NHS
Telford and Wrekin
Clinical Commissioning Group

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NB: Always access the electronic version of this PGD to ensure that you are using the most up to date version.

The practitioner MUST be authorised by name, under the current version of this PGD before working according to it.

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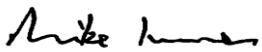
Patient Group Direction for Azithromycin for the treatment of uncomplicated genital Chlamydia trachomatis infection.

Approved By

NHS Telford and Wrekin	Name	Signature
CCG Chairman	**Mike Innes**	
Head of Medicines Management	**Jacqui Seaton**	

Date of patient group direction approved	June 2015
Date this patient group direction becomes due for review	December 2018

PGD Developed by

Title	Name
Pharmaceutical Adviser	Hitesh Patel

Azithromycin PGD administration form should be used to support supply of treatment against this PGD

STAFF CHARACTERISTICS

- Registered nurse with current NMC registration or Registered Pharmacist with current GPhC registration

Specialist competencies or qualifications:

- The service lead / lead GP has evidence that the health care professional has undertaken training as outlined in the service agreement to carry out clinical assessment of patient leading to confirmation that the patient requires treatment according to the indications listed in the PGD.

- The health care professional must provide evidence of training, appropriate annual updates and continued professional development undertaken to support their competence for administration of this treatment.

- The service lead / lead GP has proof of training by the health care professional on the legal aspects of supply or administration of medicines under a Patient Group Direction

- The service lead / lead GP has assessed the competency (against the organisational competency framework) of the healthcare professional to work to a Patient Group Direction at least every 2 years.

- Must have access to all relevant sources of information e.g. information issued by the Department of Health (DH), British National Formulary (BNF), Summary of Product Characteristics (SPC), and the clinical guideline concerning medicine(s) within this Patient Group Direction (PGD).

- The practitioner needs to re - enforce and update their knowledge and skills in this area of practice with particular reference to changes and national directives

- The registered health care practitioner is professionally accountable for supply or administration under the PGD as defined in their own profession's Code of Professional Conduct and Ethics.

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

PGDs DO NOT REMOVE INHERANT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

Azithromycin PGD administration form should be used to support supply of treatment against this PGD

CLINICAL CONDITION	
Clinical need addressed	• Men and women with confirmed uncomplicated genital Chlamydia trachomatis infection. • Sexual contacts of men/women where Chlamydia trachomatis diagnosis made in the index case. (All sexual contacts must be offered a Chlamydia screen at the point of treatment)
Inclusion criteria	• The client's medical history supports the clinical indication (confirmed uncomplicated genital Chlamydia trachomatis infection. • The client understands and consents to treatment within the Patient Group Direction. (Clients under 16 years must be assessed as meeting Fraser criteria) • Client understands that they may be contacted by a health adviser to discuss the need for any sexual partner to be tested / treated
Exclusion criteria (for full details of interacting medicines refer to current Summary of Product Characteristics (SPC) www.medicines.org.uk & BNF)	**Complicated chlamydial infection including:-** • Presence of urinary symptoms • Presence of penile discharge in men • Presence of vaginal discharge in women • Intermenstrual bleeding or change in normal bleeding pattern in women • Presence of pelvic pain in women / testicular pain in men **Any of the following conditions:-** • Presence of concomitant conjunctivitis / joint pains • Known hepatic impairment • Known porphyria • Known HIV infection • Known significant renal impairment • Recurrent chlamydial infection (Presenting within 3 months of previous treatment) **Allergies** • Known allergy to Azithromycin • Allergy to macrolides **Patients taking medications which interact with azithromycin** (please refer to SPC of product or current BNF for current information) such as; o Ciclosporin o Digoxin o Ergot derivatives o Theophylline o Reboxetine o Anticoagulants • Known or suspected pregnancy

	• Breast feeding • Client under 16 years who is felt not to meet Fraser criteria • Client aged under 16 years weighing less than 45kg
Caution / need for further advice	**Significant Renal Impairment**: No dose adjustment is necessary in patients with mild to moderate renal impairment (GFR 10–80 ml/min). Caution is advised in patients with severe renal impairment (GFR < 10 ml/min) as systemic exposure to azithromycin may be increased **Clients with cardiac arrhythmia**: Prolonged cardiac repolarisation and QT interval, imparting a risk of developing cardiac arrhythmia and torsades de pointes, have been seen in treatment with other macrolides. A similar effect with azithromycin cannot be completely ruled out in patients at increased risk for prolonged cardiac repolarisation. Therefore caution is required when treating patients: • With congenital or documented acquired QT prolongation. • Currently receiving treatment with other active substances that prolong QT interval. • With electrolyte disturbance, particularly in cases of hypokalaemia and hypomagnesaemia • With clinically relevant bradycardia, cardiac arrhythmia or severe cardiac insufficiency.
Management of excluded patients	• Refer all clients with above contra-indications to the GUM clinic (or their GP) as soon as possible. • Discuss with client reasons for exclusion and document •
Action for patients not wishing to receive care under this PGD	• Give client opportunity to discuss non-concordance. • Refer to client's own GP or GUM clinic. • Ensure client is aware of implications of not having treatment

Treatment and Drug details	
Name form and strength of medicine	Azithromycin 250mg (Tablets or Capsules)
Legal classification	• POM – Prescription only medicine.
Black triangle warning Suspected adverse reactions. Should be reported using the Yellow Card reporting scheme (www.yellowcard.gov.uk).	• No
Method of obtaining supply	• Licensed supplier • Community Pharmacies
Site for treatment	Accredited Community Pharmacies GP Practice's
Route / method	Oral
Dose	1g Azithromycin (Capsules or Tablets)

