



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* in community pharmacies within Bristol, North Somerset and South Gloucestershire

Version Number 1.2

Change History	
Version and Date	Change details
Version 1 April 2020	New template
Version 1.1 May 2020	Minor reordering (content unchanged)
Version 1.2 October 2020	Removed from criteria for inclusion: <i>Clinical epididymo-orchitis (where the practitioner is competent in management of men with testicular pain) and individuals who present with clear penile discharge where there is no access to microscopy facilities to diagnose NSU/NGU.</i> 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.
Minor amendments May 2021	Correction of spelling in interactions section – acretin amended to acitretin

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	Exclusion criteria - Glucose galactose intolerance amended to Glucose galactose malabsorption Removed from Clinical condition or situation to which this PGD applies and PGD title - clinical epididymo-orchitis
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PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	1 st April 2020
Review date	October 2022
Expiry date:	31 st March 2023

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 October 2020.

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
Amanda Cooper	Associate Director Specialist Pharmacy Service
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 (EHSCHG)
Dipti Patel	Local authority pharmacist
Dr Achyuta Nori	Consultant in Sexual Health and HIV
Dr Cindy Farmer	Chair General Training Committee, Faculty of Sexual and Reproductive Healthcare (FSRH)
Dr John Saunders	Consultant in Sexual Health and HIV

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Dr Kathy French	Pan London PGD working group
Dr Rita Browne	Consultant in Sexual Health and HIV
Dr Sarah Pillai	Pan London PGD working group
Emma Anderson	Centre for Pharmacy Postgraduate Education (CPPE)
Helen Donovan	Royal College of Nursing
Jo Jenkins (Working Group Co-ordinator)	Specialist Pharmacist (PGDs) Specialist Pharmacy Service
Jodie Crossman	Specialist Nurse. BASHH SHAN SIG Chair
Jodie Walker- Haywood	Specialist Nurse, BASHH Board Nurse Representative, BASHH SHAN SIG Secretary
Leanne Bobb	English HIV and Sexual Health Commissioners Group (EHSCHG)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Portia Jackson	Pharmacist, Cambridgeshire Community Services
Sally Hogan	British Pregnancy Advisory Service (BPAS)
Sandra Wolper	Associate Director Specialist Pharmacy Service
Silvia Ceci	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service
Tracy Rogers	Associate Director Specialist Pharmacy Service

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ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Dr Cindy Farmer	Education and Training Lead for Unity Sexual Health		22/09/2021
Debbie Campbell	Deputy Director (Medicines Optimisation) NHS BNSSG CCG		30/09/2021
Senior representative of professional group using the PGD	Michelle Jones Senior Medicines Optimisation Pharmacist (Bristol)		28/09/2021
Public Health Representative in Bristol City Council	Christina Gray Director of Public Health for Bristol		18/10/21
Public Health Representative in North Somerset Council	Matt Lenny Director of Public Health for North Somerset		11/10/21
Public Health Representative South Gloucestershire Council	Prof. Sara Blackmore Director of Public Health for South Gloucestershire		19/10/21

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1. Characteristics of staff

Qualifications and professional registration	Registered pharmacist with current GPhC registration. Currently employed or working as a locum pharmacist in a community pharmacy in Bristol, North Somerset or South Gloucestershire
Initial training	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. The healthcare professional must have completed the CPPE Safeguarding Children and adults e-learning and e-assessment module within the last 2 years
Competency assessment	<ul style="list-style-type: none"> • Individuals operating under this PGD must complete a self-declaration of competence for Chlamydia testing and/or treatment. • Staff 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	<ul style="list-style-type: none"> • Individuals operating under this PGD are personally responsible for ensuring 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 discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

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2. Clinical condition or situation to which this PGD applies

<p>Clinical condition or situation to which this PGD applies</p>	<ul style="list-style-type: none"> • Individuals who have a positive genital chlamydia result following screening by the Unity Chlamydia Screening Service. • Sexual contact of a client with a positive genital chlamydia result diagnosed through the Unity Chlamydia Screening Service.
<p>Criteria for inclusion</p>	<ul style="list-style-type: none"> • Consent given. • Individuals with a positive test for <i>Chlamydia trachomatis</i> infection in the genitals, rectum or pharynx who have been referred by Unity Sexual Health chlamydia screening service • Asymptomatic individuals of sexual contact requiring treatment and referred by Unity Sexual Health Screening Service • In a female-bodied individual where the risk of pregnancy is nil or negligible¹. • 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 who have been referred by Unity Sexual Health Screening Services. • Aged between 13 years and up to and including 24 years. All individual under the age of 18 years - follow local young person's risk assessment or equivalent local process. • In exceptional circumstances, the pharmacist may use their professional judgement to supply to a patient aged 25 years or above provided the patient meets the PGD requirements and has been referred by the Unity Chlamydia Screening

¹ Publications from the FFPRHC CEU refer to being

“Reasonably certain the woman is not pregnant” and define this as

“has not had intercourse since the last normal menses;

has been correctly and consistently using a reliable method of contraception;

is within the first 7 days of the onset of a normal menstrual period;

is within 4 weeks postpartum for non-lactating women;

is within the first 7 days post-abortion or miscarriage;

is fully or nearly fully breastfeeding, amenorrhoeic and <6 months postpartum.

