Brighton & Hove City Council

PATIENT GROUP DIRECTION

Doxycycline for the treatment of uncomplicated genital chlamydia trachomatis infection

For the supply of **Doxycycline 100mg on Patient Group Direction (PGD)** by **community pharmacists working within the boundaries of** Brighton & Hove City Council (BHCC) and contracted to provide treatment for chlamydia trachomatis infection as part of the locally commissioned Sexual Health and Contraceptive Service.

Direction no: BH 2018 12

CHANGE HISTORY	
Version/Date	Change details
BH 2018 12	Updated Summary of Product Characteristics (SPC) Updated National Institute for Health and Care Excellence (NICE) Guidance

PGD comes into effect	1st April 2023
PGD review date	1st March 2024
PGD expiry date	31st March 2025

Valid from: 1/4/23
Review date: 1/3/24
Expiry date: 31/3/25
Approving Organisation: BHCC

This PGD template has been developed by the following health professionals on behalf of Brighton & Hove City Council (BHCC):

NAME/ROLE	SIGNATURE	DATE
Dr Nicolas Pinto-Sander Consultant Sexual Health and HIV medicine		19/02/23
Janet Rittman Public Health Pharmacist		1/02/23
Alistair Hill Director of Public Health Brighton & Hove City Council		15/03/23

ORGANISATIONAL APPROVAL

The PGD is not legally valid until it has had the relevant organisational approval.

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.

PGDs do 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 the General Pharmaceutical Council (GPhC) Standards for Pharmacy Professionals and the Pharmaceutical Society of Northern Ireland (PSNI) Code of Ethics for Pharmacists.

No PGD can envisage every clinical situation. Pharmacists are expected to exercise professional judgement and discretion. In any situation where there is a concern a doctor must be consulted.

Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medicines listed only in accordance with the PGD within the specified start and expiry dates. The original copy, signed by all those concerned, should be kept in a designated place within the pharmacy, and be readily accessible for reference and audit purposes.

The pharmacist must work within the service specification agreed between the employing pharmacy and the commissioning organisation.

Patient group direction effective from 1st April 2023
BHCC authorises the use of this document by accredited community pharmacists who are working within the boundaries of Brighton & Hove
DECLARATION: I am a registered pharmacist, employed at

Name of Pharmacy	
Address	
Post Code	

Characteristics of Staff
I have read this Patient Group Direction (PGD) and confirm that: **Qualifications** I am registered with the General Pharmaceutical Council (GPhC) or Pharmaceutical Society of Northern Ireland (PSNI) **Specialist qualifications and competencies** I am competent to provide the Community Pharmacy Sexual Health and Contraceptive service because: • I have completed the accreditation and training requirements detailed in the Sexual Health and Contraceptive Service Specification. • I have completed the **Chlamydia Testing and Treatment Service** Declaration of Competence (DoC) on the Centre for Pharmacist Postgraduate Education (CPPE) website https://www.cppe.ac.uk/services/declaration-of-competence Pharmacists' personalised statement of declaration should be retained, which may need to be provided to commissioners and/or employers when required via the CPPE Viewer. • I have reviewed my competency to operate under this PGD using the NICE Competency Framework for health professionals using patient group directions

- I have completed the mandatory Health Education England Safeguarding Children level 2 and Safeguarding Adults level 2 e-learning for healthcare (this can be accessed through the CPPE website) and passed the associated level 2 assessment within the last 2 years.
- I am aware of local safeguarding policies and contact information.
- I have reviewed the local policies and documentation for this service and references associated with this PGD.
- I am aware that it is my responsibility to keep up to date with changes to the recommendations for this medicine and acknowledge any limitations to my knowledge or competence. I will complete continuing professional development as defined by the GPhC or PSNI and take part in an audit as detailed in the service specification.

Name	GPhC/PSNI registration number	Signature	Date

Authorising manager/pharmacist

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 the Community Pharmacy for the above-named health care professionals who have signed the PGD to work under it.

