Insert logo of authorising body

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 asymptomatic *Chlamydia trachomatis* in Community Pharmacy

PGD DEVELOPMENT GROUP

Date PGD template comes into effect	April 2024
Review date	February 2026
Expiry date	March 2026

Version Control

The current version of this document can be found on Pharmoutcomes and the LPC website *https://www.sps.nhs.uk/articles/doxycycline-for-use-within-sexual-health-services/*

Amendments may become necessary prior to the published expiry date. Contractors who are commissioned to provide the service will be notified of any amendments and provided with updated documentation for use by individual practitioners.

- Practitioners and organisations must check that they are using the current version of the PGD.

Revision History

Version	Date	Author	Change description
1.0 / 2021	Nov 2021	Andrew Pickard	New PGD
2.0 / 2022	Feb 2022	Andrew Pickard	Local update
3.0 / 2024	March 2024	Mercedeh Fahimi-Vahid	Update and reformatting

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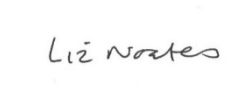
ORGANISATIONAL AUTHORISATIONS

Telford and Wrekin Council and Shropshire Council authorise this PGD for use by accredited Community Pharmacists delivering the service from community pharmacies that meet the requirements as outlined in the service specification and that have been commissioned by Telford and Wrekin Council and/or Shropshire Council.

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.

This document requires authorisation by the following individuals:

Name and Designation	Organisation	Signature	Date
Liz Noakes Statutory Director of Public Health	Telford and Wrekin Council		26.03.24
Rachel Robinson Consultant in Public Health / Deputy Statutory Director of Public Health	Shropshire Council		26/03/2024
Elizabeth Walker Deputy Director Medicines Management	NHS Shropshire Telford and Wrekin Integrated Care Board		25/03/2024
Dr Arabinda Kundu Consultant/Clinical Lead in Sexual Health	Midlands Partnership Foundation Trust		26/03/2024

Characteristics of staff

Qualifications and professional registration to be held by staff undertaking PGD	▪ Pharmacist with current General Pharmaceutical Council registration. ▪ Pharmacist authorised by Telford and Wrekin Council and/or Shropshire Council to provide a Chlamydia Treatment Service as per the Service Specification. ▪ Pharmacist is required to have suitable indemnity insurance.
Initial training	▪ The registered pharmacist 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 condition listed - to have a clear understanding of the drug to be administered including side effects, contraindications, and interactions. - to ensure safe provision of the medicines listed in accordance with the service specification. ▪ Individuals operating under this PGD must have a clear understanding of the legal requirements to operate a PGD Overview | Patient group directions | Guidance | NICE ▪ Recommended training for working under PGDs for the supply and administration of medicines - eLfH PGD elearning programme ▪ Completion of the current CPPE training packages on Sexual Health in Pharmacies Sexual health in pharmacies : CPPE and Safeguarding Vulnerable Adults and Children Safeguarding (cppe.ac.uk) ▪ Completion of the CPPE learning pack – Combating Child Sexual Exploitation (CSE): An e-learning resource for healthcare professionals Combatting CSE - An e-learning resource for healthcare professionals: CPPE
Competency assessment	▪ 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 Declaration of Competence for pharmacy services - Chlamydia Testing and Treatment Service. - be competent to follow and administer PGD showing clear understanding of indications for treatment (and subsequent actions to be taken), and the treatment itself. ▪ Individuals operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	▪ Individuals operating under this PGD have a personal responsibility to ensure their on-going competency by continually updating their knowledge and skills. ▪ Attendance at a local training event(s) approved by Telford and Wrekin Council and/or Shropshire Council is recommended where these are organised, but this is not a prerequisite for delivering this service.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

