

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)**

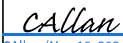

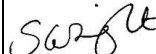
## **Supply of doxycycline for the treatment of uncomplicated *Chlamydia trachomatis*, within Community Pharmacies in Luton**

### **Version Number 2.0**

<b>Change History</b>	
<b>Version and Date</b>	<b>Change details</b>
Version 1.0 April 2020	New template developed by SPS PGD development group
Version 1.3 March 2022	Review and adoption of template by Luton Borough Council
Version 2.0 November 2024	Review of PGD in line with SPS PGD development group update July 2023

<b>PGD Development Group:</b> This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in October 2022.	
Name	Designation
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory Service (BPAS)
Gail Rowley	Quality Matron British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant MSI Reproductive Choices
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Helen Donovan	Royal College of Nursing (RCN)
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Kirsty Armstrong	National Pharmacy Integration Lead, NHS England
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Dr Kathy French	Specialist Nurse
Dr Sarah Pillai	Associate Specialist
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	NHS North East London ICB pharmacist
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Jo Jenkins (Working Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service

**PGD authorisation - The clinical content has been approved by:**

Name	Job title and organisation	Signature	Date
Carolynne Allan	Director of Pharmacy Services at ECG Healthcare. GPhC 2038268	 <small>CAAllan (Nov 18, 2024 10:33 GMT)</small>	18/11/2024
Richard Lyon	Medical Director at ECG Healthcare. GMC 6097348	 <small>Prof R Lyon (Nov 15, 2024 10:26 GMT)</small>	15/11/2024
Sally Cartwright	Director of Public Health. Luton Borough Council		19/11/2024

## Training and competency of registered healthcare professionals

<b>Qualifications and professional registration</b>	<p>Current contract of employment within the Local Authority or NHS commissioned service or the NHS Trust/organisation.</p> <p>Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.</p>
<b>Initial training</b>	<p>The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patient leading to diagnosis of the conditions listed. This training is specified in the current Service Specification</p> <p>Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines.</p> <p>The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults.</p> <p>All accredited pharmacists are responsible for maintaining the clinical knowledge appropriate to their practice by attending relevant study days, courses and by keeping abreast of evidence based practice related to sexual health.</p>
<b>Competency assessment</b>	<p>Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for Chlamydia testing and/or treatment.</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>
<b>Ongoing training and competency</b>	<p>Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance included in the PGD. If any training needs are identified these should be addressed and further training provided as required.</p> <p>Organisational PGD and/or medication training as required by Public Health Luton.</p>
<p>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.</p>	

## Clinical condition

<b>Clinical condition or situation to which this PGD applies</b>	<p>This PGD is used for the treatment of uncomplicated genital Chlamydia trachomatis infection following the Luton Borough Council local Service Specification.</p>
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<b>Criteria for inclusion</b>	<p>Where the patient has given consent.</p> <p>Aged 13 years and over. All individuals under the age of 19 years should be assessed for capacity to consent using local guidelines or Fraser Guidelines as appropriate.</p> <p>Where doxycycline is contraindicated (known allergy, previous adverse effects, pre-existing medical conditions, pregnancy) or inappropriate. (photosensitivity, likely poor adherence)</p> <p>Individuals with a positive test for Chlamydia trachomatis infection in the genitals, but without signs suggestive of complications.</p> <p>Asymptomatic individuals presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of Chlamydia trachomatis, who are unwilling/unable to defer testing after the 2 week window period.</p> <p>A single repeat treatment course for individuals who have had sexual intercourse within 7 days of receiving treatment or who have had sex with a partner untreated for the above conditions.</p>
<b>Criteria for exclusion</b>	<p>Where the patient is unwilling to give consent.</p> <p>Individuals under 13 years of age.</p> <p>Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines.</p> <p>Individuals 16 years of age and over and assessed as lacking capacity to consent.</p> <p>Known allergy or hypersensitivity to doxycycline, other tetracycline antibiotics or to any component of the product - see <a href="#">Summary of Product Characteristics</a> (SPC)</p> <p>Individuals with clinical proctitis or PID.</p> <p>Individuals with confirmed Lymphogranuloma venereum (LGV) or a contact of LGV.</p> <p>Breast feeding or known pregnancy.</p> <p>Known hepatic impairment.</p> <p>Presence of concomitant conjunctivitis and/or joint pain/swelling.</p> <p>Acute porphyria.</p> <p>Myasthenia gravis.</p> <p>Systemic Lupus Erythematosus (SLE).</p> <p>Individuals with oesophagitis and oesophageal ulcerations.</p>

