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 250mg/500mg Tablets for the treatment of uncomplicated asymptomatic Chlamydia trachomatis in Community Pharmacy

PGD DEVELOPMENT GROUP

Date PGD template comes into effect	April 2024
Review date	February 2026
Expiry date	March 2026

Version Control

The current version of this document can be found on Pharmoutcomes and the LPC website. https://www.sps.nhs.uk/articles/azithromycin-oral-for-use-within-sexual-health-services/

Amendments may become necessary prior to the published expiry date. Contractors who are commissioned to provide the service will be notified of any amendments and provided with updated documentation for use by individual practitioners.

Practitioners and organisations must check that they are using the current version of the PGD.

Revision History

Version	Date	Author	Change description
1.0 / 2021	Nov 2021	Andrew Pickard	New PGD
2.0 / 2022	Feb 2022	Andrew Pickard	Local update
3.0 / 2024	March 2024	Mercedeh Fahimi-Vahid	Update and amend format

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ORGANISATIONAL AUTHORISATIONS

Telford and Wrekin Council and Shropshire Council authorise this PGD for use by accredited Community Pharmacists delivering the service from community pharmacies that meet the requirements as outlined in the service specification and that have been commissioned by Telford and Wrekin Council and/or Shropshire Council.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met.

The authorising body accepts governance responsibility for the appropriate use of the PGD.

This document requires authorisation by the following individuals:

Name and Designation	Organisation	Signature	Date
Liz Noakes	Telford and Wrekin Council	Liz Nortes	26.03.2024
Statutory Director of Public Health		_	
Rachel Robinson	Shropshire Council	£5580000	26/03/2024
Consultant in Public Health / Deputy Statutory Director of Public Health			
Elizabeth Walker Deputy Director Medicines	NHS Shropshire Telford and Wrekin Integrated Care	Zeal	25/03/2024
Management Medicines	Board		
Dr Arabinda Kundu	Midlands Partnership		26/03/2024
Consultant/Clinical Lead in Sexual Health	Foundation Trust	Denil.	

Characteristics of staff

2024

 Qualifications professional registration to be held by staff undertaking PGD Pharmacist authorised by Telford and Wrekin Counce Shropshire Council to provide a Chlamydia Treatment Sper the Service Specification. Pharmacist is required to have suitable indemnity insurar The registered pharmacist authorised to operate under must have undertaken appropriate education and train successfully completed the competencies: to undertake clinical assessment of patient leading to of the condition listed to have a clear understanding of the drug to be admincluding side effects, contraindications, and interaction with the service specification. 	til and/or ervice as nce. this PGD ning and diagnosis ninistered ons.
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- to ensure safe provision of the medicines listed in acc	
 Individuals operating under this PGD must have understanding of the legal requirements to operate Overview Patient group directions Guidance NICE 	
 Recommended training for working under PGDs for the su administration of medicines - eLfH PGD elearning progra 	
 Completion of the current CPPE training packages of Health in Pharmacies <u>Sexual health in pharmacies</u>: <u>CF</u> Safeguarding Vulnerable Adults and Children <u>Safe</u> (<u>cppe.ac.uk</u>) 	PE and
 Completion of the CPPE learning pack – Combating Chil Exploitation (CSE): An e-learning resource for he professionals <u>Combatting CSE - An e-learning resource</u> 	ealthcare
Competency • Individuals operating under this PGD must:	
- be assessed as competent (see Appendix A) or co self-declaration of competence for Chlamydia testin treatment Declaration of Competence for pharmacy season Chlamydia Testing and Treatment Service.	ig and/or
- be competent to follow and administer PGD show understanding of indications for treatment (and sul	•
actions to be taken), and the treatment itself.	
 Individuals operating under this PGD are encouraged their competency using the NICE Competency Frame health professionals using patient group directions 	
Ongoing training and Individuals operating under this PGD have a responsibility to ensure their on-going competency by competency	personal ontinually
updating their knowledge and skills. • Attendance at a local training event(s) approved by Te Wrekin Council and/or Shropshire Council is recommend these are organised, but this is not a prerequisite for deliv service.	lford and ed where
The decision to supply any medication rests with the individual registered health profession must abide by the PCD and any associated organisational policies	onal who

must abide by the PGD and any associated organisational policies.

