

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*, for practice nurses in Primary Care and Community Pharmacists providing No Worries service through the Public Health Service contract commissioned by Wiltshire Council.

Version Number 1.3

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 1.3 January 2022	Addition of local information specific to service in Wiltshire

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See

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Appendix A). The most recent and in date final signed version of the PGD must be used.

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	1 st April 2022
Review date	October 2023
Expiry date:	31 st March 2025

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 October 2020. This PGD template had also been modified to include information and details specific to Wiltshire Council in January 2022.

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
Amanda Cooper	Associate Director Specialist Pharmacy Service
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 (EHSCHG)
Dipti Patel	Local authority pharmacist
Dr Achyuta Nori	Consultant in Sexual Health and HIV
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Dr John Saunders	Consultant in Sexual Health and HIV
Dr Kathy French	Pan London PGD working group
Dr Rita Browne	Consultant in Sexual Health and HIV

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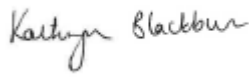
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Dr Sarah Pillai	Pan London PGD working group
Emma Anderson	Centre for Pharmacy Postgraduate Education (CPPE)
Helen Donovan	Royal College of Nursing
Jo Jenkins (Woking Group Co-ordinator)	Specialist Pharmacist (PGDs) Specialist Pharmacy Service
Jodie Crossman	Specialist Nurse. BASHH SHAN SIG Chair
Jodie Walker-Haywood	Specialist Nurse, BASHH Board Nurse Representative, BASHH SHAN SIG Secretary
Leanne Bobb	English HIV and Sexual Health Commissioners Group (EHSCHG)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Portia Jackson	Pharmacist, Cambridgeshire Community Services
Sally Hogan	British Pregnancy Advisory Service (BPAS)
Sandra Wolper	Associate Director Specialist Pharmacy Service
Silvia Ceci	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service
Tracy Rogers	Associate Director Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Chris Loader	Lead Nurse / Service manager Wiltshire Sexual Health (WiSe) Salisbury Foundation Trust		29.03.22
Paul Clarke	Associate Director Medicines Optimisation BSW CCG		18.03.22
Professor Kate Blackburn	Director of Public Health Wiltshire Council		21.03.22

1. Characteristics of staff

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<p>Qualifications and professional registration</p>	<p>Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation.</p> <p>Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.</p> <p>Registered Nurse with current Nursing and Midwifery Council (NMC) registration and family planning experience.</p> <p>Registered Pharmacist who has received training to undertake administration and supply of medicines under Patient Group Directions and are competent in management of contraception care, working in a community pharmacy under the No Worries Public Health Service Contract</p>
<p>Initial training</p>	<p>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.</p> <p>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 advised in the RCN Sexual Health Education directory.</p> <ul style="list-style-type: none"> • Have undertaken appropriate training for working under patient group directions for the supply and administration of medicines • Have been assessed as competent to work with this PGD • Have undertaken training in the role, care and administration of the medicine specified in this PGD, as specified by the Registered health professional authorisation sheet • Have access to the current BNF (https://www.medicinescomplete.com/mc/bnf/current) <p>Pharmacists providing No Worries services are required to complete the required training:</p> <ul style="list-style-type: none"> • Declaration of Competence (DoC) for Chlamydia testing & treatment and Emergency Contraception • CPPE packages should be completed as part of the DoC process and updated every three years: Sexual Health in pharmacies, Emergency Contraception, Dealing with difficult discussions or Consultation skills for pharmacy practice and Safeguarding children and vulnerable adults

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	<ul style="list-style-type: none"> An enhanced DBS certificate is in place
Competency assessment	<ul style="list-style-type: none"> Individuals operating under this PGD must be assessed as competent (see Appendix A) and complete a declaration of competence (DoC) for Chlamydia testing & treatment and Emergency Contraception . 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	<ul style="list-style-type: none"> 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.
<p>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.</p>	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	<ul style="list-style-type: none"> For No Worries participating GP surgeries or Community pharmacist through Public Health Service contract commissioned by Wiltshire Council For treatment of known uncomplicated genital <i>Chlamydia trachomatis</i> infection, where the laboratory result has been confirmed through Wiltshire Sexual Health (WiSe), Salisbury Foundation Trust. Telephone: 01722 425120 Email: shc-tr.sexualhealth@nhs.net Sexual contact(s) of a client with a positive genital Chlamydia trachomatis result diagnosed through Wiltshire Sexual Health (WiSe), Salisbury Foundation Trust (no upper age limit). Excluded from use of Doxycycline PGD
Criteria for inclusion	<ul style="list-style-type: none"> Male and female aged 24 years and under (Individuals under 16 years old must be assessed as Fraser competent) who have a positive genital Chlamydia trachomatis result and have provided valid consent to treatment. The No Worries participating pharmacy will receive notification from WiSe. The pharmacy will be notified of the reference number through PharmOutcomes. A sexual contact(s) of an individual with a confirmed Chlamydia trachomatis infection through WiSe, many attend without contacting WiSe beforehand, please treat if they can

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	<p>provide their sexual contacts reference number (no upper age limit)</p> <ul style="list-style-type: none"> • Where doxycycline is contraindicated (known allergy, previous adverse effects, pre-existing medical conditions) or inappropriate (photosensitivity, likely poor adherence): <ul style="list-style-type: none"> ○ Individuals with a laboratory confirmed <i>genital Chlamydia trachomatis</i> infection • A sexual contact(s) of an individual with a confirmed <i>Chlamydia trachomatis</i> infection through WiSe, many attend without contacting WiSe beforehand, please treat if they can provide their sexual contacts reference number (no upper age limit) • Consent given.
<p>Criteria for exclusion</p>	<ul style="list-style-type: none"> • The pharmacy has not received notification from WiSe or the individual is unable to provide a reference number. Contact WiSe to discuss to support treatment. • 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. <p>Medical history</p> <ul style="list-style-type: none"> • Individuals with suspected and/or confirmed symptomatic rectal <i>Chlamydia trachomatis</i>. • Individual with complicated <i>Chlamydia trachomatis</i> infection such as (epididymitis and/or testicular pain or a clinical diagnosis of Pelvic Inflammatory Disease (PID)) • Individuals with suspected or confirmed Lymphogranuloma venereum (LVG) • Known severe hepatic impairment • Known severe renal impairment • Current/past history of cardiac rhythm or conduction disturbance • Presence of concomitant conjunctivitis and/or joint pain/swelling