	Any concurrent interacting medicine(s) – see Drug Interactions section or refer to <a href="#">Interactions A to Z   BNF   NICE</a> )
<b>Cautions including any relevant action to be taken</b>	<p>If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented.</p> <p>Individuals taking the following medication should be advised that additional monitoring is required – advise individual to contact service who prescribe/monitor the affected medications:</p> <ul style="list-style-type: none"> <li>• ciclosporin – monitoring of ciclosporin levels may be indicated</li> <li>• phenindione – INR monitoring advised</li> <li>• warfarin – INR monitoring advised</li> </ul> <p>Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.</p>
<b>Action to be taken if the individual is excluded or declines treatment</b>	<p>If the presenting individual is under 13 years of age the healthcare professional should speak to the local safeguarding lead and follow the local safeguarding policy (note under 13 years of age excluded from treatment under this PGD).</p> <p>If declined ensure individual is aware of the need for treatment and the potential consequences of not receiving treatment.</p> <p>Explain the reasons for exclusion to the individual and document in the consultation record.</p> <p>Record reason for decline in the consultation record.</p> <p>Consider if azithromycin can be used (see separate PGD).</p> <p>Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.</p>

## Description of treatment

<b>Name, strength &amp; formulation of drug</b>	Doxycycline 50mg or 100mg capsules or 100mg dispersible tablets.
<b>Legal category</b>	POM
<b>Route of administration</b>	Oral
<b>‘Off label’ use</b>	Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label

	<p>administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management.</p> <p>Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.</p>
<b>Dose and frequency of administration</b>	100mg twice daily
<b>Duration of treatment</b>	7 days
<b>Quantity to be supplied</b>	7 day supply - appropriately labelled pack/s to a total quantity of 28x50mg, 14x100mg capsules or 14x100mg dispersible tablets.
<b>Storage</b>	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
<b>Drug interactions</b>	<p>All concurrent medications should be reviewed for interactions. The interactions listed as severe/concurrent use to be avoided in the BNF are:</p> <ul style="list-style-type: none"> <li>• Acenocoumarol</li> <li>• Acitretin</li> <li>• Alitretinoin</li> <li>• Isotretinoin</li> <li>• Lithium</li> <li>• Tretinoin</li> </ul> <p>A detailed list of all drug interactions is available in the <a href="#">BNF</a> or the product <a href="#">SPC</a></p>
<b>Identification &amp; management of adverse reactions</b>	<p>A detailed list of adverse reactions is available in the <a href="#">SPC</a> and <a href="#">BNF</a></p> <p>The following side effects are reported as common in the doxycycline SPC, but note this list may not reflect all reported side effects:</p> <p><i>hypersensitivity reactions, headache, nausea, vomiting, photosensitivity skin reactions, rash including maculopapular, erythematous rashes and Henoch-Schonlein purpura, urticaria, hypotension, pericarditis, tachycardia, dyspnoea, peripheral oedema.</i></p>
<b>Management of and reporting procedure for adverse reactions</b>	<p>Healthcare professionals and individuals 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="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a>.</p> <p>Record all adverse drug reactions (ADRs) in the individual's medical record. Report any adverse reactions via organisation incident policy.</p>

<p><b>Written information and further advice to be provided</b></p>	<p>Give the patient information leaflet (PIL) provided with the original pack.</p> <p>Explain mode of action, side effects, and benefits of the medicine.</p> <p>Advise to swallow the capsules whole with plenty of fluids during meals while sitting or standing and well before bedtime to prevent irritation to the oesophagus.</p> <p>Advise not to take antacids or preparations containing calcium, iron, zinc and magnesium salts at the same time as doxycycline, including those medications purchased.</p> <p>Advise to avoid exposure to direct sunlight or ultraviolet light.</p> <p>Verbal and written information on Chlamydia trachomatis.</p> <p>Discuss implications of incompletely treated/untreated infection of self or partner.</p> <p>Advise to abstain completely from sexual intercourse (even with condoms) including oral sex, during treatment and until treatment course completed and until partner(s) treatment completed. Where not achievable advise on use of condoms.</p> <p>Discuss risk of re-infection and further transmission of infection, if after treatment sexual intercourse takes place with an untreated partner/s.</p> <p>Discuss partner/s notification and issue contact slips if appropriate.</p> <p>Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs).</p> <p>Where treatment is not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services.</p>
<p><b>Advice/follow up treatment</b></p>	<p>The individual should be advised to seek medical advice in the event of an adverse reaction.</p> <p>Follow local protocol for Chlamydia follow up and partner notification.</p> <p>Individuals who have not had a full STI screen (or who did not have Chlamydia diagnosed in a sexual health clinic) should be advised to attend an appropriate service for a full STI screen.</p> <p>Routine follow-up for uncomplicated Chlamydia following treatment with doxycycline is unnecessary, except in the following situations where local protocols should be followed:</p> <ul style="list-style-type: none"> <li>○ Where poor compliance is suspected</li> <li>○ Where symptoms persist</li> <li>○ Rectal infections</li> <li>○ Under 25 year olds</li> </ul>

<b>Records</b>	<p>Make records of the following:</p> <ul style="list-style-type: none"> <li>• The consent of the individual and <ul style="list-style-type: none"> <li>○ If individual is under 13 years of age record action taken</li> <li>○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.</li> <li>○ If individual over 16 years of age and not competent, record action taken</li> </ul> </li> <li>• If individual not treated under PGD record action taken</li> <li>• Name of individual, address, date of birth</li> <li>• GP contact details where appropriate</li> <li>• Relevant past and present medical and sexual history, including medication history.</li> <li>• Examination or microbiology finding/s where relevant.</li> <li>• Any known allergies and nature of reaction</li> <li>• Name of registered health professional</li> <li>• Name of medication supplied</li> <li>• Date of supply</li> <li>• Dose supplied</li> <li>• Quantity supplied including batch number and expiry date</li> <li>• Advice given about the medication including side effects, benefits, and when and what to do if any concerns</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>• Any referral arrangements made</li> <li>• Any supply outside the terms of the product marketing authorisation</li> <li>• Recorded that supplied via Patient Group Direction (PGD)</li> </ul> <p>Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.</p> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
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## Key references

- Electronic Medicines Compendium [accessed June 2023] <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>
- BASHH CEG September 2018 – Update on the treatment of *Chlamydia trachomatis* (CT) infection <https://www.bashhguidelines.org/media/1191/update-on-the-treatment-of-chlamydia-trachomatis-infection-final-16-9-18.pdf>
- BASHH UK National Guideline on the management of non-gonococcal urethritis [www.bashhguidelines.org/media/1051/ngu-2015.pdf](http://www.bashhguidelines.org/media/1051/ngu-2015.pdf);
- British Association for Sexual Health and HIV national guideline for the management of infection with *Mycoplasma genitalium* [Mycoplasma Genitalium 2018 | BASHH](#)
- Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 <https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines>

## Registered health professional authorisation sheet

### Supply of doxycycline for the treatment of uncomplicated Chlamydia trachomatis, within Community Pharmacies in Luton

Valid from: 1<sup>st</sup> November 2024

Expiry: 31<sup>st</sup> March 2027

#### 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.

<b>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.</b>			
Name	Designation	Signature	Date

#### Authorising manager

<b>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 Luton Pharmacies for the above named health care professionals who have signed the PGD to work under it.</b>			
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.