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MANCHESTER CITY COUNCIL

PATIENT GROUP DIRECTION FOR THE SUPPLY OF

Azithromycin 250mg Tablets or Capsules

By registered pharmacist for the treatment of *Chlamydia trachomatis* infection in community pharmacies

Version: 2.2

Valid from: 1st April 2019

Expires on: 31st March 2021

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it The most recent and in date final signed version of the PGD should be used

AZITHROMYCIN 250MG CAPSULES OR TABLETS COMMUNITY PHARMACY – TREATMENT OF CHLAMYDIA TRACHOMATIS	P.O.M. [Prescription Only Medicine]

DOCUMENT CONTROL – PGD Ready for authorisation

Document Location

Copies of this PGD can be obtained from.

Name:	Manchester City Council
Address:	Public Health Manchester, Manchester City Council, Town Hall Extension, Manchester M60 2LA
Telephone:	0161 234 3391

Revision History

The latest and master version of the unsigned PGD is held by Manchester Health and Care Commissioning

REVISION DATE	ACTIONED BY	SUMMARY OF CHANGES	VERSION
05/02/2019	SMcK	Updated MHRA website details	2 1
05/02/2019	SMcK	Updated approval group and signatories	2 1
05/02/2019	SMck	Updated dose and frequency in line with BASHH guidelines	2 1
05/02/2019	SMcK	Updated unlicensed /off label use - to state off label use	2 1
05/02/2019	SMcK	Reference 10 and 11 added	2 1
05/02/2019	SMcK	Minor amendment – max/min treatment period updated to duration	2 1
28/02/2019	JKS	Minor amendments to references	2 2

Approvals

This PGD must be approved by the following before distribution

NAME	TITLE	DATE OF ISSUE	VERSION
David Regan	Director of Public Health at Manchester City Council	12/03/2019	2 2
Connie Chen	GP Prescribing Lead, Manchester Health and Care Commissioning, Chair of the Manchester Area Prescribing Committee	06/03/2019	2 2
Dipesh Raghwani	Clinical Lead Greater Manchester Local Pharmaceutical Committee (GM LPC)	06/03/2019	2 2

Distribution

This PGD has been distributed to during its development·

NAME	TITLE	DATE OF ISSUE	VERSION
Susan McKernan	Lead Pharmacist and Deputy Head of Medicines Optimisation for Manchester CCG	12/03/2019	2 2
Paula Russell	Principal Pharmacist, Regional Drug and Therapeutics Centre	12/03/2019	2 2
Jatinder Saimbi	Medicines Optimisation Pharmacist and NMP Lead, Manchester Health and Care Commissioning	12/03/2019	2 2
Dr Philipa James	Dr Philippa James Cornbrook Medical Practice (DFSRH)	12/03/2019	2 2
Dr Ahmed Qamruddin	Consultant Microbiologist @ ORC Site	12/03/2019	2 2

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PGD Development

Reviewed by:	Jatinder Saimbi (Author)	Medicines Optimisation Pharmacist and NMP Lead, Manchester Health and Care Commissioning
	Susan McKernan	Lead Pharmacist and Deputy Head of Medicines Optimisation for Manchester CCG
	Paula Russell	Principal Pharmacist, Regional Drug and Therapeutics Centre

Date applicable:	1st April 2019
Review date:	1st October 2020
Expiry date:	31st March 2021

PGD Authorisation

This Patient Group Direction has been approved for use in the Manchester City Council area by:

Designation	**Name**	**Signature**	**Date**
Senior Pharmacist **(Lead Pharmacist and Deputy Head of Medicines Optimisation)**	Susan McKernan		20/3/19
Doctor **(GP Prescribing Lead)**	Connie Chen	cchen	20/3/19.
Clinical Lead **(Greater Manchester Local Pharmaceutical Committee (GM LPC)**	Dipesh Raghwani		27/3/19.
Authorised Signatory for Manchester City Council **(Director of Public Health)**	David Regan	David Regan	3 4 19

