Patient Group Direction for Azithromycin for the treatment of uncomplicated genital chlamydia trachomatis infection.

**Document Title:** Patient Group Direction for Azithromycin for the treatment of uncomplicated genital chlamydia trachomatis infection.

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**Author/Owner:** Jacqui Seaton, Head of Medicines Management

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**Document Overseeing Group:** Medicines Management

**Placement in Framework:**

**Approval Level:**

**Date of Approval:** September 2019

**Review Date:** September 2021

**Amendment Dates:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Page(s)</th>
<th>Brief Description</th>
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</thead>
<tbody>
<tr>
<td>February 2013</td>
<td></td>
<td>Amended review date</td>
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<td>March 2013</td>
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<td>Approved for use by NHS T&amp;W Clinical Commissioning Group</td>
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<td>November 2014</td>
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<td>Amended review date</td>
</tr>
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<td>June 2015</td>
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<td>Amended review date – no changes made</td>
</tr>
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<td>June 2018</td>
<td></td>
<td>Amended review date – no changes made</td>
</tr>
<tr>
<td>January 2019</td>
<td></td>
<td>Amended / rewritten following updated guidance from British Association for Sexual Health and HIV (BASHH)</td>
</tr>
</tbody>
</table>

**NB:** Always access the electronic version of this PGD to ensure that you are using the most up to date version.

The practitioner MUST be authorised by name, under the current version of this PGD before working according to it.
Patient Group Direction for Azithromycin for the treatment of uncomplicated genital Chlamydia trachomatis infection.

The use of azithromycin is considered second line treatment for uncomplicated asymptomatic chlamydia infection if doxycycline is contraindicated.

Approved By

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head of Medicines Management - Telford and Wrekin Clinical Commissioning Group</td>
<td>Jacqui Seaton</td>
</tr>
<tr>
<td>Consultant/Clinical Director Sexual Health Service (MPFT)</td>
<td>Dr Arabinda Kundu</td>
</tr>
<tr>
<td>Consultant in Public Health – Telford &amp; Wrekin Council</td>
<td>Helen Onions</td>
</tr>
<tr>
<td>Clinical Chair, Telford &amp; Wrekin CCG</td>
<td>Dr Jo Leahy</td>
</tr>
</tbody>
</table>

Date of patient group direction approved | September 2019
Date this patient group direction becomes due for review | September 2021

PGD Developed by

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical Adviser (Telford and Wrekin CCG)</td>
<td>Hitesh Patel</td>
</tr>
<tr>
<td>Consultant/Clinical Director Sexual Health Service (MPFT)</td>
<td>Dr Arabinda Kundu</td>
</tr>
</tbody>
</table>

Azithromycin PGD administration form should be used to support supply of treatment against this PGD
STAFF CHARACTERISTICS

- Working for providers of NHS Pharmaceutical Services within NHS Telford and Wrekin CCG
- GPhC registered Pharmacist deemed competent in the administration and supply of Doxycycline for the treatment of uncomplicated genital chlamydia trachomatis infection. The pharmacist will have due regard for the General Pharmaceutical Council Standards of conduct, ethics and performance.

Specialist competencies or qualifications:
- The healthcare professional must have a good understanding of the NICE Good Practice Guidance on Patient Group Directions
- The clinical manager or service lead has evidence that the registered healthcare professional has undertaken training to carry out clinical assessment of patient leading to confirmation that the patient requires treatment according to the indications listed in the PGD.
- The healthcare professional must provide evidence of training, appropriate annual updates and continued professional development undertaken to support their competence for administration of this treatment.
- Completion of current online CPPE training package on Sexual Health services in community pharmacy
- Completion of CPPE safeguarding children and vulnerable adults level 1, Combating CSE and NHS Spotting the signs of child sexual exploitation (e-assessment learning)
- The clinical manager or service lead has proof of training by the healthcare professional on the legal aspects of supply or administration of medicines under a Patient Group Direction
- The clinical manager or service lead has assessed the competency of the healthcare professional to work to a Patient Group Direction at least every 2 years (for pharmacists this will usually be in the form of training and a self-declaration of competency) The NICE competency framework for people authorising PGDs and the NICE competency framework for healthcare professionals using Patient Group Directions should be used to support this assessment.
- Must have access to all relevant sources of information e.g. information issued by the Department of Health (DH), British National Formulary (BNF), Summary of Product Characteristics (SPC), and any clinical guidelines concerning medicine(s) within this Patient Group Direction (PGD).
- All staff operating within the PGD must update their knowledge and skills in this area of practice with particular reference to changes and national directives. Staff must have a good understanding of the BASHH guideline.
- All staff operating within the PGD must be Competent to follow and administer patient group direction - showing clear understanding of indications for treatment, exclusions from treatment (and subsequent action to be taken) and the treatment itself.
- All staff operating within the PGD should have a clear understanding of the drug administered including side effects and contraindications
- The registered healthcare practitioner is professionally accountable for supply or administration under the PGD as defined in their own profession’s Code of Professional Conduct and Ethics.

