

PATIENT GROUP DIRECTION

For Administration and Supply of Azithromycin, Doxycycline and Erythromycin for Chlamydia

Ratification Date: February 2011

PGD expiry date: January 2013

Please check with the clinical lead, medicines management team or NHS Cambridgeshire website for the most recent version of the PGD before proceeding.

Names and signatures of the multidisciplinary group, which drew up this PGD

NAME	DESIGNATION/TITLE	SIGNATURE	DATE
Dr Susie Forster	Consultant GU Medicine, Cambridgeshire Community Services	SIGNED ON	
Kelvin Rowland-Jones	Principal Pharmacist Community Pharmacy Services	SIGNED ON	
Kathryn Faulkner	Chlamydia Screening Programme Coordinator	SIGNED ON	

Approved by	Senior Medicines Management Team	
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Signatures for Ratification

NAME	DESIGNATION/TITLE	SIGNATURE	DATE
Sue Ashwell	Chief Pharmacist	SIGNED ON	
Christine Macleod	Acting Medical Director	SIGNED ON	

Authorisation of Employer (if not employed by NHS Cambridgeshire)

NAME	DESIGNATION/TITLE	SIGNATURE	DATE

Each registered practitioner authorised to supply and/or administer medication under this PGD must have read, understood and signed this version of the PGD and completed the agreement to practice form before attempting to work according to it

Document Control Sheet

Rationale	This PGD was developed to enable patients with Chlamydia to be treated in a consistent and timely manner by accredited community pharmacists working within community pharmacies with a consulting room in Cambridgeshire
Documents replaced or superseded by this PGD.	PGD for Community pharmacists For Administration and Supply of Azithromycin, Doxycycline and Erythromycin for Chlamydia ratified February 2009.
Development and Consultation:	Developed by the Cambridgeshire PCT Medicines Management Team in consultation with: Dr Sani Aliyu, Microbiologist, Addenbrookes Hospital Tim Richards, Community Pharmacist, Chair Local Pharmaceutical Committee Ann Ladlow , Community Pharmacist
Dissemination	Chlamydia Screening Programme, Local Pharmaceutical Committee and community pharmacies in Cambridgeshire
Accessibility	Cambridgeshire NHS website
Implementation	Each registered practitioner authorised to supply and/or administer medication under this PGD must have read, understood and signed it and completed the agreement to practice form before attempting to work according to it
Training	See PGD
Audit	See PGD
Review	<u>Principal Pharmacist – Community Pharmacy services</u> Review should be initiated 3 months before the expiry date unless a review is required in response to a change to the medicine(s) covered by this PGD
Equality and Diversity	The Medicine Safety and Governance Group has carried out a Rapid Equality & Diversity Impact Assessment and concluded the document is compliant with the PCT Equality and Diversity Policy.

Standards for Better Health

Domain	How?
Safety	PGD documentation provides consistent approach to patient care This document sets out the information specified in law as that required for a Patient Group Direction.
Clinical and Cost Effectiveness	PGDs are evidence based. They allow the patient to be treated by the most appropriate health professional at the first point of contact.
Governance	PGD ensures standardisation of care. PGDs are a legal requirement for healthcare professionals (who are not independent prescribers) to be able to administer or supply medicines without a prescription. Practitioners working under the PGD must sign up to it and keep the specified records, thus providing an audit trail and accountability.
Patient Focus	Healthcare professionals respond to patients' needs in an appropriate and timely manner. It is specified that all aspects of the patients treatment, including any medicines supplied or administered are discussed with the patient Every patient is treated as an individual
Accessible and Responsive Care	Healthcare professionals respond to patients' needs in an appropriate and timely manner. The documentation allows specified healthcare professionals to supply or administer medicines without a prescription.
Public Health	Chlamydia is a public health priority and this PGD will facilitate its early treatment at the first point of contact with the primary care team. Health promotion is an integral part of each consultation.

