Treatment of uncomplicated urinary tract infections (UTI) in women by Community Pharmacists - Service Specification with PGD

1 SERVICE DESCRIPTION

This service is being commissioned by Oxfordshire Clinical Commissioning Group (OCCG). The service will be regularly reviewed and OCCG will retain any rights to amend or cancel the service with 3 months' notice to the pharmacy. If a national service is introduced at any time, the local scheme will be stopped after a 30 day wind-down period. The scheme will run until 31st March 2019, information on extended dates will be provided if appropriate.

Pharmacies included in the scheme will provide advice and support to people on the management of uncomplicated Urinary Tract Infections (UTIs), including where necessary, the supply of trimethoprim for the treatment of the UTI.

The service is part of the response to urgent care pressures to encourage people to use pharmacy as the first point of access to primary care for the treatment of self-limiting conditions.

2 AIMS AND OUTCOMES

The overall aim of the scheme is to ensure that patients can access self-care advice for the treatment of UTIs and, where appropriate, can be supplied with trimethoprim (at NHS expense if the patient is exempt, otherwise a standard prescription fee will be taken), to treat their UTI. This provides an alternative location from which patients can seek advice and treatment, rather than seeking treatment via a prescription from their GP or out of hours (OOH) provider, or via a walk-in centre or accident and emergency.

- Promote self-care through community pharmacy, including the provision of advice and where appropriate medicines without the need of a GP appointment;
- Operate a sign posting system from local medical practices to community pharmacy;
- Improve working relationships between GPs and Pharmacies;
- Improve primary, urgent and emergency care capacity by reducing the workload of those providers related to UTIs;
- Provide evidence based care in line with local and national guidelines.

3 SERVICE OUTLINE

3.1 The pharmacist is responsible for the appropriate running of this service. The supply of prescription-only medicines must be undertaken by a pharmacist.

3.2 The pharmacist will provide advice on the treatment of symptoms to people seeking such advice in the pharmacy. Patients may be supplied with appropriate medicine from Patient Group Direction (PGD) (Appendix 2). The quantity of medicinal treatment supplied should be as outlined in the PGD only.

3.3 This service is for patients who are both exempt and non-exempt from prescription charges. The patient should be asked to confirm their exemption and sign the declaration (Appendix 1). If they are not exempt, the staff member will explain that they will be required to pay the appropriate prescription charge if medication is supplied.

3.4 The declarations should be stored in the pharmacy and be made available if requested by the commissioner for audit purposes.
3.5 To be eligible for this service the patient must present to the pharmacy.
3.6 The pharmacy contractor must maintain appropriate records to ensure effective ongoing service delivery and audit. This will include recording the consultation and any medicine that is supplied on PharmOutcomes and the Patient Medication Record (PMR).
3.7 The consultation should take place in the consultation room.
3.8 The patient is at liberty to refuse the service should they wish to do so.

4 ELIGIBILITY CRITERIA

4.1 This service is available to any patient who is registered at a GP Practice in Oxfordshire.
4.2 Both patients who are exempt and non-exempt from prescription charges are eligible for the service. The patient should be asked to complete the declaration of exemption (Appendix 1), or pay a prescription charge if they are non-exempt.
4.3 Patients not registered with a GP practice included in the service should be advised appropriately and if treatment is thought to be indicated they should be signposted to an appropriate NHS service provider locally.
4.4 The patient must meet the criteria set out in the PGD (appendix 2)

5 TRAINING AND PREMISES REQUIREMENTS

5.1 The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service. Further training is available at www.cppe.ac.uk, relevant training articles are listed under the Minor Ailments Declaration of Competence.
5.2 The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service are aware of and operate within local protocols.
5.3 All Pharmacists working at participating pharmacies and providing the scheme should ensure that they continue, through continuing education and CPD, to keep up to date with guidance issued around the treatment.
5.4 Pharmacists working at participating pharmacies can provide this enhanced service if they have successfully completed the appropriate training listed on the PGD and have completed the Declaration of Competence.
5.5 Pharmacies providing the scheme should have a Standard Operating Procedure (SOP) in place, which must be understood and signed by all staff providing the service.
5.6 All Pharmacists providing the service will have to self-declare their competence on PharmOutcomes the first time they enter a consultation.
5.7 All patients accessing the service should be offered the use of a consultation room to ensure patient privacy.
5.8 A pharmacy must be fully compliant with their Essential Services before being commissioned to provide the service. If the pharmacy becomes non-compliant with their Essential Services the scheme may be withdrawn.
5.9 The Agreement to Practise form at the end of the PGD must be authorised by a senior person who is responsible for ensuring that only fully competent, qualified and trained health professionals use PGD within the provider organisation. Any pharmacist providing the service must also sign the Agreement to Practise. This should be retained on site for 6 years.

