PATIENT GROUP DIRECTION

Supply of azithromycin 250mg tablets or capsules and 500mg tablets by registered pharmacists for the treatment of uncomplicated genital Chlamydia trachomatis infection in Community Pharmacy, where first line treatment with doxycycline is contraindicated or unsuitable

Version 5.0

Valid from: 7th January 2021

Expires on: 6th January 2023

This Patient Group Direction (PGD) must only be used by registered health 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.

AZITHROMYCIN 250MG TABLETS OR CAPSULES AND 500MG TABLETS

P.O.M.
[Prescription Only Medicine]

DOCUMENT CONTROL – PGD Ready for authorisation

Document Location

Copies of this PGD can be obtained from:

Name:	Rochdale Council
Address:	No. 1 Riverside, Smith Street, Rochdale OL16 1XU
Telephone:	01706 652888

Revision History

The latest and master version of the unsigned PGD is held by Greater Manchester joint Commissioning Team.

Revision date & actioned by	Summary of changes		Version
29/08/2018 S Woods	Finalised document ready for signing.		3.0
19/12/2018 S Woods	Final formatting for sign off.		4.0
27/10/2020 K Osowska	Technical review of the PGD		4.1
	Section of the PGD	Changes made:	
	Title of the PGD	Title was amended to reflect that azithromycin should be used when doxycycline is contraindicated or unsuitable.	
	Characteristics of staff	As per national PGD on the treatment of Chlamydia trachomatis (version 1.1) the pharmacists providing azithromycin under this PGD are required to complete local training on safeguarding children and vulnerable adults. Therefore this section of the PGD was amended to reflect this training requirement.	
	Criteria for inclusion	Information amended to reflect on the use of azithromycin only if doxycycline treatment occurs contraindicated or inappropriate.	
		Added information on the treatment of breast-feeding women.	
	Criteria for exclusion	Added 3 exclusion criteria as per national PGD (version 1.1): • Consent not given	

		• Individuals 16 years of age and over and assessed as lacking capacity to consent • Individuals with known azithromycin resistance	
27/10/2020 K Osowska	Cautions (including any relevant action to be taken)	Amended information about the allergy to azithromycin excipients.	4.1
		Added information about pregnant patients and patients being at risk of pregnancy	
		Added information on breast-feeding women	
		Added information about recording the assessment based on Fraser guidelines of 16 years old patients	
		Added information on contacting the local safeguarding lead in case of individuals under 13 years of age	
		Added information on contacting with appropriate prescriber if there is uncertainty around patient treatment.	
		Added information that the reason of exclusion should be explained and recorded.	
	Action if patient excluded from the treatment	Added information that the reason of decline should be recorded among all actions taken.	
	Action if patient or carer declines treatment	Added information about referring pregnant, being at risk to be pregnant and breast-feeding women to appropriate prescriber for further consultation.	
	Storage	The information about the storage was amended as per national PGD to (version 1.1): Medicines must be stored securely according to national guidelines and in accordance with the product SmPC.	
	Unlicensed/ off label use	This section was amended as per national PGD (version 1.1) to reflect off label use of azithromycin under this PGD:	

		'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 (SmPC). 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' 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.'	
	Drug interactions	This section was amended with the list of severe interactions as per BNF.	
	Records	This section was amended as per national PGD (version 1.1) around the minimum required information which is required to be recorded in patients: • Under 13 years of age • Under 16 years of age • Over 16 years of age	
		Record Management Code of Practice for Health and Social Care 2016 recommends the following storage periods for health records: • 8 years (in adults) or until 25th birthday in a child (age 26 if entry made when young person was 17), or 8 years after death. changed to: PGD records should be stored for adults aged 18 years and over for 8 years and for children until the 25th birthday or for 8 years after a child's death (as per SPS Retention of Pharmacy	

