Northamptonshire Healthcare NHS Foundation Trust

Patient Group Direction

for the Supply and / or Administration

of Azithromycin

By Authorised Registered Pharmacists, working in Primary Care settings, accredited to provide Chlamydia Screening and Treatment

Working in partnership with Northamptonshire Healthcare NHS Foundation Trust

For the treatment of Chlamydia trachomatis

Approved by MMC:	10 th May 2022
Expiry Date:	31 st May 2024
Review Start Date	1 st October 2023

Directorate & Service: Specialist Ambulatory Services in the Ambulatory, Therapy & Diabetes Services stack, Adults and Children's Directorate.

Department responsible for review: Northamptonshire Integrated Sexual Health & HIV Service

Reference number: PGD109 version 2.0

Authorised on behalf of NHFT by

Signature

......Date: 13.05.2022.....

Dr Itai Matumbike Medical Director

to verify that the Trust's clinical governance framework for PGDs has been followed

PATIENT GROUP DIRECTION (PGD) APPROVAL FORM

Title of PGD: Patient Group Direction for the Supply and / or Administration of Azithromycin By Authorised Registered Pharmacists, working in Primary Care settings, accredited to provide Chlamydia Screening and treatment					
Review		Expiry date (if review): 31 st May 2022			
tr		shire Integrate	ed Sex	gs accredited to provide Chlamydia Screening and cual Health and HIV service. All NCSP (National Chlamy	dia
	irectorate: Adults and Children's Directorate; A herapy & Diabetes Services	mbulatory,		Service & Department: Specialist Ambulatory Services Northamptonshire Integrated Sexual Health & HIV Ser NISHH)	
T	etails and declaration of PGD Workgroup ne Lead Author confirms that a PGD is legal and a evelopment of the PGD and agree to be a co-aut			llowing have reviewed and support this proposal for sal is approved.	
Jo	b title & name of post holder			Signature and date	
A g d	ead Author (Registered Health Professional) / Lea s senior registered health professional representi roup, I confirm that use by the group of health pr escribed in this PGD is appropriate and within the	ing the staff rofessionals		AA 29.04.2	2
	icy Milemore, Senior Nurse				
_	onsultant r Sophie Herbert			Avert 04.05.2	2
D	rectorate Pharmacist				
v	jay Patel, HIV Specialist Pharmacist			29.04.22	2
	dditional authors				
Lisa Knight-Smith, Sexual Health Outreach Lead, NHFT			him Kuytt Out	2	
S	Service Governance Approval				
	The following managers have responsibility for service delivered under the PGD. and confirm they authorise use of the new / re			governance (clinical and legal), and financial support of t r specialty	he
Jo	b title & name of post holder			Signature and date	
	inical Lead r Lynn Riddell			Jun Riddel) 03.05.2	22
	inical Director eorge Flanagan			06.05.22	
	The current version of any policy, procedure, p responsibility of all staff to ensure that they are	-		is the version held on the NHFT internet. It is the ent version	
	PGD109 – Azithromycin 2g for Chlamydia (Community Pharmacists) May 2022 – May 2024	2 of 20		Implementation Date: 1 st June 2022	

Head of Service Tracey Dempster	Traay Dumpter 04.05.22
Appointed Practitioner in Charge	
Lucy Milemore, Senior Nurse	4AA
	29.04.22
Clinical Executive / Directorate Governance Approval	
The Clinical Executive / Directorate has agreed that a PGD is the	most appropriate route to provide this clinical activity and has
reviewed and supports operation of this PGD	
Date approved by Directorate meeting: 12/05/2022	
Deputy Medical Director (print name)	Signature
Dr Sachin Sankar	Such Saler

PGD109 – Azithromycin 2g for Chlamydia			
responsibility of all staff to ensure that they are following the current version			
The current version of any policy, procedure, protocol or guideline is the version	held on the NHFT internet. It is the		

PGD109 – Azithromycin 2g for Chlamydia		
(Community Pharmacists) May 2022 –	3 of 20	Implementation Date: 1 st June 2022
May 2024		