Page 3 of 13 PATIENT GROUP DIRECTION-Supply of azithromycin 250mg/500mg tablets for the treatment of uncomplicated Chlamydia trachomatis – April

Clinical Details

Clinical Details Clinical condition or situation to which this PGD applies	 Uncomplicated asymptomatic genital chlamydia trachomatis infection. Asymptomatic individuals presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of chlamydia trachomatis infection. The use of azithromycin is considered second line treatment for asymptomatic chlamydia infection if doxycycline is contra-indicated.
Aims	To reduce the risks of short- and longer-term complications associated with chlamydia infection such as pelvic inflammatory disease and tubal infertility.
Criteria for inclusion Use BNF/BNFC/SPC. Consider any clinical guidelines or policies that are available locally or nationally, e.g. BASHH / NICE	 Informed consent is given. Where doxycycline is contraindicated (known allergy, previous adverse effects, pre-existing medical conditions, pregnancy, or breastfeeding) or inappropriate (photosensitivity, likely poor adherence): Individuals aged 15 years and over with a positive test result for Chlamydia trachomatis infection in the genitals following screening, but without signs suggestive of complications/remains asymptomatic. Asymptomatic individuals presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of Chlamydia trachomatis, 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.
Criteria for exclusion	 Informed consent not given. Individuals under 15 years of age. Individuals <18 years of age with a body weight of <45kg- (alternative dosage forms are available for this cohort NB: this falls outside this PGD) Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. Gillick competency and Fraser guidelines Individuals 16 years of age and over and assessed as lacking capacity to consent. Medical history Symptoms suggestive of other STIs such as unusual vaginal discharge, or penile discharge; 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 or suspected proctitis/prostatitis. Urethritis. Known severe hepatic impairment. Known severe hepatic impairment (eGFR <10ml/min/1.73m²/ CKD stage 5) Current/past history of cardiac disease, cardiac rhythm or conduction disturbance. Electrolyte disturbances, particularly hypokalaemia/ hypomagnesaemia Presence of concomitant conjunctivitis and/or joint pain/swelling Acute porphyria Myasthenia gravis

Valid from: Review date: Expiry date:

 Rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption

Medication history

- Any concurrent interacting medicine(s) where interaction is severe or clinically significant – 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: <u>CredibleMeds</u>; 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 <u>Summary of Product</u> Characteristics - Azithromycin
- Individuals with known azithromycin resistance.

Please refer to current BNF https://bnf.nice.org.uk/ and SPC for full details https://bnf.nice.org.uk/ and SPC for full details https://www.medicines.org.uk/emc/

Supply to young persons

- If the individual is less than 16 years of age, then they must be assessed for competency based on Fraser guidelines. If they are deemed as being 'Fraser Competent' then a supply can be made and documented in the records.
- Pharmacists must use their professional judgement when considering 'Safeguarding' issues related to sexual activity in young persons.
- If the presenting individual under 13 years of age requests treatment for chlamydia, and there is a reasonable concern that sexual activity has taken place, the pharmacist should always speak to local safeguarding lead and follow the local safeguarding policy. (Note under 15 years of age excluded from treatment under this PGD).
- Local contacts:
 - <u>Family Connect</u> in Telford and Wrekin (01952 385385 / after 5pm and on weekends contact the emergency duty team 01952 676500) or
 - Initial Contact Team in Shropshire (0345 678 9021 / Out of hours 0345 678 9040) Safeguarding Children / Shropshire Council Useful Contacts
- There must always be a presumption that the case will be referred to the Children's Social Care Services in the area where the child lives. A record of the referral should be maintained in the pharmacy. The pharmacy may also adopt: Regional Child Protection Procedures for West Mildands
- If you think the child or young person is in immediate danger telephone 999

Action to be taken if the individual is excluded or declines treatment

- If declined ensure individual is aware of the need for treatment and the potential consequences of not receiving treatment.
- Record reason for decline in the consultation record.
- Explain the reasons for exclusion to the individual and document in the consultation record and/or PharmOutcomes.
- Where required refer the individual to a suitable health service provider e.g. refer to Sexual Health Clinic (0300 123 0994) or the individuals GP and/or provide them with information about further options.
- Pregnant individuals / individuals known to be at risk of pregnancy who decline azithromycin treatment should be referred to a prescriber for further consultation.

