

This Patient Group Direction (PGD) must only be used by registered healthcare professionals 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.

PATIENT GROUP DIRECTION (PGD)

Supply of azithromycin for the treatment of uncomplicated Chlamydia trachomatis, uncomplicated Mycoplasma genitalium and non- gonococcal/non-specific urethritis in Brighton and Sussex University Hospitals NHS Trust Sexual Health & Contraception (SHAC) Service

Version Number 1.0

Change History	
Version and Date	Change details
Version 1 April 2020	New template

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	1 st April 2020
Review date	October 2022
Expiry date:	31 st March 2023

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the British Association for Sexual Health and HIV (BASHH) in April 2020.

This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation
Ali Grant	Highly Specialist Clinical Pharmacist: HIV, Sexual and Reproductive Health
Alison Crompton	Community pharmacy
Amanda Cooper	Associate Director Specialist Pharmacy Service
Andrea Smith	Community pharmacy
Carmel Lloyd	Royal College of Midwives
Chetna Parmar	Pharmacist adviser, Umbrella
Clare Livingstone	Royal College of Midwives
Deborah Redknapp	English HIV and Sexual Health Commissioners Group (EHSHCG)
Dipti Patel	Local authority pharmacist
Dr Achyuta Nori	Consultant in Sexual Health and HIV
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Dr John Saunders	Consultant in Sexual Health and HIV
Dr Kathy French	Pan London PGD working group
Dr Rita Browne	Consultant in Sexual Health and HIV
Dr Sarah Pillai	Pan London PGD working group
Emma Anderson	Centre for Pharmacy Postgraduate Education (CPPE)
Helen Donovan	Royal College of Nursing
Jo Jenkins (Woking Group Co-ordinator)	Specialist Pharmacist (PGDs) Specialist Pharmacy Service
Jodie Crossman	Specialist Nurse. BASHH SHAN SIG Chair
Jodie Walker-Haywood	Specialist Nurse, BASHH Board Nurse Representative, BASHH SHAN SIG Secretary
Leanne Bobb	English HIV and Sexual Health Commissioners Group (EHSHCG)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Portia Jackson	Pharmacist, Cambridgeshire Community Services
Sally Hogan	British Pregnancy Advisory Service (BPAS)
Sandra Wolper	Associate Director Specialist Pharmacy Service
Silvia Ceci	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service
Tracy Rogers	Associate Director Specialist Pharmacy Service

Approved date JUNE 2020

Expiry date 31 MARCH 2023

PGD approval - meets local need and guidelines

Name	Job title and organisation	Signature	Date
Lead author: Reproductive Health PGDs Short Life Working Group	As listed on Page 2/3		
Lead Doctor: Dr Juliet Bowie	Associate Specialist, SHAC Service, BSUH	Email approval	02/07/20
Lead pharmacist: Claire Richardson	Lead Pharmacist, HIV & Sexual Health Service, BSUH	Email approval	07/07/20
Antimicrobial specialist: Elizabeth Harries	Antimicrobial Pharmacist, BSUH	Email approval	04/06/20
Lead Clinician for area: Dr Debbie Williams	Consultant (HIV & GUM), SHAC, BSUH	Email approval	02/07/20
Reviewed by: Dr Daniel Richardson	Consultant HIV & SHAC Service, BSUH	Email approval	01/07/20
Representative of other professional group using PGD: Wendy Gardiner	Advanced Nurse Practitioner, SHAC Service, BSUH	Email approval	01/07/20

Organisational authorisations

Brighton & Sussex University Hospitals NHS Trust authorises this PGD for use by the services or providers listed below:
Sexual Health & Contraception (SHAC) Service.
Limitations to authorisation
Only Registered Nurses who work within the SHAC Service and are signed to the PGD.

Name	Signature & Name	Date
Chair of PGD Group	Joanne Pendlebury	Email approval 07/07/20
Chief Pharmacist	Mike Cross	Email approval 24/07/20
Medicines Governance Group chair	Mike Okorie	Email approval 27/07/20

Local enquiries regarding the use of this PGD may be directed to Bsuh.pgdgroup@nhs.net or PGD group chair.

Appendix 1 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD.

