



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 nongonococcal/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	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.		

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	December 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.

Reference Number: 61(S) Azithromycin for Chlamydia v2.1





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	Specialist Pharmacist PGDs and Medicine Mechanisms,
Group Co-ordinator)	Specialist Pharmacy Service
Jodie Crossman	Specialist Nurse. BASHH SHAN SIG Chair
Belinda Loftus	Specialist Nurse, BASHH Board Nurse Representative,
Dantia Indiana	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

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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 23rd March 2023 (minor update 23rd November 2023)

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

Position of signatory	Name	Signature	Date
Deputy Chief Nurse	Jo Wain	J.Wo.	13/12/2023
Head of Medicines Management	Kate Needham	LINDED	13/12/2023
Medical Director	Dr Ben Pearson	Benleavon.	13/12/2023
Lead Clinician	Dr Ade Apoola	20 A Apollon	13/12/2023
Specialist in Antimicrobial Therapy	Cerina Nanuan	Quuan	13/12/2023

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.

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

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1. Characteristics of staff

Qualifications and	Current contract of employment within a Local Authority or NHS	
professional registration	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.	
	advised in the Norv Ocada Health Eddeallon directory.	
	Individual has undertaken appropriate training for working under	
	PGDs for the supply and administration of medicines.	
	Recommended training - <u>eLfH PGD elearning programme</u>	
	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 <u>NICE Competency Framework for</u> 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 	
	employing Trust/organisation.	
The decision to supply any medication rests with the individual registered health professional who		
must abide by the PGD and any associated organisational policies.		

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2. Clinical condition or situation to which this PGD applies

Clinical condition or cituation	Harrier Bastad and Stall above and and demonstrate Sta
Clinical condition or situation to which this PGD applies	Uncomplicated genital, pharyngeal and/or asymptomatic rectal <i>Chlamydia trachomatis</i> infection
to which this i Ob applies	 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): Individuals with a positive test for Chlamydia trachomatis
	infection in the genitals, pharynx or rectum
	(asymptomatic) but without signs suggestive of
	complications.
	 Individuals with a microscopic diagnosis of 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 <i>Chlamydia trachomatis</i> , 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.
	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
	NOTE – all criteria for inclusion within the BASHH approved
	national PGD templates for sexual health are based on
Criteria for exclusion	diagnostic management in line with BASHH guidance.
Criteria for exclusion	Consent not given. Individuals under 12 years of age.
	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 <i>Chlamydia trachomatis</i> infection
	such as (epididymitis and/or testicular pain or a clinical
	diagnosis of Pelvic Inflammatory Disease (PID)

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	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). • 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.

3. Description of treatment

Name, strength & formulation of drug	Azithromycin 250mg capsules or tablets or azithromycin 200mg/5ml Powder for Oral Suspension. If 250mg capsules are unavailable the 500mg capsules or tablets may be issued under this PGD.
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

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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.
Day One: 1g taken as a single dose Day Two: 500mg once daily Day Three: 500mg once daily
For uncomplicated <i>Mycoplasma genitalium</i> 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.
3 days.
Appropriately labelled pack 8x250mg capsules/tablets or appropriate quantity of reconstituted oral suspension 4 x 500mg capsules/tablets may be supplied if 250mg capsules are unavailable. A single repeat course can be supplied under the PGD if vomiting occurs within 3 hours of a dose being taken.
Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
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: Berotralstat Chloroquine Colchicine Dabigatran Digoxin Edoxaban Hydroxychloroquine Rifabutin Talazoparib Ticagrelor Topotecan Vinblastine

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Identification & management of adverse reactions	 Vincristine Vindesine Vinflunine Vinorelbine 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®) 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	Medication:
advice to be given to individual	 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.

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	 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
Follow up treatment	 health services. The individual should be advised to seek medical advice in the event of an adverse reaction. Follow local protocol for <i>Chlamydia trachomatis/Mycoplasma genitalium</i> follow up and partner notification. Individuals with <i>Chlamydia trachomatis/Mycoplasma genitalium</i> who have not had a full STI screen (or who did not have <i>Chlamydia trachomatis/mycoplasma genitalium</i> 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 <i>Chlamydia trachomatis</i> following treatment with azithromycin is unnecessary, except in the following situations where local protocols should be followed: Pregnancy. Where poor compliance is suspected Where symptoms persist Rectal infections

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	 Under 25 year olds
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 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 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.

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.

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	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 years.
Continuing Training &	Evidence of Continuing Professional Development in ISHS
Education	nurse role.
Education	Tiurse role.
	The nurse should be aware of any change to the
	recommendations for the medicines listed.
	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	Electronic Medicines Compendium
September 2022, September	http://www.medicines.org.uk/
2023)	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 <i>Mycoplasma</i>
	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

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Appendix A - Registered health professional authorisation sheet

PGD Name/Version: PGD 61(S) Azithromycin for Chlamydia v2.1 **Valid from:** December 2023 **Expiry:** 31 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.

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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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