Change history

Version number	Change details	Date
1.0	New template	20.04.20
	New dose – to be compliant with updated BASHH guidelines	20.04.20
	Updated exclusion criteria	24.05.20
2.0	Review/Drug interactions and side-effects updated	22.04.22

Glossary

Abbreviation	Definition
BASHH	British Association for Sexual Health and HIV
BNF	British National Formulary
NICE	National Institute for Health and Care Excellence
NISHHS	Northamptonshire Integrated Sexual Health and HIV Service

PGD109 – Azithromycin 2g for Chlamydia		
(Community Pharmacists) May 2022 –	4 of 20	Implementation Date: 1 st June 2022
May 2024		

Summary of need for this PGD

Direction for the supply*/administration* of:	Azithromycin
* delete if appropriate	
Clinical need which this direction is intended	Patients infected with uncomplicated genital
to address	Chlamydia trachomatis.
	Asymptomatic patients who are contacts of
	individuals with confirmed genital Chlamydia
	trachomatis
Objectives of care this direction will provide	To reduce the spread and incidence of chlamydia
	within the population.
	To utilise the skills of clinically trained healthcare
	professionals in primary care
	To improve patient access to medication and reduce
	waiting times for treatment
	To increase patient choice as to where to access
	treatment for Chlamydia
	To provide prompt, appropriate treatment for
	patients with Chlamydia
Key References including relevant national	DoH Crown Report, 1998. A Report on the Supply and
guidance	Administration of Medicines under Group Protocols (link)
	Health Service Circular - HSC2000/026 Patient Group
	Directions [England Only]; Department of Health,
	Health Service Circular 9 th August 2000 (description
	of legislation and additional guidance)(link)
	Human Medicines Regulations 2012 SI 1916 (contains
	current legislation on PGDs) (link)
	NICE Medicines Practice Guidance 2 (MPG2) Patient
	Group Directions. Published August 2013. Updated
	February 2014. Last updated March 2017. (link)

PGD109 – Azithromycin 2g for Chlamydia		
(Community Pharmacists) May 2022 –	5 of 20	Implementation Date: 1 st June 2022
May 2024		

NICE Competency Frameworks for Healthcare Professionals developing / reviewing, authorising and using Patient Group Directions January 2014 (link)
BNF / cBNF / Medicines for Children
BASHH CEG September 2018 – Update on the treatment of Chlamydia trachomatis (CT) infection <u>https://www.bashhguidelines.org/media/1191/updat</u> <u>e-on-the-treatment-of-chlamydia-trachomatis-</u> infection-final-16-9-18.pdf
2010 Chlamydia trachomatis UK testing guidelines Summary of Product Characteristics eMC Azithromycin – various products. Accessed April 2022

PGD109 – Azithromycin 2g for Chlamydia		
(Community Pharmacists) May 2022 –	6 of 20	Implementation Date: 1 st June 2022
May 2024		

Clinical condition or situation to whic	h this PGD applies
1. Definition of condition or situation to which this PGD applies	Chlamydia trachomatis is a bacterium, which reproduces inside body cells. It is believed to be the most common sexually transmitted bacterial infection because it often causes no obvious symptoms, but it can have serious long-term health effects including infertility, ectopic pregnancy and miscarriage.
2. Criteria for confirming condition	 Referral from NISHH. Laboratory results are reviewed by a member of staff from NISHH and the patient referred to a named community pharmacy for treatment with azithromycin if: the patient has a laboratory-confirmed genital Chlamydia trachomatis infection the patient has asymptomatic sexual contact of a confirmed case of genital Chlamydia infection in female patients with an intra-uterine device in-situ, the patient
3. Clinical criteria under which patient will be eligible for inclusion in this direction Consult clinicians working in the relevant area. Use BNF/BNFC/SPC. Take into account any clinical guidelines or policies that are available locally or nationally, e.g. BASHH/NICE/JCVI/SIGN/CKS	 does not have symptoms of pelvic inflammatory disease 4. first-line treatment with doxycycline is not appropriate Practitioners should make use of the patient's medical history (from notes or by talking to the patient) for information relevant to the decision making process. Persons aged 16-24 years of age and their partners of any age. Persons aged 15-16 years of age assessed as Fraser competent (appendix 1). Asymptomatic uncomplicated chlamydial infection Asymptomatic sexual contact of a confirmed case of genital Chlamydia infection Valid consent obtained.
4. Those criteria which exclude the patient from treatment under this direction For 4, 4a and 4b: Consult clinicians working in the relevant area. Use BNF/BNFC/SPC. Take into account any clinical guidelines or policies that are available locally or nationally, e.g. BASHH/NICE/JCVI/SIGN/CKS	 15 - 16 years of age and not Fraser competent Less than 15 years of age More than 24 years of age Breastfeeding Known allergy to azithromycin or other macrolide or ketolide antibiotic e.g. erythromycin, clarithromycin, telithromycin Any concurrent interacting medicine(s) Known hepatic or renal impairment Known HIV infection Patient complaining of other symptoms suggestive of complicated infection i.e. pelvic pain, dyspareunia, intermenstrual bleeding, post coital bleeding Patients not referred by NISHH (e.g. walk-in clients) Male patients with testicular swelling Some brands of azithromycin are contra-indicated in patients

