NHS Grampian

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

Lead Author:	Consultation Group:	Approver:
Principal Pharmacist, Pharmacy and Medicines Directorate	See relevant page in the PGD	NHSG Medicines Guidelines and Policies Group
Signature: 		**Signature:** 
Identifier: NHSG/PGD/CPAzi/ MGPG983	**Review Date:** September 2020	**Date Approved:** September 2018
	Expiry Date: September 2021	

NHS Grampian 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 Board. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 3.2 (Amended February 2019)

Revision History:

Date of change	Approval date of PGD that is being superseded	Summary of Changes	Section heading
June 2018	March 2016	2 yearly update to new PGD template.	
July 2018	March 2016	Add Uncomplicated Genital Infection	Title and throughout
July 2018	March 2016	Add in tablets	Title and throughout
July 2018	March 2016	Update consultation group	Page ii
August 2018	March 2016	Added Myasthenia Gravis as an exclusion	Exclusion criteria
Dec 2018	March 2016	Title changed to include doxycycline.	Throughout
Dec 2018	Aug 2018	Updated inclusion and dose information following update to BASSH guidance.	Inclusion criteria and Dose/Maximum total dose
February 2019	Aug 2018	Patient changed to individual throughout except in reference to Patient Group Direction (PGD).	Throughout

NHS Grampian Identifier: NHSG/PGD/ CPAzi/MGPG983
Replaces: NHSG/PGD/CPAzi/MGPG983, Version 3.1
Keyword(s): PGD Patient Group Direction Azithromycin, Chlamydia, Community Pharmacy

Policy Statement: It is the responsibility of individual Pharmacist 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 individual safety. The expiry date should not be more than 3 years from the date the PGD was authorised.

Document:	Drafted:	June 2018
	Completed:	August 2018
	Approved:	September 2018 (October 2018)
	Amended:	February 2019

Organisational Authorisation

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

PGD Developed/Reviewed by

Medical Practitioner	**Name:** Dr Ambreen Butt **Health Board:** NHSG **Title:** Consultant in Sexual Health **Contact email:** susan.brechin@nhs.net **Signature** .....
Senior representative of the professional group who will provide care under the direction.	**Name:** Elizabeth Kemp **Health Board:** NHSG **Title:** Principal Pharmacist, P&MD **Contact email:** e.kemp@nhs.net **Signature** .....
Lead Author (if different from above)	**Name:** **Health Board:** **Title :** **Contact email:** **Signature** .....
Pharmacist	**Name:** Samantha Reid **Health Board:** NHSG **Title :** Community Pharmacist **Contact email:** Samantha.reid7@nhs.net **Signature** .....

Authorised on Behalf of NHSG by

Subgroup	Chair Name	Signature	Date Signed
NHS Grampian Medicines Guidelines and Policies Group	Lesley Thomson		October 2018

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:**
Elizabeth Kemp	**Lead Author:** Principle Pharmacist, Pharmacy and Medicines Directorate
Samantha Reid	**Pharmacist:** Community Pharmacy
Dr Ambreen Butt	Clinical Lead in Sexual Health
Frances Adamson	Medicines Management Specialist Nurse
Dr Sarah Wallage	**Medical Practitioner:** Consultant in Sexual Health
Dr Noha El Sakka	Consultant and Service Clinical Director Medical Microbiology and Virology
Suzanne Brittain	Antibiotic Pharmacist

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

Clinical indication to which this PGD applies

Definition of situation/condition	This Patient Group Direction (PGD) will authorise Pharmacists to supply/administer azithromycin tablets to individuals who are either unable to take doxycycline (first line treatment) and with a laboratory confirmed, positive 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. Sexually active individuals are at risk of sexually transmitted infections, *Chlamydia trachomatis* is the most prevalent bacterial infection. Genital chlamydia infection can cause considerable short and long term morbidity. The sequelae of chlamydia infection include pelvic inflammatory disease, ectopic pregnancy and tubal infertility in females, epididymo-orchitis in males, and reactive arthritis. Azithromycin is a macrolide antibiotic indicated for the treatment of uncomplicated genital chlamydia infection. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC) and 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 Child protection procedures should be followed in all individuals under the age of 16 – see link below: http://nhsgintranet.grampian.scot.nhs.uk/depts/ChildProtection/Pages/default.aspx • Asymptomatic individuals who are sexual contacts of someone with a positive chlamydia test and an uncomplicated genital presentation.