Name	**Designation**	**Signature**	**Date**

1. Clinical conditions or situation to which this Patient Group Direction applies

1.1 Definition of clinical situation for use	The supply of doxycycline 100mg for the treatment of uncomplicated genital, pharyngeal and/or rectal *Chlamydia trachomatis* infection. Asymptomatic individuals presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of uncomplicated genital, pharyngeal and/or rectal *Chlamydia trachomatis* infection.
1.2 Criteria for inclusion	• Individual (index patient) or sexual contact of individual with a positive, asymptomatic diagnosis of genital chlamydia trachomatis infection evidenced by contact slip, text message or other written confirmation from the Chlamydia Screening Programme (CSP). • Asymptomatic individuals presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of chlamydia who are unwilling 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. • A single repeat treatment course for individuals (or sexual contact of individual) who did not complete the 7-day treatment course. • Individual or sexual contact of individual must be able to give **informed consent** to treatment. Informed consent is the process by which an individual learns about and understands the purpose, benefits, and potential risks of a treatment and then agrees to receive the treatment. • Aged 13 years or over. All individuals under the age of 19 years – follow local young person's risk assessment or equivalent local protocol. • If the individual is under 16 years old, they must be assessed as Fraser competent (see Appendix 1) or if not assessed as Fraser Competent accompanied by one or both parents, or a legal guardian and consents to the treatment being given. • Individual consents to consultation and medication supply by a pharmacist without referral to a doctor.
1.3 Criteria for exclusion	**Personal Characteristics** • Individuals aged under 16 years who are assessed as **not** competent using Fraser Guidelines. • If under 13 years of age, follow the local safeguarding children policy. • Individuals 16 years old over and assessed as lacking capacity to consent. • Individual wishes to see a doctor.

	• Safeguarding or child sexual exploitation (CSE) concerns- refer to section 1.5. **Medical History** • Suspected complicated chlamydia infection. • Confirmed or contact of lymphogranuloma venereum (LGV). • Individual is pregnant or breastfeeding. • Hepatic impairment or those receiving potentially hepatotoxic drugs. • Severe renal impairment. • Presence of urinary symptoms. • Presence of penile discharge, epididymitis or testicular pain • Presence of concomitant conjunctivitis and /or joint pain/swelling. • Fever. • Presence of pelvic pain or suspected pelvic Inflammatory Disease (PID). • Porphyria. • Known Myasthenia Gravis. • Known Systemic Lupus Erythematosis. • Individuals with oesophagitis and oesophageal ulcerations. • Individuals with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency should not take doxycycline. **Medication History** • Known allergy or hypersensitivity to Doxycycline or other tetracycline antibiotics BNF (British National Formulary) | NICE for the full list) or any constituent of the medication refer to the Summary of Product Characteristics (SPC) https://www.medicines.org.uk/emc • Individual taking an interacting medicine. **See section 2.11.**
1.4 CAUTIONS: Need for further advice or action to be taken	• Doxycycline is contraindicated in **pregnancy**. The risks associated with the use of tetracyclines during pregnancy are predominantly due to effects on teeth and skeletal development. • Tetracyclines are excreted into milk and are therefore contraindicated in nursing mothers. (see above about use during tooth/ skeletal development). • Individuals likely to be exposed to direct sunlight or ultraviolet light (sun lamps) should be advised that this reaction can occur with tetracycline drugs and treatment should be discontinued at the first evidence of skin erythema and to contact the Sexual Health and Contraceptive service (SHAC) for further advice. • Visual disturbances such as blurring of vision may occur during treatment with doxycycline and in such cases; individuals must refrain from driving or operating machinery.

	• 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
	• Sexual contacts of the index patient treated under the PGD should be encouraged to consent to their telephone number being shared with the CSP, to enable contact tracing and a follow-up to the treatment. Information shared will be treated confidentially. If the individual does not consent to sharing the information, treatment can still be provided.
	• Sexual contacts of the index patient treated under the PGD should be encouraged to complete a chlamydia test before starting treatment. The test should be completed on the day of the consultation so that treatment can start immediately. See section 2.12.
	• Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.

1.5 Action to be taken if the individual is excluded or declines treatment	• Signpost/refer to Sexual Health and Contraception (SHAC) service or GP as soon as possible with information about further options. Link to SHAC website http://brightonsexualhealth.com • If complicated chlamydia infection or other sexually transmitted infection (STI) suspected refer to SHAC. • A Best Interest assessment should be undertaken by an authorised prescribing practitioner for individuals who lack capacity to consent. http://www.legislation.gov.uk/ukpga/2005/9/contents • If child is < 13 years follow the local safeguarding children policy. • **Safeguarding** (including child sexual exploitation) concerns identified at presentation should be referred to the Brighton and Hove Safeguarding Children Partnership (BHSCP) Home - BHSCP • Follow local safeguarding arrangements for vulnerable adults when appropriate. https://www.brighton-hove.gov.uk/adult-social-care/keep-people-safe/help-adult-risk-abuse-or-neglect. • If the individual declines treatment discuss implications, and the potential consequences of not receiving treatment. Record the declination on PharmOutcomes and inform the CSP. • Document all actions taken.

