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* infection and asymptomatic *Chlamydia trachomatis* infection by registered pharmacies in Suffolk

Version Number 1.3

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: *Clinical epididymo-orchitis (where the practitioner is competent in management of men with testicular pain) and*

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	individuals who present with clear penile discharge where there is no access to microscopy facilities to diagnose NSU/NGU. 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.*
1.3 Minor amendments May 2021	Correction of spelling in interactions section – acretin amended to acitretin. 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

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	1st April 2020
Review date	October 2022
Expiry date:	31st 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 (EHSHCG)
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

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 (Woking 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 (EHSHCG)
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

PGD Development

Name	**Job title and organisation**	**Signature**	**Date**
Tim Meadows	Medicines Information Pharmacist, Midlands and East Medicines Advice Service		07/09/21
Sharna Allen	Health Improvement Commissioner, Public Health Suffolk		17/06/21
Tania Farrow	Chief Officer, Suffolk Local Pharmaceutical Committee		18/06/21

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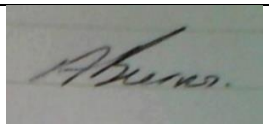
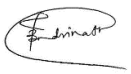
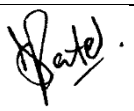
Alison Amstutz	Senior Health Improvement Commissioner, Public Health Suffolk		
Nettie Burns	Clinical Governance and Quality Manager, Public Health Suffolk		**18/06/2021**

ORGANISATIONAL AUTHORISATIONS

Role	Name	Job title and organisation	Signature	Date
Senior doctor	Dr Padmanabhan Badrinath	Consultant in Public Health Medicine, Suffolk County Council		18/06/21
Senior pharmacist	Dipti Patel	Pharmaceutical adviser		14/09/21
Person signing on behalf of authorising body	Stuart Keeble	Director of Public health, Suffolk County Council		21/09/21

1. Professional Qualifications

Reference Number: PGD 139

Valid from: 1st July 2021

Review date: October 2022

Expiry date: 31 March 2023

Qualifications and professional registration	Community Pharmacists currently registered with the General Pharmaceutical Council (GPhC), who are working in a pharmacy contracted to the authorising body. Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
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. Recommended requirement for training would be successful completion of a relevant sexual health module/course accredited or endorsed by the BASHH, CPPE, RCN or a university or advised in the RCN Sexual Health Education directory. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults.

Competency assessment	The registered health professional operating under this PGD:
	• must complete the CPPE self-declaration of competence for chlamydia testing and treatment services (https://www.cppe.ac.uk/services/docs/chlamydia%20testing%20and%20treatment.pdf)
	• Must be able to satisfy the requirements of the self-declaration of qualifications and competence to deliver sexual health services according the following CPPE programmes:
	  ○ Sexual Health in Pharmacies
	  ○ Safeguarding Children and Vulnerable Adults
	• Must demonstrate an appropriate level of understanding and knowledge as detailed in the NICE Competency Framework for health professionals using patient group directions
	• Must have read and understood the context and content of this PGD

Ongoing training and competency	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 and should undertake additional training as appropriate when a training need is identified. • Should undertake regular training and updates in safeguarding children and / or vulnerable adults. • A record of training and competence must be maintained

The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.

2. Clinical condition or situation to which this PGD applies.

Clinical condition or situation to which this PGD applies	• Asymptomatic individuals with laboratory confirmed genital *Chlamydia trachomatis* infection (the index case) • Asymptomatic sexual contacts of the above. NB: Contacts must present in person to be treated under this PGD. • Individuals with an uncomplicated, laboratory confirmed genital *Chlamydia trachomatis* infection
Criteria for inclusion	• Asymptomatic individuals with a positive test for *Chlamydia trachomatis* infection in the genitals, rectum or pharynx. • Individuals with a positive test for uncomplicated *Chlamydia trachomatis* infection in the genitals, rectum or pharynx. • Asymptomatic individuals presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of chlamydia, NSU/NGU PID or epididymo-orchitis who are unwilling/unable to defer testing after the 2-week window period. • Consent given. • Aged 13 years and over. All individual under the age of 19 years - follow local young person's risk assessment or equivalent local process.
Criteria for exclusion	**NB: Patients excluded from this PGD must be referred promptly to the local Sexual Health Service.** • 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. **Medical history** • 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. • Glucose galactose malabsorption Sucrose-isomaltase insufficiency. **Medication history** • 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
Cautions 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 should speak to local safeguarding lead and follow the local safeguarding policy (note under 13 years of age excluded from treatment under this PGD). Information on referral to the local safeguarding team should be recorded via PharmOutcomes using the under 13's pathway template. • Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.
Action to be taken if the individual is excluded or declines treatment	• Patients excluded from the PGD must be referred to the local sexual health service as promptly as possible as per the local chlamydia treatment pathway which can be found on Pharmoutcomes. • Explain the reasons for exclusion to the individual and document reasons for exclusion and action taken on the PharmOutcomes service template associated with the referral.

	• If declined ensure individual is aware of the need for treatment and the potential consequences of not receiving treatment. • Record reason for decline and actions taken on the PharmOutcomes service template associated with the referral. Where required refer the individual to a suitable health service provider (e.g. iCaSH or registered GP surgery) if appropriate and/or provide them with information about further options.

3. Description of treatment

Name, strength & formulation of drug	Doxycycline 50mg or 100mg capsules or 100mg dispersible tablets. NB: The treatments in this PGD are written according to national BASHH guidance, however the healthcare professional should also refer to the local formulary or other local supporting guidance for selection of the most appropriate preparation for the individual.
Legal category	POM
Route of administration	Oral
Off label use	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
Quantity to be supplied	7-day supply - appropriately labelled pack of 28x50mg, 14x100mg capsules or 14x100mg dispersible tablets.

Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	All concurrent medications should be reviewed for interactions. The interactions listed as severe 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
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.
Management of and reporting procedure for adverse reactions	• 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 adverse drug reactions (ADRs) in the patient's medical record. • All incidents and near misses must be reported via Pharmoutcomes in accordance with the Suffolk County Council Public Health Serious Incident Reporting 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 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. • Advise to complete the whole course. • Advise to avoid alcohol for the duration of treatment. **Condition:** • Verbal and written information on *Chlamydia trachomatis*/ *Mycoplasma genitalium*/NGU/NSU treatment (available here). • 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 advise that any contacts should contact iCaSH directly if they are symptomatic, or access STI screening via the iCaSH online Express Test service if asymptomatic. • 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.
Follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction. • Follow up and partner notification is the responsibility of the referring iCaSH service. • Individuals who have not had a full STI screen should be advised to attend an appropriate service for a full STI screen. • Routine follow-up for uncomplicated Chlamydia following treatment with doxycycline is unnecessary, except in the following situations where local protocols should be followed: ○ Where poor compliance is suspected.

	○ Where symptoms persist.
Records	**Record:** • 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 • 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. • 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 via Pharmoutcomes 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 be kept via Pharmoutcomes for audit purposes in accordance with local policy.

4. Key references

Key references (accessed February 2020)	• 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 *Chlamydia trachomatis* (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 www.bashhguidelines.org/media/1051/ngu-2015.pdf; • British Association for Sexual Health and HIV national guideline for the management of infection with *Mycoplasma genitalium* 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

Appendix A - Registered health professional authorisation sheet

PGD Name/Version **Valid from:** **Expiry:**

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**

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.