This Patient Group Direction (PGD) must only be used by registered healthcare professionals 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.

PATIENT GROUP DIRECTION (PGD)

For the supply of Doxycycline for the treatment of uncomplicated Chlamydia trachomatis by Registered Nurses and Midwives in BPAS Clinics.

Version Number 2.2

Change History	
Version and Date	Change Details
Version 1.0 April 2020	New template *Version 1.0 not adopted by BPAS*
Version 1.1 May 2020	Minor reordering (content unchanged) *Version 1.1 not adopted by BPAS*
Version 1.2 October 2020	• Removed from criteria for inclusion: Clinical epididymo-orchitis *not relevant to BPAS client group* • Advisory wording added to inclusion criteria section: NOTE – all criteria for inclusion within the BASHH approved national PGD templates for sexual health are based on diagnostic management in line with BASHH guidance. Where services do not have access to diagnostics and treatment is syndromic then the PGD template will need to be locally adapted to reflect local practice being mindful of the BASHH guidance. *Version 1.2 not adopted by BPAS*
Version 2.0 April 2023	Updated template due to expiry – no significant changes to clinical content. *Version 2.0 approved for use in BPAS 03/03/2023* Amendments by BPAS: • References to pharyngeal and rectal Chlamydia trachomatis infection removed as not applicable to BPAS • References to Mycoplasma genitalium removed as not applicable to BPAS • References to non-gonococcal or non-specific urethritis removed as not applicable to BPAS • Equivocal Chlamydia trachomatis result added to inclusion criteria
Version 2.1 July 2023	• Updated exclusion criteria – removed “Sucrose or fructose intolerance, glucose galactose malabsorption, sucrose-isomaltase insufficiency”.
Version 2.2 May 2024	• Removal of equivocal chlamydia result from clinical condition in which to treat • Change exclusion criteria from under 12 years to under 13 years in line with safeguarding guidance

Valid from: 01/08/2024
Review Date: September 2025
Expiry Date: 31/03/2026

N.B. Review and update may occur prior to this period if national guidance changes or legal or clinical issues arise.

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	April 2023
Review date:	September 2025
Expiry date:	March 2026

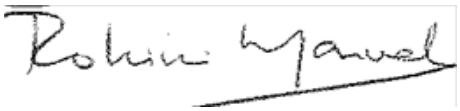
This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by British Association for Sexual Health and HIV (BASHH)/BASHH Bacterial Special Interest Group (BSIG) in January 2023.

This section MUST REMAIN when a PGD is adopted by an organisation.

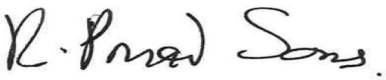
Name	Designation
Ali Grant	Highly Specialist Clinical Pharmacist: HIV, Sexual and Reproductive Health
Alison Crompton	Community pharmacy
Andrea Smith	Community pharmacy
Carmel Lloyd	Royal College of Midwives
Chetna Parmar	Pharmacist adviser, Umbrella
Clare Livingstone	Royal College of Midwives
Deborah Redknapp	English HIV and Sexual Health Commissioners Group (EHSHCG)
Dipti Patel	Local authority pharmacist
Dr Achyuta Nori	Consultant in Sexual Health and HIV
Dr Cindy Farmer	Vice President, General Training Faculty of Sexual and Reproductive Healthcare (FSRH)
Dr John Saunders	Consultant in Sexual Health and HIV
Dr Kathy French	Pan London PGD working group
Dr Rachael Jones	Consultant in HIV and Sexual Health, Chelsea and Westminster NHS Foundation Trust
Dr Rita Browne	Consultant in Sexual Health and HIV
Dr Sarah Pillai	Associate Specialist Sexual Health
Emma Anderson	Centre for Pharmacy Postgraduate Education (CPPE)
	Royal College of Nursing
Jo Jenkins (Working Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms, Specialist Pharmacy Service
Jodie Crossman	Specialist Nurse. BASHH SHAN SIG Chair
Belinda Loftus	Specialist Nurse, BASHH Board Nurse Representative, BASHH SHAN SIG Secretary
Portia Jackson	Pharmacist, Cambridgeshire Community Services
Sally Hogan	British Pregnancy Advisory Service (BPAS)
Sandra Wolper	Associate Director Specialist Pharmacy Service
Tracy Rogers	Associate Director Specialist Pharmacy Service

BPAS PGD Organisational Authorisations:

This PGD is not legally valid until it has had the relevant organisational authorisations below.

