

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: 26/01/2019

Expires on: 25/01/2021

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:	Trafford Council
Address:	Public Health, Trafford Town Hall, Talbot Road, Stretford, M32 0TH
Telephone:	0161 912 3431

Revision History

The latest and master version of the unsigned PGD is held by Trafford CCG medicines optimisation.

Revision date & actioned by	Summary of changes	Version
07/01/2019 S.Ahmed	<p>Updated to reflect new guidance from BASHH clinical effectiveness group, treatment of <i>Chlamydia trachomatis</i> (CT) infection, September 2018.</p> <p>Under ‘2. Clinical condition or situation to which the direction applies’ changed:</p> <p>Trafford Council have three Patient Group Directions (PGD) for the treatment of <i>Chlamydia trachomatis</i> infection, in their area.</p> <ul style="list-style-type: none"> ▪ This PGD for azithromycin must be considered for first line use, especially where there are concerns about compliance, unless exclusions apply or there are concomitant medication considerations. ▪ The PGD for doxycycline must be considered for second line use, unless exclusions apply or there are concomitant medication considerations. <p>To:</p> <p>Trafford Council have three Patient Group Directions (PGD) for the treatment of <i>Chlamydia trachomatis</i> infection, in their area.</p> <ul style="list-style-type: none"> ▪ The PGD for doxycycline must be considered for first line use, unless exclusions apply or there are concomitant medication considerations. ▪ This PGD for azithromycin must be considered for second line use, unless exclusions apply or there are concomitant medication considerations. 	4.0

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Approvals

This PGD must be approved by the following before distribution:

NAME	TITLE	DATE OF ISSUE	VERSION
Leigh Lord	Head of Medicines Optimisation, Trafford CCG	07/01/2019	4.0
Dr Mark Jarvis	Clinical Director, Trafford CCG	07/01/2019	4.0
Eleanor Roaf	Interim Director of Public Health, Trafford Council	07/01/2019	4.0
Dipesh Raghvani	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 Mark Jarvis	Clinical Director, Trafford CCG	09/01/2018	2.3
		02/02/2018	2.3
		07/03/2018	3.0
		07/01/2019	4.0
Dipesh Raghvani	Clinical Lead, GM LPC	09/01/2018	2.3
		02/02/2018	2.3
		07/03/2018	3.0
		07/01/2019	4.0
Andrew Martin	Strategic Medicines Optimisation Pharmacist, GMSS	14/02/2018	2.3
		07/03/2018	3.0
Leigh Lord	Head of Medicines Optimisation, Trafford CCG	07/01/2019	4.0

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PGD Development

Originally developed / Reviewed by:	Saquib Ahmed (Author)	Senior Medicines Optimisation Pharmacist, Trafford CCG
	Dr Mark Jarvis	Clinical Director, Trafford CCG
	Dipesh Raghwani	Clinical Lead, GM LPC

Date applicable:	26 th January 2019
Review date:	31 st July 2020
Expiry date:	25 th January 2021

PGD Authorisation

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

<i>Designation</i>	Name	Signature	Date
Senior Pharmacist (Head of medicines optimisation, Trafford CCG)	Leigh Lord		18.1.2019
Doctor (Clinical Director, Trafford CCG)	Dr. Mark Jarvis		18.1.2019
Pharmacist Representative (Clinical Lead, Greater Manchester LPC)	Dipesh Raghwani		23.11.2019
Author (Senior Medicines Optimisation Pharmacist, Trafford CCG)	Saquib Ahmed		07/01/2019
Authorising Signatory (Interim Director of Public Health, Trafford Council)	Eleanor Roaf		22.1.19

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1. Characteristics of Staff

Qualifications required	<ul style="list-style-type: none"> ▪ Pharmacist with current General Pharmaceutical Council registration ▪ Work in a Community Pharmacy within the Trafford Council area
Additional requirements	<ul style="list-style-type: none"> ▪ 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 <i>Declaration of Competence for pharmacy services – Chlamydia screening and treatment document</i> (https://www.cppe.ac.uk/services/declaration-of-competence#navTop). ▪ 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	<ul style="list-style-type: none"> ▪ 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 including emergency contraception ▪ Must assess and maintain their own competence on the medicine supplied under this PGD in line with the requirements contained within the <i>Declaration of Competence for pharmacy services – Chlamydia screening and treatment document</i> ▪ 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 <i>Declaration of Competence for pharmacy services – Chlamydia screening and treatment document</i> .