YOU MUST BE AUTHORISED BY NAME BY YOUR MANAGER UNDER THE CURRENT VERSION OF THIS PGD
BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT
PGDs DO NOT REMOVE INHERANT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY
Always ensure that you are using the most up to date version of this PGD
<table>
<thead>
<tr>
<th><strong>CLINICAL CONDITION</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim</strong></td>
<td>To reduce the risks of short and longer term complications associated with chlamydia infection such as pelvic inflammatory disease and tubal infertility</td>
</tr>
</tbody>
</table>
| **Indication**         | Men and women with confirmed uncomplicated genital Chlamydia trachomatis infection.  
                          | Sexual contacts of men/women where Chlamydia trachomatis diagnosis confirmed in the index case.  
                          | NB The use of azithromycin is considered second line treatment for uncomplicated asymptomatic chlamydia infection in individuals who are allergic to, intolerant of or have a contraindication to doxycycline.  
                          | (All sexual contacts must be offered a Chlamydia screen at the point of treatment) |
| **Inclusion criteria** | Individuals aged 15 years and over who have a positive genital chlamydial result following screening. (Clients under 16 years must be assessed as meeting Fraser criteria(Appendix 1))  
                          | Sexual contacts of clients with a positive genital chlamydial result that are aged 15 years and over. (Clients under 16 years must be assessed as meeting Fraser criteria (Appendix 1))  
                          | Retreatment in case of possible reinfection if intercourse has taken place within the recommended 7 days of abstinence since treatment course was completed (both index patient and partner) |
| **Exclusion criteria** | Complicated chlamydial infection:  
                          | Women  
                          | Dysuria  
                          | Presence of vaginal discharge in women  
                          | Intermenstrual bleeding or change in normal bleeding pattern in women  
                          | Presence of pelvic pain in women  
                          | Suspected pelvic inflammatory disease  
                          | Lower abdominal pain  
                          | Men  
                          | Dysuria  
                          | Presence of penile discharge  
                          | Presence of testicular pain  
                          | Urethritis  
                          | Known or suspected proctitis/prostatitis  
                          | Any of the following clinical conditions / patient parameters (women and men):  
                          | Clients under 15 years of age  
                          | Presence of concomitant conjunctivitis / joint pains  
                          | Known hepatic impairment  
                          | Cardiac disease and those with clinically relevant bradycardia, cardiac arrhythmia or severe cardiac insufficiency.  
                          | Congenital or acquired QT prolongation  
                          | Known electrolyte disturbance particularly in cases of hypokalemia and hypomagnesaemia |
- Myasthenia gravis
- Known porphyria
- Known HIV infection
- Known significant renal impairment
- Recurrent chlamydial infection (Presenting within 3 months of previous treatment)
- Known or suspected pregnancy
- Breast feeding
- Patients that weigh less than 45kg

**Allergies**
- Known or suspected allergy to Azithromycin or other macrolide antibiotics or to any of the product excipients.