Management of individuals requiring referral	Where required refer the individual to a suitable health service provider and document referral details in patient records and/or PharmOutcomes Female with pelvic pain, consider immediate referral to Sexual Health Clinic (0300 123 0994). If pain severe, refer to local A&E department. Symptoms suggestive of other STI – consider immediate referral to Sexual
	 Health Clinic Male with scrotal pain, consider immediate referral to local A&E department. If vomiting occurs within 2 hours of taking initial dose, refer to Sexual Health Clinic or GP for re-evaluation.

Description of treatment

Name, strength & formulation of drug	Azithromycin 250mg or 500mg tablets
Legal category	Prescription Only Medicine (POM)
Route of administration	Oral
Storage	Medicines must be stored securely according to national guidelines and in accordance with the products SPC: <u>Azithromycin 500mg Tablets</u> / <u>Azithromycin 250mg film-coated tablets</u>
Off label use	Best practice advice is given by <u>BASHH</u> and is used as the reference guidance in this PGD and may vary from the <u>Summary of Product Characteristics (SPC)</u> .
	 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. 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. 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 community 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 community 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
	 The tablets can be taken with or without food with a glass of water. The remaining daily doses should be taken at the same time each day.

Duration of treatment	3 days.
Quantity to be	 Appropriately labelled pack of 4x500mg tablets or 8x250mg tablets.
supplied	The wording 'Supplied via PGD' should also be added to the label.
	A single repeat course can be supplied under the PGD if vomiting
David interactions	occurs within 3 hours of a dose being taken. All concurrent medications should be reviewed for interactions. The list of
Drug interactions	interactions and information given below is not exhaustive, a detailed list of all drug interactions is available in the <u>BNF</u> or the product <u>SPC</u> . 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
	- Colonidine - Dabigatran
	- Digoxin
	- Edoxaban
	- Hydroxychloroquine
	- Rifabutin
	- Talazoparib
	- Ticagrelor - Topotecan
	- Vinblastine
	- Vincristine
	- Vindesine
	- Vinflunine
	- Vinorelbine
	 Concomitant use of another medication known to cause QT prolongation (e.g. amiodarone, 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®)
	The SPC highlights important, clinically significant interactions as follows: • Warfarin — occasionally and unpredictably, the effects of warfarin
	may be markedly increased by macrolides. o Monitor the international normalized ratio (INR), and adjust the warfarin dose accordingly.
	Statins — the manufacturer reports post-marketing cases of
	rhabdomyolysis in people taking azithromycin with statins. o Advise the person to report any muscle pain, tenderness, or weakness.
	Ciclosporin — azithromycin can affect clearance of ciclosporin. If co- administration of these drugs is necessary, ciclosporin levels should
	be monitored and the dose adjusted accordingly Fract derivatives - Due to the theoretical possibility of ergotism, the
	 Ergot derivatives - Due to the theoretical possibility of ergotism, the concurrent use of azithromycin with ergot derivatives is contra- indicated in this PGD.
	maiotion in the LOD.

- Antacids can reduce peak serum concentrations of azithromycin so must not be taken at the same time. Azithromycin must be taken at least 1 hour before or 2 hours after antacids.
- Digoxin and Colchicine concomitant administration can result in increased serum levels of digoxin and colchicine and therefore signs of toxicity should be monitored.
- Hydroxychloroquine and chloroquine Observational data have shown that co-administration of azithromycin with hydroxychloroquine in patients with rheumatoid arthritis is associated with an increased risk of cardiovascular events and cardiovascular mortality. A similar potential risk is associated with chloroquine and therefore concurrent use with azithromycin is contraindicated in this PGD.
- Drugs that prolong the QT interval (such as amiodarone, sotalol, terfenadine, and amisulpride) — all macrolides can prolong the QT interval, and concomitant use of drugs that prolong the QT interval is not recommended.
- Drugs that cause hypokalaemia (such as diuretics, corticosteroids, short-acting beta-2 agonists) — hypokalaemia is a risk factor for QT prolongation.