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1. Characteristics of staff

Qualifications and professional registration	<p>Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation.</p> <p>Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.</p>
Initial training	<p>The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patient leading to diagnosis of the conditions listed.</p> <p>Recommended requirement for training would be successful completion of a relevant sexual health module/course accredited or endorsed by the BASHH, CPPE, RCN or a university or advised in the RCN Sexual Health Education directory.</p> <p>The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults.</p> <p>Register and complete PGD training module (certificate can be printed out as evidence) https://portal.e-lfh.org.uk/ (3 yearly)</p> <p>Has undertaken training appropriate to recognise and manage allergic/anaphylactic reactions.</p> <p>Has undertaken appropriate Trust resuscitation training.</p>
Competency assessment	<ul style="list-style-type: none"> • Individuals operating under this PGD must be assessed as competent (see section 7) or complete a self-declaration of competence for Chlamydia testing and/or treatment. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	<ul style="list-style-type: none"> • Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation, including: <ul style="list-style-type: none"> ➤ PGD e-learning 3 yearly ➤ Up to date with mandatory training
<p>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.</p>	

2. Clinical condition or situation to which this PGD applies

<p>Clinical condition or situation to which this PGD applies</p>	<ul style="list-style-type: none"> • Uncomplicated genital, pharyngeal and/or asymptomatic rectal <i>Chlamydia trachomatis</i> infection • Non-gonococcal or non-specific urethritis (NGU, NSU). • Uncomplicated <i>Mycoplasma genitalium</i> following completion of course of doxycycline (see doxycycline PGD). • Asymptomatic individuals presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of with any of the conditions detailed below.
<p>Criteria for inclusion</p>	<ul style="list-style-type: none"> • Where doxycycline is contraindicated (known allergy, previous adverse effects, pre-existing medical conditions) or inappropriate (photosensitivity, likely poor adherence): <ul style="list-style-type: none"> ○ Individuals with a positive test for Chlamydia trachomatis infection in the genitals, rectum (asymptomatic) or pharynx but without signs suggestive of complications. ○ Individuals with a microscopic diagnosis of non-gonococcal or non-specific urethritis (NGU, NSU). ○ Asymptomatic individuals presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of chlamydia, NSU/NGU, PID or epididymo-orchitis who are unwilling/unable to defer testing after the 2 week window period. ○ A single repeat treatment course for individuals who have had sexual intercourse within 7 days of receiving treatment or who have had sex with partner untreated for the above conditions. • Individuals with a definite diagnosis of uncomplicated <i>Mycoplasma genitalium</i> where a course of doxycycline has been completed within the previous two weeks (where resistance testing is available, confirmed macrolide sensitivity). • Consent given. • Aged 13 years and over. All individual under the age of 19 years - follow local young person's risk assessment or equivalent local process.
<p>Criteria for exclusion</p>	<ul style="list-style-type: none"> • Consent not given. • Individuals under 13 years of age. • Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. <p>Medical history</p> <ul style="list-style-type: none"> • Individuals with suspected and/or confirmed symptomatic rectal Chlamydia. • Individual with complicated Chlamydia infection such as (epididymitis and/or testicular pain or a clinical diagnosis of Pelvic Inflammatory Disease (PID) • Individuals with suspected or confirmed Lymphogranuloma venereum (LVG) • Known severe hepatic impairment

	<ul style="list-style-type: none"> • Known severe renal impairment • Current/past history of cardiac rhythm or conduction disturbance • Presence of concomitant conjunctivitis and/or joint pain/swelling • Acute porphyria • Myasthenia gravis <p>Medication history</p> <ul style="list-style-type: none"> • Any concurrent interacting medicine(s) – see Section 4 Drug interactions. • Known hypersensitivity or allergy to the azithromycin or other tetracycline antibiotics or to any component of the product - see Summary of Product Characteristics • Individuals with known azithromycin resistance.
<p>Cautions including any relevant action to be taken</p>	<ul style="list-style-type: none"> • Some brands of azithromycin contain soya or soya lecithin and are therefore contraindicated in individuals with an allergy to soya or peanuts. If individual is allergic, check manufacturer’s information for brand being used and if necessary, exclude from PGD or select an alternative suitable brand if available. • Pregnant individuals/individuals known to be at risk of pregnancy – the SPC states that there is limited data on use in pregnancy however BASHH guidelines state: “While adverse pregnancy outcomes are unlikely with the 2g total azithromycin dose, individuals should be advised of the lack of data.” The individual must be informed that although the use of azithromycin in pregnancy is thought to be safe, there is limited research available and be fully informed of the risks and benefits of this treatment. • Breastfeeding individuals – BASHH states that ‘Very low levels of azithromycin are detected in breast milk, and systemic exposure in infants does not exceed that observed when azithromycin is administered for treatment, therefore risk is considered to be low’.
<p>Action to be taken if the individual is excluded or declines treatment</p>	<ul style="list-style-type: none"> • If declined ensure individual is aware of the need for treatment and the potential consequences of not receiving treatment. • Pregnant individuals/individuals known to be at risk of pregnancy who decline azithromycin treatment should be referred to a prescriber for further consultation. • Explain the reasons for exclusion to the individual and document in the consultation record. • Record reason for decline in the consultation record. • Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.