Insert logo of authorising body

Clinical Details

Clinical condition or situation to which this PGD applies	▪ Uncomplicated Asymptomatic Genital *Chlamydia trachomatis* infection ▪ Asymptomatic individuals presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of chlamydia trachomatis infection. **The use of doxycycline is considered first line treatment for asymptomatic chlamydia infection.**
Aims	To reduce the risks of short- and longer-term complications associated with chlamydia infection such as pelvic inflammatory disease and tubal infertility.
Criteria for inclusion Use BNF/BNFC/SPC. Consider any clinical guidelines or policies that are available locally or nationally, e.g. BASHH / NICE	▪ Informed consent is given. ▪ Individuals aged 15 years and over with a positive test result for genital chlamydial trachomatis infection following screening, and when azithromycin cannot be used. ▪ Asymptomatic individuals presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of chlamydia, who are unwilling/unable to defer testing after the 2-week window period. ▪ A single repeat treatment course for individuals who have had sexual intercourse within 7 days of receiving treatment or who have had sex with partner untreated for the above condition.
Criteria for exclusion	▪ Informed consent not given. ▪ Individuals under 15 years of age. ▪ Individuals under 16 years old and assessed as lacking capacity to consent using Gillick competency and Fraser guidelines. ▪ Individuals 16 years of age and over and assessed as lacking capacity to consent. **Medical history** ▪ Known/ suspected pregnancy. ▪ Breastfeeding. ▪ Suspected pelvic inflammatory disease. ▪ Pelvic pain which has recent onset. ▪ Symptoms suggestive of other STIs such as unusual vaginal discharge for women or penile discharge in men. ▪ Known or suspected proctitis/prostatitis. ▪ New or unusual testicular pain. ▪ Urethritis. ▪ Individuals with confirmed Lymphogranuloma venereum (LGV) or a contact of LGV. ▪ Known hepatic impairment. ▪ Presence of concomitant conjunctivitis and/or joint pain/swelling. ▪ Previous history of acute porphyria. ▪ Myasthenia gravis. ▪ Systemic Lupus Erythematosus (SLE). ▪ Individuals with oesophagitis and oesophageal ulcerations. **Medication history** ▪ Any concurrent interacting medicine(s) where interaction is severe or clinically significant –Doxycycline Interactions (see also interaction section below) Known allergy or suspected hypersensitivity to doxycycline, other tetracycline antibiotics or to any component of the product – see Summary of Product Characteristics Doxycycline 100mg Capsules

Supply to young persons	▪ If the individual is less than 16 years of age, then they must be assessed for competency based on Fraser guidelines. If they are deemed as being 'Fraser Competent' then a supply can be made and documented in the records. ▪ Pharmacists must use their professional judgement when considering 'Safeguarding' issues related to sexual activity in young persons. If the presenting individual under 13 years of age requests treatment for chlamydia, and there is a reasonable concern that sexual activity has taken place, the pharmacist should always speak to local safeguarding lead and follow the local safeguarding policy. (Note under 15 years of age excluded from treatment under this PGD). Local contacts: - Family Connect in Telford and Wrekin (01952 385385 / after 5pm and on weekends contact the emergency duty team 01952 676500) or - Initial Contact Team in Shropshire (0345 678 9021 / Out of hours - 0345 678 9040) Safeguarding Children / Shropshire Council Useful Contacts ▪ There must always be a presumption that the case will be referred to the Children's Social Care Services in the area where the child lives. A record of the referral should be maintained in the pharmacy. The pharmacy may also adopt: Regional Child Protection Procedures for West Mildands **If you think the child or young person is in immediate danger telephone 999**
Action to be taken if the individual is excluded or declines treatment	▪ If declined ensure individual is aware of the need for treatment and the potential consequences of not receiving treatment. ▪ Record reason for decline in the consultation record. ▪ Where exclusion criteria apply, explain the reasons for exclusion to the individual and document in the consultation record and/or PharmOutcomes . ▪ Consider if azithromycin can be used (see separate PGD). ▪ Refer to Sexual Health Clinic (0300 123 0994) or the individuals GP.
Management of individuals requiring referral	Where required refer the individual to a suitable health service provider if appropriate and document referral details in patient records and/or PharmOutcomes ▪ Female with pelvic pain, consider immediate referral to Sexual Health Clinic (0300 123 0994). If pain severe, refer to local A&E department. ▪ Symptoms suggestive of other STI – consider immediate referral to Sexual Health Clinic. ▪ Male with scrotal pain, consider immediate referral to local A&E department. ▪ If vomiting occurs within 3 hours of taking initial dose, refer to Sexual Health Clinic or GP for re-evaluation.

