Patient Group Direction for the Supply of Azithromycin as first line treatment from Accredited Warwickshire Community Pharmacies by an Accredited Pharmacist

Valid from: 18\textsuperscript{th} March 2013 Reviewed: February 2013 Valid Until: 31\textsuperscript{st} March 2014

After reviewing with an option to extend up to a further 12 months.

Clinical Department/Service: Community Pharmacy

Subject to all the conditions and criteria below, this Patient Group Direction allows a trained pharmacist in an accredited pharmacy to supply from the pharmacy, appropriately packaged, the named drug to patients for self-administration without the need for a prescription from a doctor. The pharmacist must have completed additional training and confirm that they are professionally competent to operate, and agree to work within, this Patient Group Direction. For further product information the Pharmacist should refer to the Summary of Product Characteristics and the BNF

1. Clinical Condition

<table>
<thead>
<tr>
<th>1.1</th>
<th>Clearly define situation/condition</th>
<th>Uncomplicated genital \textit{Chlamydia trachomatis} infection and sexual contacts of confirmed \textit{Chlamydia trachomatis} infection.</th>
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</thead>
<tbody>
<tr>
<td></td>
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<td>• Male or female clients 15 years of age and over who have a positive genital chlamydial result following screening.</td>
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<td>• Sexual contacts of clients with a positive genital chlamydial result as epidemiological treatment.</td>
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<table>
<thead>
<tr>
<th>1.2</th>
<th>Criteria for inclusion</th>
<th>As above</th>
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<tbody>
<tr>
<td></td>
<td>Note: under 16’s must be assessed using Fraser guidelines</td>
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<table>
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<tr>
<th>1.3</th>
<th>Criteria for exclusion</th>
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<tr>
<td></td>
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<td>• Age 14 years and under</td>
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<td></td>
<td>• Breastfeeding</td>
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<td></td>
<td></td>
<td>• Established pregnancy</td>
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<td></td>
<td></td>
<td>• Risk of pregnancy\textsuperscript{1}</td>
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<td></td>
<td></td>
<td>• History of hepatic or renal disease</td>
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<td></td>
<td></td>
<td>• Porphyria</td>
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<tr>
<td></td>
<td></td>
<td>• History of cardiac disease</td>
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<tr>
<td></td>
<td></td>
<td>• HIV positive client</td>
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<tr>
<td></td>
<td></td>
<td>• Male clients with scrotal pain</td>
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<tr>
<td></td>
<td></td>
<td>• Female clients with pelvic pain</td>
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<tr>
<td></td>
<td></td>
<td>• Presence of genital tract symptoms, e.g. urinary symptoms such as stinging when passing urine, penile discharge,</td>
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<td>unusual vaginal discharge and/or bleeding</td>
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<td></td>
<td></td>
<td>• Concomitant conjunctivitis and/or joint pain</td>
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</tbody>
</table>

\textsuperscript{1} Pregnancy risk is variable but may be defined as occurring when the menstrual period is late in relation to the woman’s usual pattern and/or vaginal sexual intercourse has taken place since the last normal menstrual period and:

• no contraception method has been used; OR
• there has not been full compliance with the contraception method used; OR
• the effectiveness of the contraception method has been reduced.

For women using the combined oral contraceptive pill compliance and effectiveness in the previous cycle should be checked, particularly in the last 7 days of the active pill pack.

If there is any doubt whether a pregnancy risk exists medical advice must be sought.
### 1.4 Cautions

- Allergy or hypersensitivity to azithromycin or other macrolide antibiotics e.g. erythromycin
- Patients taking interacting medicines - check BNF for current information

### 1.5 Action if patient excluded

Explain reasons for exclusion with client and document. Consider whether doxycycline PGD could be used.
- If not refer to GUM or GP as soon as possible (as per local arrangements).
- Male client with scrotal pain: consider immediate referral to A&E to exclude torsion of the testis
- Female client with pelvic pain: consider immediate referral to GUM or Gynaecology on-call service
- Presence of genital tract symptoms: consider immediate referral to GUM
- Concomitant conjunctivitis and/or join pain: consider immediate referral to GUM or local A&E Department.

Record in records

### 1.6 Action if patient declines or does not adhere to care under the protocol

Record and in particular, any refusal of treatment. Emphasise the importance of treatment and potential risks if not treated e.g. Pelvic infection, infertility, risk to sexual partners etc.

### 2. Description of Treatment

- **Name of medicine, strength, form, to be supplied**: Azithromycin 250mg oral tablets x 4

- **Legal status**: Prescription only medicine (POM)

- **Licensed or unlicensed**: Licensed

- **Dose(s)**: 1 gram as a single dose (taken as 4 x 250mg tablets)

- **Route/Method of Administration**: Oral (supervised administration is recommended)

- **Frequency of Administration**: Single dose

- **Total dose and number of times treatment can be administered over what period of time**: A second dose can be given if patient does not abstain from intercourse as directed.

