

**PATIENT GROUP DIRECTION FOR THE ADMINISTRATION OF  
AZITHROMYCIN FOR TREATMENT OF CONFIRMED UNCOMPLICATED  
CHLAMYDIA TRACHOMATIC INFECTION (PATIENT OR PARTNER)  
PRESENTING WITH TREATMENT VOUCHER TO COMMUNITY PHARMACISTS**

**MANAGEMENT OF PATIENT GROUP DIRECTION**

This Patient Group Direction must be read, agreed to and signed by all healthcare professionals involved in its use. The original signed copy should be held by a designated person and must be easily accessible to healthcare professionals in the clinical setting. In all cases the healthcare professional will follow the code of conduct as defined by their professional body.

	Name	Signature	Date
<b>Developed by LOCAL DEVELOPMENT TEAM</b>			
Doctor	Dr Sharon Cameron		
Practitioner	Aileen Muir		
Pharmacist	Garry Todd		

<b>Approved by PGD SUB-GROUP OF THE MEDICINES POLICY COMMITTEE</b>			
Chairperson	Garry Todd		

<b>Approved by AUTHORISED NHS LOTHIAN DRUGS AND THERAPEUTICS COMMITTEE</b>			
Chairperson/Deputy of Committee	Dr Richard Williams		

<b>AUTHORISED BY</b>			
Medical Director	Dr D Farquharson		

<b>LOCAL MANAGEMENT</b>			
Practice/Ward/Department/Directorate			
Clinical Lead			
Practitioner Manager (if applicable)			
Pharmacist (if applicable)			
Name of Designated PGD Holder <small>(Responsible for ensuring names of healthcare professionals issuing under this PGD are kept up to date)</small>			

DATE AUTHORISED FOR USE	REVIEW DATE	EXPIRY DATE
24/06/2013	24/06/2015	24/06/2016



1. CHARACTERISTICS OF STAFF	
<b>Define Practitioner Group</b>	Community Pharmacist registered with General Pharmaceutical Council
<b>Qualifications Required</b>	Current GPhC Registration
<b>Additional requirements</b>	<ul style="list-style-type: none"> <li>▪ Undertaken Continuing Professional Development (CPD) to ensure understanding of areas related to the pharmacy service in relation to Chlamydia infection</li> <li>▪ Undertaken appropriate training to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD</li> <li>▪ Undertaken appropriate training for working under PGDs for the supply and administration of medicines, including completion of PGD module on LearnPro.</li> <li>▪ Undertaken training provided by NHS Lothian Sexual and reproductive health service</li> </ul>
<b>Continued training requirements</b>	<ul style="list-style-type: none"> <li>▪ Updates on the management of Chlamydia infection when appropriate</li> </ul>

2. DESCRIPTION OF TREATMENT	
<b>Names of Medicines included</b>	Azithromycin 250mg Capsules Azithromycin 500mg tablets
<b>Marketing Authorisation</b> (previously UK Product Licence)	YES
<b>Outwith terms of the Summary of Product Characteristics</b>	NO
<b>Controlled Drugs</b> If YES, consultation with CDGT to check legal compliance	NO
<b>Antibiotic</b> If YES, consultation with Microbiologist/Antimicrobial Management Team	YES YES - AMT
<b>Children under 13 years of age to be treated</b> If YES, consultation with Neonatologist, Paediatrician, Public Health or Unscheduled Care	NO
<b>Record / Audit trail</b>	<ul style="list-style-type: none"> <li>▪ Treatment voucher to be returned to health advisors at Chalmers Centre.</li> </ul>