Exclusion criteria	• Under the age of 13 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). • Pregnancy • Breastfeeding • Men and women complaining of symptoms suggestive of an STI prior to a confirmed chlamydia diagnosis • Allergy to azithromycin, erythromycin, clarithromycin or any macrolide or ketolide antibiotic • Known anaphylactic hypersensitivity to azithromycin or any of its excipients • Severe hepatic impairment • Taking medicines that interact with Azithromycin (see current BNF Appendix 1 for full list or the SmPC • Suspected **complicated** chlamydia infection, i.e. women with a positive Chlamydia result complaining of pelvic pain/pain during vaginal sex and men with a positive Chlamydia test result complaining of testicular pain must be referred to a GP or a genitourinary medicine/sexual health clinic • The presence of rectal chlamydia infection • Individuals with Myasthenia Gravis.
Precautions and special warnings	Azithromycin should be used with caution in individuals with QT prolongation, individuals taking other medicines which could cause QT prolongation, individuals with electrolyte disturbances or those with clinically relevant bradycardia, cardiac arrhythmia or severe cardiac insufficiency.
Referral criteria	Individuals who fall into the categories detailed in the exclusion criteria. Individuals seeking repeat treatment because they vomited within 2 hours of taking the initial dose of azithromycin. Individuals, who following a diagnosis and treatment for uncomplicated genital chlamydia infection report having unprotected vaginal, anal, or oral sex with an untreated partner likely to have chlamydia infection.

Action if excluded from treatment	Medical advice should be sought – refer to General Practitioner/Consultant (relevant medical practitioner) or a genitourinary medicine/sexual health clinic. The reason why the individual was excluded under the PGD will be documented in the appropriate medical record.
Action if treatment declined	Individuals should be advised of the risks and consequences of not receiving treatment. Refer to General Practitioner/Consultant (relevant medical practitioner) or a genitourinary medicine/sexual health clinic. Record outcome in Patient Medication Record if appropriate, or relevant medical record.
Consent	Prior to the supply/administration of the drug, valid consent must be obtained. Consent must be in line with current NHSG consent policy.

Description of treatment available under the PGD

Name form and strength of medicine	Azithromycin 250mg/500mg Tablets
Legal status	Azithromycin 250mg/500mg Tablets 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.
Dosage/Maximum Total Dose	1 gram as a single dose followed by 500mg daily for 2 days; 8 x 250mg tablets or 4 x 500mg tablets.
Frequency of dose/Duration of treatment	One single dose of 1 gram followed by 500mg for 2 days. Three days treatment
Maximum or minimum treatment period	Three days treatment.
Route/Method of administration	Oral.

Quantity to be supplied and/or administered	2 gram as either: 8 x 250mg tablets or 4 x 500mg tablets.
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)	Ideally the dose should be supervised on the day, however individuals can be supplied with the azithromycin to take at a later time. If the azithromycin is taken on the premises, individuals should not leave if they are feeling unwell without speaking to the pharmacist first. If necessary a doctor or the individuals's GP should be contacted for advice.
Advice (Verbal)	Advice should be given on what to expect and what to do for major and minor reactions. Individuals should be advised to go to their GP practice or genitourinary medicine/sexual health clinic for further treatment if vomiting occurs within 2 hours of taking azithromycin. Individuals should be advised to abstain from having oral, anal or vaginal sex, even with a condom, until they, and their current partners, have been treated and for one week thereafter. Individuals should receive information regarding chlamydia infection at the time of antibiotic treatment, and must be advised to notify any sexual partners.
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made accessible to the individual, parent, guardian, or person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. Copies of PIL and SmPCs for medicines can be found at http://www.medicines.org.uk or http://www.mhra.gov.uk/spc-pil/index.htm
Identifying and managing possible adverse reactions	Common side effects: • GI side effects including nausea, vomiting, diarrhoea and abdominal discomfort • Dizziness

