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Oldham Council

PATIENT GROUP DIRECTION FOR THE SUPPLY OF

AZITHROMYCIN 250MG TABLETS OR CAPSULES

By registered Pharmacists for the Treatment of *Chlamydia trachomatis* in Community Pharmacy

Version 4.0

Valid from: 7th January 2019

Expires on: 6th January 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.

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DOCUMENT CONTROL – PGD Ready for authorisation

Document Location

Copies of this PGD can be obtained from:

Name:	Oldham Council
Address:	Civic Centre, West Street, Oldham, OL1 1UT
Telephone:	0161 770 3000

Revision History

The latest and master version of the unsigned PGD is held by Greater Manchester Shared Services.

Revision date & actioned by	Summary of changes	Version
02/05/2018 S Woods	Finalise for signatures	3.0
18/10/2018 S Woods	Review prompted by update in BASHH guidance September 2018. **2. Clinical condition or situation to which the direction applies.** Under 'Indication (Clinical condition or situation to which this PGD applies) changed from: Patients either known or suspected of having uncomplicated genital Chlamydia trachomatis infection identified by the local screening service and in line with the current service specification. To: Patients either known or suspected of having uncomplicated genital *Chlamydia trachomatis* infection identified by the local screening service and in line with the current service specification. There are two Patient Group Directions (PGD) in the Oldham 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. Under 'Criteria for inclusion' removed the bullet point: ▪ Re-treatment of an individual who has received azithromycin for the above indications but has vomited the dose within 3 hours of taking it. Under' Cautions (including any relevant action to be taken)' removed: If under 13 years of age the local safeguarding team must be contacted and the patient referred to a doctor / independent prescriber. *Information on under 13s should usually be shared, but if a decision is*	3.1

	made not to disclose there should be discussion with a named or designated doctor for child protection, with a record of the decision stating the reasons. Under 'Action if excluded' amended the second bullet point from: ▪ If excluded because the patient is under 13 years of age, then the safeguarding team must be contacted. To: ▪ 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 discussion with a named or designated nurse or doctor for child protection, with a record of the decision stating the reasons. **3. Details of medicine** Under 'Name, strength & formulation of drug' added 500mg tablets as an option. Under 'Dose and frequency' changed from: 1g (4 x 250mg) as a single dose, normally to be taken as directly observed therapy. To: 1g as a single dose, then 500mg daily for two days. Under 'Quantity to be administered and/or supplied' changed from: 4 x 250mg capsules or tablets Treatment is provided for patient consumption at the time of consultation; where consumption is required off-site the tablets or capsules should be provided in a suitably labelled box. To: 8 x 250mg capsules or tablets or 4 x 500mg tablets Under 'Maximum or minimum treatment periods changed from: ▪ Normally one dose of 4 x 250mg capsules or tablets. ▪ An additional dose can be given if a patient vomits within 3 hours of the initial dose. To: Three days Also updated table of Very common and common adverse effects in line with BNF. **5. Patient Information** Under 'Advice to be given to the patient or carer' removed the bullet point: ▪ If vomiting occurs within 3 hours of taking capsules/tablets offer option of repeat dose of Azithromycin (under PGD) or referral to appropriate doctor/ independent nurse prescriber for alternative	

	treatment Under 'Labelling' changed from: If it is necessary to give medication to a patient to take away with them then it must be labelled in accordance with current legislation. To: Medication supplied to the patient must be labelled in accordance with current legislation. **6. References used to develop this PGD** All checked and updated as necessary.	
21/11/2018 S Woods	Based on feedback from Dr C. Stevenson **3. Details of medicine** Under 'Dose and frequency' added: If a patient vomits within 3 hours of taking the initial dose then a further 1g dose can be given. And under 'Quantity to be administered and/or supplied' added: Should the patient vomit within 3 hours of the first dose then an additional: 4 x 250mg capsules or tablets or 2 x 500mg tablets can be supplied. However, if the patient vomits again or on subsequent doses then they should be referred to an appropriate doctor/independent nurse prescriber or sexual health clinic; this should be done in conjunction with the local screening service. **5. Patient Information** Under 'Advice to be given to the patient or carer' added the bullet point: ▪ If the patient vomits within 3 hours of the initial dose then they should return to the pharmacy and may be provided with an additional 1g dose, but if they vomit on that additional dose or subsequent 500mg doses they will be referred to an appropriate doctor/independent nurse prescriber or sexual health clinic; this will be done in conjunction with the local screening service.	3.2
11/12/2018	Finalised and formatted for sign off.	4.0

