

# PATIENT GROUP DIRECTION FOR THE SUPPLY OF ERYTHROMYCIN 250MG TABLETS

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.

<b>ERYTHROMYCIN 250MG TABLETS</b>	<b>P.O.M.</b> [Prescription Only Medicine]
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DOCUMENT CONTROL – PGD Ready for authorisation

**Document Location**

Copies of this PGD can be obtained from:

<b>Name:</b>	Trafford Council
<b>Address:</b>	Public Health, Trafford Town Hall, Talbot Road, Stretford, M32 0TH
<b>Telephone:</b>	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
23/11/2018 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><b>Under ‘2. Clinical condition or situation to which the direction applies’ changed:</b></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"> <li>▪ The 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.</li> <li>▪ The PGD for doxycycline must be considered for second line use, unless exclusions apply or there are concomitant medication considerations.</li> </ul> <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"> <li>▪ The PGD for doxycycline must be considered for first line use, unless exclusions apply or there are concomitant medication considerations.</li> <li>▪ The PGD for azithromycin must be considered for second line use, unless exclusions apply or there are concomitant medication considerations.</li> </ul>	4.0

<b>ERYTHROMYCIN 250MG TABLETS</b>	<b>P.O.M.</b> [Prescription Only Medicine]
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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
		07/01/2019	3.0
Leigh Lord	Head of Medicines Optimisation, Trafford CCG	07/01/2019	4.0

<b>ERYTHROMYCIN 250MG TABLETS</b>	<b>P.O.M.</b> [Prescription Only Medicine]
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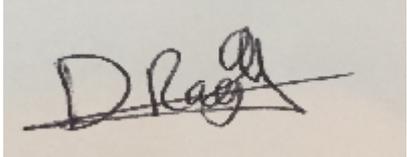
**PGD Development**

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

<b>Date applicable:</b>	26 <sup>th</sup> January 2019
<b>Review date:</b>	31 <sup>st</sup> July 2020
<b>Expiry date:</b>	25 <sup>th</sup> January 2021

**PGD Authorisation**

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

Designation	Name	Signature	Date
<b>Senior Pharmacist</b> (Head of medicines optimisation, Trafford CCG)	Leigh Lord		18.1.2019
<b>Doctor</b> (Clinical Director, Trafford CCG)	Dr Mark Jarvis		18.1.2019
<b>Pharmacist Representative</b> (Clinical Lead, Greater Manchester LPC)	Dipesh M Raghwani		23.1.2019
<b>Author</b> (Senior Medicines Optimisation Pharmacist, Trafford CCG)	Saquib Ahmed		07/01/2019
<b>Trafford Council</b> (Interim Director of Public Health, Trafford Council)	Eleanor Roaf		22.1.19

<b>ERYTHROMYCIN 250MG TABLETS</b>	<b>P.O.M.</b> [Prescription Only Medicine]
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**1. Characteristics of Staff**

<b>Qualifications required</b>	<ul style="list-style-type: none"> <li>▪ Pharmacist with current General Pharmaceutical Council registration</li> <li>▪ Work in a Community Pharmacy within Trafford Council area</li> </ul>
<b>Additional requirements</b>	<ul style="list-style-type: none"> <li>▪ Has undertaken training in the use of PGDs</li> <li>▪ Has undertaken training which enables the pharmacist to make a clinical assessment in order to establish the need and supply erythromycin according to this PGD as detailed in the service specification.</li> <li>▪ 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> (<a href="https://www.cppe.ac.uk/services/declaration-of-competence#navTop">https://www.cppe.ac.uk/services/declaration-of-competence#navTop</a>).</li> <li>▪ 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.</li> </ul>
<b>Continued training requirements</b>	<ul style="list-style-type: none"> <li>▪ The pharmacist should be aware of any change to the recommendations for the medicine listed.</li> <li>▪ Must be able to show regular update in the field of contraceptive and reproductive health care including emergency contraception</li> <li>▪ 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></li> <li>▪ It is the responsibility of the pharmacist to keep up-to-date with continuing professional development</li> <li>▪ 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.</li> </ul>
<b>Suggested supporting learning</b>	It is essential that pharmacists complete and satisfy the competencies detailed in the CPPE and NHS Health Education North West <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 the training received.**

<b>ERYTHROMYCIN 250MG TABLETS</b>	<b>P.O.M.</b> [Prescription Only Medicine]
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**2. Clinical condition or situation to which the direction applies.**

