



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*, uncomplicated *Mycoplasma genitalium* or non-gonococcal/non-specific urethritis in

Integrated Sexual Health Services (ISHS) Derbyshire Community Health Services

Version Number 2.1

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 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.	
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	
Version 2.0 April 2023	Updated template due to expiry – no significant changes to clinical content.	
Version 2.1 July 2023	Updated exclusion criteria – removed "Sucrose or fructose intolerance, glucose galactose malabsorption, sucrose-isomaltase insufficiency". Removed any reference to treatment of epididymo-orchitis.	

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PGD DEVELOPMENT GROUP		
Date PGD template comes into Review date	effect: April 2023 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)
Heather Randle	Royal College of Nursing
Jo Jenkins (Working Group Coordinator to Version 2.0)	Lead Pharmacist PGDs and Medicine Mechanisms, SPS
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	Director Specialist Pharmacy Service
Rosie Furner (Working Group Co- ordinator from Version 2.1)	Specialist Pharmacist PGDs and Medicine Mechanisms, SPS





ORGANISATIONAL AUTHORISATIONS

PATIENT GROUP DIRECTION DEVELOPMENT WORKING GROUP

This PGD has been agreed by doctors, and/or expert clinical practitioners, pharmacist and representative healthcare professionals from the trust stated below for use within Integrated Sexual Health Services (ISHS)
University of Derby and Burton Teaching Hospitals Foundation Trust (UHDBFT) and Derbyshire Community Health Services Foundation Trust (DCHSFT)

PATIENT GROUP DIRECTION AUTHORISATION

PGD approved by PGD Working Group on 27th September 2023

This PGD is authorised for use on behalf of DCHS by the following signatories:

Position of signatory	Name	Signature	Date
Director of Nursing, AHPs & Quality	Michelle Bateman	Mabalean	11/10/2023
Head of Medicines Management	Kate Needham	LANDED	11/10/2023
Deputy Medical Director	Dr Seema Kumari	Sunakunani	11/10/2023
Lead Clinician	Dr Ade Apoola	2 A Apolla	11/10/2023
Specialist in Antimicrobial Therapy	Cerina Nanuan	Canuan	11/10/2023

REVIEWED FOR DCHS BY:		
Date	Name	Position
September	Lisa Walton	ISHS Specialist Nurse Practitioner
2023	Dr Ade Apoola	ISHS Lead Clinician
	Cerina Manuan	IP&C Pharmacist

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 their own Code of Professional Conduct. Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medication(s) listed only in accordance with the PGD.

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1. Characteristics of staff

Qualifications and professional registration	Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation.
	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 as advised in the RCN Sexual Health Education directory.
	Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme
	The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults.
	For advice on additional local training requirements see Section 4: Characteristics of DCHS ISHS Staff.
Competency assessment	 Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for Chlamydia testing and/or treatment. 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	Individuals operating under this PGD are personally
competency	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 applying Trust/organisation
The decision to supply only as a	by employing Trust/organisation.
	cation rests with the individual registered health professional who associated organisational policies.
must ablue by the FGD and any	associated digariisational policies.





2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD	Genital, pharyngeal and/or rectal <i>Chlamydia trachomatis</i> infection
applies	Uncomplicated Mycoplasma genitalium infection.
арриос	Non-gonococcal or non-specific urethritis (NGU, NSU).
	,
	Asymptomatic individuals presenting within 2 weeks of sexual appropriate of the propriate of the propri
	contact with an individual with a confirmed diagnosis of any of
	the conditions detailed below.
Criteria for inclusion	Individuals with a positive test for Chlamydia trachomatis
	infection in the genitals, rectum or pharynx.
	Individuals with a positive test for Mycoplasma genitalium
	(without a clinical diagnosis of pelvic inflammatory disease
	(PID) in women) as initial treatment prior to further
	antimicrobial therapy where <i>Mycoplasma genitalium</i> is known
	to be sensitive to macrolides or is of unknown resistance
	status.
	 Individuals with a microscopic diagnosis of NGU or NSU.
	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.
	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 conditions.
	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	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
	Presence of concomitant conjunctivitis and/or joint
	pain/swelling ,
	Acute porphyria
	Myasthenia gravis
	Systemic Lupus Erythematosus (SLE)
	 Individuals with oesophagitis and oesophageal ulcerations.

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	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 (SPC)
Cautions including any	If the individual is less than 16 years of age an assessment
relevant action to be taken	based on Fraser guidelines must be made and documented.
	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 advisedwarfarin – INR monitoring advised
	Discuss with appropriate medical/independent non-medical
	prescriber any medical condition or medication of which the
	healthcare professional is unsure or uncertain.
	Safeguarding: Where there are any safeguarding concerns
	refer to local policies for safeguarding adults and children
	and/or seek advice from the safeguarding lead/team in the
	organisation. Document the concern and outcome in the
	healthcare record.
	DCHS: Safeguarding adults and children policies on DCHS SharePoint.
	DCHS Safeguarding Team: 01773 850000.
	East Midland's Children and Young People's Sexual Assault
	Service (EMCYPSAS): 0800 183 0023 (24-hour service).
Action to be taken if the	If the presenting individual is under 13 years of age the
individual is excluded or	healthcare professional should speak to the local
declines treatment	safeguarding lead and follow the local safeguarding policy
	(note under 13 years of age excluded from treatment under
	this PGD).
	If declined ensure individual is aware of the need for treatment
	and the potential consequences of not receiving treatment.
	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 a suitable health service
	provider if appropriate and/or provide them with information
	about further options.