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Approvals
This PGD must be approved by the following before distribution:

NAME	TITLE	DATE OF ISSUE	VERSION
Dr Charlotte Stevenson	Public Health Consultant, Oldham Council	07/01/2019	4.0
Andrew Martin	Strategic Medicines Optimisation Pharmacist, GMSS	07/01/2019	4.0
Katrina Stephens	Acting Director of Public Health, Oldham Council	07/01/2019	4.0
Dipesh Raghwani	Clinical Lead, GM LPC	07/01/2019	4.0

Distribution

This PGD has been distributed, during its development, to:

NAME	TITLE	DATE OF ISSUE	VERSION
Dr Charlotte Stevenson	Public Health Consultant, Oldham Council	01/11/2018 21/11/2018 11/12/2018	3.1 3.2 4.0
Dipesh Raghwani	Clinical Lead, GM LPC	01/11/2018 21/11/2018 11/12/2018	3.1 3.2 4.0
Lianne Davies	Public Health & Wellbeing Manager, Oldham Council	01/11/2018 21/11/2018 11/12/2018	3.1 3.2 4.0
Andrew Martin	Strategic Medicines Optimisation Pharmacist, GMSS	21/11/2018 11/12/2018	3.2 4.0

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PGD Development

Originally developed / Reviewed by:	Stephen Woods (Author)	Senior Medicines Optimisation Pharmacist, Greater Manchester Shared Service
	Dr Charlotte Stevenson	Public Health Consultant, Oldham Council
	Dipesh Raghwani	Clinical Lead, GM LPC

Date applicable:	7th January 2019
Review date:	1st September 2020
Expiry date:	6th January 2021

PGD Authorisation

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

Designation	Name	Signature	Date
Senior Pharmacist (Strategic Medicines Optimisation Pharmacist, GM Shared Services)	Andrew Martin	A. Martin	12/12/18
Doctor (Public Health Consultant, Oldham Council)	Dr Charlotte Stevenson		7/1/19
Community Pharmacy Representative (Clinical Lead, GM LPC)	Dipesh Raghwani		14/12/18
Author (Senior Medicines Optimisation Pharmacist, GM Shared Services)	Stephen Woods		12/12/18
Authorising Signatory (Acting Director of Public Health, Oldham Council)	Katrina Stephens	KJStephens	2/1/19

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1. Characteristics of Staff

Qualifications required	▪ Pharmacist with current General Pharmaceutical Council registration ▪ Work in a Community Pharmacy within the Oldham Council area
Additional requirements	▪ Has undertaken training in the use of PGDs ▪ Has undertaken 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 Centre for Postgraduate Pharmacy Education (CPPE) and NHS Health Education England *Declaration of Competence for pharmacy services – Chlamydia screening and treatment document* (https://www.cppe.ac.uk/services/declaration-of-competence). ▪ 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 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 England *Declaration of Competence for 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 the local screening service and in line with the current service specification. There are two Patient Group Directions (PGD) in the Oldham 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. The local screening service will notify pharmacies of infected individuals and identified sexual contacts asking to attend that pharmacy. ▪ 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 NHS doctor / independent non-medical prescriber.*
Criteria for exclusion[1] **Continued on next page.**	▪ 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 ▪ Known allergy or hypersensitivity to macrolide antibiotics or any constituent of the medication.

[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.

