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

PATIENT GROUP DIRECTION (PGD)

For the 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 BPAS clinics.

Version Number 2.1

Change History	
Version and Date	Change Details
1.0 July 2020	New template. *Version not used in BPAS.*
1.1 October 2020	Removed from criteria for inclusion: *Individuals who present with mucopurulent penile or cervical discharge where there is no access to microscopy facilities to diagnose GND.* Advisory wording added to inclusion criteria section: ***NOTE** – all criteria for inclusion within the BASHH approved national PGD templates for sexual health are based on diagnostic management in line with BASHH guidance. Where services do not have access to diagnostics and treatment is syndromic then the PGD template will need to be locally adapted to reflect local practice being mindful of the BASHH guidance.* Injection site specific administration information removed. *Version not used in BPAS.*
1.2 January 2022	For clarity 'For adults and children aged over 13 years weighing less than 50kg a dose of 1g must be split (i.e. two 500mg doses) and injected at different sites.' Removed from Dosing and frequency of administration section and replaced in updated Route of Administration section with 'Note ceftriaxone PGDs SPC states that up to 1g can be administered as a single IM injection. In adults and children aged over 13 years weighing <50kg consider splitting the dose and injecting at different sites to reduce discomfort.' Supporting reference added. *Version adapted for use in BPAS 09/05/23.*
2.0 April 2023	Updated template: adverse effects section revised. Minor formatting/wording changes to align with other SPS sexual and reproductive health PGD templates. *Version adapted for use in BPAS 09/05/23.*
2.1 June 2024	Clarified information related to interactions. Moved to cautions as no clinically significant interactions with ceftriaxone or lidocaine. Added advice on oral typhoid. Updated membership of SLWG. Added "current contract of employment with BPAS" to staff authorised. Additional facilities and supplies section added in line with SPS template

Valid from: 01/08/2024
Review Date: February 2026
Expiry Date: 30/06/26

N.B. Review and update may occur prior to this period if national guidance changes or legal or clinical issues arise.

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	1 July 2023
Review date:	February 2026
Expiry date:	30 June 2026

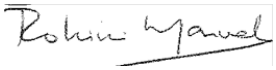
This PGD template has been peer reviewed by the Sexual Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the British Association for Sexual Health and HIV (BASHH)/BASHH Bacterial Special Interest Group (BSIG) in February 2023.

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

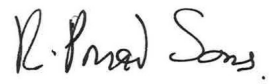
Name	Designation
Ali Grant	Highly Specialist Clinical Pharmacist: HIV, Sexual and Reproductive Health
Alison Crompton	Community pharmacy
Amy Moore	Principal Pharmacist The Wolverton Centre, Kingston Hospital NHS Foundation Trust
Chetna Parmar	Pharmacist adviser, Umbrella
Dipti Patel	Local authority pharmacist
Dr Achyuta Nori	Consultant in Sexual Health and HIV
Dr Cindy Farmer	Vice President, Professional Learning and Development Faculty of Sexual and Reproductive Healthcare (FSRH)
Dr John Saunders	Consultant in Sexual Health and HIV
Dr Rachael Jones	Consultant in HIV and Sexual Health, Chelsea, and Westminster NHS Foundation Trust
Dr Rita Browne	Consultant in Sexual Health and HIV
Emma Anderson	Centre for Pharmacy Postgraduate Education (CPPE)
Heather Randle	Royal College of Nursing
Rosie Furner (Working Group Co-ordinator)	Specialist Pharmacist – Medicines Governance, Medicines Use and Safety, Specialist Pharmacy Service
Jo Jenkins	Lead Pharmacist PGDs and Medicine Mechanisms, Specialist Pharmacy Service
Jodie Crossman	Specialist Nurse. BASHH SHAN SIG Chair
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee, Faculty of Sexual and Reproductive Healthcare (FSRH)
Portia Jackson	Pharmacist, Cambridgeshire Community Services
Sandra Wolper	Associate Director, Medicines Use and Safety, Specialist Pharmacy Service
Sim Sesane	CASH Nurse Consultant, MSI Reproductive Choices
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Vicky Garner	British Pregnancy Advisory Service (BPAS)
Ali Grant	Highly Specialist Clinical Pharmacist: HIV, Sexual and Reproductive Health

BPAS PGD Organisational Authorisations:

This PGD is not legally valid until it has had the relevant organisational authorisations below.

