NHS
Rotherham Doncaster and South Humber
NHS Foundation Trust

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 azithromycin for the treatment of uncomplicated *Chlamydia trachomatis*, uncomplicated *Mycoplasma genitalium* and non-gonococcal/non-specific urethritis in Rotherham, Doncaster and South Humber (RDaSH) NHS Foundation Trust

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	Advisory wording added to inclusion criteria section: NOTE – all criteria for inclusion within the BASHH approved national PGD templates for sexual health are based on diagnostic management in line with BASHH guidance. ~~Where services do not have access to diagnostics and treatment~~ is syndromic then the PGD template will need to be locally adapted to reflect local practice being mindful of the BASHH guidance.
Version 2.0 April 2023	Updated template due to expiry – no significant changes to clinical content.
Version 2.1 October 2023	Updated PGD development group members. Statement added regarding risk of prolongation of QT interval with interacting drugs added to exclusions and reflected in interactions section.

Reference Number: 2.1
Valid from: April 2023
Review date: September 2025
Expiry date: 30th March 2026

PGD DEVELOPMENT GROUP

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

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

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

Name	Designation
Ali Grant	Highly Specialist Clinical Pharmacist: HIV, Sexual and Reproductive Health
Alison Crompton	Community pharmacy
Andrea Smith	Community pharmacy
Carmel Lloyd	Royal College of Midwives
Chetna Parmar	Pharmacist adviser, Umbrella
Clare Livingstone	Royal College of Midwives
Deborah Redknapp	English HIV and Sexual Health Commissioners Group (EHSHCG)
Dipti Patel	Local authority pharmacist
Dr Achyuta Nori	Consultant in Sexual Health and HIV
Dr Cindy Farmer	Vice President, General Training Faculty of Sexual and Reproductive Healthcare (FSRH)
Dr John Saunders	Consultant in Sexual Health and HIV
Dr 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	Lead Pharmacist PGDs and Medicine Mechanisms, Specialist Pharmacy Service
Rosie Furner (Working Group Co-ordinator)	Specialist Pharmacist PGDs and Medicine Mechanisms, Specialist Pharmacy Service
Jodie Crossman	Specialist Nurse. BASHH SHAN SIG Chair
Belinda Loftus	Specialist Nurse, BASHH Board Nurse Representative, BASHH SHAN SIG Secretary
Portia Jackson	Pharmacist, Cambridgeshire Community Services
Sally Hogan	British Pregnancy Advisory Service (BPAS)
Sandra Wolper	Associate Director Specialist Pharmacy Service
Tracy Rogers	Associate Director Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Dr Graeme Tosh	Medical Director		22/11/23
Stephen Davies	Chief Pharmacist	Davies	22/11/23
Sheila Lloyd	Director of Nursing and AHPs	Lloyd	22/11/23
Anil Rajpal	Senior Pharmacist		22/11/23
Tina Proctor	Nurse Consultant *Senior representative of professional group using the PGD*		29/11/23

Committee Approval:

NAME	DATE
Medicines Management Committee	

Date of Implementation	

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.
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 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.	

Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	• Uncomplicated genital, pharyngeal and/or asymptomatic rectal *Chlamydia trachomatis* infection • Uncomplicated *Mycoplasma genitalium* following completion of course of doxycycline (see doxycycline PGD). • 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 with any of the conditions detailed below.
Criteria for inclusion	• **Where doxycycline is contraindicated (known allergy, previous adverse effects, pre-existing medical conditions, pregnancy) or inappropriate (photosensitivity, likely poor adherence):** o Individuals with a positive test for *Chlamydia trachomatis* infection in the genitals, pharynx or rectum (asymptomatic) but without signs suggestive of complications. o Individuals with a microscopic diagnosis of non-gonococcal or non-specific urethritis (NGU, NSU). o Asymptomatic individuals presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of *Chlamydia trachomatis*, NSU/NGU, PID or epididymo-orchitis who are unwilling/unable to defer testing after the 2 week window period. o 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. • Individuals with a definite diagnosis of uncomplicated *Mycoplasma genitalium* where a course of doxycycline has been completed within the previous two weeks (where resistance testing is available, confirmed macrolide sensitivity). • 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.
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 suspected and/or confirmed symptomatic rectal *Chlamydia trachomatis*.