Criteria for exclusion **Continued from previous page.**	▪ Any medicine known to interact with azithromycin including drugs known to prolong QT interval see the current British National Formulary (BNF) (http://www.medicinescomplete.com/mc/) or the Summary of Product Characteristics (SPC) (http://www.medicines.org.uk/emc/) ▪ Non-genital *Chlamydia trachomatis* infection ▪ Complicated *Chlamydia* infection in males e.g. with epididymitis or testicular pain ▪ Complicated *Chlamydia* infection in females e.g. pelvic pain or suspected pelvic inflammatory disease. ▪ Porphyria ▪ 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
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.
Action if excluded	▪ Refer to appropriate doctor/independent nurse prescriber or sexual health clinic; this should be done in conjunction with the local screening service. ▪ 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 discussion with a named or designated nurse or doctor for child protection, with a record of the decision stating the reasons.[2] ▪ Document all actions taken.
Action if patient or carer declines treatment	▪ Make individual aware of the need for treatment and refer to appropriate doctor/independent nurse prescriber or sexual health clinic; this should be done in conjunction with the local screening service. ▪ 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)

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3. Details of medicine

Name, strength & formulation of drug	Azithromycin 250mg capsules or tablets and 500mg tablets
Presentation	Oral capsules or tablets
Storage	Store below 25ºC
Legal category	POM
Black Triangle▼	No
Unlicensed / off label use	None
Route / method	Oral
Dose and frequency	1g as a single dose, then 500mg daily for two days. If a patient vomits within 3 hours of taking the initial dose then a further 1g dose can be given.
Quantity to be administered and/or supplied	8 x 250mg capsules or tablets or 4 x 500mg tablets Should the patient vomit within 3 hours of the first dose then an additional: 4 x 250mg capsules or tablets or 2 x 500mg tablets can be supplied. However, if the patient vomits again or on subsequent doses then they should be referred to an appropriate doctor/independent nurse prescriber or sexual health clinic; this should be done in conjunction with the local screening service.
Maximum or minimum treatment periods	Three days
Drug interactions	▪ 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 PGD cannot be complied with the patient must be referred to a suitable independent prescriber.

Identification & management of adverse reactions[3]

Very common and common adverse effects	
Appetite decreased, headache, pancreatitis	Arthralgia, hearing impairment, sensation abnormal
Diarrhoea, nausea, vomiting	Gastrointestinal discomfort, Gastrointestinal disorders
Dizziness, vision disorders, eye discomfort	Skin reactions , sleep disorders, 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 http://yellowcard.mhra.gov.uk)

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, from 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 (age 26 if entry made when young person was 17), 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/carer 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 ▪ If the patient vomits within 3 hours of the initial dose then they should return to the pharmacy and may be provided with an additional 1g dose, but if they vomit on that additional dose or subsequent 500mg doses they will be referred to an appropriate doctor/independent nurse prescriber or sexual health clinic; this will be done in conjunction with the local screening service. ▪ 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

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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 17th October 2018.
   - UK national guideline for the management of gonorrhoea in adults, 2011. Accessed 18th October 2018.
   - 2015 UK National Guideline on the management of non-gonococcal urethritis. (Updated May 2017). Accessed 18th October 2018.
   - 2018 United Kingdom Guideline for the Management of PID. Accessed 18th October 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 18th October 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 18th October 2018.
   - Azithromycin 500mg Film-coated tablets, Generics UK T/A Mylan. Date of last revision 17/07/2018 https://www.medicines.org.uk/emc/product/8426/smpc. Accessed 18th October 2018.
3. British National Formulary Online
   - BNF Online. https://www.medicinescomplete.com. Accessed 18th October 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 18th October 2018.
5. General Pharmaceutical Council.
   - Standards for pharmacy professionals, May 2017. https://www.pharmacyregulation.org/standards Accessed 18th October 2018.
   - Guidance on maintaining clear sexual boundaries, May 2017. https://www.pharmacyregulation.org/standards/guidance. 18th October 2018.

References continued

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 18th October 2018.

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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 ongoing 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.