Name	Job title and organisation	Signature	Date
Mary Sexton	BPAS Clinical Director		19/08/2024
Dr Julie Miller	BPAS Deputy Medical Director		16/08/2024
Kalpesh Thakrar	BPAS Lead Pharmacist		30/07/2024
Prof Rohini Manuel	BPAS Consultant Microbiologist		29/08/2024

Authorising Body:

Cheshire and Merseyside ICB	*Rowan Pritchard-Jones*		*07/11/2024*

Responsible person who has approved this PGD on behalf of BPAS	Name: Heidi Stewart Position: BPAS Chief Executive Signature:  Date: 22/08/2024

Glossary	
BPAS	British Pregnancy Advisory Service
BASHH	British Association for Sexual Health and HIV
BLS	Basic life support
BNF	British National Formulary
GUM	Genitourinary medicine
IM	Intramuscular
MHRA	Medicines Health Regulatory Agency
NAAT	Nucleic Acid Amplification Testing
NICE	National Institute for Health and Care Excellence
NMC	Nursing and Midwifery Council
SmPC	Summary of medicinal product characteristics
STI	Sexually transmitted infection
TTO	To take out

1. Characteristics of staff authorised to use this PGD:	
Qualifications and professional registration	• NMC Registered Nurse • NMC Registered Midwife With a current contract of employment with BPAS Practitioners must also fulfil the additional requirements listed below.
Initial training	Pharmacological knowledge relating to the administration and supply of the medicine, its uses, contraindications, dosage, and adverse effects. Additionally, practitioners: • Must have completed appropriate training for working under a PGD for the supply / administration of medicines (see training requirements in the BPAS PGD policy) • Must be familiar with the medicine and observant to changes in the BNF and Summary of Product Characteristics (SmPC) • Must be competent in the recognition and management of adverse reactions, including anaphylaxis. • Must be competent in the administration of adrenaline for anaphylaxis and have up to date Basic Life Support (BLS) skills as a minimum. • Must have access to the PGD and the BPAS Sexually Transmitted Infection Testing and Results clinical policy and procedure • Must have completed BPAS STI Training available on the BPAS e-learning platform. • Further recommended training: e-Learning for Health e-Sexual and Reproductive Health 9. STIs • Must have completed required training (including updates) in safeguarding children and vulnerable adults. **The practitioner must be authorised by name, under the current version and terms of this PGD in the Approved Practitioner List before working to it.**
Competency Assessment	Practitioners working under this PGD are required to review their own competency using the NICE Competency Framework for Health Professionals using Patient Group Directions Practitioners working under this PGD must be assessed as competent or complete a self-declaration of competence to use this PGD (see appendix A). **Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines 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.**
Ongoing training and competency	• Practitioners must complete 3-yearly PGD Theory Refresher training and competency assessment. • Practitioners working under this PGD are responsible for ensuring they remain up to date with the use of the medicines and guidance included in

	the PGD, ensuring any training needs identified are addressed with further training. • Practitioners must make sure they are aware of any changes to the recommendations for this medication. • Practitioners must ensure they remain up to date with relevant clinical skills, management of anaphylaxis, BLS (as a minimum), with evidence of continued professional development. • Practitioners are responsible for maintaining their competency to work under this PGD
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policy.	

2. Clinical condition or situation to which this PGD applies:	
Clinical condition or situation to which this PGD applies	Treatment of individual with uncomplicated *Neisseria gonorrhoeae* infection
Inclusion criteria	Individuals who have a confirmed positive Nucleic Acid Amplification Testing (NAAT) for *Neisseria gonorrhoeae*
Exclusion criteria	• Clients not suitable for treatment at BPAS *(N.B. please refer to BPAS suitability criteria)* • **Personal characteristics** • Individuals under 13 years of age (Before the day of their 13th birthday) • Individuals aged under 16 years of age and assessed as not competent using Fraser guidelines. • Individuals aged 16 years and over and assessed as not competent to consent. ○ These individuals may still be able to receive ceftriaxone as treatment, but they must be referred to a prescriber to assess suitability and obtain a patient specific direction. **Medical history** • Known allergy or hypersensitivity to ceftriaxone and/or other cephalosporin antibiotics and/or known immediate or delayed hypersensitivity reaction to penicillin or other beta-lactam antibiotics. • Contraindications to lidocaine e.g. known cardiac arrhythmias, complete heart block, bradycardia, hypovolaemia. • Known hypersensitivity to lidocaine and/or other anaesthetics of the amide type. • Individuals with or suspected to have pelvic inflammatory disease. • Severe hepatic impairment or severe renal impairment (eGFR <10ml/min/Stage 5) • Intramuscular injection is contraindicated e.g. where individual has known thrombocytopenia (low platelet count) or coagulopathy (bleeding tendency) or is receiving treatment with anticoagulants. • Acute porphyria *(N.B. porphyria is a contraindication to treatment at BPAS – please refer to the BPAS Treatment Suitability Tool)* • Known epilepsy. • Known myasthenia gravis. • Less than 3 days before receiving, or within 3 days after receiving, oral typhoid vaccine