Pregnancy testing if available adds weight to the exclusion of pregnancy but only if ≥ 3 weeks since the last episode of unprotected sexual intercourse”.

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	Programme
Criteria for exclusion	<ul style="list-style-type: none">• The pharmacy has not received confirmation from Unity Screening Office that the individual has tested positive for <i>Chlamydia trachomatis</i>• The pharmacy has not received confirmation that the individual is a sexual contact of a client with a positive chlamydia result diagnosed through the Unity Screening Service.• If the chlamydia Unity Screening Office have determined that azithromycin is the treatment to be used in this client, please refer to the PGD for the supply of azithromycin• 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.
Criteria for exclusion continued	<p>Medical history</p> <ul style="list-style-type: none">• Individuals with clinical proctitis or PID• Individuals with confirmed Lymphogranuloma venereum (LGV) or a contact of LGV.• Breast feeding• Known pregnancy• Known hepatic impairment• Known severe renal impairment• Presence of concomitant conjunctivitis and/or joint pain/swelling• Acute porphyria• Myasthenia gravis• Systemic Lupus Erythematosus (SLE)• Individuals with oesophagitis and oesophageal ulcerations.• Sucrose or fructose intolerance.

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	<ul style="list-style-type: none">• Glucose galactose malabsorption• Sucrose-isomaltase insufficiency.• Known or suspected alcohol dependency <p>Medication history</p> <ul style="list-style-type: none">• Any concurrent interacting medicine(s) – see Section 4 Drug interactions• Known allergy or hypersensitivity to doxycycline, other tetracycline antibiotics or to any component of the product - see Summary of Product Characteristics
<p>Cautions including any relevant action to be taken</p> <p>Cautions including any relevant action to be taken continued</p>	<ul style="list-style-type: none">• 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 should speak to local safeguarding lead and follow the local safeguarding policy (note under 13 years of age excluded from treatment under this PGD).• Photosensitivity manifesting with exaggerated sunburn is a known side effect of doxycycline. Patients likely to be exposed to direct sunlight or ultraviolet light should be advised that this reaction can occur and that treatment should be discontinued at the first evidence of skin erythema. Patients should be advised to use sunscreens of an appropriate factor and given advice on avoidance of sun exposure.• Oesophagitis and oesophageal ulceration has been reported in patients taking doxycycline. This can be mitigated by taking with sufficient fluid and avoiding taking doses immediately before going to bed.• Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain. <p>Interacting medications and actions</p> <ul style="list-style-type: none">• There have been reports of prolonged prothrombin time in patients taking warfarin and doxycycline. Tetracyclines depress plasma prothrombin activity. Considering referring patient for INR monitoring

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	<ul style="list-style-type: none">• The absorption of doxycycline may be impaired by concurrently administered antacids containing aluminium, calcium, magnesium or other drugs containing these cautions; oral zinc, iron salts or bismuth preparations. Dosages should be maximally separate
Action to be taken if the individual is excluded or declines treatment	<ul style="list-style-type: none">• If declined ensure individual is aware of the need for treatment and the potential consequences of not receiving treatment.• Contact the Chlamydia Screening Office (0117 342 9600) to advise them that the patient is excluded under this PGD• Explain the reasons for exclusion to the individual and document in the consultation record.• Record reason for decline in the consultation record.• Consider if azithromycin can be used (see separate PGD).• Where required refer the individual to Unity sexual health screening service, clinic or GP if appropriate and/or provide them with information about further options.

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3. Description of treatment

Name, strength & formulation of drug	Doxycycline 50mg or 100mg capsules
Legal category	POM
Route of administration	Oral
Off label use	<p>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.</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>
Dose and frequency of administration	100mg twice daily
Duration of treatment	7 days
Quantity to be supplied	7 day supply - appropriately labelled pack of 28x50mg, 14x100mg capsules
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	<p>All concurrent medications should be reviewed for interactions.</p> <p>The interactions listed as severe/concurrent use to be avoided in the BNF are:</p> <ul style="list-style-type: none">• Acitretin