Instructions on identifying and managing Adverse Drug Reactions	<ul style="list-style-type: none"> • Advise patient on management of the adverse effect • Report any suspected ADR to a medical practitioner as soon as possible if clinically relevant. • Use the Yellow Card System to report adverse drug reactions directly to the Committee on Safety of Medicines (MHRA). Guidance on the use of the Yellow Card System and Yellow Cards are available in the current BNF
Advice to patient/client	<ul style="list-style-type: none"> • Explain treatment and any further instructions to aid compliance • Swallow whole with plenty of water • Important to finish the course even if the condition appears to have resolved. • Advise patient to abstain from sex (vaginal/anal/oral and genital contact) during treatment and for one week after own treatment and should continue to refrain from sex until one week after their partner(s) have completed treatment, all results are back and any follow up appointments they or their partners have are completed. Give leaflet on condom use and safer sex. • Always provide the manufacturers Patient Information Leaflet and any specific local/ national service leaflets, ensure patient is able to read and understand any information supplied • Patients taking coumarins (eg. warfarin) must be advised to inform the service that monitors their INR that they are taking erythromycin • Advise patient of follow up arrangements
Follow up	<ul style="list-style-type: none"> • All patients will be followed up by the Chlamydia Screening Programme to confirm compliance post treatment • Test of cure should be performed after five weeks from completion of the course of antibiotics
Storage and Handling	<ul style="list-style-type: none"> • Storage and handling of medicines must comply with the current guidelines and local policy.

***Please note:**

Listed above are the interactions with commonly used medicines and the main side effects. If the patient/client is taking a medicine not listed above or reports other possible side effects refer to the current BNF, Patient Information Leaflet or electronic medicines compendium <http://www.medicines.org> or seek advice from pharmacist or medicines information department.

4. Facilities and supplies that must be available	
Medicine to be stocked	<p>Azithromycin capsules/tablets 250mg x 4 Azithromycin oral suspension 200mg /5ml x 30ml Doxycycline capsules/tablets 100mg x 14 Erythromycin capsules/tablets 250mg x 56</p> <ul style="list-style-type: none"> All medicines supplied to take away must meet the EC Labelling and Leaflet Directive. Minimum requirements include: Patient Name, Date, Name and address of clinic and "Keep out of children's reach" All medicines must be supplied with the manufacturer's Patient Information Leaflet.
Storage	<ul style="list-style-type: none"> Storage and handling of medicines must comply with the current guidelines and local policy.
Consultations	<ul style="list-style-type: none"> All consultations must be conducted in a consulting room or other area approved for the provision of Medication Usage Reviews
Reporting incidents	<ul style="list-style-type: none"> Incidents and near misses must be reported using the Cambridgeshire PCT Incident Reporting form (DATIX) which should be forwarded to the Risk Manager as soon as possible OR via employer's critical incident reporting system.
Other requirements	<ul style="list-style-type: none"> Current BNF Supplies of relevant Patient Information Leaflets

5. Records to be kept for audit purposes	
Patient details	<ul style="list-style-type: none"> Patient identifiers Allergies to the supplied medications or their excipients Any reason for exclusion and action taken Document patient consent or refusal Advice sought from medical/specialist service Details of any adverse reactions experienced by the patient and action taken Verbal and written advice given to patient Follow up and referral details
Records of administration	<ul style="list-style-type: none"> Name of Medicine Administration, date, time, route and dose administered Reason for administration Full name, signature and registration of practitioner supplying treatment or record in patient's notes on clinical system
Records of supply	<ul style="list-style-type: none"> Medicine supplied, dose, route, frequency and quantity Date and time of supply Reason for supply Full name, signature and registration of practitioner supplying treatment or record in patient's notes on clinical system
Audit	<ul style="list-style-type: none"> Annual audit must be carried out by the clinical lead Antibiotic use under PGD must be audited by an external reviewer Records of patients who have received treatment under the PGD must be accessible for audit purposes Regulations require that there is a secure system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and out-goings on a patient-by-patient basis. Audit may include evidence of authorised practitioners signatures, appropriate supply, standards of documentation; follow up arrangements, advice and information given to patients, reporting of adverse effects and incidents. <p>The EC Labelling and Leaflet Directive applies to all medicines supplied under the Patient Group Direction. The pack should be labelled with the following information:</p>

	<ul style="list-style-type: none"> • The address of the clinical area where supply is made • 'Keep out of reach of children' • Directions for use • The name of the patient or patient ID number • Date of supply <p>The patient information leaflet (PIL) from the package must be provided to each patient on every occasion, in addition to verbal advice.</p>
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6. References

