CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR ASYMPTOMATIC CHLAMYDIA TRACHOMATIS INFECTION Azithromycin 250mg/500mg tablets

Version Control

This document is only valid on the day it was printed

The current version of this document can be found on Pharmoutcomes and the LPC website http://www.southstaffslpc.co.uk/services/emergency-hormonal-contraception/

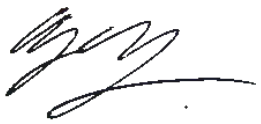
Revision History

Version	Date	Author	Change description
1.0 / 2022	Feb 2022	Andrew Pickard	New PGD

Authorisation

This document requires authorisation by the following individuals:

Management	
PGD Author	Andrew Pickard, Pharmacy Advisor - NHS England & Improvement Midlands (Staffordshire and Shropshire)

Authorisation			
Name and Designation	**Organisation**	**Signature**	**Date**
Richard Harling – Lead Doctor	Staffordshire County Council		30/03/2022
Dr Arabinda Kundu – Consultant /Clinical Director in Sexual Health	Midlands Partnership Foundation Trust		15/03/2022
Andrew Pickard - Pharmacy Advisor	NHS England & Improvement Midlands		07/03/22

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.

Staff Characteristics	
1. Professional qualifications to be held by staff undertaking PGD	Community pharmacists authorised by Central Health Solutions under contract to Staffordshire County Council to provide a Chlamydia Treatment Service as per the Service Specification.
2. Competencies required to be held by staff undertaking this PGD	• Has a clear understanding of the legal requirements to operate a PGD Overview | Patient group directions | Guidance | NICE • Competent to follow and administer PGD showing clear understanding of indications for treatment (and subsequent actions to be taken), and the treatment itself. • Has a clear understanding of the drug to be administered including side effects and contraindications. • All clinicians operating within the PGD have a personal responsibility to ensure their on-going competency by continually updating their knowledge and skills.
3. Specialist qualifications, training, experience and competence considered relevant to the clinical condition treated under this PGD	• The community pharmacist must be registered with the General Pharmaceutical Council • Completion of the current CPPE training packages on Sexual Health in Pharmacies Sexual health in pharmacies : CPPE and Safeguarding Vulnerable Adults and Children Safeguarding children and adults at risk: a guide for the pharmacy team : CPPE • Completion of the CPPE learning pack – Combating CSE: An e-learning resource for healthcare professionals is required Combatting CSE - An e-learning resource for healthcare professionals: CPPE • Attendance at a local training event(s) approved by Staffordshire County Council is recommended where these are organised, but this is not a prerequisite for delivering this service.

CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR ASYMPTOMATIC CHLAMYDIA TRACHOMATIS INFECTION
Azithromycin 250mg/500mg tablets

Clinical Details	
Indication	Asymptomatic genital chlamydia trachomatis infection and sexual contacts of confirmed 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.
Inclusion Criteria	• Informed consent is given • Individuals aged 15 years and over who have a positive genital chlamydial result following screening, and when doxycycline cannot be used. • Sexual contacts of individuals with a positive genital chlamydial result that are aged 15 years and over, and when doxycycline cannot be used. • Retreatment in case of possible reinfection if intercourse has taken place within the recommended 7 days of abstinence since treatment dose taken.
Exclusion Criteria	**Women** • Pregnant/suspected pregnancy/breastfeeding • Suspected pelvic inflammatory disease • Pelvic pain which has recent onset • Symptoms suggestive of other STIs such as unusual vaginal discharge **Men** • Known or suspected proctitis/prostatitis • New or unusual testicular pain • Urethritis • Symptoms suggestive of other STIs such as penile discharge **Women and Men** • Informed consent not given • Individuals under 15 years of age • Individuals who weigh less than 45kg • Known or suspected hypersensitivity to azithromycin or other macrolide antibiotics or to any of the excipients. • Cardiac disease and those with clinically relevant bradycardia, cardiac arrhythmia or severe cardiac insufficiency. • Congenital or documented acquired QT prolongation • Moderate or severe impaired liver function • Severely impaired kidney function • Electrolyte disturbance, particularly in cases of hypokalaemia and hypomagnesaemia • Myasthenia gravis

