Bath & North East Somerset Council

PATIENT GROUP DIRECTION (PGD) FOR AZITHROMYCIN 250mg & 500mg TABLETS & CAPSULES

Section 1
CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR AZITHROMYCIN 250mg & 500mg TABLETS & CAPSULES

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

Organisation and service	
Bath & North East Somerset Council	▪ Community pharmacies working under the Sexual Health enhanced services contract commissioned by B&NES Council ▪ General Practices (B&NES CCG)
Period	
Date PGD comes into effect	1st May 2018
Expiry date	30th April 2020
Staff characteristics	
Professional qualifications	Registered Pharmacist with current General Pharmaceutical Council Practising Registration working under the Sexual Health enhanced services contract
Specialist competencies or qualifications **Specialist competencies or qualifications** (continued)	Must fit all the following criteria: ▪ have undertaken appropriate training for working under patient group directions for the supply and administration of medicines ▪ have been assessed as competent to work with this PGD ▪ have undertaken training in the role, care and administration of the medicine specified in this PGD, as specified by the individual authorising organisation ▪ Pharmacists: have undertaken appropriate continuing professional development around sexual health testing and treatment, and can provide evidence of this CPD, or who have undertaken relevant training, as specified by the relevant authorising organisation ▪ have access to a current of the BNF (https://www.medicinescomplete.com/mc/bnf/current)
Continuing training and education	▪ The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development
Clinical Details	
Indication	For the treatment of known uncomplicated genital *chlamydia*

	trachomatis and contacts of chlamydia.

Inclusion criteria	▪ Male and female clients, within the age group which the service is commissioned to treat, who have a positive genital chlamydia result following screening.
	▪ Sexual contact of client with positive genital chlamydia result (no upper age limit).
	▪ 45kg or over in weight
	▪ Consent and are competent to consent to treatment
	▪ **If the client is under 16** discuss the value of parental support and encourage client to inform parent(s). An assessment of the Fraser Guidelines on Competency must be made:
	  ▪ Mature enough to understand the advice and implications
	  ▪ Cannot be persuaded to discuss with parents
	  ▪ Likely to have had or continue to have sexual intercourse
	  ▪ Physical or mental health likely to suffer if does not receive contraceptive help
	  ▪ In the clients best interest to receive contraception without parental consent

Exclusion criteria	▪ No valid consent
	▪ Not competent under Fraser Guidelines
	▪ Under 45 kg in weight – refer to GP
	▪ Allergy or hypersensitivity to azithromycin, macrolide antibiotics, ketolide antibiotics, or to any excipient
	▪ Breastfeeding
	▪ Established pregnancy
	▪ Severe hepatic or renal disease
	▪ History of cardiac disease
	▪ Bradycardia
	▪ Cardiac arrhythmia
	▪ Myasthenia gravis
	▪ Rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption
	▪ Patient takes:
	  ➢ Ciclosporin
	  ➢ Digoxin
	  ➢ Disopyramide
	  ➢ Quinidine
	  ➢ Amiodarone
	  ➢ Cisapride
	  ➢ Pimozide
	  ➢ Moxifloxacin
	  ➢ Droperidol
	  ➢ Reboxetine
	  ➢ Artenimol with piperaquine
	  ➢ Theophylline
	  ➢ Rifabutin
	  ➢ Ergot or ergotamine
	  ➢ Procainamide
	  ➢ Sotalol
	  ➢ Terfenadine
	  ➢ Citalopram
	  ➢ Levofloxacin
	  ➢ Mizolastine
	  ➢ Artemether with lumetantrine

	Any other drug known to increase the QT interval (See current SPC (https://www.medicines.org.uk/emc)).
Action if patient declines or is excluded	▪ Explain consequences of not treating ▪ Refer to appropriate doctor or service, according to local situation and arrangements, e.g. sexual health service, within an appropriate timescale as per local guidelines ▪ Document reason for exclusion or refusal and action taken
Circumstances under which further advice should be sought from a doctor and arrangements for referral	Predisposition to QT interval prolongation (including electrolyte disturbances, particularly hypokalaemia or hypomagnesaemia), congenital or documented QT prolongation – obtain advice from, or refer to an appropriate doctor in line with local guidance. Discuss option of referral to sexual health service for screening for other sexually transmitted infections. ▪ If under 13 years old, follow local safeguarding policy
Drug Details	
Name, form & strength of medicine	Azithromycin 250mg or 500mg tablets or capsules
Legal Status/classification of medicine	Prescription only medicine (POM)
Route/method of administration	Oral Tablets should be taken with or after food and with half a glass of water Capsules should be swallowed whole and taken at least one hour before and at least two hours after food. Indigestion remedies must not be taken 2 hours before or 2 hours after taking any azithromycin preparation.
Dosage	1 gram (4 x 250mg tablets/capsules, or 2 x 500mgtablets/capsules). **NB must give a full patient pack and not split packs.**
Frequency	Single dose
Duration of treatment	Single dose