2. Description of Treatment

2.1 Name, strength & formulation of drug	Doxycycline 100mg or 50mg capsules or 100mg dispersible tablets. Doxycycline 100mg capsules are the preferable formulation however if not suitable for individuals or if medicine shortages occur then doxycycline 50mg capsules or doxycycline 100mg dispersible tablets can be used instead.
2.2 Legal status	Prescription only medicine (POM)
2.3 Storage of products	Medicines must be stored securely according to national guidelines and in accordance with the Summary of Product Characteristics (SPC) Home - electronic medicines compendium (emc)
2.4 Off label use	This medicine can only be supplied according to the SPC. Drugs should be stored according to the conditions detailed in section 2.3. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs 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 administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with the pharmacy/Medicines Management.
2.5 Dose and frequency of administration	• One 100mg capsule/tablet twice a day for 7 days • Two 50mg capsules twice a day for 7 days Take with or after food
2.6 Duration of treatment	7 days
2.7 Quantity to be supplied	7-day supply - appropriately labelled pack of 28x50mg, 14x100mg capsules or 14x100mg dispersible tablets.
2.8 Route of administration	• Oral. • Take with plenty of fluid in either the resting or standing position and well before going to bed to reduce the likelihood of oesophageal irritation and ulceration.

	• If gastric irritation occurs, it is recommended that the capsule is taken with food or milk
2.9 Labelling requirements	• Label as per the legislation for a prescription only medicine (POM) • The patient information leaflet (PIL) must be given to the individual
2.10 Number of times treatment may be administered	• Treatment can be provided once • Individuals that are reinfected before completing the 7-day treatment course or who fail to complete the 7-day course can be supplied a single repeat treatment course
2.11 Identification & Management of Adverse Reactions	A detailed list of adverse reactions is available in the SPC and BNF The following side effects are common with doxycycline (but may not reflect all reported side effects): • Hypersensitivity reactions • Headache • Nausea • Vomiting • Rashes including maculopapular and erythematous rashes, exfoliative dermatitis, erythema. • Photosensitivity skin reactions. In the event of untoward or unexpected adverse reactions: If necessary, seek appropriate emergency advice and assistance. Document in the individual patient medication record and complete incident procedure if adverse reaction is severe (refer to local organisational policy) Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at https://yellowcard.mhra.gov.uk/ The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.

2.12 Drug interactions	**Refer to these sources of information for the full list of drug interactions and for further information:** • Summary of Product Characteristics (SmPC) https://www.medicines.org.uk/emc • British National Formulary (BNF) - current edition Appendix 1 or https://www.bnf.org • Stockley's Drug Interactions https://about.medicinescomplete.com/publication/stockleys-drug-interactions/ All concurrent medications should be reviewed for interactions. **The interactions listed as severe/concurrent use to be avoided in the BNF are**: • Acitretin • Alitretinoin • Isotretinoin • Lithium • Tretinoin A detailed list of all drug interactions is available in the BNF or the product SPC If necessary, access the individuals **NHS Summary Care Record (SCR)** (with consent) if individuals are uncertain about the medications they are taking.
2.12 Written information and further advice to be provided	• Discuss confidentiality and how information will be shared with the CSP. • Advise to swallow the capsules whole with plenty of fluids after food, while sitting or standing and well before bedtime to prevent irritation to the oesophagus. • Do not take indigestion remedies concurrently – avoid antacids and calcium, magnesium and iron salts two hours before and one hour after taking doxycycline. • Individuals likely to be exposed to direct sunlight or ultraviolet light should be advised that this reaction can occur with tetracycline drugs and treatment should be discontinued at the first evidence of skin erythema. Individuals should be advised to avoid exposure to sunlight or sun lamps. • Advise to space doses evenly throughout the day and to keep taking until the 7-day course is finished. • Refer to the PIL explain content and supply a copy • Inform individual of possible side effects and their management. • Individuals should be advised that they will not be clear of chlamydia until the 7-day treatment course has been completed.