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	<ul style="list-style-type: none"> • Alitretinoin • Isotretinoin • Lithium • Tretinoin • Barbituates • Carbamazepine • Phenytoin • Penicillin antibiotics • Methoxyflurane • Ergotamine • Ciclosporin • Drugs that induce hepatic enzymes such as rifampicin • Quinapril <p>A detailed list of all drug interactions is available in the BNF or the product SPC</p>
<p>Identification & management of adverse reactions</p>	<p>A detailed list of adverse reactions is available in the SPC and BNF</p> <p>The following side effects are common with doxycycline (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> • Hypersensitivity reactions • Headache • Nausea • Vomiting • Rashes including maculopapular and erythematous rashes, exfoliative dermatitis, erythema. • Photosensitivity skin reactions.
<p>Management of and reporting procedure for adverse reactions</p>	<ul style="list-style-type: none"> • 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 • Advise the client to contact their GP or a sexual health clinic if

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	<p>the client experiences any adverse effects to the treatment.</p> <ul style="list-style-type: none"> Record all adverse drug reactions (ADRs) in the patient's medical record. Report via organisation incident policy. <p>Anaphylaxis</p> <p>Before administering any medication, the possibility of anaphylaxis must be considered, and appropriate medical treatment should be available for immediate use in case of anaphylactic reactions.</p> <p>For further information, please see the resuscitation council guidelines.</p> <p>http://www.resus.org.uk/pages/glalqos.htm</p> <p>http://www.resus.org.uk/pages/reaction.pdf</p>
<p>Written information and further advice to be given to individual</p>	<p>Medication:</p> <ul style="list-style-type: none"> 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. Advise to avoid exposure to direct sunlight or ultraviolet light. If vomiting occurs after taking a dose of doxycycline advise individual to contact the chlamydia screening service for advice on 0117 342 6900 In females taking oral contraceptives, if they do experience vomiting or diarrhoea after taking doxycycline, this may lead to contraceptive failure. They should refer to the instruction leaflet that comes with their oral contraceptive pill, to minimise the risk of contraceptive failure. There is no interaction between doxycycline and oral contraceptives; the warning is related to risk of vomiting/diarrhoea after taking doxycycline

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<p>Written information and further advice to be given to individual continued</p>	<p>Condition:</p> <ul style="list-style-type: none"> • Individuals should be offered verbal, written and/or digital information on their diagnosis and management (Information on Chlamydia and other sexually transmitted diseases is available from: http://www.fpa.org.uk/helpandadvice/sexuallytransmittedinfectionsstis/chlamydia) • Discuss implications of incompletely treated/untreated infection of self or partner. The importance of sexual partner(s) being evaluated and treated should be highlighted. • 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) • Advise the patient to contact the sexual health clinic in 5 weeks for a retest
<p>Follow up treatment</p>	<ul style="list-style-type: none"> • The individual should be advised to contact Unity Sexual Health Service for a retest after 5 weeks • The individual should be advised to seek medical advice in the event of an adverse reaction. • If clients cannot be treated under this PGD, they should be referred back to the Unity Chlamydia Screening Office (0117 342 6900), or their GP, or a Unity Sexual Health Service • Routine follow-up for uncomplicated Chlamydia following treatment with doxycycline is unnecessary. Follow advice from Unity Chlamydia Screening Service in the following situations: <ul style="list-style-type: none"> ○ Where poor compliance is suspected. ○ Where symptoms persist. ○ Rectal infections

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Records	<p>Record the supply in the patient's medication records, and the below information onto PharmOutcomes in line with the service protocol. Following the PharmOutcomes template will result in all of the required information being recorded</p> <p>Record:</p> <ul style="list-style-type: none">• The consent of the individual and<ul style="list-style-type: none">○ 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• 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 in line with local procedures.• 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

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	<ul style="list-style-type: none"> • Any supply outside the terms of the product marketing authorisation • Recorded that supplied via Patient Group Direction (PGD) <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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4. Key references

Key references (accessed February 2020)	<ul style="list-style-type: none"> • BNSSG Primary Care Antimicrobial Guidelines v8.1 2021 https://remedy.bnssgccg.nhs.uk/formulary-adult/local-guidelines/5-infections-guidelines/ • Electronic Medicines Compendium 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 <i>Chlamydia trachomatis</i> (CT) infection https://www.bashhguidelines.org/media/1191/update-on-the-treatment-of-chlamydia-trachomatis-infection-final-16-9-18.pdf • BASSH UK National Guideline on the • management of non-gonococcal urethritis
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	<p>www.bashhguidelines.org/media/1051/ngu-2015.pdf;</p> <ul style="list-style-type: none">• British Association for Sexual Health and HIV national guideline for the management of infection with <i>Mycoplasma genitalium</i> www.bashhguidelines.org/media/1198/mg-2018.pdf• 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
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Appendix A - Registered health professional authorisation sheet

PGD Name/Version: Doxycycline Valid from: October 2021 Expiry: 31/03/2023

Before signing this PGD, check that the document has had the necessary authorisations. 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.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

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.			
Name	Designation	Signature	Date

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