Maximum or minimum treatment period	Single dose
Quantity to supply/administer	Either: 4 x 250mg tablets or capsules or 2 x 500mg tablets or capsules Preferably as supervised consumption. **NB must give a full patient pack and not split packs.**
Storage	Store below 25 °C in a dry place, in original packaging

Cautions	Safeguarding procedures must be considered for any young person under the age of 18 years old and local procedures followed if appropriate.
Interactions	▪ Azithromycin may increase bleeding time in patients taking oral anticoagulants so such patients should be advised to check for signs of over-anticoagulation (e.g. unexplained bruising, difficulty stopping minor cuts from bleeding), and if these occur refer immediately to the healthcare provider managing the anticoagulation. All patients who take oral anticoagulants should report the dose of azithromycin at the next INR check. ▪ Antacids have been shown to affect the absorption of azithromycin. To reduce the risk of treatment failure azithromycin should be administered at least 2 hours after any antacid, and no antacid should be taken for at least 1 hour after the azithromycin administration. ▪ Nelfinavir - Dose adjustment is not necessary, but the increased potential for known side-effects of azithromycin should be considered ▪ Azithromycin may inactivate oral typhoid vaccine. Therefore oral typhoid vaccine should not be taken less than 3 days after the azithromycin dose and azithromycin should not be used for at least 3 days after the final dose of oral typhoid vaccine (see reference below for Vivotif®). ▪ Colchicine possible increase risk of colchicine toxicity – suspended or reduced dose of colchicine may be indicated – seek advice from colchicine prescriber. This is not a full list of all possible interactions see British National Formulary (BNF) or Summary of Product Characteristics (SPC) (available at https://www.medicinescomplete.com/mc/bnf/current or http://www.medicines.org.uk/emc/default.aspx) for full details.
Side effects	Like many medicines, Azithromycin may occasionally cause side effects. However, this is usually with longer courses of azithromycin treatment. Rare but serious allergic reaction such as swelling of the body, face, lips or throat. Very occasionally, these effects may be severe causing shortness of breath, shock or collapse. **Very common** (occurs in more than 1 in 10 users): diarrhoea,, abdominal pain, nausea, flatulence **Common** (occurs in less than 1 in 10 users): vomiting, poor appetite, dizziness, headache, pins and needles, changes in taste, blurred or double vision, poor hearing, being sick, indigestion, rash, itching, joint pain, tiredness

Side effects (continued)	**Less common** Constipation, gastritis, chest pain, oedema, anxiety, sleep disturbances, hypoaesthesia, leucopenia, photosensitivity; **Rarely** agitation; also reported syncope, convulsions, smell disturbances, interstitial nephritis, acute renal failure, thrombocytopenia, haemolytic anaemia, tongue discoloration NB: This is not a full list of side effects. It is a summary of those that are common, clinically significant or severe. See British National Formulary (BNF) or Summary of Product Characteristics (SPC) (available at https://www.medicinescomplete.com/mc/bnf/current or http://www.medicines.org.uk/emc/default.aspx) for full details of adverse effects. **Suspected Adverse Reactions** If an adverse reaction is suspected this should be reported to the Medicines Healthcare products Regulatory Agency (MHRA) through the Yellow card reporting scheme, which can be found in the back of the BNF or on the web site: http://www.mhra.gov.uk or www.yellowcard.gov.uk *Any adverse reaction associated with the use of this PGD, which is reported through the Yellow Card System, should additionally be reported via the organisations adverse incident reporting system.*
Advice to patient	▪ Provide verbal and written information on Chlamydia infection and its treatment, including azithromycin patient information leaflet ▪ All patients <25years old who test positive for chlamydia should be offered a repeat test around 3 months after treatment of the initial infection and obtain a local Chlamydia Screening Programme (CSP) kit (via GP, community pharmacy or sexual health service) Advise regarding potential side effects ▪ Abstain completely from sexual contact (genital, oral or anal, even with condoms) until they and their partner(s) have completed therapy and waited 7 days. Warn that if sexual contact takes place with an untreated partner there is a risk of re-infection ▪ Discuss implications if incomplete/untreated infection of self or partner ▪ If vomiting occurs within 3 hours of taking tablets they may not work properly so client should return for re-evaluation as soon as possible. ▪ Signpost the patient to the sexual health service for other

	sexually transmitted infection tests.
Follow up actions	Use local safeguarding procedures if there is any concern regarding a child's (under 18 years old) sexual activities.
Audit trail	
Records/audit trail	▪ Date ▪ Patient's name, address, date of birth and consent given by patient/parent/guardian ▪ Contact details of GP (if registered) ▪ Indication for use ▪ Dose form administered (tablets or capsules) ▪ Batch number ▪ Expiry date ▪ Date of administration ▪ Patient information leaflet(s) offered ▪ Advice given to patient/parent/guardian (including side effects) ▪ Referral arrangements (including self-care) ▪ Name and designation of healthcare professional who administered or supplied the medication. ▪ Details of any adverse drug reaction and actions taken including documentation in the patient's medical record ▪ Any additional advice sought from a doctor or other health care professional