5.10 The signed agreement must be kept in the pharmacy along with the PGD and be available for inspection on request.

6 SERVICE AVAILABILITY

6.1 All pharmacists including regular locums must be able to provide the service, and be appropriately trained in the operation of the service. The services will be available to all patients who request a consultation and for a minimum of 80% of the total weekly opening hours.
6.2 If the pharmacy for whatever reason cannot provide the service, then the patient should be directed to the nearest pharmacy that can.
6.3 The pharmacy should inform the commissioner if they are unable to provide the service for an extended period (defined as 1 week or more) due to any circumstances.
6.4 If the pharmacy wishes to withdraw from the scheme, 3 months' notice must be given to the commissioner.
6.5 Should trimethoprim be unavailable the Pharmacy should notify the CCG with estimated availability date if possible.

7 QUALITY STANDARDS

7.1 The pharmacy has appropriate commissioner provided health promotion and self-care material available for the user group and promotes its uptake.
7.2 The pharmacy participates in any commissioner organised audit or post payment verification of service provision.
7.3 The pharmacy should co-operate with any commissioner-led assessment of patient experience.
7.4 The pharmacist ensures that clinical advice given is in line with national/local guidelines.
7.5 The pharmacist ensures that any patient incidents that occur are reported via their normal pathway.
7.6 The pharmacist ensures that the pharmacy has a complaints procedure in place that meets the NHS pharmaceutical contractual standards.

8 SAFEGUARDING

Health providers are required to demonstrate that they have safeguarding leadership and commitment at all levels of their organisation. They must be fully engaged in and support local accountability and assurance structures. Most importantly, they must ensure a culture exists where safeguarding is everybody's business and poor practice is identified and tackled. The provider will ensure that their senior management are committed to safeguarding children and adults demonstrating that they have robust governance structures and systems in place in line with all statutory and mandatory requirements.

9 CONSULTATION FORM & PAYMENT

9.1 PharmOutcomes will be used for the purposes of audit and the claiming of payment.
9.2 The pharmacist must complete one consultation record for each patient. The consultation should be recorded on PharmOutcomes and on the patients Patient Medication Record (PMR).

9.3 The supply must labelled appropriately and must state “supplied under PGD”

9.4 The details of the consultation should be entered onto PharmOutcomes as soon as possible after the consultation has taken place and in all cases **within 24 hours**. The PharmOutcomes system will send a secure email to the patient’s GP to inform of the supply so that the information can be added to the PMR.

9.5 Where no exemption from prescription charges applies, the pharmacy must collect the appropriate charge and this amount will be deducted from the payment made to the pharmacy for service provision.

9.6 For every consultation recorded on PharmOutcomes (irrespective of whether trimethoprim is supplied) the pharmacy will be paid £10 (including VAT) to include; set up costs (SOP development, staff training etc.) time to provide the service and completing PharmOutcomes information. The cost of drugs supplied will also be reimbursed.

9.7 Payments and medication cost reimbursement will be made based on the information recorded on PharmOutcomes.

9.8 Drug costs are automatically priced using the electronic Dictionary of Medicines and Devices (DM&D) at the time of dispensing.

10 CONFIDENTIALITY

Both parties shall adhere to the requirements of the Data Protection Act 1988 and the Freedom of Information Act 2000

11 INDEMNITY INSURANCE

The Pharmacy shall maintain adequate insurance for public liability and professional indemnity against any claims which may arise out of the terms and conditions of this agreement.

Any litigation resulting from an accident or negligence on behalf of the Pharmacy is the responsibility of the Pharmacy who will meet the costs and any claims for compensation, at no cost to OCCG.

Contact Details

OCCG Contacts	Details
Ailsa Whyte Prescribing Adviser	ailsa.whyte@oxfordshireccg.nhs.uk 0780 246 2157
Claire Critchley Medicines Optimisation Lead	claire.critchley@oxfordshireccg.nhs.uk 01865 336862
Medicines Optimisation Team Team Contact Details	OCCG.medicines@nhs.net 01865 336 800 Oxfordshire Clinical Commissioning Group Jubilee House 5510 John Smith Drive Oxfordshire Business Park South Cowley Oxford OX4 2LH

Appendix 1: Exemption Declaration for PGD Supply

Patient Name…….. DOB……..