Cautions including any relevant action to be taken

A detailed list of Special warnings and precautions for use is available in the <u>SPC</u>

- Visual impairment and vision blurred may have an effect on a patient's ability to drive or operate machinery.
- Dizziness and drowsiness may occur with azithromycin.
 - Individuals experiencing these side effect should avoid driving or operating machinery.
- Pseudomembranous colitis should be considered in patients who get diarrhoea after starting treatment with azithromycin.
- Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. difficile.
 - Clostridoides difficile associated diarrhoea (CDAD) must be considered in all patients who present with diarrhoea following antibiotic use [may range in severity from mild diarrhoea to fatal colitis].
 - Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antimicrobial agents.
 - In case of CDAD anti-peristaltics are contraindicated.
- 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 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.
Identification of	A detailed list of adverse reactions is available in the SPC and BNF
adverse reactions	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	Individuals should be advised of common side effects and
reporting procedure	management.
for adverse drug	 An individual presenting with a suspected serious ADR should be
reactions (ADR)	referred to their GP.
	 Individuals should be advised to seek urgent medical attention if they
	develop early symptoms of anaphylaxis such as breathlessness or
	swelling.
	 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 ADRs in the individual's medical record.
	 Report any adverse reactions via organisation incident policy.
Written information	Medication:
and further advice to	 Give patient information leaflet (PIL) provided with the original pack.
be given to individual	Explain mode of action, side effects, and benefits of the medicine
be given to marvidual	 Azithromycin tablets can be taken at any time in relation to food.
	If vomiting occurs within 3 hours of taking tablets offer option of repeat
	dose of azithromycin (under PGD).
	Where possible avoid the use of antacids.
	•
	 In patients receiving both azithromycin and antacids, the medicinal products should not be taken simultaneously, but with an interval of azithromycin being taken at least one hour before or 2 hours

after the antacid.

- In females taking oral contraceptives, if they do experience vomiting or have severe diarrhoea for more than 24 hours after taking azithromycin tablets, this may lead to contraceptive failure. Refer to the instruction leaflet included with the relevant oral contraceptive pill to manage the risk of contraceptive failure.
 - There is no interaction between azithromycin and oral contraceptives; the warning is related to the risk of vomiting/diarrhoea after taking azithromycin.
 Common questions about azithromycin - NHS (www.nhs.uk)

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 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.
- All individuals with confirmed chlamydia infection should be advised to contact their local sexual health clinic for partner notification purposes.
- All individuals with confirmed chlamydia infection should be encouraged to be screened for other sexually transmitted infections (STIs).
- Offer condoms and advice on safer sex practices.
- Where treatment not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services.
 - Sexual Health Clinic Tel No: 0300 123 0994
 - Sexual Health Service Information

Follow up treatment

- The individual should be advised to seek medical advice in the event of an adverse reaction.
- Individuals with Chlamydia trachomatis who have not had a full sexually transmitted infections (STIs) 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.
- Routine follow-up/TOC (test of cure) for uncomplicated Chlamydia trachomatis following treatment with azithromycin is unnecessary, except in the following situations:
 - Pregnancy.
 - Where poor compliance is suspected.
 - Where symptoms persist.
 - Rectal infections.
 - Under 25-year-olds.
 - Mycoplasma genitalium infection.

Records In discussion with the individual enter consultation details onto the relevant module within PharmOutcomes or complete the paper proforma if unable to access PharmOutcomes at the time of the consultation. Informed verbal consent should be obtained. Consent: 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 a safeguarding referral is made, a record of the referral must be maintained in the pharmacy. If individual not treated under PGD record action taken If the individual is excluded, a record of the reason for exclusion must be documented within PharmOutcomes, and any specific advice that has been given. 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 medication supplied. Date of supply. Dose supplied. Date of supply. Dose supplied. Advice given about the medication including side effects, benefits, and when and what to do if any concerns. Advice given about the medication send actions taken. Any referral arrangements made. Any referral arrangements made. 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 adults for a period of 10 years after attendance and for children until the child is 25 years old.		TOC should be performed >3 weeks after treatment.
module within PharmOutcomes or complete the paper proforma if unable to access PharmOutcomes at the time of the consultation. Informed verbal consent should be obtained. Consent: 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 a safeguarding referral is made, a record of the referral must be maintained in the pharmacy. If individual not treated under PGD record action taken If the individual is excluded, a record of the reason for exclusion must be documented within PharmOutcomes, and any specific advice that has been given. 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. 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 erecords) and securely kept for adults for a period of 10 years after attendance and for children until the child is 25 years old.		Chlamydia trachomatis/urethritis (microguide.global)
 Consent: 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 a safeguarding referral is made, a record of the referral must be maintained in the pharmacy. If individual not treated under PGD record action taken If the individual is excluded, a record of the reason for exclusion must be documented within PharmOutcomes, and any specific advice that has been given. 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 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 about the medication included 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 erecords) and securely kept for adults for a period of 10 years after attendance and for children until the child is 25 years old. Computerised patient medication records of all individuals receiving treatment under this PGD are recommended to be kept. 	Records	module within PharmOutcomes or complete the paper proforma if unable
 All records should be clear, legible, and contemporaneous. 		 Informed verbal consent should be obtained. Consent: 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 a safeguarding referral is made, a record of the referral must be maintained in the pharmacy. If individual not treated under PGD record action taken If the individual is excluded, a record of the reason for exclusion must be documented within PharmOutcomes, and any specific advice that has been given. 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. 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 erecords) and securely kept for adults for a period of 10 years after attendance and for children until the child is 25 years old. Computerised patient medication records of all individuals receiving treatment under this PGD are recommended to be kept.