Cautions/Circumstances in which further advice should be sought (including any relevant action to be taken)	• If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented.
	• If the presenting individual is under 13 years of age the healthcare professional should speak to the Safeguarding team and follow the BPAS policy for local safeguarding policy for Safeguarding and Management of Clients Aged under 18 (note under 13 years of age excluded from treatment under this PGD).
	• **Individuals who are breastfeeding or pregnant and choosing to continue their pregnancy.** The individual should be informed of the following risks and benefits of this treatment:
	  ○ Breastfeeding – for further information refer to the BPAS clinical policy and procedure appendix: Recommendations for Breastfeeding Clients taking Medicines that may be excreted into Breast Milk
	  ○ That although the use of ceftriaxone in pregnancy is thought to be safe there is limited research available. However, its use is recommended by current BASHH guidelines.
	  ○ Lidocaine can cross the placenta, but the benefit of treatment is thought to outweigh the risk to the continuing pregnancy and the unborn of leaving the gonorrhoea untreated.
	  ○ The availability of alternative treatment options and referral to a prescriber if requested.
	• Discuss with appropriate prescriber or pharmacist any medical condition or medication of which the healthcare professional is unsure or uncertain.

Action to be taken if the individual is excluded or declines treatment	• If declined, ensure individual is aware of other treatment options, the need for treatment and potential consequences of not receiving treatment, including not being able to have an abortion procedure. • Record reason for decline in the client's clinical record. • Explain the reasons for exclusion to the individual. • Discuss with a clinic doctor, if not available, discuss with a Regional Clinical Director or refer to local NHS sexual health or genitourinary medicine (GUM) services as clinically indicated • Water for Injection may be used as the diluent if a client is lidocaine sensitive - a patient specific direction must be obtained. • Document reasons for decline/exclusion in the client's clinical record, including any advice given
Arrangements for referral for medical advice	• Inform and discuss with the doctor in clinic. If not available, discuss with either a regional clinical director or refer to local NHS sexual health or GUM services as clinically indicated. • In the event of a medical emergency, e.g., anaphylaxis, provide immediate care in line with UK Resuscitation Council guidance, dial 999 to summon a paramedic response and initiate emergency transfer to NHS care. • Document findings/action taken in individual's record

3. Description of treatment:	
Name, strength and formulation medicine	Ceftriaxone injection (dry powder vial) reconstituted with lidocaine 1% w/v injection. The 1g dose will be given from either 4x250 mg vials or 1 g vial as follows: **Using 4x250 mg vials to administer 1 g:** Each 250 mg vial of ceftriaxone should be reconstituted with 1mL lidocaine 1% w/v injection. The entire contents of the four vials should be drawn up to give the total dose of 1 g to be administered. **Using 1 g vial:** The 1 g vial should be reconstituted with 3.5 ml lidocaine 1% w/v injection. **Displacement values:** it is the responsibility of the practitioner to check the manufacturer's literature for displacement values, to ensure that the correct dose is administered. Discard any unused injection.
Legal category	POM
Route / method of administration	• Deep intramuscular injection • Note ceftriaxone PGDs SmPC states that up to 1 g can be administered as a single IM injection. In adults and children aged over 13 years weighing <50 kg considers splitting the dose and injecting at different sites to reduce discomfort.
Indicate any off-label use (if relevant)	The indication for use and dose of ceftriaxone stated in this PGD are taken from the British Association for Sexual Health and HIV (BASHH) guideline. Not all available licensed ceftriaxone products include this indication/dose within their licence and as such use may be off label. 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 BPAS medicines management team must be consulted. Where medicines have been assessed by the medicines management team 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 the medicines management team. 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.
Dose and frequency of administration	1 g administered as a single (stat) dose

