



Patient Group Direction for the administration or supply of

**Azithromycin as part of
 Chlamydia Screening Programme
 By Pharmacist or Nurse**

Developed in partnership with the Sexual
 Health Service (Gloucestershire)

Authorisation of Supply or Administration

**Practice/Pharmacy
 locality name and address:**

Sanger House
 5220 Valiant Court
 Gloucester Business Park
 Brockworth
 Gloucestershire
 GL3 4FE

This document has been written and authorised on the understanding that it remains
 in its entirety with no additions, omissions or alterations

Prepared By: The Countywide Patient Group Directions Working Party

Date Direction Comes Into Force: 1.04.2016

Date Direction Expires: 31.03.2018

Chief executives should ensure that any current or new PGDs comply with new legal
 requirements and the guidance set out in circular HSC 2000/026

Version number	Change details	Date
2016 - 2018	<ul style="list-style-type: none"> • Addition of new NMC Code 2015 • Additional information around competent children declining to provide consent • Records section updated • Interactions list updated • Additional information regarding excipients of tablet form • NMC consent reference added • BNF for children reference added • BASHH guidelines and links added • Removal of reference to young person's Sexual Health Services Assessment and the template • Change to CCG/GCC signature section 	March 2016
2014 - 2016	Reviewed/updated	

Purpose of the Patient Group Directions (PGDs)

To enable a nurse or pharmacist (or other specified healthcare professional) who has received specific, appropriate training and has been assessed as competent to administer drugs in accordance with the following patient group direction and recommendations issued by The Medicines and Healthcare Products Regulations Agency 2014 - Patient group directions: who can use them, The Code: Professional standards of practice and behaviour for nurses and midwives (2015) and the NMC Standards for Medicines Management (2008) and the NMC Guidelines for Record Keeping (2007) or GPhC Standards of Conduct, Ethics and Performance July 2012 for Pharmacists and Pharmacy Technicians. <http://www.pharmacyregulation.org/standards>

The PGDs may be adopted for use by General Practice Surgeries, for practice nurses to use. This PGD must be signed off by the Pharmacy Clinical Governance Lead to authorise its use within the pharmacy

All information contained within this document was correct at the time of going to press. It is acknowledged that systems and processes change over time and that new drugs may be introduced. As licences vary, if a new brand is introduced it will not necessarily be covered within its corresponding PGD. If there are changes to practice, or the need for more PGDs to be developed, please contact the Head of Medicine Management at NHS Gloucestershire Clinical Commissioning Group (CCG).

For full product information please refer to the appropriate Summary of Product Characteristics (SPC) or visit the website at: www.emc.medicines.org.uk

Clinic manager/clinical governance lead agreement:

(For all premises other than community pharmacies)

Medical approval for the supply/administration of oral Azithromycin under PGD within the following setting:

I,, (name of clinic manager/clinical governance lead for clinic/surgery), give authorisation on behalf of:

(Clinic site/location).....

Signature Date.....

All Departments/Pharmacy Contractors should retain a 'fully signed' copy (both signatures ie Clinical Governance Lead and trained PGD user (below) for their files.

NOTE: All GP surgeries should also return a copy of this signed off page to

*Karen Pitney,
Public Health Outcome Manager
Gloucestershire County Council
Shire Hall
Westgate Street
Gloucester
GL1 2TG*

Tel 01452328611 or email: karen.pitney@gloucestershire.gov.uk

Individual Nurse/ Pharmacist Agreement:

By signing this Patient Group Direction (PGD) you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligation or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence. You cannot delegate tasks under this PGD to anyone else.

If this is an update or replacement PGD please ensure that all older versions are withdrawn from use with immediate effect.

It is your responsibility to make sure you are using the current version.

- I have read and understood the Azithromycin Patient Group Direction, and agree to administer/issue it as detailed in the PGD within(site/location).
- I agree that I fulfil the professional and additional criteria specified in the PGD and am competent to operate under this PGD
- By agreeing to act as an authorised practitioner under this PGD I am extending my role but this extension has not been a compulsory requirement.

NAME OF NURSE OR PHARMACIST AND REGISTRATION NUMBER	SIGNATURE	DATE	LOCATION(S)

Please note: All practitioners using the PGD should retain a 'fully signed' copy for their personal use/files.

The signatures required to comply with a 'fully signed copy' are:

1. The signature of the practitioner themselves (above)
2. The signature of the Clinical Governance Pharmacist for the Pharmacy (page 9) or Clinical Governance Lead for the GP surgery premises (page 2). This demonstrates the PGD has been approved for use at each location.