	• Discuss implications of incompletely treated/untreated infection of self or partner. • Sexual contact, including oral sex and sex with a condom should be avoided until partner has also completed the 7-day treatment course. • Individuals known to be taking part in high-risk sexual activity should be treated and advised to consult SHAC or GP. • Individuals that develop unusual or persistent side effects or symptoms of sexually transmitted infections should be referred to SHAC or their GP. • Advise individuals (index patient) that the CSP will contact them in 7 days to review the treatment and to discuss partner notifications. Sexual partners in the last 6 months will need to have testing and treatment. • Individuals treated as a sexual contact of an index patient should be given a chlamydia test and advised to complete and return (postal return) to the CSP before starting the treatment. The test should be completed on the day of the consultation so that treatment can start immediately. • Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs) • Refer individuals to the Sexwise website www.sexwise.org.uk website for further information. • Give the individual a CSP treatment information pack (includes chlamydia test, condoms and SHAC contact information).
Advice/follow-up treatment	• Advise all individuals treated to retest for chlamydia in 3 months. • The individual should be advised to seek medical advice in the event of an adverse reaction • 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
Records	Record the consultation and clinical assessment as prompted on the Pharmoutcomes (PO) chlamydia treatment template, including additional notes on the patient medication record (PMR) when necessary. The Pharmoutcomes template will record the following information: • Informed consent of the individual (index patient or sexual contact. • CSP index code • Safeguarding referral if relevant.

	• If consent given to share information: Name, DOB, telephone number. • Relevant past and present medical history including medication history. • If individual is under 16 years of age document competency using Fraser guidelines • If individual is under 13 years of age record action taken. • Drug name, manufacturer of product, batch number and expiry date of product. • Dose and quantity supplied. • Date supplied and by whom. • Advice given to individual (including side effects). • Whether sexual contact was treated today. • Confirmation that advice was given to abstain from all sexual contact until the 7-day treatment is finished. • Details of any adverse drug reaction and action taken. • Any referral arrangements. • For adults all PGD documentation in a patient's clinical record must be kept for 8 years after the last entry. • For children all PGD documentation in a patient's clinical record must be kept until the child is 25 years old or for 8 years after a child's death. All records should be clear, legible, and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

5. References

1. British Association for Sexual Health and HIV (BASHH) guidelines for the management of infection with Chlamydia trachomatis 2015 (updated 26 September 2018) https://www.bashh.org/guidelines
2. National Institute for Health and Care Excellence (NICE) Patient Group Directions (March 2017) https://www.nice.org.uk/Guidance/MPG2
3. The Faculty of Sexual and Reproductive Healthcare (FSRH): Service Standards for Confidentiality in Sexual and Reproductive Health Services (June 2020) https://www.fsrh.org/news/fsrh-publishes-updated-service-standards-for-consultations-in/
4. British National Formulary (BNF) ww.bnf.org.uk
5. Summary of product characteristics (SPC) for Doxycycline 100mg Capsules https://www.medicines.org.uk/emc/product/13082/smpc
6. The Pharmaceutical Society of Northern Ireland (PSNI), The code of ethics for pharmacists in Northern Ireland http://www.psni.org.uk/about/code-of-ethics-and-standards/
7. General Pharmaceutical Council: Standards for Pharmacy Professionals May 2017 https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017_0.pdf
8. Centre for Postgraduate Pharmacist Education (CPPE) Declaration of Competence. https://www.cppe.ac.uk/services/declaration-of-competence
9. NHS Specialist Pharmacy Service. Doxycycline for the treatment of uncomplicated genital chlamydia trachomatis and non-gonococcal/non-specific urethritis: PGD template https://www.sps.nhs.uk/articles/doxycycline-for-the-treatment-of-uncomplicated-genital-chlamydia-trachomatis-and-non-gonococcal-non-specific-urethritis-pgd-template/

Appendix 1

Under 16s- Fraser Guidelines

In England, Wales, and Northern Ireland, in order to provide contraception to young people under 16 years of age without parental consent, it is considered good practice to follow the Fraser Guidelines.

While the Fraser Guidelines below relate specifically to contraceptive advice or treatment, the principles are applicable to other sexual health services for young people under 16. A young person's age should not be a barrier to them accessing condoms.

Competence is demonstrated if the young person is able to:

Understand the treatment, its purpose and nature, and why it is being proposed
Understand its benefits, risks and alternatives
Understand in broader terms what the consequences of the treatment will be
Retain the information for long enough to use it and weigh it up in order to arrive at a decision.

A young person is competent to consent to contraceptive advice or treatment if:

- The young person understands the professional's advice
- The professional cannot persuade the young person to inform their parents or allow the professional to inform the parents that they are seeking contraceptive advice.
- The young person is very likely to begin or continue having intercourse with or without the contraceptive treatment.
- Unless they receive contraceptive advice or treatment, the young person's physical or mental health or both are likely to suffer.
- The young person's best interests require the professional to give contraceptive advice, treatment or both without parental consent.

Reference

- Faculty of Sexual and Reproductive Healthcare Clinical Guideline: Contraceptive Choices for Young People Clinical Effectiveness Unit March 2010 (Amended May 2019)

https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-young-people-mar-2010/