**Interacting medication**
Patients taking medications which interact with azithromycin, particularly those known to prolong the QT interval (please refer to SPC of product or current BNF for current information) such as;
- Ciclosporin
- Digoxin
- Ergot derivatives
- Theophylline
- Reboxetine
- Anticoagulants

Please refer to current BNF [http://bnf.org/bnf](http://bnf.org/bnf) and SPC [www.medicines.org.uk/emc](http://www.medicines.org.uk/emc) for full details

**Consent**
Client who does not consent to treatment under this PGD
Client under 16 years who is felt not to meet Fraser criteria

<table>
<thead>
<tr>
<th>Supply to young persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>- If a young person (aged &lt;16 years) requests treatment for Chlamydia, then they must be assessed for competency. If they are deemed as being ‘Fraser Competent’ then a supply can be made, but this must be documented in the records. Pharmacists must use their professional judgement when considering ‘Safeguarding’ issues related to sexual activity in young persons.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Management of excluded patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Explain reasons for exclusion and document all details in the clients PharmOutcomes record</td>
</tr>
<tr>
<td>- Refer to local sexual health clinic (0300 123 0994) or the clients GP</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Management of patients requiring referral</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Female client with pelvic pain, consider immediate referral to Sexual Health Clinic (0300 123 0994). If pain severe, refer to local A&amp;E department</td>
</tr>
<tr>
<td>- Symptoms suggestive of other STI – consider immediate referral to Sexual Health Clinic</td>
</tr>
<tr>
<td>- Male client with scrotal pain, consider immediate referral to local A&amp;E department</td>
</tr>
<tr>
<td>- If vomiting occurs within 2 hours of taking initial dose, refer to Sexual Health Clinic or GP for re-evaluation.</td>
</tr>
<tr>
<td>- Document referral details in patient records and/or PharmOutcomes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Action for patients not wishing to receive care under this PGD</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Give client opportunity to discuss non-concordance.</td>
</tr>
<tr>
<td>- Refer to client’s own GP or Sexual Health Clinic (0300 123 0994) clinic.</td>
</tr>
<tr>
<td>- Ensure client is aware of implications of not having treatment</td>
</tr>
</tbody>
</table>
### Treatment and Drug details

<table>
<thead>
<tr>
<th>Name form and strength of medicine</th>
<th>Azithromycin 250mg / 500mg Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Legal classification</strong></td>
<td>POM – Prescription only medicine.</td>
</tr>
<tr>
<td><strong>Black triangle warning</strong></td>
<td>No</td>
</tr>
<tr>
<td><strong>Method of obtaining supply</strong></td>
<td>Licensed supplier, Community Pharmacies</td>
</tr>
<tr>
<td><strong>Site for treatment</strong></td>
<td>Accredited Community Pharmacies</td>
</tr>
<tr>
<td><strong>Route / method</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Dose</strong></td>
<td>A single 1 gram dose followed by 500mg ONCE DAILY for TWO days (i.e. course of treatment taken over 3 days)</td>
</tr>
<tr>
<td><strong>Number of times treatment may be administered</strong></td>
<td>Once only, in any three month period. (A second course of treatment may be offered in the case of possible re-infection. Sexual intercourse (including oral sex) should be avoided until the client and their partner(s) have completed treatment (or waited 7 days after treatment with azithromycin). Clients presenting within three months from previous treatment should be referred to GP or Sexual Health Services</td>
</tr>
<tr>
<td><strong>Quantity to be supplied or administered</strong></td>
<td>Either 8 x 250mg tablets or 4 x 500mg tablets</td>
</tr>
<tr>
<td><strong>Labelling Requirements</strong></td>
<td>Medication should be issued directly to client, Pack must be individually labelled, Labels must have the following information. - Client name, Date of supply, Full details of medication supplied, Quantity, Directions for use, Address of Pharmacy, Contact details Pharmacy, The words ‘keep out of children’s reach’ or words of similar meaning, The wording ‘Supplied via PGD’ should also be added to the label.</td>
</tr>
<tr>
<td><strong>Caution / need for further advice</strong></td>
<td><strong>Significant renal impairment</strong>: No dose adjustment is necessary in patients with mild to moderate renal impairment (GFR 10–80 ml/min). Caution is advised in patients with severe renal impairment (GFR &lt; 10 ml/min) as systemic exposure to azithromycin may be increased</td>
</tr>
</tbody>
</table>

**NB** label and supply the entire treatment course, however the initial 1 gram Azithromycin dose should be taken at the time of the consultation.
azithromycin, the use of azithromycin should be undertaken with caution in patients with significant hepatic disease.