PGD109 – Azithromycin 2g for Chlamydia		
(Community Pharmacists) May 2022 –	7 of 20	Implementation Date: 1 st June 2022
May 2024		

4a. Patients who have a complex medical history (e.g. multiple clinical conditions) MAY be treated under this PGD if the practitioner judges it safe to do so, basing his/her assessment on the following criteria:	 with a known allergy to soya and peanuts – check brand before issuing. Patients who do not consent to treatment under this patient group direction Not applicable
 4b. Cautions including any relevant action to be taken Note: if the decision for action is to consult with a doctor/dentist, you should exclude this group of patients. 	Not applicable
5. Details of action to be followed for patients excluded under this direction	 Patients must be referred to the Chlamydia Screening Service (CSS) or a Doctor in GU Medicine for advice and provision of treatment. Refer on if child protection issues are identified as likely, in line with LSCBN Interagency Procedures. Follow local Safeguarding Children Inter-Agency Procedures If pregnancy is ongoing or probable refer client on to Northamptonshire Integrated Sexual Health Clinic Record in patient notes: reasons for exclusion action taken risks explained to patient and / or alternative treatment if any
6. Details of action to be followed if patient or carer declines to receive, or do not adhere to care under this direction	 Advise on consequences of untreated Chlamydia infection Refer to Northamptonshire Integrated Sexual Health Clinic and ensure documentation reflects informed client choice Patients who refuse treatment under this patient group direction will be referred to an appropriate medical practitioner; and a record made in the patient's notes of: reasons why treatment declined action taken if treatment declined risks explained to patient and / or alternative treatment if any

PGD109 – Azithromycin 2g for Chlamydia		
(Community Pharmacists) May 2022 –	8 of 20	Implementation Date: 1 st June 2022
May 2024		

Characteristics of staff practising und	er this PGD
1. Qualifications and professional registration; to be held by staff undertaking this direction (e.g. registered Nurse, additional qualifications)	 Pharmacist registered with the General Pharmaceutical Council and working at a community pharmacy providing the "Chlamydia screening and treatment" locally enhanced service (LES). Pharmacist must have undertaken appropriate training which has been accredited by the CPPE (Centre for Pharmacy Postgraduate Education)
2. Specialist qualification, training, experience and competence considered necessary and relevant to the clinical condition treated under this direction	Completion of CPPE pre-workshop book (Chlamydia testing and treatment - PH/CHLAMYD16/PW) Attendance at relevant local CPPE accredited training workshop Understanding of Fraser competence assessment (see Appendix 1).
3. Initial Training Including specialist qualifications, training, experience and competence considered necessary and relevant to the medicine administered under this direction	 Attendance at relevant local CPPE training workshop (Sexual Health) Understanding of Fraser competence assessment (see Appendix 1). Training in the use of PGDs. Practitioners must have successfully completed the Education and Training requirements in Appendix 3 of the MMPr023 Proposal Authorisation Use and Review of PGDs.
4 Competency assessment	 Practitioners must: have their request to seek authorisation to practice under this PGD approved by their line manager and the Appointed Practitioner in Charge. be successfully assessed as competent in all the relevant clinical skills by an appropriate practitioner (the PGD Consultant Lead, other prescriber or their authorising manager as appropriate). be successfully assessed as competent to practice under this PGD using either an assessment tool developed by the PGD Working Party or the NICE MPG2 competency framework for healthcare professionals using PGDs – by their authorising manager. have a fully-signed competency statement and authorisation form for practice under this PGD, signed by the practitioner and his/her authorising manager be included in the service register of practitioners authorised to act under this PGD - maintained by each Appointed Practitioner in Charge

