



Isle of Wight Clinical Commissioning Group

PATIENT GROUP DIRECTION

The supply of

Azithromycin 1g as a single dose

by registered community pharmacists
for patients aged under 25 years in receipt of a positive test result
to *Chlamydia trachomatis*
and for treatment of their contacts (Chlamydia Treatment Service)

In Community Pharmacy for Isle of Wight Public Health Commissioned Services

This Patient Group Direction (PGD) must only be used by registered Accredited Community Pharmacists who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Version number: 2

Change history

Version number	Change details	Date
1	Draft reformatted to standard template format & update of information to current standards	08/06/2015
2	Review	2018

PGD approval date/ Valid from:	1.4.2018
CCG implementation date:	1.4.2018
Review date:	1.1.2020
Expiry Date:	31.3.2020



Azithromycin PGD Accountability Record

PGD Review Group

Name	Job title and organisation	Signature	Date
Lead author	Caroline Allen Deputy Head of Medicines Management	<i>Caroline Allen</i>	13.18
Lead pharmacist	David France Medicines Management Pharmacist	<i>D.S. France</i>	1.3.18
Community Pharmacist	Richard Butler		

PGD Authorisation

This Azithromycin PGD has been approved and authorised for use by:

CCG Clinical Approval

Name	Authorising Professional	Signature	Date
Dr Oommen John	Clinical Commissioning Group (CCG) Clinical Governance lead	<i>[Signature]</i>	9/3/18
Melanie Rogers	CCG Director of Nursing and Quality	<i>[Signature]</i>	23/2/18
Tracy Savage	CCG Assistant Director of Medicines Optimisation / PGD Lead	<i>[Signature]</i>	27/2/18

Verifying the PGDs on behalf of Isle of Wight Council Public Health

Dr Sallie Bacon	Director of Public Health Isle of Wight Council	<i>[Signature]</i>	29/03/2018
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Provider Organisation (adoption if needed)

	Name	Authorising Professional	Signature	Date
On behalf of Community Pharmacy company		Manager of healthcare professional		

Please note:

Individuals signing as the 'manager of the healthcare professionals using the PGD' have the responsibility to ensure **ALL** staff working to the PGD legally recognised to do so. Staff should be trained and competent, and their competency should be regularly updated

Training and competency of registered Pharmacists

	Requirements of registered Pharmacists working under the PGD
Qualifications and professional registration	Registration with General Pharmaceutical Council of Great Britain (GPhC)
Initial training	<ul style="list-style-type: none"> • Completion of education in both the legal and professional aspects of PGD administration and the supply of medicines using: <ul style="list-style-type: none"> ○ GPhC codes of Professional Conduct ○ Legal framework of PGD's ○ Medicine, Ethics and Practice: Royal Pharmaceutical Society (RPS) ○ Successful completion of self-assessment of competency form in the use of this medicine for the indications stated • The Pharmacist must complete electronic declaration (enrolment) via PharmOutcomes, by clicking on azithromycin PGD tab.
Competency assessment (CPPE Declaration of Competence)	<p>College of Pharmacy Postgraduate Education (CPPE) distance learning:</p> <ul style="list-style-type: none"> • CPPE Chlamydia testing and treatment workshop: https://www.cppe.ac.uk/programmes//chlamydia-k-05..... Currently not available • CPPE e-learning Sexual health in pharmacies: https://www.cppe.ac.uk/programmes//sexual-e-01 • CPPE e-assessment Sexual health in pharmacies: https://www.cppe.ac.uk/programmes//sexual-a-10/ • CPPE e-learning Dealing with difficult discussions: https://www.cppe.ac.uk/programmes//diffdisc-e-01/ • CPPE e-assessment Dealing with difficult discussions: https://www.cppe.ac.uk/programmes//diffdisc-a-01/ • CPPE e-learning Safeguarding children and vulnerable adults: https://www.cppe.ac.uk/programmes//safegrding-e-0... • CPPE e-assessment Safeguarding children and vulnerable adults level 2 2018: https://www.cppe.ac.uk/programmes//safegrdingl2-a...
Additional requirements	<ul style="list-style-type: none"> • Access to supplies of Azithromycin 250mg Tablets • Access to British National Formulary • Organisational policy on operating under PGD's
Ongoing training and competency	<ul style="list-style-type: none"> • All pharmacists are accountable for maintaining and improving their professional knowledge and competence. • This must be demonstrated in accordance with the GPhC codes of professional conduct

Retain a copy of each version of the Patient Group Direction for ten years. A copy of this PGD should be given to the CCG, Public Health at IOW council, the healthcare professional(s) listed above, their manager(s) and the original is to be retained by the Prescribing Advisor/ Manager.