	• Known or suspected sero-reactive arthritis • Known or suspected conjunctivitis • Sucrose intolerance such as glucose galactose malabsorption or Lapp lactase deficiency • Clinically significant interaction(s) with other medication, particularly those known to prolong the QT interval, ergot derivatives and chloroquine or hydroxychloroquine. **Please refer to current BNF** https://bnf.nice.org.uk/ **and SPC for full details** https://www.medicines.org.uk/emc/

Supply to young persons	If a young person (aged <16 years) requests treatment for chlamydia, then they must be assessed for competency. If they are deemed as being 'Fraser Competent' then a supply can be made, but this must be documented in the records. If the young person is not deemed to be 'Fraser Competent' advice must be sought from First Response Team on: 0800 1313126 (or the Emergency Duty Team on 0345 6042886 outside of office hours). Practitioners should discuss with First Response the remaining need for the child to have treatment for chlamydia. Further guidance can be found at: Gillick competence and Fraser guidelines | NSPCC Learning Pharmacists must be aware of, and comply with the relevant safeguarding expectations from Staffordshire Safeguarding Board regarding sexual activity in young people: Safeguarding Practice Guidance - Staffordshire Safeguarding Children Board (staffsscb.org.uk) If a child under 13 years requests treatment for chlamydia, and there is a reasonable concern that sexual activity has taken place, the pharmacist should always contact the First Response team on 0800 1313 126 (or the Emergency Duty Team on 0345 6042886 outside of office hours) and 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. If you think the child or young person is in immediate danger telephone 999
Management of excluded individuals	• Explain reason for exclusion with the individual and document in patient records and/or PharmOutcomes • Refer to local Sexual Health Clinic or the individuals GP

Management of individuals requiring referral	• Female with pelvic pain, consider immediate referral to Sexual Health Clinic. 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. • Document referral details in patient records and/or PharmOutcomes

Treatment and Drug Details	
Name, form & strength of medicine	Azithromycin 250mg / 500mg tablets
Legal classification	Prescription Only Medicine (POM)
Storage	Store below 25ºC
Route/method	Oral
Dosage/frequency/duration of treatment	A single 1 gram dose followed by 500mg daily for two days The tablets can be taken with or without food. The tablets should be taken with ½ glass of water.
Quantity to supply/administer	Either 8 x 250mg tablets or 4 x 500mg tablets
Labelling requirements	The single 1 gram dose should be taken at the time of the consultation, and therefore labelling is not required. As the individual will be taking the remainder of the medication away with them to complete the course, it must be supplied to them with the same labelling and other information which they would otherwise receive if the medicine had been supplied against a prescription. The wording 'Supplied via PGD' should also be added to the label.
Cautions/	• Dizziness and drowsiness may occur with azithromycin, so individuals should avoid driving or operating machinery if they experience this side effect. • Consider pseudomembranous colitis if an individual develops severe diarrhoea after treatment with azithromycin • Rare serious allergic reactions including anaphylaxis have been reported with azithromycin *Clostridium difficile*-associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents including clarithromycin, and may range in severity from mild diarrhoea to fatal colitis. CDAD must be considered in all individuals who present with diarrhoea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents
Side effects/Adverse Reactions	Azithromycin is well tolerated with a low incidence of side effects. • Gastrointestinal adverse effects, such as nausea, vomiting, diarrhoea, and abdominal discomfort • Less common side effects include deafness, tinnitus, rash, pruritis, fatigue, arthralgia and anorexia. **Please refer to current BNF** http://bnf.org/bnf **and SPC** www.medicines.org.uk/emc **for full details** All serious adverse reactions must be reported to MHRA via

	the Yellow Card System www.yellowcard.gov.uk . An individual presenting with a suspected serious ADR should be referred to their GP.