3. MEDICINES and CLINICAL CONDITION	
<b>Name of medicine</b>	Azithromycin 250mg Capsules Azithromycin 500mg Tablets
<b>Define situation/condition</b>	To treat women aged 16 years of age or over, or men aged 16 years of age or over, diagnosed with confirmed asymptomatic genital <i>Chlamydia trachomatis</i> (or partners of the index case) presenting to pharmacist with treatment voucher
<b>Criteria for inclusion (including patient group)</b>	<ul style="list-style-type: none"> <li>▪ Women aged 16 years or over, who have had a positive result, or whose partner has), for <i>Chlamydia trachomatis</i></li> <li>▪ Men aged 16 years or over, who have had a positive result, or whose partner has, presenting to pharmacist with treatment voucher</li> </ul>
<b>Criteria for exclusion</b>	<ul style="list-style-type: none"> <li>▪ Female under 16 years old</li> <li>▪ Male under 16 years old</li> <li>▪ Children under 45kg body weight</li> <li>▪ Women with signs and symptoms of Chlamydia infection eg. lower abdominal/pelvic pain, intermenstrual or post coital bleeding, dysuria, unusual vaginal discharge.</li> <li>▪ Men with signs and symptoms of Chlamydia i.e. dysuria penile discharge, painful swelling of the genitalia.</li> <li>▪ Patients who are clinically unwell (febrile and in acute pain)</li> <li>▪ Breast-feeding mothers, pregnant women, or women who are possibly pregnant. (but new LJJ allow us to use azithromycin)</li> <li>▪ Patients with known hypersensitivity to azithromycin, erythromycin, clarithromycin or any macrolide antibiotics, or any of the constituents of the capsule.</li> <li>▪ History of liver disease.</li> <li>▪ History of severe renal impairment.</li> <li>▪ Porphyria</li> <li>▪ Known cardiac arrhythmia</li> <li>▪ Weight less than 45kg</li> <li>▪ Known hypersensitivity to any component of the medicine</li> <li>▪ Informed non consent</li> </ul>
<b>Action if excluded</b>	<ul style="list-style-type: none"> <li>▪ Advise to contact either patient's own GP, the Department of Genito Urinary Medicine or Family Planning Service</li> </ul>
<b>Action if patient declines</b>	<ul style="list-style-type: none"> <li>▪ Advise to contact either patient's own GP, the Department of Genito Urinary Medicine or Family Planning Service</li> <li>▪ Audit of reason for declining.</li> </ul>
<b>Pharmaceutical form and strength of medicine</b>	Azithromycin 250mg Capsules or 500mg tablets
<b>POM / P / GSL / ▼</b>	POM

<b>Dose/s</b>	1 Gram (2 tablets or 4 capsules) as a single dose
<b>Route/Method</b>	Oral
<b>Frequency (To include maximum/minimum timescales)</b>	Two tablets of 500mg as a single dose or four capsules of 250mg to be given as a single dose  Supply/administration - Azithromycin is to be administered but not supplied to the patient. Medication not to be supplied to index cases for partner treatment
<b>Total dose/number</b>	One dose of 1 Gram (Two tablets of 500mg or four capsules of 250mg) only.
<b>Drug interactions and action to be taken</b>	<ul style="list-style-type: none"> <li>▪ Patients prescribed other contra-indicated medicines eg. <ul style="list-style-type: none"> <li>- Ciclosporin</li> <li>- Digoxin</li> <li>- Terfenadine</li> <li>- Theophylline</li> <li>- ergot derivatives</li> </ul> </li> </ul> <p>NB. This list is not exhaustive. Azithromycin has the potential to interact with many drugs</p> <p>Refer to Appendix 1 of BNF for latest information on interactions</p> <p>Refer to doctor if necessary.</p>
<b>Cautions (including action to be taken if caution applies)</b>	<ul style="list-style-type: none"> <li>▪ None</li> </ul>
<b>Adverse reactions and side effects including actions to be taken if adverse drug reaction is suspected (▼ - include yellow card details)</b>	<ul style="list-style-type: none"> <li>▪ May cause nausea, vomiting, diarrhoea and abdominal discomfort (pain/cramps)</li> <li>▪ Advise to contact nurse/GP if side effects occur.</li> <li>▪ If a serious adverse reaction is suspected please report to the Commission on Human Medicines (CHM) via the Yellow Card Scheme <a href="http://yellowcard.mhra.gov.uk/">http://yellowcard.mhra.gov.uk/</a></li> </ul>
<b>Additional advice and information</b>	<ul style="list-style-type: none"> <li>▪ Patients are fully informed about the infection, advantages of testing and treatment, the mode of action, side effects, advantages and disadvantages, and method of administration of the medicine</li> <li>▪ Advise to contact either patient's own GP, the Department of Genito Urinary Medicine or Family Planning Service</li> <li>▪ Pharmacists should be aware of child protection issues in children under 16 years of age.</li> <li>▪ If vomiting occurs within 2 hours of taking the Azithromycin, the person should be advised to re-attend the pharmacy where a further dose will be supplied. If the pharmacy is closed, the person should be advised to re-attend when the pharmacy next opens, or to attend GUM or GP if they prefer.</li> <li>▪ Manufacturers Patient Information Leaflet should be offered.</li> </ul>

<b>Referral, patient monitoring and follow-up</b>	Return of treatment voucher to the Chalmers Centre.
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#### 4. REFERENCES

1. Summary of Product Characteristics last accessed 21/05/2013 via <http://www.medicines.org.uk>
2. <http://www.bnf.org> last accessed 21/05/2013