Number of times treatment may be administered	• Once only, in any three month period. • Clients presenting within three months from previous treatment should be referred to GUM.
Quantity to be supplied or administered	4 x 250mg (Capsules or Tablets)
Side effects *Full details of side effects are available in the SPC.* *www.medicines.org.uk* *Suspected adverse reactions to drugs including vaccines should be reported on the yellow card available at the back of the BNF. Also at www.yellowcard.gov.uk*	Incidence of side effects is generally low. **Gastro intestinal disturbances** Anorexia, nausea, vomiting, diarrhoea, constipation, dyspepsia, abdominal discomfort. **Hypersensitivity reactions** e.g. pruritus, rash, photosensitivity, angioneurotic oedema, anaphylaxis, **Haematological effects** Thrombocytopenia, transient mild reductions in neutrophil counts. **Hepatic effects** Abnormal liver function, hepatitis, cholestatic jaundice. **CNS effects** Dizziness, vertigo, convulsions, headache, somnolence. **Senses** Taste disturbance, hearing impairment.
Labelling Requirements	Dose must be taken at Clinic / Pharmacy as a single dose *(If the patient is not taking the tablets/capsules immediately in the pharmacy, then the medication must be labelled with the patient's name, details of the medication given (including directions for use) and the name and address of the pharmacy.)*
Additional Information	**NOT IN SCOPE OF THIS PGD For information only** - Use of Azithromycin in pregnancy for the treatment of uncomplicated genital Chlamydia trachomatis infection. Azithromycin may be used when the client is at risk of pregnancy or has an established pregnancy, if the available alternative erythromycin 500mg bd for 14 days, is either not acceptable to the client or cannot be tolerated by the client; in line with guidelines from British Association for Sexual Health and HIV and World Health Organisation. **ALL PREGNANT WOMEN MUST BE REFERRED TO THEIR GP**
Advice to patient / carer	• Tablets / Capsules should be swallowed whole with plenty of fluids, advise no food for one hour after taking capsules. • Avoid exposure to sunlight or sunlamps for one week after treatment. • Warn of risk of gastro intestinal upset and skin rashes • Avoid iron and indigestion remedies for a few hours either side of the stat dose • Advise patient to return if s/he experiences vomiting within 3 hours of taking dose • Give leaflet on condom use and safer sex and Chlamydia • Client should be advised to abstain from unprotected sex (vaginal/anal/oral and genital contact) during treatment and for one week after own treatment and should continue to refrain from unprotected sex until one week after partner has completed treatment. • Emphasise importance and need for client's sexual partner/s to be treated • Provide leaflets on Chlamydia and Azithromycin for the patient

Follow up	• No follow up required unless reaction to medication in which case the patient should return promptly to the GP • If symptoms persist the patient should be reviewed by a doctor/senior nurse in 2 weeks.
Suspected Adverse reactions	• Patient presenting with suspected adverse drug reaction should be referred to a doctor for further investigations. • All adverse reactions should be reported to the MHRA, using the yellow ADR card system available in the BNF. www.yellowcard.mhra.gov.uk
Error reporting	• Any incidents or near miss issues must be reported via the organisation's internal reporting system.

RECORD KEEPING	
Documentation needed / treatment records to be kept for audit purposes *A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.*	• Patient's name, address, date of birth • Manufacturer / brand of product, batch number, expiry date • Record of informed consent • Date of supply • Quantity supplied • Advice given to client • Details of staff who supplied (sign and print name) • Details of any adverse drug reactions, and action taken • Reconciliation – stock balances should be reconcilable with receipts, administration, records and disposal on a patient by patient basis.

REFERENCES	
	BNF Current Edition
	SIGN Guidance Management of genital Chlamydia trachomatis infection. 2000
	National Chlamydia Screening Programme for England – core requirements 3 edition 2006 DH
	Azithromycin Product SPC www.medicine.org.uk
	BASHH Clinical Effectiveness Group (2010). Standards for the management of sexually transmitted infections. http://www.bashh.org/about/bashh_publications

Register of practitioners qualified to administer and / or supply **Azithromycin** **under this Patient Group Direction**	
Name of clinical manager / GP Lead	
Signature of clinical manager / GP Lead	Date:
A copy of this page should be retained by the authorising manager for 25 years for audit purposes	
Please state clinical area where this PGD is in use	

Healthcare professional individual declaration

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

- **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.
- All practitioners operating in accordance with this PGD should have a current, signed copy of it readily available for reference.
- If a practitioner is asked to supply, or administer a medicine not covered by this or any other PGD then a patient specific direction is required from a doctor, dentist or independent prescriber.

Name of professional (please print)	Signature	Authorising Manager (Must sign against each entry)	Date of authorisation

Healthcare professionals working under a PGD must have received appropriate training and been assessed as competent to administer/supply the medicine referred to in the PGD. The clinical lead should review competency of authorised practitioner/s at least annually. Training certificates must be available for inspection.

Authorisation to use this PGD does not remove inherent professional responsibility and accountability

A copy of this authorisation form must be printed off, signed and dated by the healthcare professional authorised to use this PGD. This should be retained by the service provider (e.g. GP practice) and readily available for inspection (e.g. CQC).

Appendix 1

The Fraser Guidelines (in the context of treatment for STI)

- The young person understands the advice and has sufficient maturity to understand what is involved.
- That the doctor/nurse could not persuade the young person to inform their parents, nor allow the doctor/nurse to inform them.
- That the young person would be very likely to begin or continue having sexual intercourse with or without treatment for the infection.
- That without treatment, the young person's physical or mental health would suffer.
- That it would be in the young person's best interest to give such advice or treatment without parental consent.
- Under 16s have a right to confidentiality whether asking for advice on STIs or any medical treatment.

(Adapted from the Family Planning Association Fact-sheet No 12, 1997)