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.

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

<p>Indication (Clinical condition or situation to which this PGD applies)</p>	<p>Patients either known or suspected of having uncomplicated genital <i>Chlamydia trachomatis</i> infection identified by the local screening service and in line with the current service specification.</p> <p>Trafford Council have three Patient Group Directions (PGD) for the treatment of <i>Chlamydia trachomatis</i> infection, in their area.</p> <ul style="list-style-type: none"> ▪ The PGD for doxycycline must be considered for first line use, unless exclusions apply or there are concomitant medication considerations. ▪ This PGD for azithromycin must be considered for second line use, unless exclusions apply or there are concomitant medication considerations. ▪ The PGD for erythromycin should be considered for third line use or can be used where there is a risk of pregnancy, established pregnancy, or breastfeeding, unless exclusions apply or there are concomitant medication considerations.
<p>Criteria for inclusion</p>	<ul style="list-style-type: none"> ▪ Male or female patients either with a laboratory-confirmed positive genital <i>Chlamydia trachomatis</i> infection or who is a sexual contact of any patient who has a laboratory-confirmed positive genital <i>Chlamydia trachomatis</i> infection. The local screening service 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 section 5. Patient Information - Advice to be given to the patient or carer). ▪ Understand the risks, benefits and side effects ▪ Are competent to consent to treatment ▪ Meet Fraser guidelines, if under 16 years of age. <i>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.</i> ▪ Re-treatment of an individual who has received azithromycin for the above indications but has vomited the dose within 3 hours of taking it.
<p>Criteria for exclusion¹ Continued on next page.</p>	<ul style="list-style-type: none"> ▪ 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.

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Criteria for exclusion Continued from previous page.	<ul style="list-style-type: none"> ▪ 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 <i>Chlamydia trachomatis</i> infection ▪ Complicated <i>Chlamydia</i> infection in males e.g. with epididymitis or testicular pain ▪ Complicated <i>Chlamydia</i> 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)	<p>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.</p> <p>If under 13 years of age the local safeguarding team must be contacted and the patient referred to a doctor / independent prescriber.</p> <p><i>Information on under 13s should usually be shared, but if a decision is 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.²</i></p>
Action if excluded	<ul style="list-style-type: none"> ▪ 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, then the safeguarding team must be contacted. ▪ Document all actions taken.
Action if patient or carer declines treatment	<ul style="list-style-type: none"> ▪ 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
Presentation	Oral capsules or tablets
Storage	Store below 25°C
Legal category	POM
Black Triangle ▼	No
Unlicensed / off label use	None
Route / method	Oral
Dose and frequency	1g (4 x 250mg) as a single dose on day 1, followed by 500mg (2 x 250mg) as a single dose on day 2 and 500mg (2 x 250mg) as a single dose on day 3.
Quantity to be administered and/or supplied	Supply 8 x 250mg capsules or tablets in a suitably labelled box.
Maximum or minimum treatment periods	Supply full course of 8 capsules or tablets.
Drug interactions	<ul style="list-style-type: none"> ▪ 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.

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Identification & management of adverse reactions³

Very common and common adverse effects	
Very common (≥ 10%)	Common (≥ 1/100 to <1/10)
Diarrhoea	Dizziness, Headache
Abdominal pain	Vomiting, dyspepsia
Nausea, Flatulence	Rash, Pruritis

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>)

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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 and the Data Protection Act.