This patient does not pay because:

A	☐	is under 16 years of age
B	☐	is 16, 17 or 18 and in full time education
C	☐	is 60 years of age over
D	☐	has a valid maternity exemption certificate
E	☐	has a valid medical exemption certificate
F	☐	has a valid prescription prepayment certificate
G	☐	Has a war pension exemption certificate
L	☐	is name on a current HC2 charge certificate
H	☐	*gets income support
K	☐	*gets income based jobseekers allowance
M	☐	*Is entitled to, or named on, a valid NHS Tax Credit Exemption Certificate
S	☐	* Has a partner who gets Pension Credit guarantee credit
N	☐	**NOT EXEMPT**

*Name DOB NI Number

I am the; patient ☐ Patients Representative ☐

Was evidence of exemption seen? Yes ☐ No ☐

Signed:…… Date:……

Appendix 2: Patient Group Direction (PGD)

Treatment of uncomplicated urinary tract infections (UTI) in women by Community Pharmacists

This Patient Group Direction (PGD) must only be used by pharmacists registered with the General Pharmaceutical Council (GPhC) who have been named and authorised by their organisation to practise under it. The most recent and in date final signed version of the PGD should be used.

Version number: Final 2.1

Version number	Change details	Date
Draft 0.1	Draft PGD for supply through Community Pharmacy	April 2016
Draft 0.2	Amended after comments from LPC, APCO & OPCOG	May 2016
Final 1.0	Final version	June 2016
Draft Update 1.1	Reviewed and suggested amendments made by OCCG	July 2017
Draft Update 1.2	Reviewed and amended by OCCG. Please note clinical changes include; **Altered Inclusion criteria:** • Must present with 3 or more symptoms (unless both dysuria and frequency present) **Added Exclusion criteria:** • History of recurrent UTI's i.e. More than 2 in 6 months, or 3 in previous 12 months • hospitalisation for more than 7 days in the last 6 months, • known previous UTI resistant to trimethoprim, cephalosporins, or quinolones • Immunocompromised patients or patients taking immunosuppressants or DMARDs. **Added Cautions:** • unresolving urinary symptoms, recent travel to a country with increased resistance	July 2017
Draft Update 1.3	Reviewed and amended after comments from LPC.	July 2017
Draft Update 2.0	**Added Exclusion Criteria:** • Patients taking Tacrolimus • Severe hepatic insufficiency. • Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galacactose malabsorption **Added Cautions:** • Patients with diabetes can be more prone to UTIs. A UTI could also indicate poor blood glucose control. Discuss the importance of reporting any recurrent symptoms to their GP.	August 2017
Final Version 2.1	Final Version	Sept 2017

PGD approval date/ Valid from:	11/10/2017	CCG implementation date:	20/11/2017
Review date:	31/01/2019	Expiry Date:	31/03/2019

PGD Accountability Record

PGD Development Group

Name	Job Title and Organisation	Signature	Date
Claire Critchley	Lead Pharmacist, OCCG	Claire Critchley	11.10.17
Louisa Griffiths	Medicines Optimisation Pharmacist, OCCG	L. Griffiths	11.10.17
Ailsa Whyte	Prescribing Adviser, OCCG		13.10.17
Andrew Burnett	GP Clinical Lead, OCCG		12.10.17
Carol Trower	Chief Officer, Thames Valley LPC	C T Trower	11/10/17

PGD Authorisation

This PGD has been approved and authorised for use by:

Name	Authorising Professional	Signature	Date
Sula Wiltshire	CCG Director of Quality		16/10/17
Miles Carter	CCG GP Clinical Lead		24/10/17
Sara Wilds	Head of Medicines Optimisation (Pharmacist)	S Wilds	16/10/17

Training and competency of registered community pharmacists

	Requirements of registered pharmacist working under the PGD
Qualifications and professional registration	Pharmacist's Registration (current and full) with General Pharmaceutical Council
Initial training	• Pharmacists to familiarise themselves with NICE guidance http://www.nice.org.uk/advice/ktt10/chapter/evidence-context and Clinical Knowledge Summaries Urinary Tract Infections (lower) Women https://cks.nice.org.uk/urinary-tract-infection-lower-women • Complete the CPPE Minor Ailments Declaration of Competence. • CPPE training on Reducing Antimicrobial Resistance is suggested for additional information
Declaration of Competence	Minor Ailments DoC to be completed via the Centre for Pharmacy Postgraduate Education (CPPE) **https://www.cppe.ac.uk/services/declaration-of-competence**
Ongoing training and competency	All Pharmacists are personally accountable for their practice and in the exercise of professional accountability there is a requirement to maintain and improve their professional knowledge and competence.

Retain a copy of each version of the Patient Group Direction for six years. A copy of this PGD should be kept on site. The CCG would expect a signed copy on request which would be signed by all pharmacists operating under the PGD in that pharmacy.