All Departments/Pharmacy Contractors should retain a 'fully signed' copy (both signatures as above) of the PGD for their files and/or this should be sent on to the head of service for their reference.

To The Pharmacy Contractor:

All Pharmacies should return a fully completed copy of page 9 and Appendix 1 (Page 12) to:

*Karen Pitney,
Public Health Outcome Manager
Gloucestershire County Council
Shire Hall
Westgate Street
Gloucester
GL1 2TG*

Tel 01452328611 or email: karen.pitney@gloucestershire.gov.uk

Patient Group Direction for:
Azithromycin as part of Chlamydia screening programme

Developed in partnership with the Sexual Health Service (Gloucestershire)

1. Medicine details

Medicine name	Azithromycin
Form (eg. tabs, inj, etc.)	Tablets or capsules (subject to the local agreement)
Strength	250mg (tablets or capsules) and 500mg (tablets)
Dose including frequency	1G as a single dose (this may be given as 4 x 250mg tablets or capsules or 2 x 500mg tablets)
Legal category (POM, GSL or P)	POM
Route of administration	<p>Oral - self administration</p> <p>Tablets: Dose to be taken in the presence of the nurse or pharmacist irrespective of last meal.</p> <p>Capsules: Note: In the case of capsules being supplied please confirm patient has empty stomach (i.e. at least 1 hour before and 2 hours after food) if stomach is not empty consider using tablets. If the dose is not taken immediately an original pack of Azithromycin should be supplied using pharmacy supplied stock (NOTE: If the patient decides to take the capsules away, and is not usually exempt from prescription charges the NHS fee will apply. Therefore as immediate treatment onsite is preferable – consider tablets where possible, or discuss options with patient.) Add the patient's name, directions for use (if not already on the label) and date supplied to the label of the pack and record issue.</p>
Duration of treatment	Single dose
Administration details	<ul style="list-style-type: none"> • Tablets may be taken with or without food. • Capsules should be taken on an empty stomach i.e. at least 1 hour before or if recently eaten leave a gap of at least 2 hours after food. (See notes above) • Avoid indigestion remedies for two hours either side of taking this medicine
Storage instructions	<ul style="list-style-type: none"> • Keep in a secure dry place below 25 °C • Protect from light • Use only if within expiry date
Potential adverse reactions <i>Consult the BNF for a more comprehensive list of potential ADRs and for a full list, the manufacturers Specification of Product Characteristics (SPC) available at www.emc.medicines.org.uk</i>	<p>Very common (>10% incidence): Diarrhoea, abdominal pain, nausea, flatulence</p> <p>Common (1- 10% incidence): Vomiting, , dizziness, headache, anorexia, dyspepsia, fatigue, parathesia, taste disturbance, pruritus, rash, arthralgia</p>
Management of adverse reactions	<p>If an adverse reaction occurs:</p> <ul style="list-style-type: none"> • Stop treatment • Inform patient's GP as soon as possible • Document details • Notify GP • The nurse/pharmacist should report any reaction to the MHRA (Medicines & Healthcare Products Regulatory Agency), using the yellow card system via the following link: http://yellowcard.mhra.gov.uk/

2. Administration/supply criteria

Clinical area	GP Surgery or Community Pharmacy
Clinical condition or situation	At the request of the Chlamydia Screening Office/Sexual Health Services following a positive result for Chlamydia as part of the National Chlamydia Screening Programme.
Eligibility criteria	<p>For all clients the following must be fulfilled in addition to the other criteria:</p> <ul style="list-style-type: none"> • Persons weighing 45kg (7st 1lb) or more <p>Other eligibility criteria:</p> <ol style="list-style-type: none"> 1. Any persons aged 15 - 24 years taking part in the Chlamydia screening programme that has a positive test. 2. Any person aged 15-16 years only eligible if appropriate assessment of competence has been made. (See separate assessment form below on page 12) 3. Partners of positive index patients (any age). These people must undertake a Chlamydia test to enable additional sexual contacts to be traced and treated 4. Patients who have already been treated but who vomited dose within 3 hours and attend for re-treatment
Exclusion criteria	<ul style="list-style-type: none"> • Partners of positive index patients who decline a test. • Persons weighing 45kg (7st 1lb) or less • Patients not on the Chlamydia screening programme • Anyone under 16 who has not had appropriate assessment of competence • Anyone under 15 years -refer to a doctor • Any medicine known to interact with Azithromycin including drugs known to prolong QT interval • Complicated chlamydial infection in males e.g. epididymo-orchitis • Complicated chlamydia infection in females e.g. pelvic inflammatory disease • Porphyria • Myasthenia Gravis • Previous history of cardiac arrhythmia • Hepatic impairment • Renal impairment • Allergy to Azithromycin or any other macrolide antibiotic e.g. erythromycin • Allergy to any of the excipients of the preparations. (NOTE: Some brands of Azithromycin tablets contain soya lecithin which might be a source of soya protein and should therefore not be taken by patients allergic to soya or peanut due to the risk of hypersensitivity reactions please check SPC as appropriate before supplying tablets. Azithromycin capsules do not contain soya protein.)
Cautions - seek further advice	<p><u>Pregnancy (known or suspected):</u> Cannot be given. Refer patient to Gloucestershire Sexual Health Services.</p> <p><u>Breast feeding:</u> Transmitted dose is less than licensed dose in neonates and infants-discuss treatment with Gloucestershire Sexual Health Services</p> <p><i>Gloucestershire Sexual Health Services:0300 421 6500</i> (Continued)</p>