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5. Patient Information

<p>Written information to be given to the patient or carer</p>	<p>The patient/carer should be given the following written information if appropriate:</p> <ul style="list-style-type: none"> ▪ The product specific patient information sheet supplied with the medicine. ▪ Any other suitable information with regard to their treatment.
<p>Advice to be given to the patient or carer</p>	<p>The patient/carer should be given the following information verbally if appropriate and requested:</p> <ul style="list-style-type: none"> ▪ Information on <i>Chlamydia trachomatis</i> ▪ 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. ▪ 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 ▪ 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 in 3 weeks' time. ▪ 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: <ul style="list-style-type: none"> ➢ 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: <ul style="list-style-type: none"> ✓ 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). ✓ of the option of seeing an appropriate NHS doctor / independent non-medical prescriber / sexual health clinic
<p>Labelling</p>	<p>Medication supplied to the patient must be labelled in accordance with current legislation.</p>

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6. References used to develop this PGD

1. British Association for Sexual Health and HIV (BASHH) Clinical Effectiveness Guidelines:
 - Update on the treatment of *Chlamydia trachomatis* (CT) infection, September 2018.
<https://www.bashhguidelines.org/media/1191/update-on-the-treatment-of-chlamydia-trachomatis-infection-final-16-9-18.pdf>. Accessed 23rd November 2018.
 - 2015 UK national guideline for the management of *Chlamydia trachomatis*.
<https://www.bashhguidelines.org/media/1045/chlamydia-2015.pdf>. Accessed 5th October 2017.
 - UK national guideline for the management of gonorrhoea in adults, 2011. <https://www.bashhguidelines.org/media/1044/gc-2011.pdf>. Accessed 5th October 2017.
 - 2015 UK National Guideline on the management of non-gonococcal urethritis. <https://www.bashhguidelines.org/media/1051/ngu-2015.pdf>. Accessed 5th October 2017.
 - Management of PID 2011 – updated June 201.
<https://www.bashhguidelines.org/media/1143/pid-2012.pdf>. Accessed 5th October 2017.
2. Scottish Intercollegiate Guidelines Network (SIGN)
 - SIGN 109 (2009): Management of genital *Chlamydia trachomatis* infection. <http://www.sign.ac.uk/assets/sign109.pdf>. Accessed 5th October 2017.
3. Public Health England (PHE)
 - PHE (September 2017): Management of infection guidance for primary care for consultation and local adaptation
<https://www.gov.uk/government/publications/managing-common-infections-guidance-for-primary-care>. Accessed 5th October 2017.
 - PHE (2011): Diagnosis of *Chlamydia trachomatis*; Quick Reference Guide for General Practices (Updated September 2014)
<https://www.gov.uk/government/publications/chlamydia-trachomatis-diagnosis-guide-for-general-practices>. Accessed 5th October 2017.
4. World Health Organisation
 - WHO Guidelines for the treatment of *Chlamydia trachomatis* (2016)
<http://www.who.int/reproductivehealth/publications/rtis/chlamydia-treatment-guidelines/en/>. Accessed 5th October 2017.
5. Manufacturers' Summaries of Product Characteristics (SPC)
 - Azithromycin film coated Tablets 250mg, Sandoz Ltd. Date of last revision of the text 10/06/2015
<https://www.medicines.org.uk/emc/medicine/26131>. Accessed 5th October 2017.

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- Zithromax 250mg capsules, Pfizer Limited. Date of last revision of the text 15/07/2016
<https://www.medicines.org.uk/emc/medicine/1477>. Accessed 5th October 2017.

6. 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 5th October 2017.

7. General Pharmaceutical Council.

- Standards for pharmacy professionals, May 2017.
<https://www.pharmacyregulation.org/standards> Accessed 5th October 2017.
- Standards for Continuing professional development, September 2010. <https://www.pharmacyregulation.org/standards/continuing-professional-development>. Accessed 5th October 2017.
- Guidance on maintaining clear sexual boundaries, February 2012.
<https://www.pharmacyregulation.org/standards/guidance>. 5th October 2017.

8. 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 3rd November 2017.

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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.