

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*, in participating No Worries providers in GP practice or Community pharmacy.

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.	

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PGD DEVELOPMENT GROUP

Date PGD template comes into	April 2023
effect:	
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	Specialist Pharmacist PGDs and Medicine		
(Working Group Co-	Mechanisms, Specialist Pharmacy Service		
ordinator)			
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		

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ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Dr Amy Pearce	Consultant in Sexual Health	10	24/3/25
	and HIV	ILlouise	
	WiSe, Salisbury District	April.	
Senior doctor	Hospital	1	
Paul Clarke	Associate Director of	001.	25/03/25
	Pharmacy	I Chil.	
Senior pharmacist	-		
	BSW ICB		
Professor Kate	Director of Public Health		27/02/2025
Blackburn		Vait Rlackbur	
	Wiltshire Council	Kartyn Blackbur	
Person signing on behalf		0	
of authorising body			
Chris Loader	Lead Nurse and Service Lead		21/3/25
	Nurse		
	WiSe, Salisbury District		
	Hospital		

1. Characteristics of staff

Qualifications and professional registration	GP Practice or pharmacy within Wiltshire that have signed up to deliver No Worries through the Public Health Services contract 2024 - 2029
	Registered Nurse with a current Nursing and Midwifery Council (NMC) registration and reproductive health experience.
	Registered Pharmacist with current GPhC registration. Currently employed or working as a locum pharmacist in a community pharmacy.
	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 - <u>eLfH PGD elearning programme</u>
	The healthcare professional has completed training and is up to date with 1 April 2024 to 31 March 2029 No Worries Young People's Sexual Health Service specification and requirements for safeguarding children and vulnerable adults.

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	Pharmacists are required to complete the required training: Declaration of Competence (DoC) for Chlamydia testing and treatment CPPE and / or e-learning for healthcare packages should be completed as part of the DoC process and updated every three years Have a valid enhanced DBS certificate.	
Competency assessment	 Individuals operating under this PGD must be assessed as competent (see Appendix A) and complete the 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		

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	For use by No Worries participating GP practice or pharmacy within Wiltshire signed up to deliver No Worries through the Public Health Services contract 2024 -2029 Uncomplicated genital Chlamydia trachomatis infection Individuals with a confirmed positive Chlamydia result following screening by Wiltshire Sexual Health (WiSe), Salisbury Foundation Trust. Telephone: 01722 425120 Email: shc-tr.sexualhealth@nhs.net	
	 A sexual contact of an individual that has a confirmed positive Chlamydia result through WiSe 	
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 <i>Chlamydia trachomatis</i> infection in the genitals. Individuals aged 24 years and under (13 – 24 years) 	

professional who must abide by the PGD and any associated organisational policies

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- A positive test for *Chlamydia trachomatis* infection in the genitals and referred by WiSe.
- A sexual contact of an individual with a confirmed positive Chlamydia trachomatis infection and referred by WiSe, there is no upper age limit for a sexual contact. Pharmacies will be notified through PharmOutcomes.
- Consent given.
- Individual aged 13 15 to follow local young person's risk assessment.

Criteria for exclusion

- The GP practice or pharmacy hasn't received confirmation from WiSe that the individual has tested positive for Chlamydia trachomatis.
- The GP practice or pharmacy hasn't received confirmation that the individual is a sexual contact of an individual with a positive Chlamydia result diagnosed through WiSe.
- 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/1.73m²/ 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®)

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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).
- Contact WiSe to advise them the individual is excluded or has declined treatment under this PGD. Pharmacies can notify WiSe through PharmOutcomes
- Provide the individual with information about further options.
- 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.

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3. Description of treatment

Name, strength & formulation of drug	Azithromycin 250mg or 500mg capsules or tablets.			
Legal category	POM			
Route of	Oral			
administration				
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			
Duration of treatment	3 days.			
Quantity to be supplied	Appropriately labelled pack of 4x500mg capsules/tablets or 8x250mg capsules/tablets.			
	A single repeat course can be supplied under the PGD if vomiting occurs within 3 hours of a dose being taken.			

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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: Berotralstat Chloroquine Colchicine Dabigatran Digoxin Edoxaban Hydroxychloroquine Rifabutin Talazoparib Ticagrelor Topotecan Vinblastine Vincristine Vindesine Vindesine Vingunine 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		
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		
	AnorexiaVomiting		
	Dyspepsia		
	Dizziness		
	Headache		
	 Diarrhoea Abdominal pain/discomfort Flatulence 		
	Rash		

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	Pruritus
	Arthralgia
	Fatigue
	Visual impairment
	Deafness
	Paraesthesia
	Dysgeusia
Management of and	Healthcare professionals and patients/carers are
reporting procedure	encouraged to report suspected adverse reactions to the
for adverse reactions	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	Medication:
and further advice to	Give patient information leaflet (PIL) provided with the
be given to individual	original pack. Explain mode of action, side effects, and
g	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).
	Condition:
	 Individuals diagnosed with Chlamydia trachomatis 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
	after treatment and for 7 after partner(s) treatment. Where
	not achievable advise on use of condoms.
	Offer a supply of free condoms to every individual or sexual
	contact who receives treatment.
	For ongoing supplies of free condoms advise individuals
	aged 24 years and under of the eC-Card app, more
	information is available via
	https://www.wiltshire.gov.uk/public-health-sexual-health and
	follow steps to download the app. Alternatively free condoms
	are available through participating No Worries participating.
	 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
	арріорнаю

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	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	 Inform the individual that WiSe will follow individuals up to check compliance of treatment and offer support around partner notification. Individuals with Chlamydia trachomatis/ who have not had a full STI screen (or who did not have Chlamydia trachomatis diagnosed in a sexual health clinic) should be advised to attend a sexual health clinic/service for a full STI screen. Individuals should re-test in 3 – 6 months or on change / new sexual contact if sooner. The individual should be advised to seek medical advice in the event of an adverse reaction. 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: Pregnancy. Where poor compliance is suspected Where symptoms persist Rectal infections Under 25 year olds Mycoplasma genitalium infection 	
Records	Record:	
Records	 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. 	

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- 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.

4. 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.bashhquidelines.org/media/1191/update-on-thetreatment-of-chlamydia-trachomatis-infection-final-16-9-18.pdf
- BASHH UK National Guideline on the management of nongonococcal urethritis
 - www.bashhguidelines.org/media/1051/ngu-2015.pdf;
- British Association for Sexual Health and HIV national quideline for the management of infection with Mycoplasma genitalium Mycoplasma Genitalium 2018 | BASHH
- Specialist Pharmacy Service (SPS) Identifying risk factors for developing a long QT interval https://www.sps.nhs.uk/articles/identifying-risk-factors-fordeveloping-a-long-qt-interval/#:~:text=QT
- Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professionalstandards/safe-and-secure-handling-of-medicines

Appendix A – Example registered health professional authorisation sheet PGD: No Worries Azithromycin / v2.1

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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				
Group Birection	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		
named health care professionals who have signed the PGD to work under it.		
esignation	Signature	Date
	tably trained an live authorisation fessionals who under it.	tably trained and competent to work upive authorisation on behalf offor the fessionals who have signed the PGD under it.

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. Under the public health services contract, we may request a copy of your signed Appendix A form for professionals working under this PGD for the No Worries Service

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