- **Instruction on identifying and managing any possible adverse outcomes**: If vomiting occurs within 3 hours of taking tablets client should return for re-evaluation at earliest opportunity

- **Procedure for reporting any suspected Adverse Use the yellow card at the rear of the BNF for reporting any adverse reactions.**
| **2.10** Information on follow up treatment if needed | Refer to Chlamydia screening service |
| **2.11** Detail arrangements for referral to medical advice | All clients will have been given the option to be seen by a doctor at the next available/ convenient time, either at GUM Dept, FP clinic or their own GP (already done by screening service) |
| **2.12** Written/verbal advice for patient/carer before/after treatment. Product information leaflet should be given to the patient | Tablets should be swallowed whole with a cup of water. If food has been taken within the previous 2 hours – delay administration or use alternative therapy. Clients will have been advised of this requirement when contacted by the Chlamydia screening office (CSO). Where possible avoid indigestion remedies. If using antacids, take azithromycin 1 hour before or 2 hours after taking the antacid. Abstain completely from sexual contact (even with a condom) for 7 days after treatment and for 7 days after partner(s) treated. If the client is taking oral contraception or using contraceptive patches • Advise client to continue to take contraceptive as usual. • If client is given antibiotics in first week of pill packet and they have had sex recently they may require emergency contraception. • If client is at the end of the packet for combined pill or the end of the active pills in the “every day” pills whilst taking the antibiotics or within 7 days of completing the course then advise then to start a new packet straight away. • Do not have the usual 7-day break or take the placebo tablets. • Advise client they may or may not bleed, this is normal Warn that if sexual contact takes place after treatment with an untreated partner there is a risk of re-infection. Discuss implications of incomplete/untreated infection of self or partner (check partner notification has taken place and document Side Effects **Consult current BNF for full list.** Common side effects include anorexia, dyspepsia, constipation, dizziness, headache, drowsiness. The risk of developing candidiasis (thrush). Rarer side effects include photosensitivity, hepatitis, interstitial nephritis, renal failure, paraesthesia, tinnitus and taste disturbances. |
| **2.13** Method of recording supply / administration | The following should be recorded either in the computer patient medication record or paper record (i.e. Chlamydia SLA Appendix 3): • Assessment of client need in relation to the intervention • If < 16 document whether competent under Fraser guidelines (1985) as per local protocol • Date and time of supply/administration • Name of medication supplied • Batch number and expiry date |
3. Characteristics of staff

<table>
<thead>
<tr>
<th>3.1</th>
<th>Details of qualifications and registration of individual professional operating under this PGD</th>
<th>Pharmacist registered with The General Pharmaceutical Council (GPhC)</th>
</tr>
</thead>
</table>

| 3.2 | Specialist qualification, training, experience and competence necessary and relevant to the clinical condition to be treated and medicines used in this protocol | Has completed appropriate CPPE learning programmes to provide necessary knowledge to underpin the provision of this service: 1. Sexual health in pharmacies (CPPE 2010; Open Learning) 2. Safeguarding children and vulnerable adults (CPPE 2012; e-learning) Where the learning programme provides pharmacists with an assessment or record of completion this must be kept by the pharmacist and a copy sent to the Commissioner. Has confirmed competence and confidence around administration of azithromycin under PGD, covering the following areas:  • the theory and practice of working under a sexual health PGD and the details of the PGDs involved;  • the practicalities of the service generally; and  • the clinical aspects of STI testing and treatment |

| 3.3 | Continued training requirements | It is the responsibility of the practitioner to maintain own level of competency The practitioner should be aware of any change to the recommendations for the medicine listed |

4. Management and monitoring of Patient Group Direction:

PGD developed by:

<table>
<thead>
<tr>
<th>Name &amp; Designation</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>
| Doctor             | Dr J Linnane  
Joint Director of Public Health  
NHS Warwickshire | [Signature] | 28 Feb 2013 |
| Pharmacist         | Dave Maxted  
Senior Pharmaceutical Advisor  
NHS Warwickshire | [Signature] | 28 Feb 2013 |
| Community Pharmacist | Faye Chapman  
Chair  
Warwickshire Local Pharmaceutical Committee | [Signature] | 28 Feb 2013 |
| Microbiologist     | Dr Matthew Rogers  
Consultant Microbiologist (UHCW NHS Trust) | [Signature] | 28 Feb 2013 |
Declaration by authorising body:

This PGD has been authorised by John Linnane
Joint Director of Public Health on behalf of NHS Warwickshire

Date: 28 Feb 2013

5. Standing Order for Azithromycin PGD

Part One - Agreement by Pharmacist

- I consider I am competent to supply Azithromycin under this Patient Group Direction.
- I have completed the necessary Centre for Pharmacy Postgraduate Education (CPPE) learning programmes:
  - Sexual health in pharmacies (CPPE 2010; Open Learning) (previously CPPE Sexual Health: testing and treating)
  - Safeguarding children and vulnerable adults (CPPE 2012; e-learning)
- I have submitted a copy of my CPPE certificates to the Commissioner
- I have read and understood the Patient Group Direction and agree to use it in accordance with the criteria described.

Pharmacist Name: ____________________________________________
Pharmacist GPhC number: ______________________________________
Signature: ____________________________________________________
Business Address: _____________________________________________
Date: _________________________________________________________

Part Two (to be completed by the Commissioner)

- The above named pharmacist is identified as being suitably qualified in the supply of Azithromycin
- This pharmacist has confirmed competency in the supply of Azithromycin according to this Patient Group Direction
- The above named pharmacist is hereby authorised to operate this Patient Group Direction within any accredited Warwickshire community pharmacy

Authorised by:
Name: _________________________________________________________
Position: _______________________________________________________
Signature: ______________________________________________________
Date: __________________________________________________________

Guidance notes
- Each pharmacist should complete and sign part one of the Standing Order
- Part two will be completed by an authorised person at NHS Warwickshire
- When both parts one and two are completed and signed:
  - The original will be kept by the Commissioner
  - A copy will be returned to the pharmacist
- A copy of the completed standing order should be kept in each pharmacy where a pharmacist provides the service, and retained by the accredited pharmacist
Return a complete copy of this signed agreement to:

Ann Gill
Business Support / Office Manager
Public Health Warwickshire
Communities Group
PO Box 43
Shire Hall
Warwick CV34 4SX
Tel: 01926 413775
Fax: 01926 410130
Anngill@warwickshire.gov.uk