Name	Job title and organisation	Signature	Date
Mary Sexton	BPAS Clinical Director		19/08/2024
Dr Julie Miller	BPAS Deputy Medical Director		16/08/2024
Kalpesh Thakrar	BPAS Lead Pharmacist		30/08/2024
Prof Rohini Manuel	BPAS Consultant Microbiologist		29/08/2024

Authorising Body:

Cheshire and Merseyside ICB	*Rowan Pritchard -Jones*		*07/11/2024*

Responsible person who has approved this PGD on behalf of BPAS

Name: Heidi Stewart

Position: Executive Chair

Signature: 

Date: 22/08/2024

Glossary	
BPAS	British Pregnancy Advisory Service
BASHH	British Association for Sexual Health and HIV
BLS	Basic life support
BNF	British National Formulary
GUM	Genitourinary medicine
MHRA	Medicines Health Regulatory Agency
NICE	National Institute for Health and Care Excellence
NMC	Nursing and Midwifery Council
SmPC	Summary of medicinal product characteristics
STI	Sexually transmitted infection
TTO	To take out

1. Characteristics of staff authorised to use this PGD:	
Qualifications and professional registration	• NMC Registered Nurse • NMC Registered Midwife With a current contract of employment with BPAS Practitioners must also fulfil the additional requirements listed below.
Initial training	Pharmacological knowledge relating to the administration and supply of the medicine, its uses, contraindications, dosage and adverse effects Additionally, practitioners: • Must have completed appropriate training for working under a PGD for the supply / administration of medicines (see training requirements in the BPAS PGD policy) • Must be familiar with the medicine and observant to changes in the BNF and Summary of Product Characteristics (SmPC) • Must be competent in the recognition and management of adverse reactions, including anaphylaxis • Must be competent in the administration of adrenaline for anaphylaxis and have up to date Basic Life Support (BLS) skills as a minimum • Must have access to the PGD and associated online resources • Must have completed BPAS STI Training available on MAX Learning • Further recommended training: e-Learning for Health e-Sexual and Reproductive Health 9. STIs • Must have completed required training (including updates) in safeguarding children and vulnerable adults **The practitioner must be authorised by name, under the current version and terms of this PGD in the Approved Practitioner List before working to it.**
Competency Assessment	Practitioners working under this PGD are required to review their own competency using the NICE Competency Framework for Health Professionals using Patient Group Directions Practitioners working under this PGD must be assessed as competent or complete a self-declaration of competence to use this PGD (see appendix A). **Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.**
Ongoing training and competency	• Practitioners must complete 3-yearly PGD Theory Refresher training and competency assessment • Practitioners working under this PGD are responsible for ensuring they remain up to date with the use of the medicines and guidance included in the PGD, ensuring any training needs identified are addressed with further training • Practitioners must make sure they are aware of any changes to the recommendations for this medication • Practitioners must ensure they remain up to date with relevant clinical skills, management of anaphylaxis, BLS (as a minimum), with evidence of continued professional development

	• Practitioners are responsible for maintaining their competency to work under this PGD
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policy.	

2. Clinical condition or situation to which this PGD applies:	
Clinical condition or situation to which this PGD applies	First line treatment for individuals with • Confirmed uncomplicated genital *Chlamydia trachomatis* infection

Inclusion criteria	• Individuals with a positive test for Chlamydia trachomatis infection **and** who are asymptomatic
	• Informed consent given
	• Aged 13 years and over (On or after the day of their 13th birthday)
	  ○ All individuals under the age of 18 and vulnerable adults must be appropriately risk assessed and managed in line with BPAS Safeguarding and Management of Clients Aged under 18 and BPAS Safeguarding Adults policies
	  ○ If the individual is less than 13 years of age, the healthcare professional must liaise with the BPAS Safeguarding Team and refer to the BPAS Safeguarding and Management of Clients Aged under 18

Exclusion criteria	• Consent not given • Individuals under 13 years of age • Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines • Individuals 16 years of age and over and assessed as lacking capacity to consent ○ These individuals may still be able to receive treatment, but they must be referred to a prescriber to assess suitability and obtain a patient specific direction • Individuals not suitable for treatment at BPAS *(N.B. please refer to BPAS suitability criteria)* **Medical history** • Individuals with clinical proctitis or confirmed PID • Individuals with confirmed Lymphogranuloma venereum (LGV) or a contact of LGV • Breastfeeding • Currently pregnant – refer instead to Azithromycin for the treatment of uncomplicated Chlamydia trachomatis PGD • Known hepatic impairment • Presence of concomitant conjunctivitis and/or joint pain/swelling • Acute porphyria *(N.B. porphyria is a contraindication to treatment at BPAS – please refer to the BPAS Treatment Suitability Tool)* • Myasthenia gravis • Systemic Lupus Erythematosus (SLE) • Individuals with oesophagitis and oesophageal ulcerations **Medication history** • Any concurrent interacting medicine(s) – see 'Drug Interactions' section • Known allergy or hypersensitivity to doxycycline, other tetracycline antibiotics or to any component of the product - see Summary of Product Characteristics (SmPC)