		Record and SPS Retaining PGD documentation)	
	Advice to be given to the patient and carer	Advice for pregnant patients or at risk of pregnancy or patients who are breastfeeding was amended. See below. ▪ Patients who are pregnant or at risk of being pregnant and who wish to receive treatment under this PGD should be informed that as per national guideline (BASHH) azithromycin treatment is thought to be safe however there is limited research available. These patients should be fully informed of the risks and benefits of this treatment. ▪ Patients who are breastfeeding and wish to receive treatment under this PGD should be informed that the national guideline (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'. These patients should be fully informed of the risks and benefits of azithromycin treatment and that this treatment is considered 'off label'. ▪ Pregnant women or being at risk of pregnancy or who are breastfeeding and do not wish to take azithromycin treatment should be informed of the availability of alternative treatments (e.g. erythromycin for 1 or 2 weeks or amoxicillin for 1 week) and should be referred to appropriate prescriber /sexual health clinic.	
	References used to develop this PGD	All references were reviewed, updated and amended where required.	
	Individual authorisation	This section name was changed to: 'Pharmacist authorisation sheet' The whole form was updated as per most recent SPS national PGD template	
10/12/2020 K Osowska	Title	Title was changed from: Supply of azithromycin 250mg tablets or capsules and 500mg tablets for the treatment of uncomplicated genital Chlamydia trachomatis infection, where first line treatment with doxycycline is contraindicated or unsuitable, by	4.2

		pharmacists working in Community Pharmacy To Supply of azithromycin 250mg tablets or capsules and 500mg tablets by registered pharmacists for the treatment of uncomplicated genital Chlamydia trachomatis infection in Community Pharmacy , where first line treatment with doxycycline is contraindicated or unsuitable,	
	Criteria for exclusion	Addition of one criterion as per Azithromycin national PGD template (version 1.2) • Individuals with suspected or confirmed Lymphogranuloma venereum (LVG)	
	Quantity to be administered and/or supplied	Addition of the note on remote consultations. 'The service is usually delivered face to face at the pharmacy premises. For the duration of the COVID-19 pandemic, to reduce risk of transmission, pharmacists may use their professional judgement on how they provide Chlamydia treatment service (e.g. remotely via telephone or appropriate digital methods). If the service is to be delivered remotely, the pharmacist must ensure that an appropriate consultation/clinical review takes place and the patient is seen face to face if required. Remote consultations must be conducted in a manner that ensures patient confidentiality. If the service is provided remotely, products must be supplied in a timely fashion. Supplies made utilising this temporary adjustment should be recorded as such. '	4.2
09/12/2020 K Osowska	Records	In Rochdale council all Chlamydia treatment consultations under this PGD are recorded via PharmOutcomes therefore there was a note added to reflect on this. 'The pharmacist must make an entry for each patient on the PharmOutcomes system and complete all mandatory entries as required by the service specification and this PGD'	4.2
		Bullet point 'Complete and return via a secure method any relevant forms to screening/treatment coordination organisation' was removed as it is no longer relevant.	
10/12/2020	Final formatting for sign off.		5.0

AZITHROMYCIN 250MG TABLETS OR CAPSULES AND 500MG TABLETS

P.O.M.
[Prescription Only Medicine]

Approvals
This PGD must be approved by the following before distribution:

NAME	TITLE	DATE OF ISSUE	VERSION
Dr Aggy York	Clinical Lead Heywood, Middleton & Rochdale CCG	15.12.2020	5.0
Andrew Martin	Strategic Medicines Optimisation Pharmacist, GM JCT	10.12.2020	5.0
Andrea Fallon	Director of Public Health, Rochdale Metropolitan Borough Council	05.01.2021	5.0
Luvjit Kandula	Director of Pharmacy Transformation, GM LPC	30.12.2020	5.0

Distribution

This PGD has been distributed, during its development, to:

NAME	TITLE	DATE OF ISSUE	VERSION
Dr Aggy York	Clinical Lead Heywood, Middleton & Rochdale CCG	04.11.20 14.12.20	4.1 5.0
Luvjit Kandula	Director of Pharmacy Transformation, GM LPC	04.11.20 14.12.20	4.1 5.0
Dr Keith Pearson	Head of Medicines Optimisation, HMR CCG	04.11.20 14.12.20	4.1 5.0
Lianne Davis	Public Health Specialist, Rochdale Borough Council	04.11.20 14.12.20	4.1 5.0
Andrew Martin	Strategic Medicines Optimisation Pharmacist, GM JCT	04.11.20 10.12.20	4.1 5.0

AZITHROMYCIN 250MG TABLETS OR CAPSULES AND 500MG TABLETS	P.O.M. [Prescription Only Medicine]

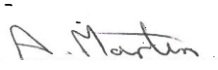
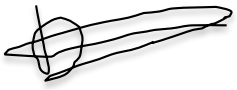
PGD Development

Originally developed / reviewed by:	Stephen Woods (author)	Senior Medicines Optimisation Pharmacist, Greater Manchester Joint Commissioning Team
	Karina Osowska (reviewer)	Advanced Medicines Optimisation Pharmacist , Greater Manchester Joint Commissioning Team
	Dr Aggy York	Clinical Lead Heywood, Middleton & Rochdale CCG
	Luvjit Kandula	Director of Pharmacy Transformation, GM LPC
	Dr Keith Pearson	Head of Medicines Optimisation, Heywood, Middleton & Rochdale CCG

Date applicable:	7th January 2021
Review date:	1st September 2022
Expiry date:	6th January 2023

PGD Authorisation

This Patient Group Direction has been approved for use in the Rochdale Metropolitan Borough Council area by:

Designation	Name	Signature	Date
Senior Pharmacist (Strategic Medicines Optimisation Pharmacist, GM JCT)	Andrew Martin		10.12.2020
Doctor (Clinical Lead Heywood, Middleton & Rochdale CCG)	Dr Aggy York		15.12.2020
Community Pharmacy Representative (Director of Pharmacy Transformation, Greater Manchester LPC)	Luvjit Kandula		30.12.2020

AZITHROMYCIN 250MG TABLETS OR CAPSULES AND 500MG TABLETS	P.O.M. [Prescription Only Medicine]

Reviewer (Advanced Medicines Optimisation Pharmacist, GM Joint Commissioning Team)	Karina Osowska		10.12.2020
Authorising Signatory (Director of Public Health, Rochdale Metropolitan Borough Council)	Andrea Fallon		05.01.2021

1. Characteristics of staff

Qualifications required	▪ Pharmacist with current General Pharmaceutical Council registration ▪ Work in a Community Pharmacy within the Rochdale Metropolitan Borough Council area
Additional requirements	▪ Has undertaken training in the use of PGDs. ▪ Has undertaken training which enables the pharmacist to make a clinical assessment in order to establish the need and supply azithromycin according to this PGD as detailed in the service specification. ▪ Has satisfied the competencies appropriate to this PGD, as detailed in the Centre for Postgraduate Pharmacy Education (CPPE) and NHS Health Education England *Declaration of Competence for pharmacy services – Chlamydia screening and treatment document* (https://www.cppe.ac.uk/services/declaration-of-competence). ▪ Has an understanding of how to deal with a possible anaphylactic reaction, this could include access to a member of staff trained in basic life support. ▪ Has completed locally required training (including updates) in safeguarding children and vulnerable adults.
Continued training requirements	▪ The pharmacist should be aware of any change to the recommendations for the medicine listed. ▪ Must be able to show regular update in the field of contraceptive and reproductive health care, in particular sexually transmitted diseases. ▪ Must assess and maintain their own competence on the medicine supplied under this PGD in line with the requirements contained within the *Declaration of Competence for pharmacy services – Chlamydia screening and treatment* document. ▪ It is the responsibility of the pharmacist to keep up-to-date with continuing professional development. ▪ It is the responsibility of the pharmacist to maintain their own competency to practice within this PGD. Further training may be necessary when the PGD is reviewed.
Suggested supporting learning	It is essential that pharmacists complete and satisfy the competencies detailed in the CPPE and NHS Health Education England *Declaration of Competence for pharmacy services – Chlamydia screening and treatment* document.