The current version of any policy, procedure, protocol or guideline is the version held on the NHFT internet. It is the
responsibility of all staff to ensure that they are following the current versionPGD109 – Azithromycin 2g for Chlamydia
(Community Pharmacists) May 2022 –
May 20249 of 20Implementation Date: 1st June 2022

	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.
5. Requirements for continuing training and education and competency for staff	Annual review at IPR and evidence of practice
supplying/administering medicines under this direction	Received relevant annual child protection training
	All registered pharmacists are personally accountable for their practice and in the exercise of professional accountability there is a requirement to maintain their own level of competence with evidence of relevant continued professional development (PREP requirements).
	n rests with the individual registered health professional who must GD and any associated organisation policies.

Description of treatment				
1. Name, form and strength of	Azithromycin			
medicine(s) supplied under this				
direction	250mg tablets/capsules			
(include▼ for black triangle	500mg tablets/c	apsules		
medicines)	200 /5 1			
	200mg/5ml oral	suspension		
2. Name, form and strength of	Not applicable			
medicine(s) administered under this				
direction,				
(include ▼ for black triangle				
medicines)				
3. Legal status of medicine(s)	-	tion will be based on the Drug Tariff price for the POM		
	preparation)			
4. Method of obtaining supplies	Supplied from st	ock within own Pharmacy Dispensary		
5. Indicate any off-label use (if	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			
relevant)				
	Characteristics (SPC).		
	This PGD include	es off label use in the following conditions:		
	The dos	e of azithromycin stated in the BASHH guideline and		
		e in this PGD is higher than the licensed dose.		
		nder 18 years of age and under 45kg weight - azithromycin		
		or capsules are not licensed for use in children or		
	adolesce	ents weighing under 45kg		
6. Method or route of administration	Oral			
	Orai			
		and supplied – advice relating to whether to take with		
	food or without	food may differ		
	Refer to: BNF/BI	IFc/SPC/Medicines for Children		
7. Dose and frequency treatment for	By mouth 1 gram once daily on day 1,			
medicine(s), including where a range				
of dose is permissible, the criteria for	then 500mg once daily on days 2 and 3 Refer to: BNF/BNFc/SPC/Medicines for Children			
deciding the dose				
PGD109 – Azithromycin 2g for Chlam (Community Pharmacists) May 2022	•	Implementation Date: 1 st June 2022		
May 2024				

May 2024

8. Duration of treatment / total dose	2g total dose as a three day course
and number of times treatment can be supplied/ administered	NB The PGD will only be used for a single supply, and a full record made.
(including maximum or minimum treatment period)	The medical team must be informed of any treatment given under this PGD by documentation in the medical notes.
9. Quantity to be supplied	Total dose 2g
	Can be supplied as tablets, capsules or oral solution (to the nearest original container)
10. Storage	The secure storage of all medicines listed in this PGD must be ensured and must be in accordance with Trust Policy and in conditions in line with the SPC.
	Storage in individual Community Pharmacy
	The Health Service Circular (HSC 2000/026) states that 'there must be a secure system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and out-goings on a patient by patient basis'. A stock control system must be put in place for pre-packs given to patients / clients to take away.
11. Contra-indications / brand	Hypersensitivity to azithromycin, or any macrolide or ketolide antibiotic.
specific information	Hypersensitivity to any excipient
	Some preparation contain soya oil - contra-indicated in patients with a peanut or soya allergy – check individual brand
	Refer to: BNF/BNFc/SPC/Medicines for Children
12. Cautions / brand specific	Refer to: BNF/BNFc/SPC/Medicines for Children
information	• Advise not to eat for 1 hour after taking (depending on brand supplied)
	Warn of possible side-effects (patient information leaflet)
	• If they take an Oral Contraceptive and suffer from diarrhoea after taking the azithromycin they should ensure they do NOT have a "pill-free" period and should abstain from sexual intercourse for 7 days.
13. Drug interactions	Refer to: BNF/BNFc/SPC/Medicines for Children
	 All concurrent medications should be reviewed for interactions. The interactions listed as severe in the BNF are: Colchicine Digoxin

(Community Pharmacists) May 2022 – 12 of 20 Implementation Date: 1 st June 2022 May 2024	PGD109 – Azithromycin 2g for Chlamydia		
May 2024	(Community Pharmacists) May 2022 –	12 of 20	Implementation Date: 1 st June 2022
1110 2021	May 2024		

	 Edoxaban Rifabutin Talazoparib Ticagrelor Topotecan Ciclosporin Antacids- Azithromycin should be taken at least 1 hour before or 2 hours after the antacid A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
14. Identification of adverse reactions	Refer to: BNF/BNFc/SPC/Medicines for Children The following side effects are very common/common with azithromycin: Nausea Anorexia Vomiting Dyspepsia Dizziness Headache Diarrhoea Abdominal pain/discomfort Flatulence Loose stools Rash Pruritus Arthralgia Fatigue Visual impairment Deafness Paraesthesia Dysgeusia A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
15. Management of adverse reactions including facilities and supplies that should be available at the site where this direction is operated	Practitioners should ensure that they are familiar with the doses, contra- indications, cautions and interactions (see BNF/BNFc/SPC) of emergency medicines that they are likely to need to use. All medication that would be required for the treatment of reactions is available from Community Pharmacy Stock

The current version of any policy, procedure, protocol or guideline is the version held on the NHFT internet. It is the responsibility of all staff to ensure that they are following the current version		
PGD109 – Azithromycin 2g for Chlamydia (Community Pharmacists) May 2022 – May 2024	13 of 20	Implementation Date: 1 st June 2022

	 Note 1 - These are not part of this patient group direction and will require prescribing by a medical practitioner as appropriate, but see note 2 below. Note 2 - Neither a prescription nor an instruction to administer is required for the following injectable drugs when administered for the purpose of saving life in an emergency: Adrénaline injection (1:1000)
16. Arrangements for referral to medical advice	Patients should be advised to seek medical advice from their GP or contact NISHH service.
17. Reporting procedure for adverse reactions	 Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions especially those with a black triangle ▼ to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <u>https://yellowcard.mhra.gov.uk</u> All medication errors, near misses and suspected adverse drug events should be reported to the (add as appropriate consultant, registrar or SHO), Record all adverse drug reactions (ADRs) in the patient's medical record All incidents should be reported via the Trust's electronic reporting system Datix
18. Written information and to be	Give marketing authorisation holder's patient information leaflet (PIL)
given to patient or carer	provided with the product.
19. Advice (including any written advice) to be given to the patient or carer before or after treatment	 Emphasise need for partner(s) to be treated. Advise no sexual intercourse for the following 7 days. Risk of re-infection from partner(s) if partner(s) have not been treated Possibility of reduced effect of contraceptive pill If they take an Oral Contraceptive and suffer from diarrhoea after taking the azithromycin they should ensure they do NOT have a "pill-free" period and should abstain from sexual intercourse for 7 days Possible concurrent medication considerations with antacids, ciclosporin, digoxin, ergot derivatives, theophylline, terfenadine, warfarin, statins and rifabutin. Check in current BNF Need to inform service if vomiting occurs within 2 hours of taking dose to assess need for repeat treatment.
20. Information about follow-up treatment	The individual/carer should be advised to seek medical advice in the event of an adverse reaction or treatment failure.

The current version of any policy, procedure, protocol or guideline is the version held on the NHFT internet. It is the		
responsibility of all staff to ensure that they are following the current version		
PGD109 – Azithromycin 2g for Chlamydia		
(Community Pharmacists) May 2022 –	rs) May 2022 – 14 of 20 Implementation Date: 1 st June 2022	
May 2024		

	Community Pharmacy
	community i narriacy
22. Treatment records	Pharmacist must complete documentation required in PharmOutcomes
	A computer or manual record of all individuals receiving this product under
	this Patient Group Direction should also be kept for audit purposes within
	each practice and designated setting
	All records should be clear, legible and contemporaneous.
	To ensure legal requirements for recording treatment are met, and to enable practice to be audited, the practitioner who administers medication under this patient group direction is responsible for informing the patient of their actions and recording the following:
	 Document all information relevant to the treatment in the <i>PharmOutcomes</i> which should include: Patient's name, address, date of birth, NHS number Patients will need to give valid informed verbal consent (in line with DoH advice on consent) to be treated under this patient group direction. This consent should be recorded (signed and dated) in the patient's notes by the practitioner following the patient group direction. Contact details of GP (if registered and if relevant) Diagnosis / relevant medical history including drug allergies and sensitivities, previous ADRs, concomitant medication, risk factors, how the patient met the inclusion criteria, confirm no exclusion criteria met, all decisions NOT to treat a patient under PGD <i>109</i> e.g. if the patient met one or more exclusion criteria or if the patient declined treatment name of registered health professional the name of the drug, strength, form, quantity supplied and / or dose administered, route (and site, if by injection) of administration date of administration/supply (and time, if administered) advice given to patient (including self-care) details of any adverse drug reaction and actions taken including documentation in the patient's medical record writing a statement that supply or administration was made using the Patient Group Direction reference - "PGD <i>109</i>

The current version of any policy, procedure, protocol or guideline is the version held on the NHFT internet. It is the
responsibility of all staff to ensure that they are following the current versionPGD109 – Azithromycin 2g for Chlamydia
(Community Pharmacists) May 2022 –
May 202415 of 20Implementation Date: 1st June 2022

	NB If any of the above has already been documented in the patient's records, the designated practitioner must be satisfied that the records are accurate (otherwise this becomes delegation).
22. Audit trail for treatment records	The Trust PGD Monitoring Framework (available on Staff Room) should be completed by the Appointed Practitioner in Charge and PGD Lead Practitioner and returned to Pharmacy by the date specified in this PGD.
	A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.
	It is the responsibility of the Appointed Practitioner in Charge, or their nominated deputy, to ensure that practice is audited for each PGD in use within their directorate annually . Audit of PGDs should be included in the Directorate Audit programme.
	In addition: Compare the total number of referrals via the service with the number confirmed to have been reviewed by a Pharmacist/Nurse (analysis of data submitted via PharmOutcomes). To be carried out annually.

MANAGEMENT AND MONITORING		
1. Authors of this direction (names and status of authors) [to sign PGD approval	Name	Lucy Milemore , Lead Nurse Practitioner, Lead Author)
form on page 2]	Name	Dr Sophie Herbert, Consultant in GU Medicine, NHFT
	Name	Lisa Knight-Smith, Sexual Health Outreach Lead, NHFT
	Name	Vijay Patel, HIV Specialist Pharmacist, NHFT
2. Professional advisory groups which have contributed to this direction (name(s) of advisory groups)	ММС	
 Name of manager authorising the use of this direction within the Directorate (Deputy Medical Director) 	Sachin San	kar
[to sign directorate PGD-approval form om page 2]		
4. Service Managers confirming the PGD is in	Clinical Lea	id: Dr Lynn Riddell
accordance with directorate and service objectives and approving its use within the	Clinical Dir	ector: George Flanaghan
relevant service area	Head of Se	rvice: Tracey Dempster
[to sign directorate PGD-approval form om page 2]	Consultant	: Dr Sophie Herbert
	Appointed	Practitioner in Charge: Lucy Milemore
5. Date of Patient Group Direction approved by MMC	10th May 2	2022
6. Expiry date	31 st May 2	024 (Not more than 2 years after approved by MMC)
	This patier	nt group direction is no longer valid after this date
7. Date this direction becomes due for review	1 st Octobe	r 2023