Clinical condition

Clinical condition or situation to which this PGD applies	Treatment of otherwise healthy women presenting with uncomplicated UTI.
Inclusion criteria	Women aged 16 – 65 years old, presenting with 3 or more symptoms (unless **both** dysuria and frequency are present, in which case patient can be included) associated with an uncomplicated UTI Symptoms include: • Dysuria (painful urination) • Increased urinary frequency and urgency of recent onset • Suprapubic tenderness (patient experiencing pain in the central lower part of the abdomen) • Polyuria (passing abnormally large volumes of dilute urine) Evidence shows if dysuria and frequency are present the likelihood of being a UTI is greater than 90% [1]
Exclusion criteria	• Female aged under 16 years of age or over 65 years of age • Males • Pregnant female, or possible pregnancy • Breast feeding mothers • Known hypersensitivity to trimethoprim • Known hypersensitivity to any ingredient of the trimethoprim product being supplied • Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galacactose malabsorption • Women presenting with symptoms of pyelonephritis i.e. Fever >38^{0}C,nausea/ vomiting, rigors, loin or severe abdominal pains/ tenderness and headache • Women who refuse treatment or do not consent to treatment. • Known renal impairment or acute kidney injury • Severe hepatic insufficiency • Blood dyscrasias • Acute porphyria • Women with abnormal vaginal discharge • Current prophylactic use of trimethoprim • Women with indwelling catheter • Haematuria (unless menstruating) • Any patient who has been treated with **trimethoprim** for UTI in the last 2 weeks, or on 2 or more occasions in the last 3 months or more than 5 during the previous 12 months. • Patients currently taking a prescribed course of antibiotics • Patients with history of recurrent UTIs (treated or untreated) i.e. More than 2 in 6 months, or 3 in previous 12 months • Women with urological abnormalities or who have had surgery involving the lower urinary tract • hospitalisation for more than 7 days in the last 6 months • unresolving urinary symptoms • known previous UTI resistant to trimethoprim, cephalosporins, or quinolones

	• Immunocompromised patients or patients taking immunosuppressants or DMARDs.
	• Patients who are currently taking medication that has a clinically significant interaction with trimethoprim (refer to most recent BNF):
	  • Antiepileptics – Phenytoin
	  • Antimalarials – pyrimethamine
	  • Azathioprine
	  • Ciclosporin
	  • Cytotoxics - mercatopurine or methotrexate
	  • Tacrolimus
	  • Warfarin

Cautions (including any relevant action to be taken)	• If patient is taking any other medications, consult BNF Appendix 1: Interactions for any potential interactions with trimethoprim • Patients with diabetes can be more prone to UTIs. A UTI could also indicate poor blood glucose control. Discuss the importance of reporting any recurrent symptoms to their GP. • Patients with actual or potential folate deficiency • Recent travel to a country with known increased resistance (e.g. a country with very highly resistant e.coli bacteremia https://resistancemap.cddep.org/AntibioticResistance.php)
Arrangements for referral for medical advice	Contact details of services available to be provided to patient, with hours of opening. Pharmacist to provide written summary of assessment of patient via PharmOutcomes electronic transfer to GP, including reason for referral
Action to be taken if patient excluded	If symptoms are mild, give self-care advice including patient information leaflet e.g. the RCGP Target Antibiotic Toolkit leaflet: Treating Your Infection – Urinary Tract Infection Leaflet (www.rcgp.org.uk/clinical-and-research/toolkits/target-antibiotics-toolkit-old.aspx). If symptoms get worse or do not improve after 24-48 hours of self-care, return to pharmacy or see G.P. Refer patient to GP, GU clinic or out of hours centre as appropriate For patients already taking a prescribed antibiotic or who has recently completed a course of antibiotics for a UTI – refer back to own GP **Immunocompromised patients or patients taking immunosuppressants or DMARDs** - seek urgent medical attentions for full blood count and liver function tests
Action to be taken if patient declines treatment	Record refusal in patient records and state reason for refusal, any action taken or advice given.