References

Key references	•	Electronic Medicines Compendium Home - electronic medicines
		compendium (emc)
	•	Electronic BNF BNF (British National Formulary) NICE
	•	NICE Medicines practice guideline "Patient Group Directions"
		Published: 02 August 2013 Last updated: 27 March 2017
		Overview Patient group directions Guidance NICE
	•	BASHH - 2015 UK national guideline for the management of infection
		with Chlamydia trachomatis
		Chlamydia 2015 BASHH
	•	BASHH CEG September 2018 – <u>Update on the treatment of <i>Chlamydia</i></u>

Page 11 of 13 PATIENT GROUP DIRECTION-Supply of azithromycin 250mg/500mg tablets for the treatment of uncomplicated Chlamydia trachomatis – April 2024

Insert logo of authorising body

trachomatis (CT) infection

Specialist Pharmacy Service (SPS) Identifying risk factors for developing a long QT interval. Published 29 March 2023 Identifying risk factors for developing a long QT interval – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

- Royal Pharmaceutical Society Safe and Secure Handling of Medicines.
 Issue date December 2018 Updated: 22 January 2024
 Professional guidance on the safe and secure handling of medicines (rpharms.com)
- Chlamydia uncomplicated genital Last revised in January 2024
 Scenario: Management | Management | Chlamydia uncomplicated genital | CKS | NICE
- Treatment summaries <u>Genital system infections</u>, <u>antibacterial therapy</u> <u>Treatment summaries | BNF | NICE</u>
- NHS STW: Microguide Antibiotic Guidance

Glossary	BNF – British National Formulary
	SPC – Summary of Product Characteristics
	PIL – Patient Information Leaflet
	PGD – Patient Group Direction
	CKS – Clinical Knowledge Summaries
	BASHH – British Association for Sexual Health and HIV

Date last reviewed: March 2024	Date for next review:
Expiry date:	Version No: 3.0 / 2024

Appendix A – Registered health professional authorisation sheet

Operation of this PGD is the responsibility of the commissioner and service providers.

PGD Name /	Supply of Azithromycin 250/500mg tablets for the treatment of uncomplicated
Version	Chlamydia trachomatis in Community Pharmacy / Version No: 3.0 / 2024
Valid from	
Expiry	

- This page must be completed and retained by each individual Pharmacist who intends to work in accordance with this PGD.
- The practitioner must be authorised by name, under the current version of this PGD before working according to it.
- Before signing this PGD, check that the document has had the necessary authorisations and is the up to date and correct version. 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.

Professional Responsibility and Declaration

- I have successfully completed the relevant training as outlined in the Service Specification and this Patient Group Direction.
- I agree to maintain my clinical knowledge appropriate to my practice in order to maintain competence to deliver this service.
- I am a registered pharmacist with the General Pharmaceutical Council.
- I confirm that indemnity insurance is in place to cover my scope of practice.
- I confirm that I have read and understood the content of this Patient Group Direction.
- I agree to supply medications listed only in accordance with the PGD.
- I am willing and competent to practise only within the bounds of my own competence and 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.

Add details on how this information is to be retained according to organisation PGD policy.

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