3. Description of treatment

<p>Name, strength & formulation of drug</p>	<p>Azithromycin 250mg or 500mg capsules or tablets or azithromycin 200mg/5ml Powder for Oral Suspension.</p> <p>NB: The treatments in this PGD are written according to</p>
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	national guidance, however the healthcare professional should also refer to the local formulary or other local supporting guidance for selection of the most appropriate preparation for the individual.
Legal category	POM
Route of administration	Oral
Off label use	<p>Best practice advice is given by BASHH and is used as the reference guidance in this PGD and may vary from the Summary of Product Characteristics (SPC).</p> <p>This PGD includes off label use in the following conditions:</p> <ul style="list-style-type: none"> • The dose of azithromycin stated in the BASHH guideline and therefore in this PGD is higher than the licensed dose. • Those under 18 years of age and under 45kg weight - azithromycin tablets or capsules are not licensed for use in children or adolescents weighing under 45 kg. • Breastfeeding individuals – BASHH states that 'Very low levels of azithromycin are detected in breast milk, and systemic exposure in infants does not exceed that observed when azithromycin is administered for treatment, therefore risk is considered to be low'. <p>Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management.</p> <p>Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.</p>
Dose and frequency of administration	<p>Day One: 1g taken as a single dose Day Two: 500mg once daily Day Three: 500mg once daily</p> <p>For uncomplicated Mycoplasma genitalium azithromycin course to be started immediately after the doxycycline course completed – where this is not achieved it must be started within 2 weeks of the doxycycline course being completed.</p>
Duration of treatment	3 days.
Quantity to be supplied	<p>Appropriately labelled pack of 4x500mg capsules/tablets or 8x250mg capsules/tablets or one bottle of reconstituted oral suspension.</p> <p>A single repeat course can be supplied under the PGD if vomiting occurs within 3 hours of a dose being taken.</p>

Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	<p>All concurrent medications should be reviewed for interactions. The interactions listed as severe in the BNF are:</p> <ul style="list-style-type: none"> • Colchicine • Digoxin • Edoxaban • Rifabutin • Talazoparib • Ticagrelor • Topotecan <p>A detailed list of all drug interactions is available in the BNF www.bnf.org or the product SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
Identification & management of adverse reactions	<p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org</p> <p>The following side effects are very common/common with azithromycin:</p> <ul style="list-style-type: none"> • Nausea • Anorexia • Vomiting • Dyspepsia • Dizziness • Headache • Diarrhoea • Abdominal pain/discomfort • Flatulence • Loose stools • Rash • Pruritus • Arthralgia • Fatigue • Visual impairment • Deafness • Paraesthesia • Dysgeusia
Management of and reporting procedure for adverse reactions	<ul style="list-style-type: none"> • Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via organisation incident policy.
Written information and further advice to be given to individual	<ul style="list-style-type: none"> • Give patient information leaflet (PIL) provided with the original pack. Explain mode of action, side effects, and benefits of the medicine • Verbal and written information on Chlamydia trachomatis/NGU/NSU/<i>Mycoplasma genitalium</i> treatment. • Azithromycin tablets can be taken at any time in relation to

	<p>food but there should be a gap between taking the tablets and antacids.</p> <ul style="list-style-type: none"> • Azithromycin capsules should be taken one hour before or two hours after food or antacids • If vomiting occurs within 3 hours of taking capsules/tablets offer option of repeat dose of azithromycin (under PGD). • Note relevant for <i>Mycoplasma genitalium</i>: Where doxycycline has been supplied for the treatment of uncomplicated <i>Mycoplasma genitalium</i> the individual should be advised that the azithromycin course should be started immediately after completion of the doxycycline course – where this is not achieved it must be started within 2 weeks of the doxycycline course being completed. If the azithromycin course is not completed within this time frame the individual should be referred to a specialist practitioner. • Discuss implications of incompletely treated/untreated infection of self or partner/s • Advise to abstain completely from sexual intercourse (even with condoms) including oral sex, during treatment, for seven days after treatment and for seven days after partner(s) treatment. Where not achievable advise on use of condoms. • Discuss risk of re-infection, and further transmission of infection, if after treatment sexual intercourse takes place with an untreated partner/s • Discuss partner notification and issue contact slips if appropriate • Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs) • Where treatment not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services.
<p>Follow up treatment</p>	<ul style="list-style-type: none"> • The individual should be advised to seek medical advice in the event of an adverse reaction. • Follow local protocol for chlamydia/<i>Mycoplasma genitalium</i> follow up and partner notification. • Individuals with chlamydia/<i>Mycoplasma genitalium</i> who have not had a full STI screen (or who did not have chlamydia/<i>mycoplasma genitalium</i> diagnosed in a sexual health clinic) should be advised to attend a sexual health clinic/service for a full STI screen. • Routine follow-up for uncomplicated <i>Chlamydia trachomatis</i> following treatment with azithromycin is unnecessary, except in the following situations where local protocols should be followed: <ul style="list-style-type: none"> ○ Pregnancy. ○ Where poor compliance is suspected. ○ Where symptoms persist. ○ Where LGV is suspected. ○ Rectal infections.
<p>Records</p>	<p>Record:</p> <ul style="list-style-type: none"> • The consent of the individual and if individual over 16 years