PGD

The supply of Azithromycin 1g by Pharmacists for Chlamydia Treatment in Community Pharmacy for Isle of Wight NHS services

Clinical condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>Uncomplicated genital <i>Chlamydia trachomatis</i> infection and sexual contacts of confirmed Chlamydia trachomatis infection as diagnosed by a positive NAAT test.</p>
<p>Inclusion criteria</p>	<ul style="list-style-type: none"> • Male or Female clients aged between 13 and 24 with laboratory evidence of <i>Chlamydia trachomatis</i> following screening and have been referred to the Community pharmacy for treatment under this PGD. • Sexual contacts age 13 and above of clients with a positive genital Chlamydia result who have been referred to/returned to the Community Pharmacy for treatment/advice following notification of positive result to the index patient. • To re-treat clients who vomited within two hours of taking original medication for the treatment of Chlamydia • Informed consent has been given • For Clients aged under 16 the conditions of the Fraser Guidelines must be understood and met
<p>Exclusion criteria</p>	<p>Absolute contraindications to use:</p> <ul style="list-style-type: none"> • Client presenting without an IWCSF number • Known allergies to azithromycin or macrolide antibiotics or any excipient • Under 13 years of age refer such clients to local child protection/safeguarding services • Under 16 years of age and assessed as not competent using Fraser guidelines refer such clients to local child protection/safeguarding services • Client aged under 16 years weighing less than 45kg • Age 25 or greater (unless a sexual contact of a client with a positive genital Chlamydia result who has been referred by the Chlamydia Screening Programme) • Breastfeeding • Established pregnancy – Refer to Sexual Health service for referral to Midwife/Health Visitor. • History of cardiac disease (including arrhythmia, electrolyte disturbances, and concomitant use of drugs that prolong the QT interval) and known cardiac disorder • Hepatic impairment • Renal impairment • Myasthenia Gravis • Porphyria • Concomitant conjunctivitis and/ or joint pain <p>If there is any uncertainty, seek specialist advice:</p> <ul style="list-style-type: none"> • Presence of genital tract symptoms:



	<ul style="list-style-type: none">○ Male clients with scrotal pain or penile discharge○ Female clients with acute pelvic / lower abdominal pain or pelvic inflammatory disease, intermenstrual or post-coital bleeding○ Urinary symptoms such as stinging when passing urine○ Unusual vaginal discharge and/ or bleeding● Complicated presentations:<ul style="list-style-type: none">○ Pelvic Inflammatory Disease (PID)○ epididymo-orchitis○ rectal chlamydia infection - rectal discharge, bleeding or pain. (Doxycycline is preferred treatment if there is evidence of rectal infection).● Known HIV or immunosuppression
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PGD

<p>Cautions (including any relevant action to be taken)</p>	<p>Cautions</p> <ul style="list-style-type: none"> • Patients with severe renal impairment. <p>Consider the possibility of sexual abuse in any child or young person with chlamydia, particularly in the following circumstances:</p> <ul style="list-style-type: none"> • The young person is 13–15 years of age, unless there is clear evidence that the STI was acquired from consensual sexual activity with a peer. • The young person is 16–17 years of age and there is no clear evidence that the STI was acquired from consensual sexual activity and/or there is a clear difference in power or mental capacity between the young person and their sexual partner, or there is concern that the young person is being exploited. • If sexual abuse is suspected, follow appropriate child protection procedures and refer to a paediatrician if necessary.
<p>Arrangements for referral for medical advice</p>	<ul style="list-style-type: none"> • Refer to registered GP, under 25 sexual health clinics or the sexual health service for further advice and support as soon as possible. • Use PharmOutcomes referral service to the sexual health service. • Explain reasons for medical advice with client and document on PharmOutcomes. • All under 16s are strongly encouraged to be referred to the Young People’s Sexual Health Nurse at the IOW NHS Trust through PharmOutcomes if client consents.
<p>Action to be taken if patient excluded</p>	<ul style="list-style-type: none"> • Refer to registered GP, under 25 sexual health clinics or the sexual health service for further advice and support as soon as possible. • Use PharmOutcomes referral service to the sexual health service. • Explain reasons for exclusion with client and document on PharmOutcomes. • All under 16s are strongly encouraged to be referred to the Young People’s Sexual Health Nurse at the IOW NHS Trust through PharmOutcomes if client consents.
<p>Actions to be taken if patient declines treatment</p>	<ul style="list-style-type: none"> • Advise patient of need for treatment. • Refer to registered GP or alternative provider of sexual health services. • All under 16s are strongly encouraged to be referred to the Young People’s Sexual Health Nurse at the IOW NHS Trust through PharmOutcomes if client consents.

