South Staffordshire & Shropshire Healthcare NHS
NHS Foundation Trust

PATIENT GROUP DIRECTION
FOR THE SUPPLY OF AZITHROMYCIN TABS/CAPS 250mg or TABS 500mg OR SUSPENSION 600mg/15mL FOR UNCOMPLICATED GENITAL *CHLAMYDIA TRACHOMATIS*, UNCOMPLICATED *NEISSERIA GONORRHOEA* INFECTIONS AND NON-GONOCOCCAL URETHRITIS

by registered nurses and midwives in Sexual and Reproductive Health services employed by South Staffordshire and Shropshire NHS Foundation Trust

This Patient Group Direction for use in South Staffordshire & Shropshire Healthcare NHS Foundation Trust and is authorised by:

Position of Signatory	Name	Signed	Date
Medical Director	Dr Abid Khan		
Chief Pharmacist	Cathy Riley		
Director of Quality & Clinical Performance	Therèsa Moyes		
Director of Nursing	Alison Bussey		

The named below, being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to supply azithromycin to patients in the Sexual and Reproductive Health Services under this Patient Group Direction

Name	Job Title	Signed	Date

This Patient Group Direction is operational from 1st October 2017.
Review date: August 2019. Expires on 31st October 2019.
Replaces PGD 2816/b

Professional Responsibility

All registered nurses and non medical prescribers being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to supply azithromycin as specified under this Patient Group direction following demonstration of the competencies below;

Professional Responsibility / Competencies

1. The registered nurse will have undertaken appropriate training in order to carry out clinical assessments of patient that requires treatment according to the indication listed in the PGD
2. Hold a recognised qualification in sexual health skills (ENB 267/BASHH competencies or equivalent post-registration qualification/in-house training/competency in STIs)
3. An introduction to sexual health is not sufficient
4. Has been assessed as competent to provide care and treatment of genital infections.
5. Has been assessed and achieved the required standard for sexual health
6. Is competent in the assessment of individuals using Fraser guidelines
7. Has undergone regular training and updating in safeguarding children and vulnerable adults
8. All nurses will have received training in the management and treatment of anaphylactic shock on an annual basis
9. Each nurse will keep a record in their professional portfolio of the updates attended during every 12 month period – This information will also form part of the team's annual training plan
10. The nurse will have due regard for the NMC Code of Conduct, Scope of Professional Practice and Standards for Medicines Management (Nursing & Midwifery Council)
11. Undertaken appropriate training and possess the competencies for working under PGDs for the supply and administration of medicines All registered nurses details and signature must be entered onto the PGD
12. Following administration a record of the date, strength, brand and dose of the medication should be recorded in the clients records and documented in the medicine card with PGD number recorded as authorisation

For full product information, always refer to the latest SPC (Summary of Product Characteristics).

If the anaphylaxis is related to a medication, please remember to report to the CSM, via a Yellow Card Report (http://emc.medicines.org.uk)

Supply/Administration of	AZITHROMYCIN 250MG CAPSULES OR TABLETS or AZITHROMYCIN 500MG TABLETS or AZITHROMYCIN SUSPENSION 600mg in 15mL
Legal Classification	Prescription Only Medicine
Black Triangle?	No
Type	Oral capsules, tablets or suspension
Storage	Supplies will be available from central stock location, pre-labelled with the correct dose and quantity by the pharmacy department. Details of service user name and date of issue must be completed on the label prior to supplying to the patient. Information leaflets must be given. Any relevant documentation must be completed.
Condition to be treated	• Uncomplicated genital *Chlamydia trachomatis* infection • Uncomplicated *Neisseria gonorrhoeae* infection (with Ceftriaxone) • Non-gonococcal urethritis (NGU) • Pharyngeal Chlamydia trachomatis infection
Inclusion Criteria	• Individuals aged 13 years or above • Individuals with a definite diagnosis of *Chlamydia trachomatis* • Individuals with a suspected or confirmed diagnosis of *Neisseria gonorrhoeae or* NSU/NGU • Sexual contacts of individuals with a positive chlamydia or gonorrhoea result or NSU or epididymo-orchitis or pelvic inflammatory disease (PID) • Re-treatment of an individual who has received azithromycin for the above indications but has vomited the dose within 3 hours of taking it • Individual who has had sexual intercourse within 7 days of receiving treatment for the above condition(s) or who has had sex with a partner untreated for the above condition(s)
Exclusion Criteria	**Personal characteristics** • Individuals aged under 16 years who are assessed as not competent using Fraser Guidelines • Adult dosages do not apply to children under 12 years of age and are therefore excluded

	Medical history • Males with epididymitis or testicular pain • Females with pelvic pain or suspected Pelvic Inflammatory Disease (PID) • Fever • Severe hepatic impairment • Severe renal impairment • Current/past history of cardiac rhythm disturbance • Presence of concomitant conjunctivitis and/or joint pain/swelling • Myasthenia gravis **Medication history** • Interacting medicines – Check Appendix 1 of current British National Formulary (BNF) • Currently receiving treatment with other active substances known to prolong QT interval • Known allergy or hypersensitivity to macrolide antibiotics or any constituent of the medication. If treating Chlamydia, consider alternative of doxycycline if appropriate • Some brands of Azithromycin use soya as an excipient, and are therefore contraindicated in individuals with an allergy to soya or peanuts. Check manufacturer's information for brand being used <u>Cautions:</u> • Choice of therapy: The treatments in this PGD are written according to national guidance, however you should also refer to your local formulary or other local supporting guidance for selection of the most appropriate preparation or regime for the individual • Perform sexually transmitted infection (STI) screen but give treatment at the same visit. <u>Do not wait for results.</u> • Discuss with appropriate doctor / independent nurse prescriber any medical condition/medicine of which the nurse is unsure/uncertain • If under 13 years of age follow local safeguarding policy • Individuals being treated for gonorrhoea should also receive Ceftriaxone (if appropriate – see separate PGD)
Action if excluded or patient declines	• Refer to appropriate doctor/ independent nurse prescriber