- Patient Group Direction For Administration and Supply of Azithromycin, Doxycycline and Erythromycin for Chlamydia, Cambridgeshire Community Services Date of ratification August 2008
- Summary of Product Characteristics, Vibramycin-50 capsules, Pfizer Ltd., Date of revision: 30 May 2006, Date accessed 18.01.11 <http://emc.medicines.org.uk/>
- Summary of Product Characteristics, Vibramycin-D, Pfizer Ltd., Date of revision 05 January 2009, Date accessed 18.01.11 <http://emc.medicines.org.uk/>
- Summary of Product Characteristics Zithromax capsules, Suspension, Pfizer Ltd., Date of revision: 18 November 2010, Date accessed 18.01.11 <http://emc.medicines.org.uk/>
- Summary of Product Characteristics Erythrocin 250, Amdipharm, Date of revision: 10 November 2010, Date accessed 18.01.11 <http://emc.medicines.org.uk/>
- Joint Formulary Committee, British National Formulary Number 60, September 2010, BMA and RPSGB Pharmaceutical Press www.bnf.org.uk
- Joint Formulary Committee, British National Formulary for Children 2010-11, BMA and RPSGB Pharmaceutical Press www.bnfc.org.uk
- HSC 2000/026, 9th August 2000 Patient Group Directions (England)
- The current legal framework for the supply and administration of medicines for use by NCSP screening sites. Dr S. Randall, DH Advisor NCSP, B. Taylor, Joint Director, Community Health London, East and South Coast Specialist Pharmacy Services.
- 2006 UK National Guidelines for the Management of Genital Tract Infection with Chlamydia trachomatis.

AGREEMENT BY HEALTH PROFESSIONAL TO ACT UNDER THE PATIENT GROUP DIRECTION

I have read and fully understand the following documents:

1. The Patient Group Direction: For Administration and Supply of Azithromycin, Doxycycline and Erythromycin for Chlamydia
2. Dated:Expiry date:
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3. BNF and SPC monographs for all drugs included in this PGD.
4. The Cambridgeshire PCT Patient Group Direction Policy

I agree to act within the terms of the Patient Group Direction and administer and/or supply medicines in accordance with the documents listed above.

I understand that my employer is vicariously liable for acts and omissions by me during my employment with them.

I understand that failure to comply with the terms and conditions of the PGD, including the expiry date and limitations on practitioners, patients, drugs and indications may render me liable to disciplinary action by my employer e.g. GP practice or PCT under their performance and conduct arrangements.

NAME: *(block capitals)* (Health Professional)

SIGNATURE: (Health Professional)

POSITION:

EMPLOYER:

SITE/PRACTICE:

DATE SIGNED:

The original must be filed in the health professional's personal file and a copy held by their manager or employer for the purposes of ensuring practice occurs only in accordance with the PGD and is only undertaken by approved practitioners.