The current version of any policy, procedure, protocol or guideline is the version held on the NHFT internet. It is the responsibility of all staff to ensure that they are following the current version		
PGD109 – Azithromycin 2g for Chlamydia (Community Pharmacists) May 2022 – May 2024	17 of 20	Implementation Date: 1 st June 2022

8. Date the annual audit return form must be	First year of cycle May 2023
submitted to MMC	Schedule audit 10 months after MMC approval date to allow time for submission to Directorate and then MMC one year after approval
	Second year of cycle: May 2024
	Schedule audit 2 months before expiry date to allow submission with PGD re-approval submission to Directorate and then MMC

PGD109 – Azithromycin 2g for Chlamydia		
(Community Pharmacists) May 2022 –	18 of 20	Implementation Date: 1 st June 2022
May 2024		

APPENDIX 1

FRASER GUIDELINES COMPETENCY TEST

For clients who are believed to be under 16 years of age. Discussion with the young person should explore the following issues at each consultation. This should be fully documented and should include an assessment of the young person's maturity.

ASSESSMENT OF FRASER GUIDELINES COMPETENCY	YES	NO
The young person could understand the advice and had sufficient maturity to understand what was involved in terms of the moral, social and emotional implications		
The young person was encouraged, but declined, to inform or seek support from their parents or to allow the health professional to inform the parents that they are seeking sexual health advice		
The young person would be very likely to begin, or to continue having, sexual intercourse with or without sexual health advice and/or treatment		
That, without sexual health advice or treatment, the young person's physical or mental health, or both, would be likely to suffer		
That the young person's best interests required them to receive sexual health advice and/or treatment without parental consent		

Taking the above into account, the pharmacist or nurse should decide if the young person is competent to receive advice and treatment. The consultation is governed by the same terms of confidentiality whether or not the health professional considers the young person competent.

Pharmacist Name:	
Pharmacist Signature:	Date:
Client Name :	

Client Signature: Date:.....

When a young person is judged not to be Fraser competent they should be referred.

The current version of any policy, procedure, protocol or guideline is the version held on the NHFT internet. It is the		
responsibility of all staff to ensure that they are following the current version		
PGD109 – Azithromycin 2g for Chlamydia (Community Pharmacists) May 2022 – May 2024	19 of 20	Implementation Date: 1 st June 2022

Registered health professional competency statement and authorisation form to act under this Patient Group Direction

A register of all practitioners authorised to practice under this PGD is maintained by the service

PGD109 Azithromycin (Community Pharmacists) v2.0 Valid from: 1st June 2022 Expiry: 31st May 2024

Before signing this form, check that the PGD document has had the necessary authorisations on page 2. Without these, this PGD is not lawfully valid.

Original: to be retained by health professional as evidence of authority to practise under this PGD **Copy:** to be submitted to the Appointed Practitioner in Charge for inclusion in the service register of Authorised PGD Practitioners

Registered health professional competency statement

Note: By signing the competency statement to practice under this PGD, you are indicating you agree to its contents and accept the responsibility and accountability that practice under this PGD entails and agree to practice only within the terms and conditions of the PGD.

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.

It is the responsibility of each individual to maintain his/her competency and ensure his/her authorisation does not lapse by arranging a competency review meeting with his/her authorising manager. **THE TRUST REQUIRES PRACTITIONERS TO BE RE-ASSESSED ANNUALLY.** Copies of the completed forms must be submitted to the Appointed Practitioner in Charge AFTER EACH RE-ASSESSMENT for continued inclusion in the service register of Authorised PGD Practitioners.

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 professional named above has declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Northamptonshire Healthcare NHS Foundation Trust for the above named health care professionals who has signed the PGD competency statement to work under it.

 Name
 Designation
 Signature
 Date

Note to authorising managerThis authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

The current version of any policy, procedure, protocol or guideline is the version held on the NHFT internet. It is the
responsibility of all staff to ensure that they are following the current version

PGD109 – Azithromycin 2g for Chlamydia		
(Community Pharmacists) May 2022 –	20 of 20	Implementation Date: 1 st June 2022
May 2024		