AZITHROMYCIN 250MG TABLETS OR CAPSULES AND 500MG TABLETS	P.O.M. [Prescription Only Medicine]

The Pharmacy Contractor is responsible for ensuring that only suitable pharmacists sign up to this PGD and should maintain a record of the names of individual pharmacists and evidence of their self-declaration and sign up to the current PGD.

AZITHROMYCIN 250MG TABLETS OR CAPSULES AND 500MG TABLETS	P.O.M. [Prescription Only Medicine]

2. Clinical condition or situation to which the direction applies.

Clinical condition or situation to which this PGD applies	Patients either known or suspected of having uncomplicated genital *Chlamydia trachomatis* infection identified by the local screening service and in line with the current service specification. There are two Patient Group Directions (PGDs) in Rochdale Metropolitan Borough Council area for the treatment of *Chlamydia trachomatis* infection. ▪ The PGD for doxycycline must be considered for first line use, unless exclusions apply or there are concomitant medication considerations. ▪ This PGD for azithromycin can be considered for second line use where doxycycline is contraindicated or not tolerated.
Criteria for inclusion	Where doxycycline is contraindicated (e.g. known allergy, previous adverse effects, pre-existing medical conditions) or inappropriate (e.g. photosensitivity, likely poor adherence): ▪ Male or female patients either with a laboratory-confirmed positive genital *Chlamydia trachomatis* infection or who is a sexual contact of any patient who has a laboratory-confirmed positive genital *Chlamydia trachomatis* infection. The local screening service will notify pharmacies of infected individuals and identified sexual contacts asking to attend that pharmacy. ▪ Have no known contraindications or allergies to azithromycin or the excipients of either formulation ▪ Pregnant and breast-feeding women willing to take (see Cautions Patient Information sections for further information) ▪ Understand the risks, benefits and side effects ▪ Are competent to consent to treatment ▪ Meet Fraser guidelines, if under 16 years of age. *Note children under 13 years of age must be notified to the local Safeguarding Team and treatment provided by an appropriate NHS doctor / independent non-medical prescriber.*
Criteria for exclusion[1]	▪ Consent not given ▪ Individuals under 16 years old who are assessed as lacking capacity to consent using Fraser Guidelines ▪ All individuals under 13 years of age or weighing less than 45kg. ▪ Individuals 16 years of age and over and assessed as lacking capacity to consent. ▪ Individuals who cannot take tablets or capsules ▪ Known allergy or hypersensitivity to azithromycin or other macrolide antibiotics or any constituent of the medication. ▪ Individuals with known azithromycin resistance ▪ Any medicine known to interact with azithromycin including drugs known to prolong QT interval see the current British National Formulary (BNF) (https://bnf.nice.org.uk/) or the Summary of Product Characteristics (SmPC) (http://www.medicines.org.uk/emc/) for further

[1] Exclusion under this Patient Group Direction (PGD) does not necessarily mean the medication is contraindicated but it may be outside the remit of the PGD and another form of authorisation may be suitable.