Drug interactions	• **Warfarin** — occasionally and unpredictably, the effects of warfarin may be markedly increased by macrolides.
	  ○ 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, although this appears to be less common than with other macrolides.
	  ○ Advise the person to report any muscle pain, tenderness, or weakness.
	  ○ Advise the person not to take their dose of statin on the same day as taking azithromycin.
	• **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
	• **Ergot derivatives**: Due to the theoretical possibility of ergotism, the concurrent use of azithromycin with ergot derivatives is contra-indicated in this PGD
	• **Antacids** – can reduce peak serum concentrations of azithromycin so must not be taken at the same time
	• **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.
	
	Please refer to current BNF http://bnf.org/bnf **and SPC** www.medicines.org.uk/emc **for full details**

Advice/follow up treatment	• Take and read patient information leaflet. • Take either 4 x 250mg tablets or 2 x 500mg tablets as a single dose with a glass of water. The remaining daily doses should be taken at the same time each day. • Tablets can be taken with or without food • Where possible avoid the use of antacids. If using antacids, take azithromycin at least one hour before, or two hours after the antacid. • In females taking oral contraceptives, if they do experience vomiting or diarrhoea 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. • Individuals and/or partner to abstain completely from sexual contact (even with a condom) for 7 days from time of treatment. • Discuss implications of incomplete treatment of individual or partner • Advise on common side effects and management, including if vomiting occurs within 2 hours of initial dose • Individuals should be advised to seek urgent medical attention if they develop early symptoms of anaphylaxis such as breathlessness, swelling or rash. • All individuals with confirmed chlamydia infection should be encouraged to be screened for other sexually transmitted infections. • All individuals with confirmed chlamydia infection should be advised to contact their local sexual health clinic for partner notification purposes. • Individuals should be advised to attend for STI screening at a GUM clinic at least one week after completion of treatment • Provide contact details for sexual health clinic.

Records and Follow Up	
Supply	Individuals should be provided with the patient information leaflet and local guide to the Sexual Health Clinic. Sexual Health Clinics in Staffordshire are run by Midlands Partnership NHS Foundation Trust (MPFT) To find out opening times in north Staffordshire (districts of Newcastle under Lyme and Staffordshire Moorlands) Telephone: 0300 7900 165 To find out opening times in southern Staffordshire (districts of Cannock, East Staffordshire, Lichfield, South Staffordshire, Stafford and Tamworth Telephone 0300 124 5022 Alternatively, opening times for MPFT clinics across Staffordshire can be found here: Home - Open Clinic All individuals, whether supplied with treatment or not should be given the local guide to Sexual Health Services.
Records/audit trail	• 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 (for individuals aged under 16 years, Fraser guidelines should be followed) • Electronic patient records and/or the completed paper proforma should be retained for adults for a period of 10 years after attendance and for children until the child is 25 years old. Computerised patient medication records are recommended to be kept. • 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. • If a safeguarding referral is made, a record of the referral must be maintained in the pharmacy
Adverse drug reactions	All serious adverse reactions must be reported to MHRA via the Yellow Card System www.yellowcard.mhra.gov.uk . An individual presenting with a suspected serious ADR should be referred to their GP.

Date last reviewed: February 2022	**Date for next review: February 2024**
Expiry date: 31st March 2024	**Version No: 1.0 / 2022**

References	Electronic Medicines Compendium - Home - electronic medicines compendium (emc) Electronic BNF - BNF British National Formulary - NICE BASHH - 2015 UK national guideline for the management of infection with *Chlamydia trachomatis* https://www.bashhguidelines.org/current-guidelines/urethritis-and-cervicitis/chlamydia-2015/ CKS – Chlamydia (uncomplicated genital) 2021 https://cks.nice.org.uk/topics/chlamydia-uncomplicated-genital/
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

Register of practitioners qualified to supply Azithromycin 250/500mg tablets via PGD

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

The practitioner must be authorised by name, under the current version of this PGD before working according to it.

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

Central Health Solutions under contract to Staffordshire County 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 Central Health Solutions.

This page must be completed and retained by each individual Pharmacist who intends to work in accordance with this PGD.

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 and that I am willing and competent to work to it within my professional code of conduct

Name of professional (please print)	Signature	Date of signing

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY