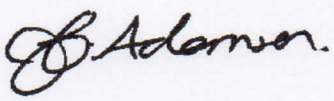
NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction For The Supply Of Azithromycin By Nurses For Treatment Of Uncomplicated Genital Chlamydia Infection, Uncomplicated Mycoplasma Genitalium And Non-Gonococcal/Non-Specific Urethritis Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from the SPS/FSRH National PGD Template by the 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/Azithro/ MGPG1155	**Review Date:** March 2023 **Expiry Date:** March 2024	**Date Approved:** March 2021

NHS Grampian, Highland, Orkney, Shetland, 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 1

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	New PGD adapted from FRSH/SPS national PGD template and supersedes NHSG/PGD/Azithro/MGPG938, NHSH 05_19_v6 and NHST Patient Group Direction for the Supply of Azithromycin	
Date of change	**Summary of Changes**	**Section heading**
January 2021	New NoS PGD adapted from FRSH/SPS national PGD and previous PGDs from NHSG, NHSH and NHST.	

NoS Identifier: NoS/PGD/Azithro/MGPG1155
Keyword(s): PGD Patient Group Direction azithromycin chlamydia urethritis mycoplasma genitalium nurse

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:	January 2021
	Completed:	February 2021
	Approved:	March 2021 (published – March 2021)
	Amended:	

Organisational Authorisations

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

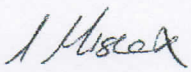
PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Ambreen Butt **Health Board:** NHSG **Title:** Consultant Sexual Health **Contact email:** ambreen.butt@nhs.scot **Signature:** .....
Senior representative of the professional group who will provide care under the direction	**Name:** Sara Beveridge **Health Board:** NHST **Title:** Clinical Nurse Specialist Sexual Health **Contact email:** Sara.Beveridge@nhs.scot **Signature:** .....
Lead author	**Name:** Frances Adamson **Health Board:** NHSG **Title:** Medicines Management Specialist Nurse NHSG **Contact email:** frances.adamson@nhs.scot **Signature:** .....
Pharmacist	**Name:** Alison MacDonald **Health Board:** NHSH **Title :** Area Antimicrobial Pharmacist Microbiology **Contact email:** alison.macdonald4@nhs.scot **Signature:** .....

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		March 2021

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		March 2021

Management and Monitoring of Patient Group Direction

PGD Consultative Group

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

Name:	Title:
Frances Adamson	**Lead Author:** Medicines Management Specialist Nurse NHSG
Alison MacDonald	**Pharmacist:** Area Antimicrobial Pharmacist Microbiology NHSH
Dr Ambreen Butt	**Medical Practitioner:** Consultant Sexual Health NHSG
Sara Beveridge	**Senior Representative:** Clinical Nurse Specialist Sexual Health NHST
Jackie Agnew	Head of Community Pharmacy Services NHSH
Kimberley MacInnes	Senior Charge Nurse Sexual Health NHSH
Julia Penn	Sexual Health Nurse Team Leader NHSG
Russell Mackay	Lead Pharmacist NHSO
Liam Callaghan	Chief Pharmacist NHSWI

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Clinical indication to which this PGD applies

Definition of situation/ Condition	This Patient Group Direction (PGD) will authorise nurses to supply azithromycin tablets or capsules to individuals aged 13 years and over, in whom doxycycline is contraindicated with a laboratory confirmed diagnosis of uncomplicated genital chlamydia infection (any site) or uncomplicated mycoplasma genitalium infection following completion of course of doxycycline (see doxycycline PGD). It also allows treatment of non-gonococcal (NGU) or non-specific urethritis (NSU) on microscopy. Treatment under this PGD may also be given to asymptomatic individuals presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of any of the conditions detailed above. This PGD should be used in conjunction with the individual Board protocols and 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 and over. • Have uncomplicated genital, pharyngeal and/or asymptomatic rectal chlamydia trachomatis infection • Have a definite diagnosis of uncomplicated mycoplasma genitalium where a course of doxycycline has been completed within the previous two weeks (where resistance testing is available, confirmed macrolide sensitivity). • Have a microscopic diagnosis of NGU or NSU. • Are asymptomatic individuals (regular or casual partners) presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of chlamydia, NSU/NGU PID or epididymo-orchitis. These individuals can be treated at the time of presentation in line with local clinic guidelines. Asymptomatic individuals presenting after 2 weeks can be treated at clinician's discretion in line with local clinic guidelines. • Require a single repeat treatment course for individuals who have had sexual intercourse within 7 days of receiving

	treatment or who have had sex with partner untreated for the above conditions. Prior to the supply 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
	• Individuals with PID. Symptoms of PID:
	  ○ lower abdominal tenderness which is usually bilateral
	  ○ fever >38°C
	• Men who have proctitis. Symptoms of proctitis;
	  ○ A frequent or continuous feeling that you need to have a bowel movement
	  ○ Rectal bleeding, rectal mucous and/or rectal pain
	  ○ A feeling of rectal fullness
	• Men who have a positive chlamydia result but have signs or symptoms of epididymo-orchitis:
	  ○ testicular tenderness
	  ○ testicular swelling
	• Known pregnancy
	• Breastfeeding
	• Severe hepatic impairment
	• Severe renal impairment
	• Individuals with Myasthenia Gravis
	• Current/past history of cardiac rhythm or conduction disturbance
	• Individuals complaining of symptoms suggestive of an Sexually Transmitted Infection (STI) prior to a confirmed chlamydia diagnosis
	• Individuals with suspected and/or confirmed symptomatic rectal chlamydia trachomatis
	
	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:
	  ○ Colchicine
	  ○ Digoxin
	  ○ Edoxaban

	○ Rifabutin ○ Talazoparib ○ Ticagrelor ○ Topotecan. 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).
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

Off label use	appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply. 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 18 years of age and under 45kg weight - azithromycin tablets or capsules are not licensed for use in children or adolescents weighing under 45kg. The individual should be informed prior to the administration that the use is off-label.
Dosage/Maximum total dose	**Uncomplicated genital chlamydia infection (any site) and NGU or NSU:** 1g as a single dose followed by 500mg daily for 2 days. Maximum total dose of **2g** to be supplied. **Uncomplicated mycoplasma genitalium** 1g as a single dose followed by 500mg daily for 2 days; Maximum total dose of **2g** to be supplied. Azithromycin course should be started immediately after completing the doxycycline course. Where this is not achieved it must be started within 2 weeks of the doxycycline course being completed. If the azithromycin course is not started within this timeframe the individual should be referred to a specialist practitioner.
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.

	NOTE: A single repeat course can be supplied under the PGD if vomiting occurs within 3 hours of a dose being taken.
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)	Follow local individual Board protocol for chlamydia follow up and partner notification. Individuals who have not had a full STI screen (or who did not have chlamydia or mycoplasma genitalium diagnosed in a sexual health clinic) should be advised to attend an appropriate service for a full STI screen. Routine follow-up for uncomplicated chlamydia following treatment with azithromycin is unnecessary, except in the following situations where local protocols should be followed: • Where poor compliance is suspected • Where symptoms persist • Rectal infections. **NOTE:** Test Of Cure (TOC) is recommended for all individuals testing positive for rectal chlamydia in line with local clinic protocols.
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 return as soon as possible to receive repeat course. Individuals should receive information regarding chlamydia infection/mycoplasma genitalium/NGU or NSU at the time of antibiotic treatment, and must be advised to notify any sexual partners, and issue contact slips if appropriate. 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). Discuss partner notification and issue contact slips if appropriate. Offer condoms and advice on safer sex practices and possible need for screening for STIs. Where treatment not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services. **Mycoplasma genitalium:** Where doxycycline has been supplied for the treatment of uncomplicated mycoplasma genitalium the individual should be advised that the azithromycin course should be started immediately after completion of the doxycycline course – where this is not achieved it must be started within 2 weeks of the doxycycline course being completed. If the azithromycin course is not completed within this time frame the individual should be referred to a specialist practitioner. 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.
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual/person with parental responsibility. 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: • nausea • anorexia • dyspepsia • headache • flatulence • abdominal pain/discomfort • vomiting • dizziness • diarrhoea • Loose stools

	• rash • pruritus • arthralgia • fatigue • paraesthesia • visual impairment • dysgeusia **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF/BNFC**: https://www.bnf.org/products/bnf-online/ **SmPC/PIL/Risk Minimisation Material:** https://www.medicines.org.uk/emc/ http://www.mhra.gov.uk/spc-pil/index.htm https://www.medicines.org.uk/emc/rmm-directory If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions using the Yellow Card System. https://yellowcard.mhra.gov.uk/
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 gel • Condoms • Copy of the current PGD for the medicine specified in the PGD.

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

Professional qualifications	Registered nurses as recognised by the Nursing and Midwifery Council (NMC).
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 • 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. Maintain up to date record of all staff authorised to supply the medicine(s) specified in this direction.

Documentation

Authorisation of supply	Sexual Health Nurses working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to supply/administer the medicine(s) specified in this PGD by their Professional Line Manager/Consultant/Practice GPs. 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: • NaSH – Sexual Health Electronic Patient Record • Individual's GP records if 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 (Accord Brand) – Date of revision of text 28/01/20, accessed 21/01/21. British National Formulary and British National Formulary for Children https://www.bnf.org/products/bnf-online/ accessed 14/01/21. BASHH CEG September 2018 – Update on the treatment of *Chlamydia trachomatis* (CT) infection BASSH UK National Guideline on the management of non-gonococcal urethritis British Association for Sexual Health and HIV national guideline for the management of infection with *Mycoplasma genitalium*

NHS Grampian NHS Highland NHS Orkney NHS Shetland 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: _____

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

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 he or she is 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 he or she understands and is 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 his or her individual code of professional practice and conduct.
Patient Group Direction For The Supply Of Azithromycin By Nurses For Treatment Of Uncomplicated Genital Chlamydia Infection, Uncomplicated Mycoplasma Genitalium And Non-Gonococcal/Non-Specific Urethritis Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles
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**