**Clients with cardiac arrhythmia:** Prolonged cardiac repolarisation and QT interval, imparting a risk of developing cardiac arrhythmia and torsades de pointes, have been seen in treatment with other macrolides. A similar effect with azithromycin cannot be completely ruled out in patients at increased risk for prolonged cardiac repolarisation. Therefore caution is required when treating patients:

- With congenital or documented acquired QT prolongation.
- Currently receiving treatment with other active substances that prolong QT interval.
- With electrolyte disturbance, particularly in cases of hypokalaemia and hypomagnesaemia
- With clinically relevant bradycardia, cardiac arrhythmia or severe cardiac insufficiency.

**Allergic reactions** As with other macrolides, rare serious allergic reactions including angioneurotic oedema and anaphylaxis have been reported alongside dermatological reactions

**Pseudomembranous colitis** has been reported following use of macrolide antibiotics. This diagnosis should therefore be taken into consideration in patients who develop diarrhoea after starting treatment with azithromycin.

### Side effects

**Metabolism and Nutrition Disorders**
- Anorexia

**Nervous System Disorders**
- Dizziness, headache, paraesthesia, dyspepsia

**Eye Disorders**
- Visual impairment

**Ear and Labyrinth Disorders**
- Deafness

**Gastrointestinal Disorders**
- Diarrhoea, abdominal pain, nausea, flatulence, vomiting, dyspepsia

**Skin and Subcutaneous Tissue Disorders**
- Pruritus and rash

**Musculoskeletal, Connective Tissue Disorders**
- Arthralgia

**General disorders**
- Fatigue

**Haematological Investigations**
- Lymphocyte count decreased, eosinophil count increased, blood bicarbonate decreased

All serious adverse reactions must be reported to MHRA via the Yellow Card System [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk)

A client presenting with a suspected serious ADR should be referred to their GP.

### Drug interactions

**Warfarin**
- Occasionally and unpredictably, the effects of warfarin may be markedly increased by macrolides.
  - Monitor the international normalized ratio (INR), and adjust the warfarin dose accordingly.
**Statins**
The manufacturer reports post-marketing cases of rhabdomyolysis in people taking azithromycin with statins, although this appears to be less common than with other macrolides.
- Advise the person to report any muscle pain, tenderness, or weakness.
- Advise the person not to take their dose of statin on the same day as taking azithromycin.

**Ciclosporin**
Azithromycin can affect clearance of ciclosporin. If co-administration of these drugs is necessary, ciclosporin levels should be monitored and the dose adjusted accordingly.

**Drugs that prolong the QT interval (such as amiodarone, sotalol, terfenadine, and amisulpride)**
All macrolides can prolong the QT interval, and concomitant use of drugs that prolong the QT interval is not recommended.

**Drugs that cause hypokalaemia (such as diuretics, corticosteroids, short-acting beta-agonists)**
Hypokalaemia is a risk factor for QT prolongation.

Please refer to current BNF [http://bnf.org/bnf](http://bnf.org/bnf) and SPC [www.medicines.org.uk/emc](http://www.medicines.org.uk/emc) for full details

**Advice to patient**
- Tablets should be swallowed whole with plenty of fluids, advise no food for one hour after taking tablets.
- Take either 4 x 250mg tablets or 2 x 500mg tablets as a single dose with a glass of water. The remaining daily doses should be taken at the same time each day, starting the day after the 1g dose has been taken.
- Advise on common side effects including gastrointestinal upset and skin rashes
- Avoid indigestion remedies for a few hours either side of the azithromycin dose
- Advise patient to return if s/he experiences vomiting within 3 hours of taking dose
- For clients taking oral contraceptives, if they do experience vomiting or diarrhoea after taking azithromycin tablets, this may lead to contraceptive failure. Refer to the instruction leaflet included with the relevant oral contraceptive pill to manage the risk of contraceptive failure. There is no interaction between azithromycin and oral contraceptives; the warning is related to the risk of vomiting/diarrhoea after taking azithromycin
- Discuss implications of incomplete treatment of client or partner
- Give leaflet on condom use and safer sex
- Client should be advised to abstain from unprotected sex (vaginal/anal/oral and genital contact) during treatment and for one week after treatment has been completed and should continue to refrain from unprotected sex until one week after partner has completed treatment.
- Patients should be advised to seek urgent medical attention if they develop early symptoms of anaphylaxis such as breathlessness, swelling or rash.
- All patients with confirmed chlamydia infection should be encouraged to be screened for other sexually transmitted infections.
- All patients with confirmed chlamydia infection should be advised to contact their local sexual health clinic for partner notification purposes.
- Provide Azithromycin product information leaflet
- Provide contact details for sexual health clinic.
  Shropshire Sexual Health Clinic Tel No: 0300 123 0994
### Follow up
- No follow up required unless reaction to medication in which case the patient should return promptly to the GP.
- If any symptoms persist the patient should be reviewed by a doctor/senior nurse in 2 weeks.
- All patients with confirmed chlamydia infection should be advised to contact their local sexual health clinic for partner notification purposes.