Description of treatment

Name, strength & formulation of drug	Doxycycline 100mg capsules
Legal category	Prescription Only Medicine (POM)
Route of administration	Oral
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC. ▪ Do not store above 25° C. Keep in the original package. Store in a dry place. Doxycycline 100mg Capsules - Special precautions for storage
Off label use	Medicines should be stored according to the conditions detailed in the Storage section. 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 community pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with community pharmacy/Medicines Management. ▪ 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.
Dose and frequency of administration	100mg twice daily
Duration of treatment	7 days
Quantity to be supplied	▪ 7-day supply - appropriately labelled pack/s to a total quantity of 14x100mg capsules. ▪ The wording 'Supplied via PGD' should be added to the label.
Drug interactions	All concurrent medications should be reviewed for interactions. The interactions listed as severe/concurrent use to be avoided in the BNF are: ▪ Acenocoumarol ▪ Acitretin ▪ Alitretinoin ▪ Isotretinoin ▪ Lithium ▪ Tretinoin The SPC highlights important, clinically significant interactions as follows: ▪ **Phenobarbital, carbamazepine, phenytoin, and primidone** — metabolism of doxycycline may be accelerated by these drugs, leading to a reduced plasma concentration. ▪ **Rifampicin** — may cause a reduction in doxycycline levels, leading to undertreatment. ▪ **Antacids, oral zinc, iron salts or bismuth preparations** — can reduce the absorption of tetracyclines. Dosages should be maximally separated

	▪ **Penicillin** – bactericidal action may be impaired so avoid giving doxycycline alongside penicillin ▪ **Methoxyflurane** – reports of fatal renal toxicity ▪ **Retinoids** – increased risk of benign intracranial hypertension ▪ **Methotrexate** - doxycycline increases the risk of methotrexate toxicity; prescribe with caution to patients on methotrexate. The following medicines have interactions that will require additional monitoring (see caution section below): ▪ Ciclosporin- doxycycline may increase the plasma concentration of ciclosporin. Co-administration should only be undertaken with appropriate monitoring. ▪ Phenindione- prolonged prothrombin time, INR monitoring/dose adjustment as appropriate ▪ Warfarin- prolonged prothrombin time, INR monitoring/dose adjustment as appropriate A detailed list of all drug interactions is available in the Doxycycline | Interactions | BNFC | NICE or the Doxycycline 100mg Capsules - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) Seek advice from an appropriate clinician/Medicines Advisory Service if required.

Cautions including any relevant action to be taken	A detailed list of Special warnings and precautions for use is available in the SPC. Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain. ▪ Individuals taking the following medication should be advised that additional monitoring is required – advise individual to contact service who prescribe/monitor the affected medications: - ciclosporin – monitoring of ciclosporin levels may be indicated. - phenindione – INR monitoring advised. - warfarin – INR monitoring advised. ▪ Serious skin reactions If serious skin reactions occur, doxycycline should be discontinued immediately, and appropriate therapy should be instituted. ▪ Photosensitivity - May cause skin sensitivity to sunlight, therefore avoid direct exposure to sunlight or ultra-violet light. - Treatment should be discontinued at the first evidence of skin erythema. ▪ Benign intracranial hypertension - Usually transient, however cases of permanent visual loss secondary to benign intracranial hypertension have been reported with tetracyclines including doxycycline. - If visual disturbance occurs during treatment, prompt ophthalmologic evaluation is warranted. Those experiencing blurred vision or visual disturbances should avoid driving or operating machinery if they experience this side effect. ▪ Clostridium difficile-associated diarrhoea (CDAD) - has been reported with use of nearly all antibacterial agents including doxycycline and may range in severity from mild diarrhoea to fatal colitis. - CDAD must be considered in all individuals who present with diarrhoea following antibiotic use. - Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. ▪ Pseudomembranous colitis - has been reported with nearly all antibacterial agents, including doxycycline, and has ranged in severity from mild to life-threatening. - It is important to consider this diagnosis in individuals who present with diarrhoea subsequent to the administration of antibacterial agents.