1. Characteristics of Staff

Qualifications required	▪ Pharmacist with a current General Pharmaceutical Council registration ▪ Work in a Community Pharmacy within the Manchester City Council area
Additional requirements	▪ Has had training in the use of PGDs ▪ Has had training which enables the pharmacist to make a clinical assessment in order to establish the need and supply azithromycin according to this PGD as detailed in the service specification. ▪ Has satisfied the competencies appropriate to this PGD, as detailed in the CPPE and NHS Health Education North West *Declaration of Competence for community pharmacy services – Chlamydia screening and treatment* document. (https //www.cppe.ac uk/services/declaration-of-competence) ▪ Is competent in the assessment of the individuals using Fraser guidelines ▪ Has undergone regular training and updating in safeguarding children and vulnerable adults ▪ Has an understanding of how to deal with a possible anaphylactic reaction, this could include access to a member of staff trained in basic life support.
Continued training requirements	▪ The pharmacist should be aware of any change to the recommendations for the medicine listed. ▪ Must be able to show regular update in the field of contraceptive and reproductive health care, in particular sexually transmitted diseases. ▪ Must assess and maintain their own competence on the medicine supplied under this PGD in line with the requirements contained within the *Declaration of Competence for community pharmacy services – Chlamydia screening and treatment* document ▪ It is the responsibility of the pharmacist to keep up-to-date with continuing professional development ▪ It is the responsibility of the pharmacist to maintain their own competency to practice within this PGD Further training may be necessary when the PGD is reviewed
Suggested supporting learning	It is essential that pharmacists complete and satisfy the competencies detailed in the CPPE and NHS Health Education North West *Declaration of Competence for community pharmacy services – Chlamydia screening and treatment* document.

The Pharmacy Contractor is responsible for ensuring that only suitable Pharmacists sign up to this PGD and should maintain a record of the names of individual Pharmacists and evidence of their self-declaration and sign up to the current PGD.

2. Clinical condition or situation to which the direction applies.

Indication (Clinical condition or situation to which this PGD applies)	Patients either known or suspected of having uncomplicated genital *Chlamydia trachomatis* infection identified by RUClear There are two Patient Group Directions (PGD) in the Manchester City Council area for the treatment of *Chlamydia trachomatis* infection. ▪ The PGD for doxycycline must be considered for first line use, unless exclusions apply or there are concomitant medication considerations ▪ This PGD for azithromycin can be considered for second line use, where doxycycline is contraindicated or not tolerated.
Criteria for inclusion	▪ Male or female patients either with a laboratory-confirmed positive genital *Chlamydia trachomatis* infection or who is a sexual contact of any patient who has a laboratory-confirmed positive genital *Chlamydia trachomatis* infection RUClear will notify pharmacies of infected individuals and identified sexual contacts asking to attend that site. ▪ Have no known contraindications or allergies to azithromycin or the excipients of either formulation ▪ Pregnant and willing to take (see Patient Information) ▪ Understand the risks, benefits and side effects ▪ Are competent to consent to treatment ▪ Meet Fraser guidelines, if under 16 years of age *Note children under 13 years of age must be notified to the local Safeguarding Team and treatment provided by an appropriate doctor / independent nurse prescriber.*

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Criteria for exclusion[1]	▪ Individuals aged under 16 years who are assessed as not competent using Fraser Guidelines ▪ All children under 13 years of age or weighing less than 45kg ▪ Individuals who cannot take tablets/capsules ▪ Non-genital *Chlamydia trachomatis* infection ▪ Complicated *Chlamydia* infection in males e.g with epididymitis or testicular pain ▪ Complicated *Chlamydia* infection in females e g. with pelvic pain or suspected Pelvic Inflammatory Disease (PID) ▪ Fever ▪ Known hepatic or renal impairment ▪ Current/past history of cardiac rhythm disturbance ▪ Myasthenia gravis – azithromycin can cause exacerbation of symptoms ▪ Concomitant conjunctivitis and/or joint pain/swelling ▪ Known allergy or hypersensitivity to macrolide antibiotics or any constituent of the medication. ▪ Patients taking concomitant medication which may interact with azithromycin, including drugs known to prolong QT interval – check for interactions in the current British National Formulary (BNF) (http://www bnf.org/bnf/index.htm) or the Summary of Product Characteristics (http //www medicines org.uk/emc/)
Reference to national / local policies or guidelines	British Association for Sexual Health and HIV (BASHH) Clinical Effectiveness Guidelines

[1] Exclusion under this Patient Group Direction (PGD) does not necessarily mean the medication is contraindicated but it may be outside the remit of the PGD and another form of authorisation may be suitable

Cautions (including any relevant action to be taken)	▪ Some brands of azithromycin use soya as an excipient, and are therefore contraindicated in individuals with an allergy to soya or peanuts Check manufacturer's information for brand being used. ▪ Reinforce need for screening for other sexually transmitted infection (STI) ▪ Refer back to RUClear for any medical condition / medicine for which the pharmacist is unsure / uncertain
Action if excluded	▪ Refer back to RUClear ▪ If excluded because the patient is under 13 years of age, information should usually be shared in accordance with local guidance, but if a decision is made not to disclose there should be a discussion with a named or designated nurse or doctor for child protection, with a record of the decision stating the reason.[2] ▪ Document all actions taken
Action if patient or carer declines treatment	▪ Make individual aware of the need for treatment and refer back to RUClear ▪ Document all actions taken

[2] Clinical Effectiveness Group, British Association for Sexual Health and HIV, United Kingdom National Guideline on the Management of Sexually Transmitted Infections and Related Conditions in Children and Young People (2010)