### Suspected Adverse reactions
- Patient presenting with suspected adverse drug reaction should be referred to a doctor for further investigations.
- All adverse reactions should be reported to the MHRA, using the yellow ADR card system available in the BNF. [www.yellowcard.mhra.gov.uk](http://www.yellowcard.mhra.gov.uk)

### Error reporting
- Any incidents or near miss issues must be reported via the organisation's internal reporting system.

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### RECORD KEEPING

#### Documentation needed / treatment records to be kept for audit purposes
- Enter all consultation details onto the relevant Pharmoutcomes module
  - Patient’s name, address, date of birth
  - Manufacturer / brand of product, batch number, expiry date
  - Record of informed consent
  - Date of supply
  - Quantity supplied
  - Advice given to client
  - Details of pharmacist who supplied
  - Details of any adverse drug reactions, and action taken

Any paper recorded consultations must be entered onto the Pharmoutcomes module within 48 hours

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### REFERENCES
- BNF Current Edition [https://www.bnf.org/](https://www.bnf.org/)
- Management of uncomplicated genital chlamydia ([https://cks.nice.org.uk/chlamydia-uncomplicated-genital#!scenario](https://cks.nice.org.uk/chlamydia-uncomplicated-genital#!scenario))
- Azithromycin Product SPC [www.medicine.org.uk](http://www.medicine.org.uk)
### Register of practitioners qualified to supply

#### Azithromycin

**under this Patient Group Direction**

<table>
<thead>
<tr>
<th>Name of clinical manager / GP Lead</th>
<th>Signature of clinical manager / GP Lead</th>
<th>Date:</th>
</tr>
</thead>
</table>

A copy of this page should be retained by the authorising manager for 25 years for audit purposes.

**Please state clinical area where this PGD is in use**

---

**Healthcare professional individual declaration**

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD:

- **PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.**
  - It is the responsibility of each professional to practice only within the bounds of their own competence.
  - All practitioners operating in accordance with this PGD should have a current, signed copy of it readily available for reference.
  - If a practitioner is asked to supply, or administer a medicine not covered by this or any other PGD then a patient specific direction is required from a doctor, dentist or independent prescriber.

<table>
<thead>
<tr>
<th>Name of professional (please print)</th>
<th>Signature</th>
<th>Authorising Manager (Must sign against each entry)</th>
<th>Date of authorisation</th>
</tr>
</thead>
</table>

Healthcare professionals working under a PGD must have received appropriate training and been assessed as competent to administer/supply the medicine referred to in the PGD. The clinical lead should review competency of authorised practitioner/s at least annually. Training certificates must be available for inspection.

**Authorisation to use this PGD does not remove inherent professional responsibility and accountability**

A copy of this authorisation form must be printed off, signed and dated by the healthcare professional authorised to use this PGD. This should be retained by the service provider (e.g. GP practice) and readily available for inspection (e.g. CQC).
Appendix 1

The Fraser Guidelines (in the context of treatment for STI)

- The young person understands the advice and has sufficient maturity to understand what is involved.

- That the doctor/nurse could not persuade the young person to inform their parents, nor allow the doctor/nurse to inform them.

- That the young person would be very likely to begin or continue having sexual intercourse with or without treatment for the infection.

- That without treatment, the young person’s physical or mental health would suffer.

- That it would be in the young person’s best interest to give such advice or treatment without parental consent.

- Under 16s have a right to confidentiality whether asking for advice on STIs or any medical treatment.

(Adapted from the Family Planning Association Fact-sheet No 12, 1997)