	information ▪ Non-genital *Chlamydia trachomatis* infection ▪ Complicated *Chlamydia* infection in males e.g. with epididymitis or testicular pain ▪ Complicated *Chlamydia* infection in females, e.g. pelvic pain or suspected pelvic inflammatory disease. ▪ Porphyria ▪ Fever ▪ Known hepatic and /or renal impairment ▪ Current/past history of cardiac rhythm or conduction disturbance ▪ Myasthenia gravis – azithromycin can cause exacerbation of symptoms ▪ Concomitant conjunctivitis and/or joint pain/swelling ▪ Individuals with suspected or confirmed Lymphogranuloma venereum (LVG)
Cautions (including any relevant action to be taken)	▪ Some brands of azithromycin contain soya or soya lecithin as an excipient, 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 SmPC 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 pharmacist 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 you are unsure or uncertain.
Action if patient excluded from the treatment	▪ Explain the reasons for exclusion to the individual and document in the consultation record along with all actions taken. ▪ Refer to appropriate medical or non-medical prescriber or sexual health clinic; this should be done in conjunction with the local screening service. ▪ If excluded because the patient is under 13 years of age, information

	should usually be shared in accordance with local guidance, but if a decision is made not to disclose there should be discussion with a named or designated healthcare professional for child protection, with a record of the decision stating the reasons.[2] ▪ Document all actions taken.
Action if patient or carer declines treatment	▪ Record reason for decline in the consultation record and document all actions taken. ▪ Make individual aware of the need for treatment and the potential consequences of not receiving it, and refer to appropriate medical and non-medical prescriber or sexual health clinic; this should be done in conjunction with the local screening service. ▪ Pregnant or breast-feeding individuals or individuals known to be at risk of pregnancy who decline azithromycin treatment should be referred to a prescriber for further consultation.

2 Clinical Effectiveness Group, British Association for Sexual Health and HIV, United Kingdom National Guideline on the Management of Sexually Transmitted Infections and Related Conditions in Children and Young People (2010)

AZITHROMYCIN 250MG TABLETS OR CAPSULES AND 500MG TABLETS	P.O.M. [Prescription Only Medicine]

3. Details of medicine

Name, strength & formulation of drug	Azithromycin 250mg capsules or tablets and 500mg tablets
Presentation	Oral capsules or tablets
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SmPC.
Legal category	POM
Black Triangle ▼	No
Unlicensed / 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 (SmPC). 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' 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.
Route / method of administration	Oral
Dose and frequency	1g as a single dose, then 500mg daily for two days. If a patient vomits within 3 hours of taking the initial dose then a further 1g dose can be given.
Quantity to be administered and/or supplied	8 x 250mg capsules or tablets or 4 x 500mg tablets Should the patient vomit within 3 hours of the first dose then an additional: 4 x 250mg capsules or tablets or 2 x 500mg tablets can be supplied. However, if the patient vomits again or on subsequent doses then they should be referred to an appropriate prescriber or sexual health clinic; this should be done in conjunction with the local screening service.

AZITHROMYCIN 250MG TABLETS OR CAPSULES AND 500MG TABLETS	P.O.M. [Prescription Only Medicine]

	Note on provision of the service during COVID 19 pandemic: **The service is usually delivered face to face at the pharmacy premises. For the duration of the COVID-19 pandemic, to reduce risk of transmission, pharmacists may use their professional judgement on how they provide Chlamydia treatment service (e.g. remotely via telephone or appropriate digital methods). If the service is to be delivered remotely, the pharmacist must ensure that an appropriate consultation/clinical review takes place and the patient is seen face to face if required. Remote consultations must be conducted in a manner that ensures patient confidentiality. If the service is provided remotely, products must be supplied in a timely fashion. Supplies made utilising this temporary adjustment should be recorded as such.**
Maximum or minimum treatment periods	Three days
Drug interactions	▪ If the patient is taking any concomitant medication or treatment it is the pharmacist's responsibility to ensure that treatment with the drug detailed in this PGD is appropriate. (For drug interaction see BNF (https://bnf.nice.org.uk/interaction/azithromycin-2.htm) or the SmPC (http://www.medicines.org.uk/emc/) or contact the Medicine Information Service at Liverpool (https://www.ukmi.nhs.uk/ukmi/directory/results/results.asp?selkeyword=liver) ▪ The interactions listed as severe in the BNF are: ➢ Colchicine ➢ Digoxin ➢ Edoxaban ➢ Rifabutin ➢ Talazoparib ➢ Ticagrelor ➢ Topotecan ▪ In case of any doubt, further advice must be sought from an appropriate health professional and recorded as having been sought before the drug is given. ▪ If the requirements of this PGD cannot be complied with the patient must be referred to a suitable independent prescriber.