3. Details of medicine

Name, strength & formulation of medicine	Azithromycin 250mg capsules or tablets
Presentation	Tablets or capsules
Storage	Do not store above 25°C.
Legal category	POM
Black Triangle▼	No
Unlicensed / off label use	Off label
Route / method	Oral
Dose and frequency[1,10, 11]	▪ 1g (4 X 250mg) orally as a single dose followed by 500mg daily for two days
Duration	Three days
Quantity to be administered and/or supplied	8 x 250mg capsules or tablets
Drug interactions[3]	▪ If the patient is taking any concomitant medication or treatment it is the practitioner's responsibility to ensure that treatment with the drug detailed in this PGD is appropriate. (For drug interaction see Appendix 1 of BNF (https //www medicinescomplete.com/mc/) or the SPC (http //www medicines org.uk/emc/) or contact the Medicine Information Service at Liverpool – telephone number inside front cover of BNF ▪ In the case of any doubt, further advice must be sought from an appropriate health professional and recorded as having been sought before the drug is given. ▪ If the requirements of this Patient Group Direction cannot be complied with the patient must be referred back to RUClear

[3]Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

Identification & management of adverse reactions[3]

Very common and common adverse effects

Appetite decreased, headache, pancreatitis	hearing impairment, arthralgia
Diarrhoea, nausea, vomiting	Gastrointestinal discomfort, Gastrointestinal disorders
Dizziness, vision disorders	Skin reactions , insomnia, vasoldilation, taste altered

With azithromycin, as with erythromycin and other macrolides, rare serious allergic reactions including angioneurotic oedema and anaphylaxis (rarely fatal) have been reported

For a full adverse effects profile, refer to the SPC (www medicines.org uk) or the most current edition of the BNF (https.//www.medicinescomplete.com/mc/)

In the event of any adverse reaction

- Record the adverse reaction in the patient consultation note
- Inform the patient's GP if the client consents to this

If appropriate report the adverse reaction under the Yellow Card scheme (forms can be found at the back of the BNF or completed online at www mhra gov uk/yellowcard)

4. Records

Records	The pharmacist must keep a record of the consultation as required in the service specification for a period of time in line with *Records Management Code of Practice for Health and Social Care 2016* (https //digital nhs.uk/codes-of-practice-handling-information) and service specification. The minimum required information to be collected is: ▪ Patient's name, address, date of birth and consent given ▪ Contact details of GP (if registered) ▪ Dose, form and date administered ▪ Batch number and expiry date. ▪ Advice given to patient (including side effects and self-care) ▪ Significant information e.g. if used off licence reason why ▪ Signature/name of health professional who administered or supplied the medication. ▪ Details of any adverse drug reaction and actions taken including documentation in the patient's record ▪ Record any follow up or referral arrangements ▪ Record refusal of treatment by pharmacist if the individual does not meet the inclusion criteria/ by individual ▪ Complete and return via a secure method any relevant forms to the screening/treatment coordinating organisation *Records Management Code of Practice for Health and Social Care 2016* recommends the following storage periods for health records: ▪ 8 years (in adults) or until 25th birthday in a child (or if the patient was 17 at the conclusion of the treatment, until their 26th birthday), or 8 years after death. Computerised patients medication records can be used where considered appropriate Data must be stored in accordance with Caldicott guidance, the Data Protection Act and the General Data Protection Regulation

5. Patient Information

Written information to be given to the patient or carer	The patient should be given the following written information if appropriate ▪ The product specific patient information sheet supplied with the medicine ▪ Any other suitable information with regard to their treatment
Advice to be given to the patient or carer	The patient/carer should be given the following information verbally if appropriate and requested ▪ Information on *Chlamydia trachomatis* ▪ Discuss possible side effects of treatment as listed in patient information leaflet ▪ Azithromycin **capsules** should be taken one hour before or two hours after food and for all formulations there should be a similar gap between taking an antacid. ▪ Reinforce importance of sexual partners seeking treatment. ▪ Repeat testing should be performed 3 months after treatment in under 25-years olds diagnosed with chlamydia and when there is a change in sexual partner. ▪ Patients and their partner(s) must abstain completely from sexual intercourse (even with condom), including oral and anal sex, for 7 days post- azithromycin treatment or completion of other treatment ▪ Provide information on practising safer sex ▪ Remind pregnant patients that a test of cure is required after 3 weeks. ▪ Reinforce the possible need for screening for other sexually transmitted infection (STI) ▪ Where clients who are pregnant or at risk of pregnancy or breastfeeding and they wish to continue to receive treatment under this PGD: ➢ The individual must have been informed that although the use of azithromycin in pregnancy and breastfeeding is thought to be safe, there is limited research available and she must be informed ✓ of the risks and benefits of this treatment as detailed in BASHH guidelines ✓ that SIGN and the World Health Organisation recommend its use in pregnancy ✓ that Public Health England recommend its use in pregnancy and breast feeding ✓ that SPCs generally state 'In pregnancy azithromycin should only be used during pregnancy if the benefit outweighs the risk' ✓ of the availability of alternative treatment (erythromycin for 1 or 2 weeks; refer to an appropriate doctor / independent nurse prescriber) ✓ of the option of seeing an appropriate NHS doctor / independent non-medical prescriber / sexual health clinic
Labelling	Medication supplied to the patient must be labelled in accordance with current legislation