Identification of adverse reactions	A detailed list of adverse reactions is available in the SPC and BNF The following side effects are reported as common in the doxycycline SPC but note this list may not reflect all reported side effects: ▪ Hypersensitivity reactions ▪ Headache ▪ Nausea ▪ Vomiting ▪ Photosensitivity skin reactions ▪ Rash including maculopapular, erythematous rashes and Henoch-Schonlein purpura ▪ Urticaria ▪ Hypotension ▪ Pericarditis ▪ Tachycardia ▪ Dyspnoea ▪ Peripheral oedema
Management of and reporting procedure for adverse drug reactions (ADR)	▪ An individual presenting with a suspected serious ADR should be referred to their GP. ▪ 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 ▪ Record all ADRs in the individual's medical record. ▪ Report any adverse reactions via organisation incident policy.
Written information and further advice to be given to individual	**Medication:** ▪ Give patient information leaflet (PIL) provided with the original pack. Explain mode of action, side effects, and benefits of the medicine ▪ Advise to take dose at regular intervals, twice daily for 7 days and complete the course. ▪ 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. ▪ Advise on common side effects and management, including if vomiting occurs within 3 hours of initial dose. ▪ Advise not to take antacids or preparations containing calcium, iron, zinc and magnesium salts at the same time as doxycycline, including those medications purchased doses should be separated as outlined within the product information. ▪ Advise to avoid exposure to direct sunlight or ultraviolet light. ▪ If the individual is taking oral contraception or using contraceptive patches: - advise to continue to take contraceptive as usual. - additional contraceptive precautions should be taken for 7 days after completion of course. - if these 7 days run beyond the end of a packet, the next packet should be started immediately without a break/ or the next patch used. In the case of ED tablets, the inactive ones should be omitted, and a new pack started.

	Condition: ▪ Individuals diagnosed with Chlamydia trachomatis should be offered information (verbal, written and/or digital) about their diagnosis and management. ▪ Discuss implications of incompletely treated/untreated infection of self or partner. ▪ 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. - A second course of treatment may be offered in the case of possible re-infection if the client has not abstained from sexual intercourse during the 7 days of treatment. ▪ Discuss risk of re-infection, and further transmission of infection, if after treatment sexual intercourse takes place with an untreated partner/s. ▪ All individuals with confirmed chlamydia infection should be advised to contact their local sexual health clinic for partner notification purposes. ▪ All individuals with confirmed chlamydia infection should be encouraged to be screened for other sexually transmitted infections (STIs). ▪ Offer condoms and advice on safer sex practices ▪ Where treatment not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services. - Sexual Health Clinic Tel No: 0300 123 0994 - Sexual Health Service Information
Follow up treatment	▪ The individual should be advised to seek medical advice in the event of an adverse reaction. ▪ Follow local protocol for Chlamydia follow up and partner notification. ▪ 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. ▪ Routine follow-up/TOC (test of cure) for uncomplicated Chlamydia trachomatis following treatment with doxycycline is unnecessary, except in the following situations: - Where poor compliance is suspected - Where symptoms persist - Rectal infections - Under 25-year-olds - Mycoplasma genitalium infection