<p>Cautions - seek further advice (continued)</p>	<p>Drug interactions:</p> <ul style="list-style-type: none"> • Absorption of Azithromycin reduced by antacids – Avoid indigestion remedies for two hours either side of Azithromycin dose. • Coumarin anticoagulants (possible enhanced anticoagulant effect) • Reboxetine (avoid concomitant use) • Mizolastine (avoid concomitant use) • Artemether with lumefantrine (avoid concomitant use) • Artemimol with piperazine (avoid concomitant use – piperazine has long half-life; there is a potential for drug interactions to occur up to 3 months after piperazine has been stopped- see BNF) • Droperidol (risk of ventricular arrhythmias) • Quetiapine (reduce dose of quetiapine) • Sertindole (avoid concomitant use) • Ritonavir (may increase plasma concentration of Azithromycin) • Digoxin (increased risk of toxicity of digoxin) • Colchicine (increased colchicine toxicity) • Ergotamine and methysergide (avoid concomitant use) • Theophylline (caution but no definite interaction) • Ciclosporin (increased plasma concentration of ciclosporin) • Bromocriptine & cabergoline (increased risk of toxicity of these two drugs) • Oral typhoid vaccine (Antibacterials should be avoided for 3 days before and 3 days after oral typhoid vaccination) • Astemizole and alfentanil (caution but no definite interaction) • Disopyramide (increased risk of toxicity) • Lomitapide – separating administration from Azithromycin by 12 hours advised by manufacturer of lomitapide • Rifabutin (increased risk of side effects including neutropenia) • Atorvastatin and Simvastatin – possible increased risk of myopathy
<p>Action to be taken for patients excluded from, declining or not adhering to the treatment</p>	<ul style="list-style-type: none"> • Patients who decline treatment should have the consequences of this decision explained (A child who is considered to be Fraser Competent can also refuse consent providing it is clear they understand consequences of refusal following an appropriate risk assessment) • Document refusal or informed dissent <p>Patients excluded from PGD should be referred to:</p> <ul style="list-style-type: none"> • Gloucestershire Sexual Health Services (0300 421 6500) • Patient's GP. <p>(Please note - Cheltenham services: The Milsom Centre replaces the sexual health service previously provided from two clinics in Cheltenham General Hospital, alongside the genito-urinary medicine clinic in Benhall and the family planning clinic in St Pauls. The Milsom Centre, 8 Milsom Street, Cheltenham, Glos. GL50 4BA Sexual Health Central Booking Line: 0300 421 6500</p> <p>NB Adults are classified as 18 years of age or over</p>