6. References used to develop this PGD

References

1. British Association for Sexual Health and HIV (BASHH) Clinical Effectiveness Guidelines (all available at https://www bashh.org/guidelines)
   - 2015 UK national guideline for the management of *Chlamydia trachomatis.* (Updated September 2018) Accessed 7th November 2018.
   - UK national guideline for the management of gonorrhoea in adults, 2011. Accessed 7th November 2018.
   - 2015 UK National Guideline on the management of non-gonococcal urethritis. (Updated May 2017) Accessed 7th November 2018.
   - 2018 United Kingdom Guideline for the Management of PID. Accessed 7th November 2018.
2. Manufacturers' Summaries of Product Characteristics (SPC)
   - Azithromycin film coated Tablets 250mg, Sandoz Ltd. Date of last revision of the text 05/04/2018 https //www medicines.org uk/emc/medicine/26131. Accessed 7th November 2018.
   - Zithromax 250mg capsules, Pfizer Limited. Date of last revision of the text 16/08/2018 https.//www medicines.org.uk/emc/product/1073. Accessed 7th November 2018
3. British National Formulary Online
   - BNF Online https://www medicinescomplete com Accessed 7th November 2018
4. Centre for Pharmacy Postgraduate Education
   - Declaration of competence for community pharmacy services, Chlamydia Testing and Treatment Service. Version 8 (Feb 2014) https //www cppe.ac.uk/services/commissioners. Accessed 7th November 2018
5. General Pharmaceutical Council
   - Standards for pharmacy professionals, May 2017. https //www pharmacyregulation org/standards Accessed 7th November 2018.
   - Guidance on maintaining clear sexual boundaries, May 2017 https //www pharmacyregulation org/standards/guidance Accessed on 7th November 2018
6. NHS Digital
   Records Management Code of Practice for Health and Social Care 2016. https://digital nhs uk/article/1202/Records-Management-Code-of-Practice-for-Health-and-Social-Care-2016. Accessed 7th November 2018

7. National Institute for Health and Care Excellence (NICE) Patient group directions Medicines practice guideline [MPG2]. Published August 2013, Updated March 2017 https //www nice.org uk/guidance/mpg2 Accessed on 7th November 2018

8. Public Health England Re-testing of those who tested positive for chlamydia. Published October 2015 https //assets publishing service.gov.uk/government/uploads/system/uploads/attachment_data/file/736122/NCSPre-testingauditfinalversion pdf Accessed on 7th November 2018

9. World Health Organisation (WHO) Guidelines for the Treatment of Chlamydia trachomatis. Published May 2016 http //apps who int/iris/bitstream/handle/10665/246165/9789241549714 eng pdf;jsessionid=AFADB6C141BCB1A607ABD11054E0E636?sequence=1 Accessed on 20th November 2018

10. National Institute for Health and Care Excellence (NICE) CKS. Chlamydia - uncomplicated genital. Revised January 2019. https://cks nice.org uk/chlamydia-uncomplicated-genital Accessed on 5th February 2019

11. GMMMG. Greater Manchester Antimicrobial Guidelines Published December 2018. http://gmmmg nhs.uk/docs/guidance/GM-Antimicrobial-guidelines-Dec-2018-v3-0.pdf Accessed on 5th January 2019.

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The Patient Group Direction is to be read, agreed to and signed by the healthcare professional and their employer The healthcare professional retains a copy of the PGD The employer retains a record of all PGDs held by healthcare professionals employed or contracted by them

Individual Authorisation

By signing this PGD you are agreeing that:

- You have read and understood the content,
- To the best of your knowledge, the content of the PGD is correct and supports best practice,
- You will act within the parameters of the PGD;
- You take responsibility for maintaining your competence and on-going training requirements to continue to use the PGD safely

Named Healthcare Professional _____

Designation· _____

The above named healthcare professional is authorised to work within the confines of this Patient Group Direction

Name of Employer _____
/ Contractor

Address of Employer _____
/ Contractor

_____

_____

_____

Signature of Employer _____
/ Contractor

I, the undersigned, have read and understood this PGD and agree to work within its confines

Signature of Named

Healthcare Professional _____

Date. _____

One copy to be retained by the named healthcare professional

One copy to be retained by the employer / contractor

The healthcare professional's details must be recorded on a register of PGDs held by their employer/contractor.