South Staffordshire & Shropshire Healthcare NHS
NHS Foundation Trust

PATIENT GROUP DIRECTION
FOR THE SUPPLY AND ADMINISTRATION OF CEFTRIAXONE INJECTION (RECONSTITUTED WITH LIDOCAINE 1% w/v INJECTION) BY INTRAMUSCULAR (IM) INJECTION FOR THE TREATMENT OF UNCOMPLICATED *NEISSERIA GONORRHOEAE* INFECTION

by Registered Nurses and Midwives in Integrated Sexual Health services employed by South Staffordshire and Shropshire NHS Foundation Trust

Penicillin allergic patients are excluded from this PGD

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 and administer ceftriaxone injection reconstituted with lidocaine 1% w/v injection to patients in Integrated Sexual Health Services under this Patient Group Direction

Name	Job Title	Signed	Date

This Patient Group Direction is operational from: 1st October 2017
Review date: Aug 2019. Expires on 31st Oct 2019
Replaces PGD3716

Professional Responsibility

All registered nurses and non medical prescribers being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to administer ceftriaxone injection 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. Qualification/training in sexual health (BASHH competencies or equivalent post registration qualification or in house training/competencies in STIs)
3. Has been assessed as competent to provide care and treatment of genital infections
4. Is competent in the use of Fraser Guidelines
5. Has undergone regular training and updating in safeguarding children and vulnerable adults
6. Is familiar with current BASHH guidelines on *Neisseria gonorrhoeae*
7. All nurses will have received training in the management and treatment of anaphylactic shock on an annual basis
8. 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
9. The nurse will have due regard for the NMC Code of Conduct, Scope of Professional Practice and Standards for Medicines Management (Nursing & Midwifery Council)
10. 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
11. 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	Ceftriaxone Injection (Reconstituted with lidocaine 1% w/v injection)
Legal Classification	Prescription Only Medicine
Black Triangle?	No
Type	Injection
Storage	Supplies will be available from central stock location. Information leaflets must be given. Any relevant documentation must be completed.
Condition to be treated	Uncomplicated *Neisseria gonorrhoeae* (GC) and contacts of gonorrhoea **NOTE:** In addition to ceftriaxone, azithromycin 1g single dose should be administered. Azithromycin should be given with ceftriaxone for treatment of gonorrhoea irrespective of results of chlamydia testing. Refer to appropriate PGD
Inclusion Criteria	**Personal Characteristics:** • Individuals suspected with a diagnosis of *Neisseria gonorrhoeae* based on microscopy (the presence of gram negative diplococci) • Sexual contact of individuals with a positive gonorrhoea result • Individuals who have had sexual intercourse within 7 days of receiving treatment or who have had sex with an untreated partner
Exclusion Criteria	**Personal Characteristics:** • Individuals under 13 years of age • Individuals aged under 16 years of age and assessed as not competent to consent using Fraser guidelines • Individuals aged 16 years and over and assessed as not competent using local safeguarding guidelines **Medical history:** • Males with epididymitis or testicular pain • Females with or suspected to have pelvic inflammatory disease • Three or more treated episodes of GC in the past 12 months • Severe hepatic impairment • Severe renal impairment

	• Proctitis
	• Risk factors for biliary stasis or biliary sludge
	• Intramuscular injection is contraindicated e.g.
	  ○ Known thrombocytopenia (low platelet count)
	  ○ Coagulopathy (bleeding tendency)
	  ○ Receiving treatment with anticoagulants
	• Contraindications to lidocaine e.g.
	  ○ Known cardiac arrthymias
	  ○ Complete heart block
	  ○ Hypovolaemia
	• Taking oral anticoagulants
	• Acute porphyria
	• Epilepsy
	• Individual is taking interacting medicines. Check Appendix 1 of current edition of the British National Formulary (BNF) for full list of interacting medicines for ceftriaxone **and** lidocaine
	• Known allergy or hypersensitivity to ceftriaxone and/or other cephalosporin antibiotics and /or known immediate or delayed hypersensitivity reaction to penicillins or other beta-lactam antibiotics (see current BNF for full list)
	• Known hypersensitivity to lidocaine and/or other anaesthetics of the amide type
	• History of renal lithiasis or hypercalciuria