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	<ul style="list-style-type: none"> • Acute porphyria • Myasthenia gravis <p>Medication history</p> <ul style="list-style-type: none"> • Any concurrent interacting medicine(s) – see Section 4 Drug interactions. • 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.
<p>Cautions including any relevant action to be taken</p>	<ul style="list-style-type: none"> • 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. • 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). • Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.
<p>Action to be taken if the individual is excluded or declines treatment</p>	<ul style="list-style-type: none"> • 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

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	<p>referred to a prescriber for further consultation.</p> <ul style="list-style-type: none"> • Explain the reasons for exclusion to the individual and document in the consultation record. • Record reason for decline and all action in the consultation record. • Notify WiSe • 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	<p>Azithromycin 250mg or 500mg capsules or tablets</p> <p>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.</p>
Legal category	POM
Route of administration	Oral
Off label use	<p>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).</p> <p>This PGD includes off label use in the following conditions:</p> <ul style="list-style-type: none"> • 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’. <p>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.</p>

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Dose and frequency of administration	<p>Day One: 1g taken as a single dose</p> <p>Day Two: 500mg once daily</p> <p>Day Three: 500mg once daily</p>
Duration of treatment	3 days.
Quantity to be supplied	<p>Appropriately labelled pack of 4x500mg capsules/tablets or 8x250mg capsules/tablets</p> <p>A single repeat course can be supplied under the PGD if vomiting occurs within 3 hours of a dose being taken.</p>
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	<p>All concurrent medications should be reviewed for interactions.</p> <p>The interactions listed as severe in the BNF are:</p> <ul style="list-style-type: none"> • Colchicine • Digoxin • Edoxaban • Rifabutin • Talazoparib • Ticagrelor • Topotecan <p>A detailed list of all drug interactions is available in the BNF or the product SPC</p>
Identification & management of adverse reactions	<p>A detailed list of adverse reactions is available in the SPC and BNF</p> <p>The following side effects are very common/common with azithromycin:</p> <ul style="list-style-type: none"> • Nausea • Anorexia • Vomiting • Dyspepsia • Dizziness • Headache

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	<ul style="list-style-type: none"> • Diarrhoea • Abdominal pain/discomfort • Flatulence • Loose stools • Rash • Pruritus • Arthralgia • Fatigue • Visual impairment • Deafness • Paraesthesia • Dysgeusia
<p>Management of and reporting procedure for adverse reactions</p>	<ul style="list-style-type: none"> • 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.
<p>Written information and further advice to be given to individual</p>	<p>Medication:</p> <ul style="list-style-type: none"> • 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. • Azithromycin capsules should be taken one hour before or two hours after food or antacids • If vomiting occurs within 3 hours of taking capsules/tablets offer option of repeat dose of azithromycin (under PGD). • Condition: • Individuals diagnosed with <i>Chlamydia trachomatis</i> 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

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	<ul style="list-style-type: none"> • Advise to abstain completely from sexual intercourse (even with condoms) including oral sex, during treatment, for seven days after treatment and for seven days after partner(s) treatment. Where not achievable advice 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 • 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	<p>WiSe will follow up all individuals who have a confirmed laboratory positive genital <i>Chlamydia trachomatis</i> result diagnosed through National Chlamydia Screening programme, Wiltshire Sexual Health (WiSe), Salisbury Foundation Trust.</p> <ul style="list-style-type: none"> • Use local child protection procedures if there is any concern regarding a child's (under 18 years old) sexual activities. • The individual should be advised to seek medical advice in the event of an adverse reaction. • Follow local protocol for <i>Chlamydia trachomatis</i> follow up and partner notification. • Individuals with <i>Chlamydia trachomatis</i> who have not had a full STI screen should be advised to attend a sexual health clinic/service for a full STI screen. • Routine follow-up for uncomplicated <i>Chlamydia trachomatis</i> following treatment with azithromycin is unnecessary, except in the following situations where local protocols should be followed: <ul style="list-style-type: none"> ○ Pregnancy. ○ Where poor compliance is suspected. ○ Where symptoms persist. ○ Rectal infections.
Records	<p>Record:</p> <ul style="list-style-type: none"> • The consent of the individual and <ul style="list-style-type: none"> ○ If individual is under 13 years of age record action

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	<p>taken</p> <ul style="list-style-type: none"> ○ 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 <ul style="list-style-type: none"> ● 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) <p>Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.</p> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
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4. Key references

Key references (accessed February 2020)	<ul style="list-style-type: none">• 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 <i>Chlamydia trachomatis</i> (CT) infection https://www.bashhguidelines.org/media/1191/update-on-the-treatment-of-chlamydia-trachomatis-infection-final-16-9-18.pdf• 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: Supply of azithromycin for the treatment of uncomplicated *Chlamydia trachomatis*, for practice nurses in Primary Care and Community Pharmacists providing No Worries service through the Public Health Service contract commissioned by Wiltshire Council.

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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.

Please email a signed copy to the No Worries, Public Health Team via:
noworries.nhswiltshire@nhs.net

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 (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.

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