of the medication yes/no

Haematuria yes/no

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

Taking interacting medications:
Check current BNF for interactions but including: Azathioprine, ciclosporin, mercaptopurine, methotrexate, phenytoin, warfarin, digoxin, pyrimethamine, rifampicin yes/no

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

Confused/dehydrated yes/no

Pregnant (confirmed or possible) yes/no

Vaginal itch/discharge yes/no

More than 2 episodes of UTI in 6 months or 3 episodes in 12 months yes/no

Previous antibiotic treatment for UTI In last 28 days yes/no

UTI Prophylaxis yes/no

Catheter in situ yes/no

Patients answering any questions Yes in this column are excluded from the PGD and must be managed as appropriate.

*Comments/Notes

(tick box if supplied)

Cystitis information leaflet ☐ Trimethoprim 200mg twice daily for 3 days (6 tablets) ☐

Pharmacist Name (print) _____

Pharmacist signature _____ Date _____