References used for this PGD

This PGD is based on the Levonorgestrel PGD developed by Virgin Care Ltd, July 2017, and was drawn up in consultation with:

Name	Speciality
Paul Moloney	Lead Pharmacist, Virgin Care B&NES
Dr Arnold Fernandes	Consultant in Genitourinary Medicine and Contraception, The Riverside Clinic, Royal United Hospital NHS Foundation Trust
Jayne Elton	Lead Nurse Practitioner, The Riverside Clinic, Royal United Hospital NHS Foundation Trust
Claire Hookway	Pharmacist, Boots The Chemist, Bath
Paul Sheehan	Public Health Commissioning and Development Manager, Bath and North East Somerset Council

Section 2

MANAGERIAL CONTENT OF PATIENT GROUP DIRECTION FOR AZITHROMYCIN 250mg & 500mg TABLETS & CAPSULES

This patient group direction must be agreed to and signed by all health care professionals involved in its writing and who use it. The Authorising Organisations lead should hold the original signed copy. The PGD must be easily accessible in the clinical setting	
Authorisation	
Specialist Medical Clinician: **Dr. Arnold Fernandes**	Name: DR. ARNOLD FERNANDES Signature:  Date: 25th April 2018 Job title: Consultant in Genitourinary Medicine and Contraception The Riverside Clinic, Royal United Hospital NHS Foundation Trust
Lead Pharmacist: **Paul Moloney**	Name: PAUL MOLONEY Signature:  Date: 25th April 2018 Job title: Lead Pharmacist, Virgin Care Ltd
Organisational Authorisation: **Dr. Bruce Laurence**	Name: DR. BRUCE LAURENCE Signature:  Date: 25th April 2018 Job title: Director of Public Health, B&NES Council

Bath & North East Somerset Council

PATIENT GROUP DIRECTION (PGD) FOR AZITHROMYCIN 250mg & 500mg TABLETS & CAPSULES

Individual Authorisation

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct

Note to Authorising Managers: Authorised staff should be provided with an individual copy of the clinical content of the PGD and a copy of the authorisation sheet showing their authorisation.

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD.

Name of Professional	Signature	Authorising Manager	Date

Name of pharmacy: (if azithromycin issued under local enhanced service)

Bath & North East Somerset Council

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Appendix 1

Self-assessment of competencies for supply/administration of AZITHROMYCIN 250mg or 500mg TABLETS or CAPSULES under patient under patient group direction

Name of Professional	Location	Date

With reference to
a) PGD for AZITHROMYCIN 250mg & 500mg TABLETS & CAPSULES
b) Patient Information Leaflet
and to be used in conjunction with
c) references contained within the PGD

Eligibility to Practice
The Practitioner will:
a) have a good working knowledge of why AZITHROMYCIN 250mg & 500mg TABLETS & CAPSULES are recommended
b) have completed my organisations approved training on Patient Group Directions
demonstrate the following competencies when administering/supplying the above named medicine AZITHROMYCIN 250mg & 500mg TABLETS & CAPSULES

	Knowledge	Signature & date
1	Identify local and national policies, Patient Group Direction and procedures used in the administration/supply of the above named medicine	
2	Describe the mode of action of the above named medicine	
3	Describe the clinical indications under which the patient is eligible for treatment	
4	Describe the contraindications/exclusions to the use of the above named medicine	
5	Explain the circumstances under which further advice from the doctor would be sought and arrangements for referral.	
6	Describe the administration process for the above named medicine including dose and site	
7	Describe any possible side effects or interactions of the above named medicine	
8	Discuss the relevant warnings and patient information to be given	
9	Explain the record keeping required in your area of work	
10	Undertake Continual Professional Development relevant to the above named medicine and the clinical area to which this PGD relates. Request updates to the PGD when changes to guidance necessitate this	

Abbreviations used in this Patient Group Direction

B&NES	Bath and North East Somerset
BNF	British National Formulary
CCG	Clinical Commissioning Group
CSP	Chlamydia Screening Programme
GP	General Practitioner
MHRA	Medicines and Healthcare products Regulatory Agency
POM	Prescription Only Medicine
SPC	Summary of Product Characteristics