Details of the medicine/ Description of treatment[3]

Name, form and strength of medicine *Include ▼for black triangle medicines*	Trimethoprim 200mg tablets
BNF Chapter Category	5.2 - Trimethoprim
Legal category	POM
Indicate any off-label use (if relevant)	N/A
Dose and frequency	One 200mg tablet to be taken every 12 hours for three days (200mg BD for 3 days)
Route/method of administration	Oral
Total Quantity to be supplied	Six 200mg tablets
Maximum treatment period	3 days
Adverse effects	***For full list of ADR's see BNF/SmP[3]*** ***Common:*** • Gastrointestinal disturbances including nausea and vomiting • Pruritis and rashes • Hyperkalaemia • Depression of haematopoiesis (usually associated with long term use) **Rarer:** • Photosensitivity • Erythema multiforme • Toxic epidermal necrosis • Allergic reactions including angioedema and anaphylaxis
Records to be kept	The following must be recorded on PharmOutcomes: • The diagnosis • Treatment recommended *(Pre-populated)* • Quantity supplied *(Pre-populated)*

	• Batch number and expiry date • Name of manufacturer • Duration of treatment *(Pre-populated)* • Date and time of supply • Any known allergies or concurrent medications • Name of Pharmacist and GPhC Number • Patient exemption or prescription fee received *Copies of records and consent forms must be kept for 2 years* *Information must be sent to the GP for entry into the patient's records* Document any allergies and other adverse drug reactions clearly in the patient records and inform GP and other relevant practitioners/ carers for further reporting and action if needed

Procedure for reporting Adverse Drug Reactions (ADRs) and Errors

All ADRs/ significant events/ near misses occurring in relation to the administration of this medicine under the PGD must be reported in the clinical record and via the pharmacy's usual incident reporting system. The commissioners should also be made aware of any errors or significant events via email (occg.medicines@nhs.net). The GP must be informed and, in cases of ADRs requiring hospital admission or resulting in serious harm, the incident reported on a yellow card to the MHRA - https://yellowcard.mhra.gov.uk/

Patient information

Written/ verbal information to be given to patient or carer	• Highlight the patient information leaflet included in the box • Advise patient to take at regular intervals • Advise the patient to complete the 3 day course even if the original infection appears better • Tablets should be swallowed whole with a full glass of water • Trimethoprim may be taken with food if it causes stomach upset • Encourage patient to maintain a good fluid intake • Advise patient that if they experience any unacceptable side effects they should see their GP for further advice • Advise patient that if a rash appears to stop the medicine and seek medical advice • Antibiotics and oral contraceptives: World Health Organisation (WHO) no longer advise that additional precautions are required when using combined hormonal contraceptives with antibiotics that are not enzyme inducers for a duration of less than 3 weeks. This is supported by the Faculty of Sexual and Reproductive Healthcare.[4] http://www.fsrh.org/pdfs/CEUguidancedruginteractionshormonal.pdf Advice should be provided around the usual precautions if nausea and vomiting should arise from taking the antibiotics • Advise patient to see GP if symptoms do not resolve after completion of course, and to take an early morning urine sample with them to the appointment. • Provide advice on ways to reduce recurrence of further episodes – Voiding after intercourse, maintaining adequate fluid intake. • Give the patient any available literature available on cystitis management • A Patient information leaflet should be given to the patient for example the RCGP Target Antibiotic Toolkit leaflet: Treating Your Infection – Urinary Tract Infection Leaflet (www.rcgp.org.uk/clinical-and-research/toolkits/target-antibiotics-toolkit-old.aspx)
Follow-up advice to be given to patient or carer	• Routine follow up is not necessary • Advise to see GP if symptoms don't resolve

Agreement to Practise

Individual Community Pharmacy Authorisation	
Community Pharmacy designated lead for professional authorisation	Name of Pharmacy: Name of Lead for this PGD: Designation: Has responsibility to ensure that only fully competent, qualified and trained professionals implement this PGD Agrees to maintain a current list of the names of individuals who may implement this PGD and to keep this with a pharmacy master copy of the PGD Signature: Date:

Agreement by Pharmacist to supply Trimethoprim 200mg Tablets in accordance with the PGD Final 2.1: Pharmacist Log

I hereby confirm that I have read the above PGD and supporting documents. I have the appropriate training and competency to safely carry out the procedures and practices mentioned above and I agree to supply the medicine in accordance with this directive:

Name of Pharmacist	GPhC Number	Signature	Date

References

1. SIGN 88 UTI 2012 http://www.sign.ac.uk/guidelines/fulltext/88/index.html

2. BNF 72 March to September 2017

3. Electronic Medicines Compendium (eMC) – SmPC & PIL access for various brands: eMC

4. Faculty of sexual and reproductive health Clinical Guidance. Clinical Effectiveness Unit Drug Interactions with Hormonal Contraception January 2011 (updated January 2012): http://www.fsrh.org/pdfs/CEUguidancedruginteractionshormonal.pdf

5. Management of Simple UTIs in Non-Pregnant Females in Primary Care (Jan 2015): OCCG Clinical Guidelines

6. Centre for Pharmacy Postgraduate Education (CPPE): CPPE - Centre for Pharmacy Postgraduate Education