	• Document all actions taken • If individual declines ensure they are aware of the need for treatment and refer to appropriate doctor/ independent nurse prescriber • Record refusal in the clinical record
Reasons for seeking further advice from doctor	• Discuss with appropriate doctor/independent nurse prescriber any medical condition or medication of which the nurse is unsure • Should the patient meet any of the exclusion criteria
Administration Route	Oral
Dose	1g as a single dose, ideally taken as directly observed therapy <u>Quantity to Supply:</u> 250mg capsules or tablets (x4) or 500mg tablets (x2) or 25mL of the 600 mg in 15 mL suspension **NB: If treating SIMULTANEOUSLY for both chlamydia and gonorrhoea, this dose will cover both. Do not give twice.** **If individual is treated for** c**hlamydia on this visit and returns later for treatment for** g**onorrhoea, then administer again with ceftriaxone (if appropriate – see Ceftriaxone PGD)** **Children under 16 years** The Summary of Product Characteristics (SPC) for Zithromax® contains no specific dosage recommendations for the treatment of genital infections in children under 16 years. BNF for Children (BNF C) states that children aged 12-18 years may receive single 1g dose of azithromycin. Individuals must be informed that the medicine is being given outside the terms of the SPC and given the option of seeing a doctor/ independent nurse prescriber.
Administration Schedule	Single Dose
Warnings/Adverse Reactions	• **Common:** Nausea, vomiting, diarrhoea, anorexia, dyspepsia • **Less common:** Dizziness, headache, drowsiness, abdominal discomfort (pain/cramps) • **More rarely:** Allergic reactions including

	angioneurotic oedema, urticaria and photosensitivity; arthralgia, hepatitis, cholestatic jaundice, interstitial nephritis, constipation, renal failure, paraesthesia, tinnitus, insomnia, syncope, convulsions and taste disturbances Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for full list and further information. In the event of untoward or unexpected adverse reactions: • Document in the individual's clinical record and inform appropriate doctor/independent nurse prescriber • Complete incident procedure if adverse reaction is severe (refer to local organisational policy) Use the yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at http://yellowcard.mhra.gov.uk/
Advice/Management of Adverse Reactions & Follow-up Action	• Verbal and written information on *Chlamydia trachomatis* and/ or NGU and its treatment • Provide Manufacturer's patient information leaflet (PIL) • Discuss possible side effects of treatment as listed in PIL • Take Azithromycin capsules one hour before or two hours after food or antacids • Azithromycin tablets can be taken at any time in relation to food but there should be a gap between taking the tablets and antacids • If vomiting occurs within 3 hours of taking capsules/tablets offer option of repeat dose of Azithromycin (under PGD) or referral to appropriate doctor/ independent nurse prescriber for alternative treatment <u>Follow Up:</u> • **Pregnant women and chlamydia –** Offer test of cure 4 weeks after azithromycin treatment as per BASHH guidelines • **All genital infections including *Neisseria gonorrhoeae* –** follow local protocol for follow

	up and partner notification • Asymptomatic individuals may undergo test of cure if specified in local protocol
Use in pregnancy and lactation	**Pregnancy:** **Advise Pregnant women or women known to be at risk of pregnancy** • Azithromycin is not licensed to treat pregnant women, however BASHH guidelines state: "The safety of azithromycin in pregnancy and in lactating mothers has not yet been fully assessed, although available data indicate that it is safe • World Health Organisation (WHO) Guidelines recommend 1gm single dose to treat *Chlamydia trachomatis* in pregnancy • BNF recommends use of azithromycin in pregnancy and lactation only if no alternative available • The individual must be informed that although the use of Azithromycin in pregnancy is thought to be safe, there is limited research available. She must: o Be fully informed of the risks and benefits of this treatment o Be informed that this use is outside the terms of the SPC o Be informed of the availability of alternative treatment (erythromycin for 1 or 2 weeks) o Give verbal consent for use outside the terms of the SPC and this must be documented in the clinical record
Records	The nurse must ensure the following is documented in the clinical record: • Individual's name, address and date of birth • Attendance date • Reason for attendance • Past and present medical, including drug history • Family history • Any known allergy • Any advice given about the medication including side effects, benefits, how to use it and when and what to do if any concerns • Details of any adverse drug reactions and what action taken • Any referral arrangements • Any supply outside the terms of the Summary of

	Product Characteristics. • The consent of the individual • If individual is under 16 years of age document competency using Fraser guidelines • If individual is under 13 years of age record action taken. • Record the name of the medication, number of packs supplied with batch numbers and expiry dates according to local policy and record the PGD number • Record any follow up arrangements • Include the signature and designation of the nurse who supplied the medication (follow local procedures for computer records)