Details of the medicine/ Description of treatment

Name, form and strength of medicine <i>Include ▼ for black triangle medicines</i>	Azithromycin (as dihydrate) [4 x 250mg Tablets]
BNF Chapter Category	5.15
Legal category	POM – Prescription only medicine
Indicate any off-label use (if relevant)	Not Applicable
Dose and frequency	4 x 250mg tablets (1gram dose) as a single dose To be swallowed whole on an empty stomach (1hr before food or 2 hours after food) not to be taken at same time as indigestion remedies - take at least 1 hour before or two hours after the antacid.
Route/method of administration	Oral
Total Quantity to be administered and/or supplied	One single dose. Administration under supervision highly recommended.
Maximum or minimum treatment period	Single dose
Adverse events and side effects	<p>Please refer to most current BNF for full details. Azithromycin is generally well tolerated. Gastro-intestinal side-effects are mild and infrequent.</p> <p>Common or very common abdominal discomfort, diarrhea, nausea, vomiting, anorexia, arthralgia, disturbances in taste, disturbances in vision, dizziness, dyspepsia, flatulence, headache, malaise, paraesthesia, reversible hearing loss (sometimes with tinnitus) after long-term therapy</p> <p>Uncommon cholestatic jaundice, hepatotoxicity, rash, anxiety, chest pain, constipation, gastritis, hypoaesthesia, leucopenia, oedema, photosensitivity, sleep disturbances</p> <p>Rare antibiotic-associated colitis, arrhythmias, pancreatitis, QT interval prolongation, Stevens-Johnson syndrome, toxic epidermal necrolysis agitation</p> <p>Frequency not known</p>

	<p>reversible hearing loss (sometimes with tinnitus) can occur after large doses acute renal failure, convulsions, haemolytic anaemia, interstitial nephritis, smell disturbances, syncope, thrombocytopenia, tongue discoloration</p> <p><i>For full list of Adverse Drug reactions (ADR's) see British National Formulary (BNF)/ Summary of Product Characteristics (SmPC)</i></p> <p>Note: Single dose Azithromycin is unlikely to cause any significant drug interaction.</p>
<p>Records to be kept</p>	<p>The following will be recorded on PharmOutcomes in the patient records:</p> <ul style="list-style-type: none"> • The diagnosis (Chlamydia) • Treatment recommended (Azithromycin tablets 250mg) • Quantity supplied (4) • Batch number and expiry date • Name of manufacturer • Duration of treatment (1 dose) • Date of supply • Name of the individual assessing the patient and making the supply <p><i>Copies of records and consent forms must be kept for 2 years Information must be sent to the GP for entry into the patients records</i></p> <p>Document any allergies and other adverse drug reactions clearly in the patient records and inform GP and other relevant practitioners/ carers for further reporting and action if needed.</p> <p>Completion of dedicated PharmOutcomes data capture with additional record entry in PMR. All referrals and notifications MUST be transmitted to Specialist Sexual Health Service as directed.</p> <p>The pharmacist must keep a record of the consultation for at least 8 years for an adult and 25 years for a child or for 8 years after death.</p>

Procedure for reporting Adverse Drug Reactions (ADRs)

All ADRs/ significant events/ near misses occurring in relation to the administration of this medicine under the PGD must be reported in the clinical record and the CCG incident reporting system. The GP must be informed and, in a case requiring hospital admission or resulting in serious harm, the incident reported on a yellow card to the Committee on the Safety of Medicines (CSM) - <http://www.bnf.org/bnf/bnf/current/yellow.htm>.