Cautions/Circumstances in which further advice should be sought from a doctor (including any relevant action to be taken)	• If the individual is less than 16 years of age, an assessment based on Fraser guidelines must be made and documented
	• If the presenting individual is under 13 years of age the healthcare professional must speak to the Safeguarding team and follow the BPAS policy for local safeguarding policy for Safeguarding and Management of Clients Aged under 18 (note under 13 years of age excluded from treatment under this PGD).
	• If not already excluded from treatment at BPAS (refer to BPAS Treatment Suitability Tool), 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
	• Discuss any medical condition or medication of which the healthcare professional if unsure or uncertain with a clinic doctor and if not available, with a Regional Clinical Director

Action to be taken if the individual is excluded	• 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). • Explain and document reasons for exclusion in the individual's clinical record • Consider if Azithromycin can be used (separate PGD) • If the test results are equivocal, arrange a retest or refer to local NHS sexual health or GUM services. • Discuss with a clinic doctor, if not available, discuss with a Regional Clinical Director or refer to local NHS sexual health or genitourinary medicine (GUM) services as clinically indicated • Document advice given in the individual's clinical record
Action to be taken if the individual or carer declines treatment	• Ensure the individual is aware of the need for treatment and the potential consequences of not receiving treatment, including not being able to have an abortion procedure • If provided by the individual, document the reasons for declining in the individual's clinical record • Consider if Azithromycin can be used (separate PGD) • Discuss with a clinic doctor, if not available, discuss with a Regional Clinical Director or refer to local NHS sexual health or GUM services as clinically indicated • Document advice given in the individual's clinical record
Arrangements for referral for medical advice	• Inform and discuss with the doctor in clinic. If not available, discuss with either a regional clinical director or refer to local NHS sexual health or GUM services as clinically indicated • In the event of a medical emergency, e.g., anaphylaxis, provide immediate care in line with UK Resuscitation Council guidance, dial 999 to summon a paramedic response and initiate emergency transfer to NHS care • Document findings/action taken in individual's record

3. Description of treatment:	
Name, strength and formulation medicine	Doxycycline 50mg or 100mg capsules

Legal category	POM
Route / method of administration	Oral
Indicate any off-label use (if relevant)	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 administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with 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
Total quantity to be administered or quantity to be supplied as TTO	7-day supply of appropriately pre-labelled TTO pack(s) containing a total quantity of: Either: • 28 x 50mg capsules OR • 14 x 100mg capsules
Storage	Stock must be securely stored in accordance with the BPAS Medicines Management policy and in conditions in line with the SmPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk

Drug interactions	All concurrent medications must be checked for interactions. The following interactions have been identified as clinically significant:
	
	• Lithium
	• Barbiturates
	• Retinoids, including:
	  ○ Acitretin
	  ○ Alitretinoin
	  ○ Isotretinoin
	  ○ Tretinoin
	• Ciclosporin
	• Methotrexate
	• Antiepileptics (carbamazepine, phenytoin and primidone)
	• Rifampicin
	• Anticoagulants
	• Strontium ranelate
	
	A detailed list of drug interactions is available from the BNF and in the SmPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk

Identification and management of adverse reactions	A detailed list of adverse reactions is available in the SmPC and BNF The following side effects are reported as common in the doxycycline SmPC 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 If necessary, seek appropriate emergency medical advice and assistance.
Management and reporting procedure for adverse reactions	Document any adverse effects in the individual's clinical records. If necessary, seek appropriate emergency medical advice and assistance as clinically indicated. Serious adverse drug reactions should be reported to the MHRA via https://yellowcard.mhra.gov.uk/ Adverse drug reactions must also be reported via Datix, including drug name, strength, formulation, batch numbers and expiry dates.
Written information and further advice to be given to the individual or carer	**Medication:** • Give patient information leaflet (PIL) provided with the original pack. Explain mode of action, side effects, and benefits of the medicine • 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 not to take antacids or preparations containing calcium, iron, zinc and magnesium salts at the same time as doxycycline, including those medications purchased. • Advise to avoid exposure to direct sunlight or ultraviolet light **Condition:** • Verbal and written information on *Chlamydia trachomatis* treatment • 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. • Discuss risk of re-infection, and further transmission of infection, if after treatment sexual intercourse takes place with an untreated partner/s • Discuss partner/s notification and issue contact slips if appropriate • Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs) • Where treatment not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services. **Additional information:**