APPENDIX 2 – DOXYCYCLINE

SECTION 3 - EXCLUSION CRITERIA FOR SUPPLY OF DOXYCYCLINE FOR CHLAMYDIA	
G Is the patient female with:	
• abdominal pain that has not been appropriately assessed by a doctor	<input type="checkbox"/> Yes <input type="checkbox"/> No
• pelvic pain or discharge or irregular bleeding or dysuria or dyspareunia	<input type="checkbox"/> Yes <input type="checkbox"/> No
H Is the patient a male with: urinary symptoms or testicular pain or penile discharge	
	<input type="checkbox"/> Yes <input type="checkbox"/> No
I Does patient have allergy to Doxycycline or other tetracycline	
	<input type="checkbox"/> Yes <input type="checkbox"/> No
J Does the patient have active acute porphyria	
	<input type="checkbox"/> Yes <input type="checkbox"/> No
K Is the patient HIV positive	
	<input type="checkbox"/> Yes <input type="checkbox"/> No
L Does the patient have kidney disease	
	<input type="checkbox"/> Yes <input type="checkbox"/> No
M Is the patient experiencing concomitant conjunctivitis / joint pain	
	<input type="checkbox"/> Yes <input type="checkbox"/> No
N Does the patient have severe liver disease or alcohol dependence	
	<input type="checkbox"/> Yes <input type="checkbox"/> No
O Does the patient have Myasthenia Gravis	
	<input type="checkbox"/> Yes <input type="checkbox"/> No
P Does the patient have Systemic lupus erythematosus	
	<input type="checkbox"/> Yes <input type="checkbox"/> No
Q Is the patient taking an interacting drug that is excludes the patient from the PGD Ergot derivatives, Ciclosporin, Oral Retinoids, Methotrexate, Penicillins or Antiepileptics	
	<input type="checkbox"/> Yes <input type="checkbox"/> No
R Any other symptoms, medical condition or drug interaction that the pharmacist does not understand.	
	<input type="checkbox"/> Yes <input type="checkbox"/> No
If the answer is yes to ANY of the questions G to R – refer to GP or GUM clinic	
SECTION 4 – PATIENT COUNSELLING FOR DOXYCYCLINE SUPPLY	
All the following subjects must be discussed before supply:	
Twice daily course for one week – must complete the course	<input type="checkbox"/> Yes <input type="checkbox"/> No
Swallow whole with a full glass of water with food and remain upright for 30 minutes	<input type="checkbox"/> Yes <input type="checkbox"/> No
Take doxycycline at least 2- 3 hours before or after any indigestion remedies	<input type="checkbox"/> Yes <input type="checkbox"/> No
Warfarin and other Coumarin-type anti-coagulants – doxycycline may prolong prothrombin time – advise patient to have INR monitored	<input type="checkbox"/> Yes <input type="checkbox"/> No
Alcohol may increase metabolism of doxycycline	<input type="checkbox"/> Yes <input type="checkbox"/> No
Women taking the combined oral contraceptive pill should be advised that the package insert containing advice from the drug company and the fpa and other patient information leaflets may advise extra precautions (condoms or abstinence) during antibiotic use and for 7 days after the antibiotics are finished. You can follow this advice if you wish. However recent evidence now suggests that additional precautions are not required to maintain contraceptive efficacy when using antibiotics with combined hormonal methods. However if the antibiotics (and/or illness) caused diarrhoea or vomiting, then the usual additional precautions relating to these conditions should be observed. The most important thing is not to stop your contraceptive pills. See Appendix 4 for full advice.	
	<input type="checkbox"/> Yes <input type="checkbox"/> No
Avoid direct exposure to bright sunlight or ultraviolet light	<input type="checkbox"/> Yes <input type="checkbox"/> No
Advise patient of common side effects. Advise them to read the Patient Information Leaflet for more information and to seek medical advice in case of severe or unexpected adverse effects	
	<input type="checkbox"/> Yes <input type="checkbox"/> No
Advise patient to abstain from sex (vaginal/anal/oral and genital contact) for one week after own treatment and should continue to refrain from sex until one week after their partner(s) have completed treatment, all results are back and any follow up appointments they or their partners have are completed.	
	<input type="checkbox"/> Yes <input type="checkbox"/> No
Advise that condoms are the only form of contraception that offer any protection against Chlamydia and should be used consistently and correctly	
	<input type="checkbox"/> Yes <input type="checkbox"/> No
Always provide the manufacturers Patient Information Leaflet and any specific local/ national service leaflets, ensure patient is able to read and understand any information supplied	
	<input type="checkbox"/> Yes <input type="checkbox"/> No
Advise patient of follow up arrangements – will be contacted by CSP post treatment	
	<input type="checkbox"/> Yes <input type="checkbox"/> No
Patient name:	Contact Number:
CONFIRMATION	
The information above and overleaf is correct to the best of my knowledge. I have been counselled on the use of this medication and understood the advice given to me. I agree to this information being shared with the Chlamydia Screening Service.	
Patient signature:	Date:

NOW PLEASE COMPLETE ACTION TAKEN (SECTION 5) AND CONFIRMATION (SECTION 6) ON ASSESSMENT FORM

APPENDIX 3 – ERYTHROMYCIN

SECTION 3 - EXCLUSION CRITERIA FOR SUPPLY OF ERYTHROMYCIN FOR CHLAMYDIA	
G Is the patient female with:	
• abdominal pain that has not been appropriately assessed by a doctor	<input type="checkbox"/> Yes <input type="checkbox"/> No
• pelvic pain or discharge or irregular bleeding or dysuria or dyspareunia	<input type="checkbox"/> Yes <input type="checkbox"/> No
H Is the patient a male with:	
urinary symptoms or testicular pain or penile discharge	<input type="checkbox"/> Yes <input type="checkbox"/> No
I Does patient have allergy to Erythromycin or other macrolide	<input type="checkbox"/> Yes <input type="checkbox"/> No
J Does the patient have active acute porphyria	<input type="checkbox"/> Yes <input type="checkbox"/> No
K Is the patient HIV positive	<input type="checkbox"/> Yes <input type="checkbox"/> No
L Does the patient have kidney disease	<input type="checkbox"/> Yes <input type="checkbox"/> No
M Is the patient experiencing concomitant conjunctivitis / joint pain	<input type="checkbox"/> Yes <input type="checkbox"/> No
N Does the patient have severe liver disease or alcohol dependence	<input type="checkbox"/> Yes <input type="checkbox"/> No
O Does the patient have Myasthenia Gravis	<input type="checkbox"/> Yes <input type="checkbox"/> No
P Has the patient had any prolonged QT interval identified on ECG investigation	<input type="checkbox"/> Yes <input type="checkbox"/> No
Q Is the patient taking an interacting drug that are designated black dot interactions in the BNF. These interactions excludes the patient from the PGD Except warfarin and other coumarine type anti coagulants see below.	<input type="checkbox"/> Yes <input type="checkbox"/> No
R Any other symptoms, medical condition or drug interaction that the pharmacist does not understand.	<input type="checkbox"/> Yes <input type="checkbox"/> No
If the answer is yes to ANY of the questions G to R – refer to GP or GUM clinic	