Records	In discussion with the individual enter consultation details onto the relevant module within PharmOutcomes or complete the paper proforma if unable to access PharmOutcomes at the time of the consultation. ▪ Informed verbal consent should be obtained. ▪ Consent: - If individual is under 13 years of age record action taken - If individual is under 16 years of age document capacity using Fraser guidelines. If not competent, record action taken. - If individual over 16 years of age and not competent, record action taken. ▪ If a safeguarding referral is made, a record of the referral must be maintained in the pharmacy. ▪ If individual not treated under PGD record action taken ▪ If the individual is excluded, a record of the reason for exclusion must be documented within PharmOutcomes, and any specific advice that has been given. ▪ Name of individual, address, date of birth. ▪ GP contact details where appropriate. ▪ Relevant past and present medical and sexual history, including medication history. ▪ Examination or microbiology finding/s where relevant. ▪ Any known allergies and nature of reaction. ▪ Name of registered health professional. ▪ Name of medication supplied. ▪ Date of supply. ▪ Dose supplied. ▪ Quantity supplied including batch number and expiry date. ▪ Advice given about the medication including side effects, benefits, and when and what to do if any concerns. ▪ Advice given, including advice given if excluded or declines treatment. ▪ Details of any adverse drug reactions and actions taken. ▪ Any referral arrangements made. ▪ Any supply outside the terms of the product marketing authorisation. ▪ Recorded that supplied via Patient Group Direction (PGD) Records should be signed and dated (or a password-controlled e-records) and securely kept for adults for a period of 10 years after attendance and for children until the child is 25 years old. Computerised patient medication records of all individuals receiving treatment under this PGD are recommended to be kept. All records should be clear, legible, and contemporaneous.

Insert logo of authorising body

References

Key references	▪ Electronic Medicines Compendium Home - electronic medicines compendium (emc) ▪ Electronic BNF BNF (British National Formulary) | NICE ▪ NICE Medicines practice guideline "Patient Group Directions" Published: 02 August 2013 Last updated: 27 March 2017 Overview | Patient group directions | Guidance | NICE ▪ BASHH - 2015 UK national guideline for the management of infection with *Chlamydia trachomatis* Chlamydia 2015 | BASHH ▪ BASHH CEG September 2018 – Update on the treatment of *Chlamydia trachomatis* (CT) infection updateonthetreatmentofchlamydiatrachomatisinfectionfinal16918.pdf (bashh.org) ▪ Royal Pharmaceutical Society Safe and Secure Handling of Medicines. Issue date December 2018 Updated: 22 January 2024 Professional guidance on the safe and secure handling of medicines (rpharms.com) ▪ Chlamydia - uncomplicated genital - Last revised in January 2024 Scenario: Management | Management | Chlamydia - uncomplicated genital | CKS | NICE ▪ Treatment summaries Genital system infections, antibacterial therapy | Treatment summaries | BNF | NICE ▪ NHS STW: Microguide Antibiotic Guidance

Glossary	BNF – British National Formulary SPC – Summary of Product Characteristics PIL – Patient Information Leaflet PGD – Patient Group Direction CKS – Clinical Knowledge Summaries BASHH – British Association for Sexual Health and HIV

Date last reviewed: March 2024	**Date for next review:**
Expiry date:	**Version No:** 3.0 / 2024

Insert logo of authorising body

Appendix A – Registered health professional authorisation sheet

Operation of this PGD is the responsibility of the commissioner and service providers.

PGD Name / Version	Supply of doxycycline 100mg capsules for the treatment of uncomplicated Chlamydia trachomatis in Community Pharmacy / Version No: 3.0 / 2024
Valid from	
Expiry	

- This page must be completed and retained by each individual Pharmacist who intends to work in accordance with this PGD.
- The practitioner must be authorised by name, under the current version of this PGD before working according to it.
- Before signing this PGD, practitioners must check that the document has had the necessary authorisations and they are using the correct version. 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.

Professional Responsibility and Declaration

- I have successfully completed the relevant training as outlined in the Service Specification and this Patient Group Direction.
- I agree to maintain my clinical knowledge appropriate to my practice in order to maintain competence to deliver this service.
- I am a registered pharmacist with the General Pharmaceutical Council.
- I confirm that indemnity insurance is in place to cover my scope of practice.
- I confirm that I have read and understood the content of this Patient Group Direction.
- I agree to supply medications listed only in accordance with the PGD.
- I am willing and competent to practise only within the bounds of my own competence and professional code of conduct.

Name	Designation	Signature	Date

Authorising manager

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.

Add details on how this information is to be retained according to organisation PGD policy.