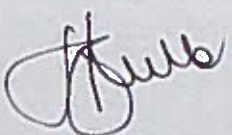
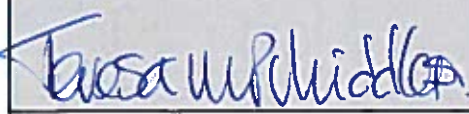
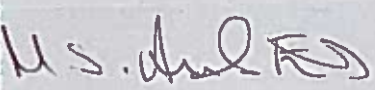
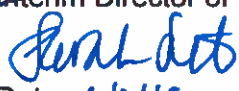
<p>Advice to be given to patient or carer <i>Provide patient information leaflet where available</i></p>	<ul style="list-style-type: none"> • Explain treatment and any follow-up needed • Inform patient of possible side effects • All patients should be advised to abstain from all sexual contact (vaginal, oral and anal) including using condoms for 7 days and until 7 days after their partners have been treated. • If patient vomits within 3 hours of taking medication then they should be advised to re-attend for retreatment or seek re-treatment via GP or Contraception and Sexual Health Services.
<p>Referral arrangements</p>	<p>Contact the appropriate doctor on call or Gloucestershire Sexual Health Services or GP (see above) if more information or advice needed</p>
<p>Consent</p>	<p>All women for whom treatment is proposed should give their valid consent to treatment at the time of administration. Written consent or documented verbal consent must be obtained before the supply of Azithromycin. A record of consent must be maintained for all patients</p> <p>For consent to be valid, the patient or person with parental responsibility must:</p> <ul style="list-style-type: none"> • be competent to take the particular decision • have received sufficient information to take it • not be acting under duress <p>Anybody aged 18 years or over (adult) is assumed to be capable of making decisions unless there is reasonable doubt.</p> <p>Anybody aged 16 years or 17 years (young person) is also assumed to be capable of making decisions unless there is reasonable doubt. If the requirements for valid consent are met, it is not legally necessary to obtain consent from the person with parental responsibility for the young person. It is however good practice to involve the young person's family in the decision making process, unless the young person specifically wishes to exclude them. If a person aged 16 or 17 years gives valid consent to treatment the person with parental responsibility cannot override that consent.</p> <p>Anybody less than 16 years of age (child) is not automatically assumed to be capable of making decisions. That capacity to make decisions is related to their maturity and level of understanding in relation to each decision, rather than their age. Anybody less than 16 years of age (child) who is considered competent in accordance with the Fraser Guidelines and understands fully what is involved in their proposed procedure can give valid consent and additional consent by a person with parental responsibility is not required. The decision of a competent child to accept treatment can then not be over-ridden by the person with parental responsibility for the child. It is however good practice to involve the child's parents in the decision making process, but take into account the wishes of a competent child about that involvement.</p> <p>The refusal of treatment by a patient less than 18 years of age might be overruled even if he/she is competent, if the treatment is deemed in his/her best interest. Anyone who lacks capacity is treated in his or her best interests.</p>

Consent (continued)	<p>Only people with 'parental responsibility' are entitled to give consent on behalf of their children until they achieve Fraser competence.</p> <p>Healthcare professionals need to carefully document the consent that is obtained. Any queries need to be discussed with an experienced colleague or sexual health services.</p> <p>For further guidance please refer to the Department of Health document consent for examination or treatment (second edition) DH 2009. Gateway reference 11911 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653_1_.pdf</p> <p>GPhC guidance on consent Feb 2014 http://www.pharmacyregulation.org/sites/default/files/gphc_guidance_on_consent_2014.pdf</p> <p>Or the Nursing Midwifery Council (NMC) guidelines for professional practice Reference guide to consent for examination or treatment, second edition 2009 : Department of Health - Publications</p>
Records required (To also allow audit trail)	<ul style="list-style-type: none"> • Issue must be recorded on PMR (or similar) or GP computer system.
Records for Community Pharmacy (to also allow audit trail)	<ul style="list-style-type: none"> • A record of administration - In the case of capsules i.e. at least 1 hour before and 2 hours after food • Patient/Partner Management Form should be completed and sent back to the Chlamydia Screening Office • Issue must be recorded on PMR (or similar) and on PharmOutcomes. <p>Claims are triggered (or generated) via PharmOutcomes proforma. <i>Patient medical records must be kept for 8 years, or if under 16 years until aged 25.</i></p> <p>Complete a Young Persons' risk assessment for all individuals under 16 years on PharmOutcomes proforma.</p>
Records for Dispensing Practice Nurses or other Nurses where Azithromycin is provided.	<p>A record of administration / supply should be made on patient medication record. This should include:</p> <ul style="list-style-type: none"> • Name or clinic number and date of birth • Address • Date of consultation • Consent • Date and time of administration • Name and form of drug • Batch number and expiry date • Dose and route of administration • Side effects (if any) • Contra-indications and medical advice given (oral and written) • GP details if relevant • Referral arrangements