SECTION 4 –PATIENT COUNSELLING FOR ERYTHROMYCIN SUPPLY	
All the following subjects must be discussed before supply:	
Twice daily course for TWO weeks – must complete the course	<input type="checkbox"/> Yes <input type="checkbox"/> No
Swallow whole with plenty of water	<input type="checkbox"/> Yes <input type="checkbox"/> No
Warfarin and other Coumarin-type anti-coagulants – erythromycin may prolong prothrombin time – advise patient to have INR monitored	<input type="checkbox"/> Yes <input type="checkbox"/> No
Advise patient of common side effects. Advise them to read the Patient Information Leaflet for more information and to seek medical advice in case of severe or unexpected adverse effects	<input type="checkbox"/> Yes <input type="checkbox"/> No
Advise patient to abstain from sex (vaginal/anal/oral and genital contact) for one week after own treatment and should continue to refrain from sex until one week after their partner(s) have completed treatment, all results are back and any follow up appointments they or their partners have are completed.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Advise that condoms are the only form of contraception that offer any protection against Chlamydia and should be used consistently and correctly	<input type="checkbox"/> Yes <input type="checkbox"/> No
Always provide the manufacturers Patient Information Leaflet and any specific local/ national service leaflets, ensure patient is able to read and understand any information supplied	<input type="checkbox"/> Yes <input type="checkbox"/> No
Advise patient of follow up arrangements - will be contacted by CSP post treatment and that test of cure should be performed after five weeks from completion of the course of antibiotics	<input type="checkbox"/> Yes <input type="checkbox"/> No
Patient name:	Contact Number:
CONFIRMATION	
The information above and overleaf is correct to the best of my knowledge. I have been counselled on the use of this medication and understood the advice given to me. I agree to this information being shared with the Chlamydia Screening Service.	
Patient signature:	Date:

NOW PLEASE COMPLETE ACTION TAKEN (SECTION 5) AND CONFIRMATION (SECTION 6) ON ASSESSMENT FORM

Appendix 4

Antibiotic interactions with COC (non-enzyme inducers)

Faculty of Sexual and Reproductive Healthcare Clinical Guidance – Drug Interactions with Hormonal Contraception (Clinical Effectiveness Unit January 2011)

The latest published guidance has revised the recommendations for extra precautions when there is concomitant use of the COC and **non-enzyme inducing** antibiotics:

“Having reviewed the available evidence, the CEU no longer advises that additional precautions are required to maintain contraceptive efficacy when using antibiotics that are not enzyme inducers with combined hormonal methods for durations of 3 weeks or less. The only proviso would be that if the antibiotics (and/or the illness) caused diarrhoea or vomiting, then the usual additional precautions relating to these conditions should be observed. The CEU would advise that health professionals remind women about the importance of correct contraceptive practice during periods of illness.

Patients presenting for emergency contraception because they have not used condoms during antibiotic use should be asked about D&V and missed/late pills. If there have been no such problems they should be advised that emergency contraception is not necessary though of course should not be denied it if they prefer to follow the manufacturer’s instructions.

Appropriate advice for patients is therefore

- The package insert and the fpa leaflets advise extra precautions (condoms or abstinence) during antibiotic use and for 7 days after antibiotics are finished. You can follow this advice if you wish.
- However, recent expert opinion reports that there is no evidence that common antibiotics will affect the efficacy of the COC and therefore extra precautions are not necessary **unless of course you experience diarrhoea and vomiting**. If this occurs, use condoms or abstain until 7 days after you are better. If this takes you beyond the end of the pack go straight on to the next one without a break.
 - If you don’t follow this advice you may need emergency contraception.
- **DO NOT STOP YOUR PILL**

(LG 01/11)