<b>Indication (Clinical condition or situation to which this PGD applies)</b>	<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"> <li>▪ The PGD for doxycycline must be considered for first line use, unless exclusions apply or there are concomitant medication considerations.</li> <li>▪ The PGD for azithromycin must be considered for second line use, unless exclusions apply or there are concomitant medication considerations.</li> <li>▪ This PGD for erythromycin should be considered for third line use or where there is a risk of pregnancy, established pregnancy, or breastfeeding, unless exclusions apply or there are concomitant medication considerations.</li> </ul>
<b>Criteria for inclusion</b>	<ul style="list-style-type: none"> <li>▪ 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.</li> <li>▪ Have no known contraindications or allergies to erythromycin, its excipients or other macrolides</li> <li>▪ Understand the risks, benefits and side effects</li> <li>▪ Are competent to consent to treatment</li> <li>▪ 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 doctor / independent nurse prescriber.</i></li> </ul>
<b>Criteria for exclusion<sup>1</sup> (continued)</b>	<ul style="list-style-type: none"> <li>▪ Individuals under 13 years of age.</li> <li>▪ Individuals aged under 16 years assessed as not competent using Fraser Guidelines</li> <li>▪ Known allergy or hypersensitivity to erythromycin or other macrolide antibiotics or any constituent of the medication.</li> <li>▪ Any medicine known to interact with erythromycin, see the current British National Formulary (BNF) (<a href="http://www.medicinescomplete.com/mc/">http://www.medicinescomplete.com/mc/</a>) or the Summary of Product Characteristics (SPC) (<a href="http://www.medicines.org.uk/emc/">http://www.medicines.org.uk/emc/</a>)</li> <li>▪ Complicated chlamydia infection in males e.g. with epididymitis or testicular pain</li> <li>▪ Complicated chlamydia infection in females e.g. pelvic pain or suspected pelvic inflammatory disease.</li> </ul>

<sup>1</sup> Exclusion under this 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.

<b>ERYTHROMYCIN 250MG TABLETS</b>	<b>P.O.M.</b> [Prescription Only Medicine]
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<b>Criteria for exclusion continued</b>	<ul style="list-style-type: none"> <li>▪ Hepatic impairment</li> <li>▪ Renal impairment</li> <li>▪ Acute porphyria</li> <li>▪ Patients with myasthenia gravis – erythromycin can cause exacerbation of symptoms</li> <li>▪ Patients with a predisposition to QT interval prolongation</li> </ul>
<b>Cautions (including any relevant action to be taken)</b>	<p>Erythromycin has been reported to cross the placental barrier in humans, but foetal plasma levels are generally low. However, there is no evidence of hazard from erythromycin in human pregnancy. It has been in widespread use for a number of years without apparent ill consequence. Animal studies have shown no hazard.</p> <p>Erythromycin is excreted in breast milk, therefore, caution should be exercised when erythromycin is administered to a nursing mother.</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.<sup>2</sup></i></p>
<b>Action if excluded</b>	<ul style="list-style-type: none"> <li>▪ Refer to appropriate doctor/independent nurse prescriber or sexual health clinic; this should be done in conjunction with the local screening service.</li> <li>▪ If excluded because the patient is under 13 years of age, then the safeguarding team must be contacted.</li> <li>▪ Document all actions taken.</li> </ul>
<b>Action if patient or carer declines treatment</b>	<ul style="list-style-type: none"> <li>▪ 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.</li> <li>▪ Document all actions taken.</li> </ul>

<sup>2</sup> 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)

<b>ERYTHROMYCIN 250MG TABLETS</b>	<b>P.O.M.</b> [Prescription Only Medicine]
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**3. Details of medicine**

<b>Name, strength &amp; formulation of drug</b>	Erythromycin 250mg tablets
<b>Presentation</b>	Treatment should be supplied in a suitably labelled box.
<b>Storage</b>	Store below 25°C
<b>Legal category</b>	POM
<b>Black Triangle ▼</b>	No
<b>Unlicensed / off label use</b>	None
<b>Route / method</b>	Oral
<b>Dose and frequency</b>	500mg (2 X 250mg tablets) twice a day for 14 days
<b>Quantity to be administered and/or supplied</b>	Supply 56 tablets
<b>Maximum or minimum treatment periods</b>	14 days treatment to be provided
<b>Disposal</b>	Any unused medicinal product or waste material should be disposed of safely.
<b>Drug interactions</b>	<ul style="list-style-type: none"> <li>▪ 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 (<a href="https://www.medicinescomplete.com/mc/">https://www.medicinescomplete.com/mc/</a>) or the SPC (<a href="http://www.medicines.org.uk/emc/">http://www.medicines.org.uk/emc/</a>) or contact the Medicine Information Service at Liverpool – telephone number inside front cover of BNF)</li> <li>▪ 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.</li> <li>▪ If the requirements of this PGD cannot be complied with the patient must be referred to a suitable independent prescriber.)</li> </ul>