Client information

Verbal advice / offer of written information for client

Azithromycin patient information leaflet (PIL) provided including information:

- Take azithromycin one hour before food or two hours after food, and not at the same time as antacids (either 1 hour before or two hours after). Supervised administration is recommended.
 - If vomiting occurs within 3 hours of taking tablets the client should return for re-evaluation and the steps outlined under the 'action if excluded' section should be followed.
 - Warn of risk of GI upset and skin rash
 - Avoid direct exposure to sunlight, UV light or sunbeds.
- **Advise that sexual intercourse (including oral sex / anal even with a condom) should be avoided until the person and their partner(s) have completed treatment (or waited 7 days after treatment with azithromycin).**
 - Warn that if sexual contact takes place after treatment with an untreated partner there is a risk of re-infection.
 - Discussion regarding safer sex and condom use for future sexual health.
 - Advised regarding issues relating to pregnancy and child birth (if appropriate).
- Discuss implications of incomplete/ untreated infection of self or partner (check partner notification has taken place and document). Supply partner notification leaflet if appropriate, discuss and inform patient that the sexual health service will make contact in seven days to check compliance.
- All patients under the age of 16 years should be strongly encouraged to be referred to the Young People's Sexual Health Nurse at the IOW NHS Trust through PharmOutcomes if client consents.

Leaflets:

- **Provide written information on the natural history of chlamydia infection, its transmission, treatment, and possible complications.** A [patient information leaflet](#) is available from the British Association for Sexual Health and HIV (BASHH).
- **Provide written information on safer sex.** An information leaflet is available from the [Family Planning Association](#).

<p>Follow-up advice to be given to client</p>	<ul style="list-style-type: none">• Inform patient that the sexual health service will make contact in seven days to check compliance.• Advise patient to repeat chlamydia test via https://www.freetest.me/ in 3-6 months to check for re-infection.• Patient should seek medical advice if any symptoms recur or develop or they have any concerns.• Warn about risk of candidiasis in patients taking antibiotics.
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PGD

Appendix 1

Key References

1. Emc SmPC Azithromycin: <https://www.medicines.org.uk/emc/product/8427>
2. Emc Azithromycin PIL: <https://www.medicines.org.uk/emc/product/8427/pil>
3. British National Formulary (BNF) <https://bnf.nice.org.uk/drug/azithromycin.html>
4. World Health Organisation. WHO Guidelines for the Treatment of Chlamydia trachomatis 2016 <http://www.who.int/reproductivehealth/publications/rtis/chlamydia-treatment-guidelines/en/>
5. National Chlamydia Screening Programme (NCSP) <https://www.gov.uk/government/collections/national-chlamydia-screening-programme-ncsp>
6. British Association of Sexual Health and HIV (BASHH) 2015 UK National Guideline for the Management of Infection with *Chlamydia trachomatis* <https://www.bashhguidelines.org/media/1045/chlamydia-2015.pdf>
7. NICE Chlamydia - uncomplicated genital June 2016 <https://cks.nice.org.uk/chlamydia-uncomplicated-genital>
8. Sexwise Chlamydia information and leaflets 2016 https://sexwise.fpa.org.uk/stis/chlamydia?utm_campaign=fpa-redirect&fpa-redirect=1

Appendix 2

Pharmacist Payment

	Drug Tariff (Jan 2018)	PharmOutcomes
Pharmacist Clinical Consultation	£8.04	£30.00 (VAT exempt)

Appendix 3

PharmOutcomes

The system will factor invoices:

- £30.00 where 'Patient type' = Contact (VAT Exempt) (Professional Cons - Contact)
- £30.00 where 'Patient type' = Index (VAT Exempt) (Professional Cons - Index)
- DM&D cost where 'Azithromycin 1g supplied' = Yes plus VAT at Standard rate (Treatment Supplied)

The system will allow data to be entered and claimed for retrospectively for 5 months (Grace period = 6 months)

Appendix 4

FRASER RULING

For clients who are believed to be less than 16 years of age, the pharmacist will assess the client’s suitability for supply. Discussion with the young person should explore the following issues at each consultation. This should be fully documented and should include an assessment of the young person’s maturity.

ASSESSMENT OF FRASER RULING	YES	NO
Understanding of advice given:		
Encouraged to involve parents:		
The effect of physical or mental health of young person if advice/treatment withheld		
Action in the best interest of the young person:		

Pharmacist’s Signature:

Client’s signature:

Date:

The group direction is to be read, agreed to, and signed by all staff it applies to. One copy is to be given to the health professional, another kept in the department.



Appendix 5

Community Pharmacy Chlamydia Treatment Supply