	• Provide BPAS guide to STI testing booklet and relevant BPAS individual information booklet relevant to their treatment, including Aftercare information

Follow-up advice to be given to the individual or carer	• Inform the individual/carer of possible side effects and their management
	• The individual/carer should be advised to seek medical advice in the event of an adverse reaction
	• Follow BPAS Sexually Transmitted Infection Testing and Results policy for managing individuals and partner notifications appropriately
	• 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 for uncomplicated Chlamydia following treatment with doxycycline is not necessary but follow up and referral may be required for individuals:
	  ○ Who become symptomatic or where symptoms persist
	  ○ Where poor compliance is suspected

Records to be kept	The following must be recorded in the client records in line with the NMC Code and BPAS' Record Keeping policy, using black ink if written:
	• The consent of the individual and
	  ○ 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 individual not treated under PGD, record action taken
	• Individual's name, date of birth, any known allergies
	• Indications for use, patient inclusion or exclusion from PGD, relevant past and current medical and sexual history, including medication history
	• Name of medication, dose and quantity supplied
	• Date and time of supply
	• Batch number and expiry date
	• Any actions taken following supply Signature, printed name and designation of registered health professional supplying and detail of double checking, if required
	• 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
	• Detail that medicine supplied / administered using a PGD
	
	Records should be signed and dated (or a password-controlled e-records) and securely kept for a defined period in line with local policy.
	
	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.

4. References and other source material:

- 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
- Electronic Medicines Compendium www.medicines.org.uk
- Electronic BNF https://bnf.nice.org.uk/
- NICE, 2017. Medicines practice guideline Patient Group Directions www.nice.org.uk/guidance/mpg2
- 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
- UK Resuscitation Council, 2021. Adult basic life support Guidelines | Resuscitation Council UK

5. Audit and ongoing monitoring of this PGD

Please refer to the 'Audit' section of the BPAS Patient Group Direction policy for additional guidance in relation to PGD audit.

The PGD audit tool is available here: British Pregnancy Advisory Service - Audit Tools - All Documents (sharepoint.com).

Units must retain a local copy of the completed audit tool as evidence.

The PGD audit criteria include:

1. Staff member has named, dated and signed the relevant PGD document
2. Individual is documented as being referred to a medical practitioner if they are excluded from treatment under the PGD and there is no suitable alternative.
3. Date and time of supply / administration is on the prescription record / CAS2.
4. Individual details – name, date of birth, allergies and any previous adverse effects are on the prescription record / CAS2.
5. Details of the medicine – name, strength, dose frequency, quantity, route and site (if by injection) of administration are on the prescription record / CAS2.
6. A statement that supply or administration is by using a PGD is on the prescription record / CAS2.
7. Name and signature (which may be electronic for CAS2 records) of the health professional supplying or administering the medicine is on the prescription record / CAS2.
8. Relevant information was provided to the individual or their carer.
9. Individual not documented to be allergic to the drug.
10. Paper documentation in related to PGDs are in black ink only.
11. Where appropriate for the medication, correct scheduling has been discussed.
12. Individual does not meet any exclusions or contraindications listed in the most up to date PGD.

Appendix A: Approved Practitioner List

Patient Group Direction (PGD) name:	Supply of Doxycycline for the treatment of uncomplicated Chlamydia trachomatis by Registered Nurses and Midwives in BPAS Clinics v 2.2	
	Valid from: 01/08/2024	**Expiry: 31/03/2026**

Registered health professional

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove 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. The practitioner MUST sign this document before they can work under this PGD.

I confirm that I have read and understood the contents of this PGD. I confirm that I am willing and competent to work to this PGD within my professional code of conduct.				
Name (print)	**Designation**	**NMC PIN**	**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 for the above-named health care professionals who have signed the PGD to work under it.				
Name	**Position**	**BPAS Treatment Unit**	**Signature**	**Date:**

Note to authorising manager

- Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.
- If registered health professional signatures need to be added at a later date, e.g. due to staffing changes, a separate Approved Practitioner List must be signed, ensuring the correct PGD name and version is detailed.
- This authorisation sheet should be retained, as specified in the BPAS PGD policy, to serve as a record of those registered health professionals authorised to work under this PGD.
- This list must be stored by the Treatment Unit in a designated folder and be available for immediate inspection, alongside any training / competency records. If a registered professional works across multiple sites, they must sign the Approved Practitioner List for each PGD at each BPAS site where they will use the PGD.