Insert logo of [authorising body](https://www.nice.org.uk/guidance/mpg2/chapter/Recommendations#terms-used-in-the-guideline)

|  |
| --- |
| 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 location/service/organisation**

Version Number 2.1

|  |
| --- |
| **Change History** |
| **Version and Date** | **Change details** |
| Version 1April 2020 | New template |
| Version 1.1May 2020 | Minor reordering (content unchanged) |
| Version 1.2October 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 acitretinExclusion criteria - Glucose galactose intolerance amended to Glucose galactose malabsorptionRemoved from Clinical condition or situation to which this PGD applies and PGD title - clinical epididymo-orchitis |
| Version 2.0April 2023 | Updated template due to expiry – no significant changes to clinical content.  |
| Version 2.1July 2023 | Updated exclusion criteria – removed “Sucrose or fructose intolerance, glucose galactose malabsorption, sucrose-isomaltase insufficiency”.Removed any reference to treatment of epididymo-orchitis. |

Each organisation using this PGD must ensure that it is formally signed by a senior pharmacist, a senior doctor and any other professional group representatives involved in its review and that it is reviewed in line with the organisations’ PGD governance system. The organisation’s governance lead must sign to authorise the PGD on behalf of the authorising organisation to ensure that this document meets legal requirements for a PGD.

**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 TrainingFaculty 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 Co-ordinator 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 |

**The PGD template is not legally valid until it has had the relevant organisational approval - see below.**

**ORGANISATIONAL AUTHORISATIONS AND OTHER LEGAL REQUIREMENTS**

**This page may be deleted if replaced with a format agreed according to local PGD policy with relevant approvals and authorisation.**

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

To ensure compliance with the law, organisations must add local authorisation details i.e. clinical authorisations and the person signing on behalf of the authorising organisation. You may either complete details below or delete and use a format agreed according to local PGD policy which complies with PGD legislation and [NICE MPG2 PGD 2017](https://www.nice.org.uk/Guidance/MPG2).

|  |  |  |  |
| --- | --- | --- | --- |
| **Name**  | **Job title and organisation**  | **Signature** | **Date** |
| **Senior doctor**  |  |  |  |
| **Senior pharmacist** |  |  |  |
| **Senior representative of professional group using the PGD**  |  |  |  |
| **Clinical specialist in microbiology**  |  |  |  |
| **Person signing on behalf of** [**authorising body**](http://publications.nice.org.uk/patient-group-directions-gpg2/appendix-a-glossary#authorising-body) |  |  |  |

It is the responsibility of the provider organisation to ensure that all legal and governance requirements for using the PGD are met.

To meet legal requirements, authorising organisations must add an Individual Practitioner Authorisation sheet or List of Authorised Practitioners. This varies according to local policy and how the service is managed but this should be a signature list or an individual agreement.

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.

**ORGANISATIONS MAY ALSO ADD:**

* Local training and competency assessment documentation
* Other supporting local guidance or information
* Links to local PGD Policy and other supporting guidance
* Audit requirements

Any reference to a Trust protocol (either clinical to be followed as part of the administration of a medication with the PGD or for any other purpose) must be referenced and hyperlinked to ensure the practitioner acting under the PGD has direct access to the protocol for reference.

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](https://www.e-lfh.org.uk/programmes/patient-group-directions/) The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults.  |
| **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](https://www.nice.org.uk/guidance/mpg2/resources)
 |
| **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 - 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.  |

1. **Clinical condition or situation to which this PGD applies**

|  |  |
| --- | --- |
| **Clinical condition or situation to which this PGD applies** | * Genital, pharyngeal and/or rectal *Chlamydia trachomatis* infection
* Uncomplicated *Mycoplasma genitalium* infection.
* Non-gonococcal or non-specific urethritis (NGU, NSU).
* Asymptomatic individuals presenting within 2 weeks of sexual 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 *Mycoplasma genitalium* 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, or PID 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.

**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.For example in this PGD template the following may be considered:* *Individuals who present with clear penile discharge where there is no access to microscopy facilities to diagnose NSU/NGU.*
 |
| **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.

**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](https://www.medicines.org.uk/emc) (SPC)
 |
| **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.
* 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 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**  | * 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).
* 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.
 |

1. **Description of treatment**

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| **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 dailyIndividuals with a diagnosis of uncomplicated *Mycoplasma 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 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](http://www.bnf.org) or the product [SPC](http://www.medicines.org.uk) |
| **Identification & management of adverse reactions** | A detailed list of adverse reactions is available in the [SPC](http://www.medicines.org.uk) and [BNF](http://www.bnf.org) 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
* Nausea
* Vomiting
* Photosensitivity skin reactions
* Rash including maculopapular, erythematous rashes and Henoch-Schonlein purpura
* Urticaria
* Hypotension
* Pericarditis
* Tachycardia
* Dyspnoea
* Peripheral oedema
 |
| **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](http://yellowcard.mhra.gov.uk)
* Record all adverse drug reactions (ADRs) in the patient’s medical record.
* Report via organisation incident 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, including those medications purchased.
* Advise to avoid exposure to direct sunlight or ultraviolet light.

**Condition:*** 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.
* 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** | **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 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. |

1. **Key references**

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| **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 *Chlamydia trachomatis* (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
* management of non-gonococcal urethritis [www.bashhguidelines.org/media/1051/ngu-2015.pdf](http://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* [Mycoplasma Genitalium 2018 | BASHH](https://www.bashh.org/resources/19/mycoplasma_genitalium_2018)
* 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 – Example 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.

|  |
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| **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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**Authorising manager**

|  |
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| **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.