Duration of treatment	One episode of treatment
Total quantity to be administered	Administration Using 4 x 250 mg ceftriaxone vials: 1 g ceftriaxone with 4 ml of 1% lidocaine **OR** Using 1 x 1 g ceftriaxone vial: 1 g ceftriaxone with 3.5 ml of 1% lidocaine
Storage	Stock must be securely stored in accordance with the BPAS Medicines Management policy and in conditions in line with the SmPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Drug interactions	There are no **clinically significant** interactions listed in the BNF where concurrent use should be avoided for either medicine included in this PGD. Therefore, there are no exclusions to administration under this PGD due to interactions. However, all concurrent medications should be reviewed for interactions and advice sought from an appropriate clinician/Medicines Advisory Service if required. A detailed list of all drug interactions is available in the BNF www.bnf.org or the product SmPC, which is available from www.medicines.org.uk
Additional facilities and supplies	• Access to working telephone. • Suitable waste disposal facilities • Immediate access to in-date anaphylaxis kit (IM adrenaline 1:1000)

Identification and management of adverse reactions	A detailed list of adverse reactions is available in the SmPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org
	
	The following side effects are common with ceftriaxone/lidocaine (but may not reflect all reported side effects):
	
	Ceftriaxone
	• Gastrointestinal – loose stools, nausea, vomiting
	• Haematological reactions (e.g. anaemia)
	• Localised injection site reaction
	
	Lidocaine
	• Gastrointestinal – nausea, vomiting
	• Urticaria
	• Localised injection site reaction
	• CNS effects include:
	  ○ Confusion
	  ○ Respiratory depression
	  ○ Convulsions
	  ○ Hypotension
	  ○ Bradycardia
	  ○ Dizziness
	If overdose or severe reaction suspected, discontinue use and if necessary, seek appropriate emergency medical advice and assistance.

Management and reporting procedure for adverse reactions	Document any adverse effects in the client's clinical records. If necessary, seek appropriate emergency medical advice and assistance as clinically indicated.

	Serious adverse drug reactions should be reported to the MHRA via https://yellowcard.mhra.gov.uk/ Adverse drug reactions must also be reported via Datix, including drug name, strength, formulation, batch numbers and expiry dates.
Written information and further advice to be given to the individual or carer	**Medication:** • Offer patient information leaflet (PIL) provided with the original pack. Explain mode of action, side effects, and benefits of the medicine • Advise the individual to stay within the department/clinic for 10-15 minutes following administration of ceftriaxone injection. Advise that they will experience a numbing sensation at the injection site due to concurrent administration of lidocaine as a diluent and the effects will gradually wear off after 1-2 hours. **Condition:** • Refer to the BPAS Sexually Transmitted Infection Testing and Results clinical policy and procedure • Provide BPAS guide to STI testing booklet and relevant BPAS individual information booklet relevant to their treatment, including Aftercare • Discuss implications of incompletely treated/untreated infection of self or partner(s). • Abstain completely from sexual intercourse (even with condom) including oral sex, for 7 days and for 7 days after partner(s) treated and follow up is complete. • 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 the need for screening for sexually transmitted infections (STIs) • Ensure the individual has contact details of local sexual health services

Follow-up advice to be given to the individual or carer	• Inform the individual/carer of possible side effects and their management.
	• The individual should be advised to seek medical advice in the event of an adverse reaction.
	• Individuals who have not had a full STI screen should be advised to attend an appropriate service for a full STI screen.
	• Individuals should be advised to attend (face to face or remotely) a sexual health clinic 2 weeks following treatment for:
	  ○ test of cure
	  ○ retaking the sexual history to explore the possibility of re-infection.
	  ○ pursuing partner notification and health promotion

Records to be kept	The following must be recorded in the individual records in line with the NMC Code and BPAS' Record Keeping policy, using black ink if written:
	• The consent of the individual and
	  ○ If individual is under 13 years of age record action taken
	  ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent, record action taken.
	  ○ If individual over 16 years of age and not competent, record action taken.
	• If individual not treated under PGD, record action taken.
	• Individual's name, date of birth, any known allergies