Action if excluded or patient declines	Refer to appropriate doctor/independent nurse prescriber <u>If Patient Declines:</u> • Make individual 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	• Ensure emergency drugs and equipment are available for the treatment of emergencies, according to local protocol • Discuss with appropriate doctor/independent nurse prescriber any medical condition or medication for which the nurse is unsure/uncertain • Do not wait for test results before treating GC contacts
Administration Route	Intramuscular Injection

	Site is the outer upper quadrant of the buttock
Dose	Single injection of 500mg ceftriaxone reconstituted with lidocaine 1% w/v injection
Administration Schedule	Ceftriaxone injection (dry powder vial) reconstituted with Lidocaine 1% w/v injection The 500 mg dose will be given from either 2x250mg vials **or** HALF a 1g vial as follows: **Using 2x250 mg vials to administer 500mg** Each 250mg vial of ceftriaxone should be constituted with 1mL lidocaine 1% w/v injection. The entire contents of the two vials should be drawn up to give the total dose of 500mg to be administered. (The volume will be slightly more than 2 mL as there is a displacement value of 0.194mL for each 250mg vial) **Using HALF a 1g vial to administer 500 mg** The 1g vial should be reconstituted with 3.5mL lidocaine 1% w/v injection Administer 2.1mL of the resulting solution to give 500mg ceftriaxone Single use only. Discard any unused injection.
Warnings/Adverse Reactions	This list may not represent all reported side effects of these medicines. Refer to current Summary of Product Characteristics (SPC) of both products for full list and further information. **Ceftriaxone** **Common side effects** • Gastrointestinal – loose stools, nausea, vomiting Haematological reactions (e.g. anaemia) **Rare side effects** • Pain or discomfort at the site of intramuscular injection immediately after administration but is usually well tolerated and transient. **Lidocaine side effects** • Nausea and vomiting • Urticaria This list may not represent all reported side effects

	of these medicines. Warn of possible side effects of treatment as listed in the Patient Information Leaflets (PILs) for both ceftriaxone and lidocaine In the event of untoward or unexpected adverse reactions: • If necessary seek appropriate emergency advice and assistance • Document in the individual's clinical record and inform appropriate doctor/independent nurse prescriber • Complete incident report if adverse reaction is severe (refer to local organisational policy) • Use 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 www.yellowcard.mhra.gov.uk. The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.
Advice/Management of Adverse Reactions & Follow-up Action	• Provide Manufacturer's Patient Information Leaflet (PIL) and discuss • Explain mode of action, side effects, and benefits of the medicine • Verbal and written information on gonorrhoea • Discuss partner notification and issue contact slips if appropriate • Offer condoms and advice on safer sex practices <u>Follow Up:</u> According to local protocol
Use in pregnancy and lactation	**Women who are pregnant or known to be at risk of pregnancy must be fully informed of the following:** • The use of these medicines in pregnancy is outside the manufacturers' SPCs. She must formally give verbal consent to treatment outside the SPCs and this must be documented in the clinical record.

	• The risks and benefits of this treatment, including:
	  ○ That although the use of ceftriaxone in pregnancy is thought to be safe there is limited research available. Its use is recommended by current national guidelines
	  ○ Lidocaine can cross the placenta but the benefit of treatment is thought to outweigh the risk to pregnancy or leaving the GC untreated
	  ○ The availability of alternative treatment.
	  ○ She should see a doctor

Records	The authorised registered nurse must ensure the following is documented in the clinical record: • Individual's name, address and date of birth • GP contact details where appropriate • Attendance date • Reason for attendance • Relevant past and present medical and family history, including drug history • Any known allergy • Relevant examination findings (where appropriate) • Sites where swabs were taken from • A statement that supply or administration is by using a PGD and the PGD number recorded • Advice given about the treatment including side effects, benefits, and when and what to do if any concerns • Details of any adverse drug reactions and what action taken • Any referral arrangements • Any administration outside the terms of the product licence • The consent of the individual • If under 13 years of age, record action taken • If individual is under 16 years of age document competency using Fraser guidelines • Individuals aged 16 years of age or more and not competent, record action taken • Record the name/brand, dose and route/site of the medication and quantity supplied • Record batch number and expiry date according to local policy and national guidelines • Record follow up and/or signposting arrangements • Any other relevant information that was provided

	to the individual • Name and signature (which may be an electronic signature) of the nurse supplying or administering the medicines (follow local procedures for computer records)