	• Individual with complicated *Chlamydia trachomatis* infection such as (epididymitis and/or testicular pain or a clinical diagnosis of Pelvic Inflammatory Disease (PID) • Individuals with suspected or confirmed Lymphogranuloma venereum (LGV) • Known severe hepatic impairment • Known severe renal impairment (eGFR <10ml/min/1.73m^2/ CKD stage 5) • Current/past history of cardiac rhythm or conduction disturbance • Presence of concomitant conjunctivitis and/or joint pain/swelling • Acute porphyria • Myasthenia gravis **Medication history** • Any concurrent interacting medicine(s) – see Drug Interactions section • Concomitant use of another medication known to cause QT prolongation (e.g. haloperidol, sotalol, terfenadine, pimozide) (For further information recommended resources include: CredibleMeds; registration required, or Sudden arrhythmic death syndrome (SADS) - Drugs to avoid) • Concomitant use of ergot derivatives such as ergotamine (Migril®) • Known hypersensitivity or allergy to the azithromycin or other macrolide antibiotics or to any component of the product - see Summary of Product Characteristics • Individuals with known azithromycin resistance.
Cautions including any relevant action to be taken	• Some brands of azithromycin contain soya or soya lecithin and are therefore contraindicated in individuals with an allergy to soya or peanuts. If individual is allergic, check manufacturer's information for brand being used and if necessary, exclude from PGD or select an alternative suitable brand if available. • Pregnant individuals/individuals known to be at risk of pregnancy – the SPC states that there is limited data on use in pregnancy however BASHH guidelines state: "While adverse pregnancy outcomes are unlikely with the 2g total azithromycin dose, individuals should be advised of the lack of data." The individual must be informed that although the use of azithromycin in pregnancy is thought to be safe, there is limited research available and be fully informed of the risks and benefits of this treatment. • Breastfeeding individuals – BASHH states that 'Very low levels of azithromycin are detected in breast milk, and systemic exposure in infants does not exceed that observed when azithromycin is administered for treatment, therefore risk is considered to be low'. • If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. • 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 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. • Pregnant individuals/individuals known to be at risk of pregnancy who decline azithromycin treatment should be referred to a prescriber for further consultation. • Explain the reasons for exclusion to the individual and document in the consultation record. • Record reason for decline in the consultation record. • Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.

Description of treatment

Name, strength & formulation of drug	Azithromycin 250mg or 500mg capsules or tablets or azithromycin 200mg/5ml Powder for Oral Suspension. NB: The treatments in this PGD are written according to national 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	Best practice advice is given by BASHH and is used as the reference guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). This PGD includes off label use in the following conditions: • The dose of azithromycin stated in the BASHH guideline and therefore in this PGD is higher than the licensed dose. • Those under 18 years of age and under 45kg weight - azithromycin tablets or capsules are not licensed for use in children or adolescents weighing under 45 kg. • Breastfeeding individuals – BASHH states that 'Very low levels of azithromycin are detected in breast milk, and systemic exposure in infants does not exceed that observed when azithromycin is administered for treatment, therefore risk is considered to be low'. 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	**Day One:** 1g taken as a single dose **Day Two:** 500mg once daily **Day Three:** 500mg once daily For uncomplicated *Mycoplasma genitalium* azithromycin course to be started immediately after the doxycycline course completed – where this is not achieved it must be started within 2 weeks of the doxycycline course being completed. If the azithromycin course is not started within this timeframe the individual should be referred to a specialist practitioner.
Duration of treatment	3 days.
Quantity to be supplied	Appropriately labelled pack of 4x500mg capsules/tablets or 8x250mg capsules/tablets or appropriate quantity of reconstituted oral suspension. A single repeat course can be supplied under the PGD if vomiting occurs within 3 hours of a dose being taken.
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. A detailed list of all drug interactions is available in the BNF or the product SPC Seek advice from an appropriate clinician/Medicines Advisory Service if required. Individuals concurrently prescribed the following medications are excluded from treatment under this PGD and must be referred to an appropriate prescriber: o Berotralstat o Chloroquine o Colchicine o Dabigatran o Digoxin o Edoxaban o Hydroxychloroquine o Rifabutin o Talazoparib o Ticagrelor o Topotecan o Vinblastine o Vincristine o Vindesine o Vinflunine o Vinorelbine o Concomitant use of another medication known to cause QT prolongation (e.g. haloperidol, sotalol, terfenadine, pimozide) (For further information recommended resources include: CredibleMeds; registration required, or Sudden arrhythmic death syndrome (SADS) - Drugs