AZITHROMYCIN 250MG TABLETS OR CAPSULES AND 500MG TABLETS	P.O.M. [Prescription Only Medicine]

Identification & management of adverse reactions

Very common and common adverse effects	
Appetite decreased, headache, pancreatitis	Arthralgia, hearing impairment, sensation abnormal
Diarrhoea, nausea, vomiting	Gastrointestinal discomfort, Gastrointestinal disorders
Dizziness, vision disorders, eye discomfort	Skin reactions , sleep disorders, vasodilation, taste altered

With azithromycin, as with erythromycin and other macrolides, rare serious allergic reactions including angioneurotic oedema and anaphylaxis (rarely fatal) have been reported.

For a full adverse effects profile, refer to the SmPC (https://www.medicines.org.uk/emc#gref) or the most current edition of the BNF (https://bnf.nice.org.uk/drug/azithromycin.html#sideEffects)

In the event of any adverse reaction:

- Record the adverse reaction in the patient consultation note
- Inform the patient's GP if the client consents to this

If appropriate report the adverse reaction under the Yellow Card scheme (forms can be found at the back of the BNF or completed online at http://yellowcard.mhra.gov.uk)

4. Records

Records	The pharmacist must make an entry for each patient on the PharmOutcomes system and complete all mandatory entries as required by the service specification and this PGD. The minimum required information to be recorded is: ▪ 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 is over 16 years of age and not competent, record action taken ▪ Patient's name, address, date of birth ▪ Contact details of GP (if registered) ▪ Any known allergies and nature of reaction ▪ Relevant past and present medical and sexual history, including medication history ▪ Name of the medication supplied ▪ Dose, form and date of supply ▪ Quantity, batch number and expiry date. ▪ Advice given to patient (including side effects and self-care) ▪ Significant information e.g. if used off licence reason why ▪ Name of pharmacist who supplied the medication ▪ Details of any adverse drug reaction and actions taken ▪ Record any follow up or referral arrangements ▪ Record refusal of treatment by pharmacist if the individual does not meet the inclusion criteria As per SPS Retention of Pharmacy Record and SPS Retaining PGD documentation: ▪ PGD records should be stored for adults aged 18 years and over for 8 years and for children until the 25th birthday or for 8 years after a child's death. Data must be stored in accordance with Caldicott guidance, the Data Protection Act and the General Data Protection Regulation.

5. Patient Information

Written information to be given to the patient or carer	The patient/carer should be given the following written information if appropriate: ▪ The product specific patient information leaflet (PIL) supplied with the original pack. ▪ Any other suitable information with regard to their treatment.
Advice to be given to the patient or carer	The patient/carer should be given the following information verbally if appropriate and requested: ▪ Information on *Chlamydia trachomatis*. ▪ Discuss possible side effects of treatment as listed in patient information leaflet. ▪ If the patient vomits within 3 hours of the initial dose then they should return to the pharmacy and may be provided with an additional 1g dose, but if they vomit on that additional dose or subsequent 500mg doses they will be referred to an appropriate prescriber or sexual health clinic; this will be done in conjunction with the local screening service. ▪ Azithromycin capsules should be taken one hour before or two hours after food and for all formulations there should be a similar gap between taking an antacid. ▪ Reinforce importance of sexual partners seeking treatment. ▪ Repeat testing should be performed 3 months after treatment in under 25-years olds diagnosed with chlamydia and when there is a change in sexual partner. ▪ Patients and their partner(s) must abstain completely from sexual intercourse (even with condom), including oral and anal sex, for 7 days post- azithromycin treatment or completion of other treatment. ▪ Provide information on practising safer sex. ▪ Remind pregnant patients that a test of cure is required after 3 weeks after completing the treatment. ▪ Reinforce the possible need for screening for other sexually transmitted infection (STI). ▪ Patients who are pregnant or at risk of being pregnant and who wish to receive treatment under this PGD should be informed that as per national guideline (BASHH) azithromycin treatment is thought to be safe however there is limited research available. These patients should be fully informed of the risks and benefits of this treatment. ▪ Patients who are breastfeeding and wish to receive treatment under this PGD should be informed that the national guideline (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'. These patients should be fully informed of the risks and benefits of azithromycin treatment and that this treatment is considered 'off label'. ▪ Pregnant women or being at risk of pregnancy or who are breastfeeding and do not wish to take azithromycin treatment should