	• Indications for use, patient inclusion, or exclusion from PGD, relevant past and current medical and sexual history, including medication history. • Name of medication, dose administered. • Site of injection • Batch number and expiry date of administered injections. • Examination including individual's weight (details if <50kg on split dosing) • Date and time of administration. • Any actions taken following administration. • Signature, printed name and designation of registered health professional administering and detail of double checking • Advice given about the medication including side effects, benefits, and when and what to do if any concerns. • Advice given, including advice given if excluded or declines treatment. • Details of any adverse drug reactions and actions taken • Any referral arrangements made. • Any administration outside the terms of the product marketing authorisation • Detail that medicine administered using a PGD. **Records should be signed and dated (or a password-controlled e-records) and securely kept for a defined period in line with local policy.** **All records should be clear, legible, and contemporaneous.** **A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.**

4. References and other source material:

- British Association for Sexual Health and HIV (BASHH) (2019) Guidelines Management of gonorrhoea in adults, 2019 https://www.bashhguidelines.org/current-guidelines/urethritis-and-cervicitis/gonorrhoea-2018/
- Electronic Medicines Compendium Ceftriaxone 1 g powder for solution for injection or infusion - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) (Last updated 16/12/19)
- Electronic Medicines Compendium ceftriaxone PIL.pdf (medicines.org.uk) (Last updated 19/08/19)
- Electronic BNF Ceftriaxone | Drugs | BNF | NICE
- NICE, 2017. Medicines practice guideline Patient Group Directions www.nice.org.uk/guidance/mpg2
- NICE Clinical Knowledge Summaries - Gonorrhoea | Health topics A to Z | CKS | NICE (Last updated August 2022)
- 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
- Queensland Hospital and Health Services; Medication Administration – Intramuscular Injection Developed by the State-wide Emergency Care of Children Working Group, March 2020 https://www.childrens.health.qld.gov.au/wp-content/uploads/PDF/qpec/nursing-skill-sheets/medication-administration-intramuscular-injection.pdfUK Resuscitation Council, 2021. Adult basic life support Guidelines | Resuscitation Council UK

5. Audit and ongoing monitoring of this PGD.

Please refer to the 'Audit' section of the BPAS Patient Group Direction policy for additional guidance in relation to PGD audit.

The PGD audit tool is available here: British Pregnancy Advisory Service - Audit Tools - All Documents (sharepoint.com).

Units must retain a local copy of the completed audit tool as evidence.

The PGD audit criteria include:

1. Staff member has named, dated, and signed the relevant PGD document.
2. Client is documented as being referred to a medical practitioner if they are excluded from treatment under the PGD and there is no suitable alternative.
3. Date and time of supply / administration is on the prescription record / CAS2.
4. Client details – name, date of birth, allergies and any previous adverse effects are on the prescription record / CAS2.
5. Details of the medicine – name, strength, dose frequency, quantity, route, and site (if by injection) of administration are on the prescription record / CAS2.
6. A statement that supplies or administration is by using a PGD is on the prescription record / CAS2.
7. Name and signature (which may be electronic for CAS2 records) of the health professional supplying or administering the medicine is on the prescription record / CAS2.
8. Relevant information was provided to the client or their carer.
9. Client not documented to be allergic to the drug.
10. Paper documentation related to PGDs are in black ink only.
11. Where appropriate for the medication, correct scheduling has been discussed.
12. Client does not meet any exclusions or contraindications listed in the most up to date PGD.

Appendix A: Approved Practitioner List

Patient Group Direction (PGD) name:	Administration of Ceftriaxone injection (reconstituted with lidocaine 1% w/v injection) by intramuscular (IM) injection for the treatment of uncomplicated Neisseria gonorrhoeae infection v2.1	
	Valid from: 01/08/2024	**Expiry: 30/06/2026**

Registered health professional

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

PGDs do not remove 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. The practitioner MUST sign this document before they can work under this PGD.

I confirm that I have read and understood the contents of this PGD. I confirm that I am willing and competent to work to this PGD within my professional code of conduct.				
Name (print)	**Designation**	**NMC PIN**	**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 for the above-named health care professionals who have signed the PGD to work under it.				
Name	**Position**	**BPAS Treatment Unit**	**Signature**	**Date:**

Note to authorising manager.

- Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.
- If registered health professional signatures need to be added at a later date, e.g. due to staffing changes, a separate Approved Practitioner List must be signed, ensuring the correct PGD name and version is detailed.
- This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD for the period specified in the BPAS PGD policy.
- This list must be stored by the Treatment Unit in a designated folder and be available for immediate inspection, alongside any training / competency records. If a registered professional works across multiple sites, they must sign the Approved Practitioner List for each PGD at each BPAS site where they will use the PGD.