	<p>of age and not competent, record action taken</p> <ul style="list-style-type: none"> • Name of individual, address, date of birth • GP contact details where appropriate • Relevant past and present medical history, including medication history. • Examination or microbiology finding/s where relevant. • Any known allergies • Name of registered health professional • Name of medication supplied • Date of supply • Dose supplied • Quantity supplied • Advice given, including advice given if excluded or declines treatment • Details of any adverse drug reactions and actions taken • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Any referral arrangements made • Any supply outside the terms of the product marketing authorisation • Recorded that supplied via Patient Group Direction (PGD) <p>Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.</p> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
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Audit

Plan for audit , It is essential for PGD renewal that audits have occurred.	Service audit to be completed using the recommended BSUH PGD audit template. N. B. Individual PGD users should keep records to audit their own use of PGDs / procedures.
Frequency	Minimum of once in lifetime of PGD 2 years after start date of PGD to inform PGD review.
Nominated lead to manage audit	Advanced Nurse Practitioner, SHAC Service will manage Service PGD audit process and support / guide those completing the audit. SHAC Nurse(s) who use the PGD will complete the service audit.

4. Key references

Key references (accessed February 2020)	<ul style="list-style-type: none">• Electronic Medicines Compendium http://www.medicines.org.uk/• Electronic BNF https://bnf.nice.org.uk/• NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2• BASHH CEG September 2018 – Update on the treatment of <i>Chlamydia trachomatis</i> (CT) infection https://www.bashhguidelines.org/media/1191/update-on-the-treatment-of-chlamydia-trachomatis-infection-final-16-9-18.pdf• BASHH CEG September 2018 – Update on the treatment of <i>Chlamydia trachomatis</i> (CT) infection https://www.bashhguidelines.org/media/1191/update-on-the-treatment-of-chlamydia-trachomatis-infection-final-16-9-18.pdf• BASSH National Guidelines on the management www.bashhguidelines.org/media/1051/ngu-2015.pdf; www.bashhguidelines.org/media/1198/mg-2018.pdf• Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines• Learning for Health https://portal.e-lfh.org.uk/• BSUH policies and procedures:<ul style="list-style-type: none">➤ C085 – Policy for Patient Group Directions: accessed on BSUH intranet https://www.bsuh.nhs.uk/search/?q=c085+policy+for+patient+group+directions➤ SHAC Service Standard Operating Procedure for supply of medicines following telephone / video consultations
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Appendix A - Registered health professional authorisation sheet

PGD Name/Version: **Supply of azithromycin for the treatment of uncomplicated Chlamydia trachomatis, uncomplicated Mycoplasma genitalium and non-gonococcal/non-specific urethritis / Version 1**

Valid from: June 2020

Expiry: 31 March 2023

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Brighton and Sussex University Hospitals NHS Trust for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

Approved date JUNE 2020

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SHAC SERVICE RETENTION OF PGD AUTHORISATION RECORDS

Records of the authorisation of nurses for the use of this PGD are stored as follows:

- **HARD COPY:**

A paper copy of the signature sheet will be kept with the PGD in the PGD Master Copy File in the SHAC Nurse Management Office.

- **ELECTRONIC RECORD:**

- A scanned copy of each authorisation sheet to be saved.
- An electronic record of SHAC Nurse authorisation for this PGD will be stored on the SHAC Service PGD Assessment Record database.
- The scanned authorisation sheets and the database are stored in the shared Integrated Sexual Health file (within the specific PGD file).

- **INDIVIDUALS:**

Individual nurses are provided with the PGD assessment sheet which details the assessment process for PGD approval for their own records. A copy of this document is stored in the individual nurses' Personal File.