	be informed of the availability of alternative treatments (e.g. erythromycin for 1 or 2 weeks or amoxicillin for 1 week) and should be referred to appropriate prescriber /sexual health clinic.
Labelling	Medication supplied to the patient must be labelled in accordance with current legislation.

6. References used to develop this PGD

References	▪ British Association for Sexual Health and HIV (BASHH) Clinical Effectiveness Guidelines (all available at https://www.bashh.org/guidelines): ▪ 2015 UK national guideline for the management of *Chlamydia trachomatis*. (Updated September 2018). ▪ Update on the treatment of Chlamydia trachomatis (CT) infection, September 2018 ▪ The use of antibiotics to treat genital infections in pregnant women, August 2017 ▪ British Association for Sexual Health and HIV national guideline for the management of infection with Mycoplasma genitalium (2018) ▪ 2015 UK National Guideline on the management of non-gonococcal urethritis. (Updated May 2018). ▪ Manufacturers' Summaries of Product Characteristics (SmPCs) ▪ Azithromycin film coated Tablets 250mg, Sandoz Ltd. Date of last revision of the text 08/08/20 ▪ Zithromax 250mg capsules, Pfizer Limited. Date of last revision of the text 05/2019. ▪ Azithromycin 500mg film-coated tablets, Sandoz Limited Date of last text revision 08/08/2020British National Formulary Online ▪ BNF Online ▪ Centre for Pharmacy Postgraduate Education ▪ Declaration of competence for community pharmacy services; Chlamydia Testing and Treatment Service. Version 8 (Feb 2014). ▪ General Pharmaceutical Council. ▪ Standards for pharmacy professionals, May 2017. ▪ Guidance on maintaining clear sexual boundaries, May 2017. ▪ NHS Digital ▪ Records Management Code of Practice for Health and Social Care 2016.

- Public Health England
- Summary of antimicrobial prescribing guidance: managing common infections, last updated February 2020
- Specialist Pharmacy Service
- Recommendations for the Retention of Pharmacy Records 2019
- Retaining PGD documentation, December 2019
- National PGD, Supply of azithromycin for the treatment of uncomplicated Chlamydia trachomatis, uncomplicated Mycoplasma genitalium and non-gonococcal/non-specific urethritis, Version 1.1 , May 2020 (currently under review)
- National PGD template, August 2020
- Azithromycin for Chlamydia national PGD template, version 1.2, October 2020

AZITHROMYCIN 250MG TABLETS OR CAPSULES AND 500MG TABLETS	P.O.M. [Prescription Only Medicine]

Pharmacist authorisation sheet

Azithromycin PGD Version 5.0 **Valid from: 07/01/2021** **Expiry: 06/01/2023**

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Pharmacist

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Name	Designation	Signature	Date

Authorising manager

I confirm that the registered pharmacists 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 pharmacists 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.

A copy of this PGD with completed pharmacist authorisation sheet should be retained and available at the pharmacy premises as a record of those pharmacists authorised to work under this PGD.