	to avoid) o Concomitant use of ergot derivatives such as ergotamine (Migril®)
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC and BNF The following side effects are very common/common with azithromycin: • Nausea • Anorexia • Vomiting • Dyspepsia • Dizziness • Headache • Diarrhoea • Abdominal pain/discomfort • Flatulence • Rash • Pruritus • Arthralgia • Fatigue • Visual impairment • Deafness • Paraesthesia • Dysgeusia
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. • 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 • Azithromycin tablets can be taken at any time in relation to food but there should be a gap between taking the tablets and antacids, including those medications purchased. • Azithromycin capsules should be taken one hour before or two hours after food or antacids, including those medications purchased. • If vomiting occurs within 3 hours of taking capsules/tablets offer option of repeat dose of azithromycin (under PGD). • **Note relevant for *Mycoplasma genitalium*:** Where doxycycline has been supplied for the treatment of uncomplicated *Mycoplasma genitalium* the individual should be advised that the azithromycin course should be started immediately after completion of the doxycycline course – where this is not achieved it must be started within 2 weeks of the doxycycline course being completed. If the azithromycin course is not completed within this time

	frame the individual should be referred to a specialist practitioner. • **Condition:** • Individuals diagnosed with *Chlamydia trachomatis* /NGU/NSU/*Mycoplasma genitalium* should be offered information (verbal, written and/or digital) about their diagnosis and management • Discuss implications of incompletely treated/untreated infection of self or partner/s • Advise to abstain completely from sexual intercourse (even with condoms) including oral sex, during treatment, for 7 days after treatment and for 7 days after partner(s) treatment • 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 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. • Follow local protocol for *Chlamydia trachomatis/Mycoplasma genitalium* follow up and partner notification. • Individuals with *Chlamydia trachomatis/Mycoplasma genitalium* who have not had a full STI screen (or who did not have *Chlamydia trachomatis/mycoplasma genitalium* diagnosed in a sexual health clinic) should be advised to attend a sexual health clinic/service for a full STI screen. • Routine follow-up/TOC for uncomplicated *Chlamydia trachomatis* following treatment with azithromycin is unnecessary, except in the following situations where local protocols should be followed: o Pregnancy. o Where poor compliance is suspected o Where symptoms persist o Rectal infections o Under 25 year olds o Mycoplasma genitalium infection
Records	**Record:** • The consent of the individual and o If individual is under 13 years of age record action taken o If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken. o 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.

Key references

Key references (accessed September 2022, September 2023)	• 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 • Specialist Pharmacy Service (SPS) Identifying risk factors for developing a long QT interval https://www.sps.nhs.uk/articles/identifying-risk-factors-for-developing-a-long-qt-interval/#:~:text=QT • 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: Azithromycin

Valid from: April 2023 **Expiry: 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 RDaSH NHS Foundation Trust 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.

This information will be retained by the Chief Pharmacist of RDASH NHS Foundation Trust