3. Description of treatment

Name atraneth 9	Dayyayalina Forma ay 100mm aanaylaa ay 100mm dianayaibla
Name, strength &	Doxycycline 50mg or 100mg capsules or 100mg dispersible
formulation of drug	tablets.
Legal category	POM
Route of administration	Oral
Off label use	Medicines should be stored according to the conditions detailed in
On label use	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	100mg twice daily
administration	Individuals with a diagnosis of uncomplicated Mysonloams
	Individuals with a diagnosis of uncomplicated <i>Mycoplasma</i> genitalium infection to follow doxycycline course with specific
	antimicrobial therapy according to resistance profile.
Duration of treatment	7 days
Quantity to be supplied	7 day supply - appropriately labelled pack/s to a total quantity of
Quantity to be supplied	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/concurrent use to be avoided in
	the BNF are:
	Acenocoumarol
	Acitretin
	Alitretinoin
	Isotretinoin
	Lithium
	Tretinoin
	A detailed list of all drug interactions is available in the BNF or the
	product SPC
Identification & management	A detailed list of adverse reactions is available in the SPC and
of adverse reactions	BNF
	The following side effects are reported as common in the
	The following side effects are reported as common in the doxycycline SPC but note this list may not reflect all reported side
	effects:
	Hypersensitivity reactions
	Headache
	■ ⊓eauache

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	Nausea
	Vomiting
	Photosensitivity skin reactions
	Rash including maculopapular, erythematous rashes and
	Henoch-Schonlein purpura
	Urticaria
	Hypotension
	Pericarditis
	Tachycardia
	Dyspnoea
	Peripheral oedema
Management of and	Healthcare professionals and patients/carers are
reporting procedure for	encouraged to report suspected adverse reactions to the
adverse reactions	Medicines and Healthcare products Regulatory Agency (MHRA)
adverse reactions	using the Yellow Card reporting scheme
	Record all adverse drug reactions (ADRs) in the patient's
	medical record.
Written information and	Report via organisation incident policy. Madienties:
Written information and	Medication:
further advice to be given to individual	Give patient information leaflet (PIL) provided with the original pack. Explain made of action side of facts, and hardfite of the
iliuiviuuai	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/ Verbal and written information on Chlamydia trachomatis/
	Mycoplasma genitalium/NGU/NSU 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.
Follow up treatment	The individual should be advised to seek medical advice in the
	event of an adverse reaction.

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NHS Foundation Trust	Mis roundation has
	 In individuals with a definite diagnosis of uncomplicated Mycoplasma genitalium infection where the doxycycline course is to be followed by a second antimicrobial (according to the resistance profile), the second antimicrobial course should be started within 2 weeks of completing the doxycycline course. If the 2nd antimicrobial course is not started within this timeframe the individual should be referred to a specialist practitioner. Follow local protocol for Chlamydia follow up and partner notification. Individuals who have not had a full STI screen (or who did not have Chlamydia diagnosed in a sexual health clinic) should be advised to attend an appropriate service for a full STI screen. Routine follow-up/TOC 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 Rectal infections Under 25 year olds Mycoplasma genitalium infection
Records	Nycopiasma genitalium infection 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,
	 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)

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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. Characteristics of DCHS ISHS staff

Qualifications	A registered nurse working within ISHS who is deemed competent by their clinical line manager and authorised by their professional lead to undertake the clinical assessment of patients leading to the identification of those suitable for management under this PGD.
Additional Local Training	Has undertaken the local training programme on the process, responsibilities and scope of PGDs. Has undertaken local training based on the use of this PGD. Has undertaken training in recognition of and treatment of anaphylaxis including basic life support in the 12 months. Has undertaken Safeguarding Children Level 3 training in the last 12 months.
	Has undertaken Safeguarding Adults Level 2 training in the last 3 vears.
Continuing Training & Education	Evidence of Continuing Professional Development in ISHS nurse role.
	The nurse should be aware of any change to the recommendations for the medicines listed.
	It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.

5. Key references

Key references (accessed September 2022)	•	Electronic Medicines Compendium [accessed June 2023] 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 BASHH UK National Guideline on the

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 management of non-gonococca www.bashhguidelines.org/medi British Association for Sexual H guideline for the management of genitalium www.bashhguideline Royal Pharmaceutical Society Sexual Medicines December 2018 https://www.rpharms.com/recogstandards/safe-and-secure-han 	lia/1051/ngu-2015.pdf; Health and HIV national of infection with Mycoplasma es.org/media/1198/mg-2018.pdf Safe and Secure Handling of gnition/setting-professional-
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Appendix A – Registered health professional authorisation sheet

PGD Name/Version: PGD 256(S) Doxycycline v2.1

Valid from: October 2023 Expiry: 31st March 2026

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 Derbyshire Community Health Services 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.

PGD Authorisation Forms shall be maintained and retained by the Service Manager who is responsible for the safe storage of the records.

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