NHS Grampian NHS Highland NHS Orkney NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction For The Supply Of Azithromycin Tablets For Treatment Of Uncomplicated Genital Chlamydia Infection Where First Line Treatment With Doxycycline Is Contraindicated By Pharmacists Working Within NHS Grampian, Highland, Orkney, Tayside And Western Isles

Lead Author: Pharmaceutical Care Services Manager **Co-ordinator:** Medicines Management Specialist Nurse NHSG	**Consultation Group**: See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/CPAzith/1576	**Review Date:** November 2026 **Expiry Date:** November 2027	**Date Approved:** November 2024

NHS Grampian, Highland, Orkney, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 5

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD supersedes NHSG/PGD/CPAzi/MGPG1221, Version 4	
Date of change	**Summary of Changes**	**Section heading**
August 2024	PGD Review.	
August 2024	Addition of new interactions listed as severe in Appendix 1 of BNF.	Exclusion criteria
October 2024	Wording changed in Verbal advice to: Individuals should receive information regarding chlamydia infection at the time of antibiotic treatment and must be actively encouraged to notify any sexual partners.	Advice (verbal)
October 2024	Local policy should be followed with respect to sharing information with the individual's GP practice.	Responsibilities of professional manager(s)

NoS Identifier: NoS/PGD/CPAzith/1576
Keyword(s): PGD Patient Group Direction Azithromycin Chlamydia, Community Pharmacy

Policy Statement: It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	August 2024
	Completed:	October 2024
	Approved:	November 2024 (published – November 2024)
	Amended and re-authorised:	

Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Ambreen Butt **Health Board:** NHS Grampian **Title:** Consultant in Sexual Health **Contact email:** ambreen.butt@nhs.scot **Signature:** ..... **Date:** 20/11/2024
Lead author	**Name:** Laura Karim **Health Board:** NHS Grampian **Title :** Pharmaceutical Services Improvement and Development Manager **Contact email:** laura.karim@nhs.scot **Signature:** ..... **Date:** 20/11/2024
Pharmacist	**Name:** Samantha Reid **Health Board:** NHS Grampian **Title :** Community Pharmacist **Contact email:** samantha.reid7@nhs.scot **Signature:** ..... **Date:** 20/11/2024

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		21/11/2024

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Adam Coldwells – Interim Chief Executive		27/11/2024

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and best practice to have a representative of the professional group who will provide care under the direction.

Name:	Title:
Laura Karim	**Lead Author:** Pharmaceutical Services Improvement and Development Manager NHSG
Samantha Reid	**Pharmacist:** Community Pharmacist
Dr Ambreen Butt	**Medical Practitioner:** Consultant in Sexual Health
Anne Marshall	**Senior Representative:** Community Pharmacist
Jodie Allan	**Co-ordinator:** Medicines Management Specialist Nurse NHSG
Alison MacDonald	Area Antimicrobial Pharmacist

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Clinical indication to which this PGD applies

Definition of situation/ Condition	This Patient Group Direction (PGD) will authorise pharmacists to supply azithromycin tablets to individuals aged 13 years and over, in whom doxycycline is contraindicated with a laboratory confirmed diagnosis of uncomplicated genital chlamydia infection. It also allows the treatment of asymptomatic sexual contacts of someone with a positive diagnosis of uncomplicated genital chlamydia infection. This PGD should be used in conjunction with the recommendations in the current British Association for Sexual Health and HIV (BASHH) relevant guidelines, British National Formulary (BNF), British National Formulary for Children (BNFC), and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	Individuals for whom doxycycline is contraindicated and are; • Aged 13 years of age and over with a positive chlamydia test and an uncomplicated genital presentation. • Asymptomatic individuals presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of chlamydia. Prior to the supply/administration of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	• Individuals under 13 years of age* • Under 16 years of age and judged to be incapable of understanding the nature and possible consequences of procedures or treatment as per Age of Legal Capacity (Scotland) Act 1991 (commonly referred to as Fraser competency). • Individuals 16 years of age and over and assessed as lacking capacity to consent. **Medical History** • Known pregnancy • Breastfeeding • Severe hepatic impairment

	• Severe renal impairment • Current/past history of cardiac rhythm or conduction disturbance • Anyone with a cervix complaining of symptoms suggestive of an sexually transmitted infection (STI) prior to a confirmed chlamydia diagnosis • Suspected **complicated** chlamydia infection, i.e. anyone with a cervix with a positive chlamydia result complaining of pelvic pain/pain during vaginal sex, and anyone with a positive chlamydia test result complaining of testicular pain must be referred to a GP or a genitourinary medicine/sexual health clinic • Individuals with suspected and/or confirmed symptomatic rectal chlamydia trachomatis • Individuals with myasthenia gravis. **Medication History** • Any concurrent interacting medicine(s) – All concurrent medications should be reviewed for interactions. The interactions listed as severe in Appendix 1 of the BNF are: o Acenocoumarol o Betrotralstat o Chloroquine o Colchicine o Dabigatran o Digoxin o Edoxaban o Hydroxychloroquine o Phenindione o Rifabutin o Talazoparib o Ticagrelor o Topotecan o Vinblastine o Vincristine o Vindesine o Vinorelbine o Warfarin. A detailed list of all drug interactions is available in the BNF or the product SmPC • Known hypersensitivity or allergy to the azithromycin , erythromycin, clarithromycin or any macrolide or ketolide antibiotic or to any component of the product - see SmPC. • Individuals with known azithromycin resistance. • Where there is no valid consent.

	*Children under the age of 13 years should not be treated under this PGD. (The child protection team must be contacted for children of 12 years and under who present having had sexual intercourse). The pharmacist must use their professional judgement to consider, and where appropriate, act on any child protection issues coming to their attention as a result of providing the service. This should be in line with local child protection procedures and any national or local guidance on under 16s sexual activity. Individuals for whom no valid consent has been received.
Precautions and special warnings	Some brands of azithromycin contain soya or soya lecithin and are therefore contraindicated in individuals with an allergy to soya or peanuts. If individual is allergic, check manufacturer's information for brand being used and if necessary, exclude from PGD or select an alternative suitable brand if available.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Inform/refer to the relevant medical practitioner if individual declines treatment and/or provide them with information about further options. Document that the supply was declined, the reason and advice given in appropriate clinical records.

Description of treatment available under the PGD

Name form and strength of medicine	Azithromycin 250mg/500mg Tablets/Capsules.
Legal status	Azithromycin 250mg/500mg Tablets/Capsules are a prescription only medicine (POM). In accordance with the MHRA all medicines supplied under a PGD must either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply.

Is the use out with the SmPC?	This PGD includes off label use in the following; • The dose of azithromycin stated in the BASHH guideline and therefore in this PGD is higher than the licensed dose. • Those under 45kg weight - azithromycin tablets or capsules are not licensed for use in adolescents weighing under 45kg. This is outside the terms of the marketing authorisation and constitutes an off-label use of the medicine. The individual/parent/carer should be informed prior to the administration that the use is off-label.
Dosage/Maximum total dose	1g as a single dose followed by 500mg daily for 2 days; Maximum total dose of 2g to be supplied.
Frequency of dose/Duration of treatment	**Day One**: 1g taken as a single dose **Day Two**: 500mg once daily **Day Three**: 500mg once daily Three day treatment.
Maximum or minimum treatment period	Maximum of 3 days
Route/Method of administration	Oral.
Quantity to be supplied	2g as either: 8 x 250mg tablets/capsules or 4 x 500mg tablets/capsules.
Storage requirements	PVC/Alu blisters: Do not store above 25°C. Store in the original packaging to protect from moisture. OPA-PVC-Alu/Alu blisters: This medicinal product does not require any special storage conditions.
Follow-up (if applicable)	If the individual returns following side effects resulting in stopping treatment or following completed treatment and still complaining of symptoms, they should be referred to GP/Consultant (relevant medical practitioner) or a sexual health clinic. Their individual medication record should be updated to record this.
Advice (Verbal)	Advice should be given on what to expect and what to do for major and minor reactions.

	Azithromycin tablets can be taken at any time in relation to food but there should be a gap between taking the tablets and antacids. Azithromycin capsules should be taken one hour before or two hours after food or antacids If vomiting occurs within 3 hours of a dose being taken advise individual to contact GP/Consultant (relevant medical practitioner) or sexual health clinic. Individuals should receive information regarding chlamydia infection at the time of antibiotic treatment and must be actively encouraged to notify any sexual partners. Discuss implications of incompletely treated/untreated infection of self or partner(s). Individuals should also be advised to abstain from having oral, anal or vaginal sex, even with a condom for the duration of treatment and until their current partners (if they have one), have completed treatment, or until they are symptom free if they have ongoing symptoms after completing prescribed treatment. Discuss risk of re-infection, and further transmission of infection, if after treatment sexual intercourse takes place with an untreated partner/s. Offer advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs). Ensure the individual has contact details of local sexual health services. If serious adverse or persistent effects occur, the individual/ person with parental responsibility should be advised to contact their GP/Accident and Emergency department/NHS24. • Individuals/carers should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme.
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.

Identifying and managing possible adverse reactions	The following side effects are very common/common with azithromycin: • anorexia • dyspepsia • headache • rash • arthralgia • paraesthesia • dysgeusia • vomiting • dizziness • fatigue • pruritus • deafness • visual impairment According to the SmPC the following investigations can be affected by administration of azithromycin; • Lymphocyte count decreased, • Eosinophil count increased • Blood bicarbonate decreased. **This list is not exhaustive. Please also refer to current BNF and manufacturers SmPC for details of all potential adverse reactions.** **BNF**: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any suspected adverse reactions using the Yellow Card System. Yellow Card Scheme - MHRA.
Facilities and supplies required	The following are to be available at sites where the medicine is to be supplied: • Appropriate storage facilities • An acceptable level of privacy to respect individual's right to confidentiality and safety • Access to a working telephone • Access to medical support (this may be via the telephone) • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this current PGD in print or electronically.

Characteristics of staff authorised to supply medicine(s) under PGD

Professional qualifications	Pharmacists whose name is currently on the register held by the General Pharmaceutical Council (GPhC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's capacity to understand the nature and purpose of the medicine supply in order to give or refuse consent • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual • Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD • Competent to undertake supply of the medicine • Competent to work under this PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken PGD training as required/set out by each individual Health Board • Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct • Have knowledge and familiarity of the following; ○ SmPC for the medicine(s) to be supplied in accordance with this PGD.
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Local policy should be followed with respect to sharing information with the individual's GP practice Maintain up to date record of all staff authorised to supply the medicine(s) specified in this direction.

Documentation

Authorisation of supply	Pharmacists working within NHS Grampian, Highland, Orkney, Tayside and Western Isles can be authorised to supply the medicine(s) specified in this PGD when they have completed local Board requirements for service registration. All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.
Record of supply	An electronic or paper record for recording the screening of individuals and the subsequent supply, or not of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum: • Date and time of supply • Individuals name and CHI • Exclusion criteria, record why the medicine was not supplied (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, dose, form, route of the medicine supplied • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who supplied the medicine • Record of any adverse effects (advise individuals GP/relevant medical practitioner). Depending on the clinical setting where supply is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • Individual service specific systems.
Audit	All records of the medicine(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines supplied under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk Azithromycin 500mg Tablets (Sandoz Limited Brand) – Date of revision of text 09/06/22, accessed 08/08/24.

	British National Formulary and British National Formulary for Children Drugs A to Z | BNF | NICE accessed 08/08/24. BASHH CEG September 2018 – Update on the treatment of *Chlamydia trachomatis* (CT) infection

NHS Grampian NHS Highland NHS Orkney NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1

Healthcare Professional Agreement to Supply Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to supply the medicine(s) contained within the following Patient Group Direction:

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I have completed the appropriate training to my professional standards enabling me to supply the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

Appendix 2

Healthcare Professionals Authorisation to Supply Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to supply the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to supply the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
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Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**