3. Characteristics of staff

Professional group	Pharmacist or Nurse with current registration
Additional personal criteria	<p>All practitioners must be:</p> <ul style="list-style-type: none"> • Contracted through a Service Agreement with Gloucestershire County Council or Gloucestershire CCG • Practice Nurses within Gloucestershire (where PGD has been adopted by the surgery) <p>All practitioners must have read and understood, and act in accordance with:</p> <ul style="list-style-type: none"> • The Medicines and Healthcare Products Regulations Agency 2014 - Patient group directions: who can use them • The Code: Professional standards of practice and behaviour for nurses and midwives (2015) • The NMC Standards for Medicines Management (2008). • The NMC Standards for the Administration of Medicines for all nursing staff (or equivalent from GPhC) • The GPhC Standards of Conduct, Ethics and Performance Sept 2012 relevant to this direction, for all pharmacists <p>In addition practitioners must have:</p> <ul style="list-style-type: none"> • Signed the signature sheet for the PGD • All professionals must have completed an approved Chlamydia Screening training programme and be prepared to accept this delegated role. • Keep up-to-date with changes to recommendations for medicines covered by this PGD <p>Follow link below for the NICE competency framework for people working under PGDs GPG2 Patient group directions: competency framework for health professionals using patient group directions (23 January 2014)</p>

4. Signatures

	NHS Gloucestershire CCG Clinical Chair Date 12/4/16 Dr Helen Miller
	NHS Gloucestershire CCG Deputy Director of Quality Teresa Middleton Date 12/4/16
	NHS Gloucestershire CCG Executive Nurse and Quality Lead Dr Marian Andrews-Evans Date 12/4/16
	Interim Director of Public Health Gloucestershire County Council  Sarah Scott Date 4/4/16
To Pharmacy Contractor: Please ensure this is signed by appropriate pharmacist and send a copy of this page and a completed copy of Appendix 1 to Karen Pitney at Shire Hall (page 12)	Clinical Governance Pharmacist (for the Pharmacy) Name (print)..... Signature..... Date.....

Bibliography

- BNF latest on line version
 BNF for children latest on line version
 British Association for Sexual Health and HIV (BASHH) Guidelines
<http://www.bashh.org/BASHH/Guidelines/Guidelines/BASHH/Guidelines/Guidelines.aspx>
 The BASHH CEG 2015 summary guidance on tests for Sexually Transmitted Infections (Updated December 2015)
 The Medicines and Healthcare Products Regulations Agency 2014
<https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them>
 Nursing and Midwifery Council: Standards for Medicines Management 2008
<http://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/nmc-standards-for-medicines-management.pdf>
[http://www.ukmi.nhs.uk/filestore/ukmiamt/Guide to NeLM 20 pages.pdf](http://www.ukmi.nhs.uk/filestore/ukmiamt/Guide%20to%20NeLM%2020%20pages.pdf)
 Summary of Product Characteristics (SPC) <http://emc.medicines.org.uk>
<http://www.doh.gov.uk>
 The Code Professional standards of practice and behaviour for nurses and midwives (2015)
<http://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/revised-new-nmc-code.pdf>
<http://www.nice.org.uk>
 GPhC Standards of conduct, ethics and performance-
https://www.pharmacyregulation.org/sites/default/files/standards_of_conduct_ethics_and_performance_july_2014.pdf
http://www.npc.nhs.uk/non_medical/resources/patient_group_directions.pdf
 NHS Gloucestershire Clinical Commissioning Group Policies

Membership of the PGD Working Group

Teresa Middleton	NHS Gloucestershire CCG Deputy Director of Quality
Helen Miller	NHS Gloucestershire CCG Clinical Chair
Marion Andrews-Evans	NHS Gloucestershire CCG Executive Nurse and Quality Lead
Karyn Probert	NHS Gloucestershire CCG Clinical Learning and Development Manager
Liz Ponting	NHS Gloucestershire CCG Senior Quality and Development Manager

Additional advice from:

Evelyne Beech	Special Interest Pharmacist - Gloucestershire Local Pharmaceutical Committee.
Louise Plumridge	Specialist Pharmacist HIV & Sexual Health Gloucestershire Care Services NHS Trust

Appendix 1

Template form for completion by Pharmacy Contractor with regard to the PGD for Azithromycin

To The Pharmacy Contractor:

Until PharmOutcomes is operational please ensure the following are sent to Karen Pitney at Shire Hall (see below):

- Copy of completed page 10 of the PGD for Azithromycin tablets
- Copy of this page

Name of Pharmacist (print)	GPhC registration number	Date of training or approval by Chlamydia Screening Programme	Signature

This page - requires the name, registration number, date of training and signature of pharmacist(s) employed by you who and will be providing Azithromycin (where appropriate) under the Service Agreement.

Name and Address of Premises:

*Karen Pitney,
Public Health Outcome Manager
Gloucestershire County Council
Shire Hall
Westgate Street
Gloucester
GL1 2TG*

Tel 01452328611 or email: karen.pitney@gloucestershire.gov.uk