<b>ERYTHROMYCIN 250MG TABLETS</b>	<b>P.O.M.</b> [Prescription Only Medicine]
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**Identification & management of adverse reactions**

<b>Commonly occurring adverse effects</b>	
Nausea	Upper abdominal discomfort
Vomiting	Diarrhoea
Pancreatitis	Anorexia
Pruritis / Urticaria	Abnormal liver function tests

As with 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](http://www.medicines.org.uk)) or the most current edition of the BNF ([www.bnf.org](http://www.bnf.org))

In the event of any adverse reaction:

- Record the adverse reaction in the patient consultation note
- Inform the patient's GP if the patient 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> )

<b>ERYTHROMYCIN 250MG TABLETS</b>	<b>P.O.M.</b> [Prescription Only Medicine]
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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 Sexual Health paper records:

- 8 years (in adults) or until 25<sup>th</sup> 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.

Ensure patient attendance fed back to relevant screening/treatment coordinating organisation in order to complete the audit trail.

**ERYTHROMYCIN 250MG TABLETS**

**P.O.M.**  
[Prescription Only Medicine]

**5. Patient Information**

<p><b>Written information to be given to the patient or carer</b></p>	<p>The patient/carer should be given the following written information if appropriate:</p> <ul style="list-style-type: none"> <li>▪ The product specific patient information sheet supplied with the medicine.</li> <li>▪ Any other suitable information with regard to their treatment.</li> </ul>
<p><b>Advice to be given to the patient or carer</b></p>	<p>The patient/carer should be given the following information verbally if appropriate and requested:</p> <ul style="list-style-type: none"> <li>▪ Information on <i>Chlamydia trachomatis</i></li> <li>▪ Discuss possible side effects of treatment as listed in patient information leaflet</li> <li>▪ Reinforce importance of sexual partners seeking treatment.</li> <li>▪ Remind patients of the need to be tested for <i>Chlamydia trachomatis</i> on an annual basis.</li> <li>▪ Abstain completely from sexual intercourse (even with condom), including oral and anal sex, until treatment is completed and their partner has completed treatment or are 7 days post-azithromycin treatment.</li> <li>▪ Repeat testing should be performed 3 months after treatment in under 25-years olds diagnosed with <i>Chlamydia</i> and when there is a change in sexual partner.</li> <li>▪ Remind pregnant patients that a test of cure is required in 3 weeks after end of treatment.</li> <li>▪ Provide information on practising safer sex.</li> </ul>
<p><b>Labelling</b></p>	<p>Medication supplied to the patient must be labelled in accordance with current legislation.</p>

<b>ERYTHROMYCIN 250MG TABLETS</b>	<b>P.O.M.</b> [Prescription Only Medicine]
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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 23<sup>rd</sup> November 2018.
  - 2015 UK national guideline for the management of *Chlamydia trachomatis*.  
<https://www.bashhguidelines.org/media/1045/chlamydia-2015.pdf>. Accessed 5<sup>th</sup> October 2017.
  - UK national guideline for the management of gonorrhoea in adults, 2011. <https://www.bashhguidelines.org/media/1044/gc-2011.pdf>. Accessed 5<sup>th</sup> October 2017.
  - 2015 UK National Guideline on the management of non-gonococcal urethritis. <https://www.bashhguidelines.org/media/1051/ngu-2015.pdf>. Accessed 5<sup>th</sup> October 2017.
  - Management of PID 2011 – updated June 201. <https://www.bashhguidelines.org/media/1143/pid-2012.pdf>. Accessed 5<sup>th</sup> 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 5<sup>th</sup> 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 5<sup>th</sup> 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 5<sup>th</sup> 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 5<sup>th</sup> October 2017.
5. Manufacturers' Summaries of Product Characteristics (SPC)
  - Erythromycin Tablets BP, Aurobindo Pharma - Milpharm Ltd. Date of last revision of the text 12/09/017.  
<http://www.medicines.org.uk/emc/medicine/23032> . Accessed 7<sup>th</sup> November 2017.

**ERYTHROMYCIN 250MG TABLETS**

**P.O.M.**  
[Prescription Only Medicine]

- Erythromycin Tablets BP 250 mg, Sovereign Medical. Date of last revision of the text 01/04/2010.  
<http://www.medicines.org.uk/emc/medicine/22904>. Accessed 7<sup>th</sup> November 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 5<sup>th</sup> October 2017.

7. General Pharmaceutical Council.

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

**ERYTHROMYCIN 250MG TABLETS**

**P.O.M.**  
[Prescription Only Medicine]

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.**