	• Headache • Malaise. Urticaria, rashes and other allergic reactions are rare, individuals experiencing signs of an allergic reaction should be advised to contact their GP or NHS24. **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 **SmPC/PIL and risk minimisation materials:** 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 the reaction to the MHRA using the Yellow Card System. https://yellowcard.mhra.gov.uk/
Facilities and supplies required	The following should be available at sites where the medication is to be supplied: • Appropriate storage facilities • An acceptable level of privacy to respect individual's right to confidentiality and safety • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities • Copies of the current PGD for the medicine specified in the PGD.

Characteristics of staff authorised to supply medicine 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 supply/administration in order for the individual to give or refuse consent

	• Having undertaken appropriate training to carry out clinical assessment of individuals leading to a diagnosis that requires treatment according to the indications listed in the PGD. • Aware of current treatment recommendations and be competent to discuss issues about the drug with the individual • Competent in the administration of the drug.
Ongoing training and competency	**All professionals working under this PGD must:** • Have attended basic life support training which is required to be updated annually • Have undertaken the NHS e-anaphylaxis training session or equivalent (including annual updates) which covers all aspects of the identification and management of anaphylaxis. • Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct • Must be familiar with the SmPC for all medicines supplied/administered in accordance with this PGD.
Professional managers/Lead Nurses will be responsible for:	Ensuring that the current PGD is available to 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/administer drug specified in PGD.

Documentation

Authorisation of supply/ administration	Pharmacists working within NHS Grampian can be authorised to supply/administer the drug specified in this PGD by the Director of Pharmacy. All authorised staff are required to read the PGD and sign the Agreement to Supply and/or Administer Medicines Under PGD (Appendix 1). This should be held in the individual practitioners records, or as agreed locally. A Certificate of Authorisation (Appendix 2) signed by the authorising doctor/manager and staff working to the PGD, should be held as agreed locally.

Record of supply/ administration	An electronic or paper record for recording the screening of individuals and the subsequent supply/administration of the drug 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/administration • Individuals name • Individuals Date of birth and CHI • Details of parent/guardian, or person with parental responsibility where applicable • Exclusion criteria, record why the drug was not supplied/administered • Consent to the administration (if not obtained elsewhere) • Signature and name in capital letters of practitioner who supplied/administered the drug • Record of any adverse effects (advise individual's doctor). Depending on the clinical setting where supply or administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • Consent forms • Child Health Information Services if appropriate • Hand–held records such as red book if appropriate • Individual's GP records if appropriate • Secondary Care Medical Notes • Occupational health systems • Individual service specific systems.
Audit	All records of the medicines(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 will be responsible for auditing completion of drug forms and collation of data.
References	Electronic Medicines Compendium http://www.medicines.org.uk Azithromycin Tablets (Generics UK T/A Mylan) – Date of revision of text 12/12/17, accessed 18/07/18 British National Formulary and the British National Formulary for Children https://www.bnf.org accessed 18/07/18

Appendix 1

Healthcare Professional Agreement to Supply Medicines Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. H&SCP, Practice

Agree to supply/administer medicines under the direction contained within the following Patient Group Direction

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

I have completed the appropriate training to my professional standards enabling me to supply/administer medicines under the above Patient Group Direction. I agree not to act beyond my professional competence nor out with the recommendations of the Patient Group Direction.

Signed: _____

Print Name: _____

Date: _____

Professional Registration No: _____

Appendix 2

Healthcare Professionals Authorisation to Supply Medicines Under Patient Group Direction

The lead nurse/professional of each clinical area is responsible for maintaining records of their clinical area where this PGD is in use, and to whom it has been disseminated.
The manager who approves a healthcare professional to supply and/or administer medicines under the patient group direction, 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 in conjunction with the Head of Profession.
The healthcare professional who is approved to supply and/or administer medicines under the direction 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 or administration is carried out within the terms of the direction, and according to his or her code of professional practice and conduct.
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
Local clinical area(s) where these healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

NHS Grampian

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

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date