NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction Administration Of Ceftriaxone Injection (Reconstituted With Lidocaine 1% W/V Injection) By Intramuscular (IM) Injection For The Treatment Of Uncomplicated *Neisseria Gonorrhoeae* Infection Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from the SPS/BASHH Administration of ceftriaxone injection (reconstituted with lidocaine 1% w/v injection) by intramuscular (IM) injection for the treatment of uncomplicated Neisseria gonorrhoeae infection, Version 2 – Published April 2023	**Consultation Group**: See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/Ceftriax/ 1449	**Review Date**: February 2026 **Expiry Date:** June 2026	**Date Approved by NoS:** 15th April 2024

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2

Revision History for NoS:

NoS PGD that has been superseded	NoS/PGD/Ceftriax/MGPG1156, Version 1	
Date of change	**Summary of Changes**	**Section heading**
November 2023	Reference to NoS Appendix 1 and 2.	Authorisation
November 2023	Statement added in about nurses being registered by the NMC.	Professional registration
November 2023	Removed SPS advised training and added TURAS NoS PGD training link added.	Initial Training
November 2023	Added in statement about capacity under the age of 13 and the legislation statement added.	Criteria for inclusion
November 2023	NICE Competency framework statement removed.	Competency assessment
November 2023	Added clinical systems utilised.	Records
February 2024	Local authority statement removed.	Qualifications and professional registration

SPS/BASHH most recent changes

Change History	
Version and Date	**Change details**
Version 1 July 2020	New template
Version 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 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 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**. Note:** June 2023 added section on 'Additional facilities and supplies'.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Authorisation

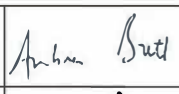
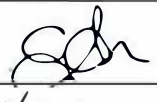
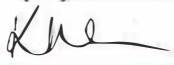
This specimen Patient Group Direction (PGD) template has been produced by SPS/BASH and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer medicines under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the medicines has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).

A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Ambreen Butt	Signature		Date Signed	20/03/2024
Pharmacist	Gayle Anderson	Signature		Date Signed	07/03/2024
Nurse	Kimberley MacInnes	Signature		Date Signed	07/03/2024

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		11/04/2024

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Adam Coldwells – Interim Chief Executive		15/04/2024

Version 2 – Approved for NoS from 15th April 2024

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	July 2023
Review date	February 2026
Expiry date:	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
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	Vice President, General Training 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 Rachael Jones	Consultant in HIV and Sexual Health, Chelsea and Westminster NHS Foundation Trust
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)
Heather Randle	Royal College of Nursing
Jo Jenkins (Working Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms, Specialist Pharmacy Service
Portia Jackson	Pharmacist, Cambridgeshire Community Services
Sally Hogan	British Pregnancy Advisory Service (BPAS)
Sandra Wolper	Associate Director, Medicines Use and Safety, Specialist Pharmacy Service
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service

1. Characteristics of staff

Qualifications and professional registration	Registered nurses and midwives as recognised by the Nursing and Midwifery Council (NMC).
Initial training	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. 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. Have undertaken NoS PGD module training on TURAS Learn. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults.
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix 1 and Appendix 2) or complete a self-declaration of competence for *Neisseria gonorrhoeae* infection testing and/or treatment.
Ongoing training and competency	• 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.
The decision to administer any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

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 and sexual contacts of individuals with a confirmed case of gonococcal infection.
Criteria for inclusion	• Individuals who have a positive identification of intracellular Gram-negative diplococci (GND) on microscopy. Cultures should be obtained. • Individuals who have a positive culture for *Neisseria gonorrhoeae* indicating sensitivity to cephalosporins. • Individuals who have a confirmed positive Nucleic Acid Amplification Testing (NAAT) for *Neisseria gonorrhoeae.* • Symptomatic sexual contact of confirmed case of gonococcal infection presenting within 14 days of exposure. Cultures should be obtained. • Asymptomatic sexual contact of confirmed case of gonococcal infection presenting within 14 days of exposure who is unwilling/unable to defer treatment until repeat testing 2 weeks after exposure. Cultures should be obtained. • Individuals with treated gonorrhoea who have had sexual contact within 7 days of receiving treatment with an untreated partner. Cultures should be obtained. • An individual under 16 years of age may give consent for the administration of ceftriaxone, provided they understand fully the benefits and risks involved. The individual should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the individual indicates that they wish to accept the administration, administration should proceed, if the healthcare professional deems the individual to have the legal capacity to consent. The Age of Legal Capacity (S) Act 1991, s2 (4) states that 'a person under the age of 16 years shall have legal capacity to consent on their own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending them, they are capable of understanding the nature and possible consequences of the procedure or treatment'.
Criteria for exclusion	**Personal characteristics** • Individuals under 13 years of age. • 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. • Sexual contacts of gonorrhoea positive individuals presenting after 14 days of exposure and are asymptomatic.

	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. • Individual is taking interacting medicines. Check product SPC/ British National Formulary (BNF) for full list of interacting medicines for ceftriaxone **and** lidocaine. • Individuals with epididymitis or testicular pain where the clinician is not competent in assessing and managing epididymitis/epididymo-orchitis. • Individuals with or suspected to have pelvic inflammatory disease where clinician is not competent in assessing and managing individuals with pelvic pain. • 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. • Known acute porphyria. • Known epilepsy. • Known myasthenia gravis.
Cautions 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 local safeguarding lead and follow the local safeguarding policy (note under 13 years of age excluded from treatment under this PGD). • **Individuals who are pregnant or breastfeeding.** The individual should be informed of the following risks and benefits of this treatment: o 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 o Lidocaine can cross the placenta but the benefit of treatment is thought to outweigh the risk to pregnancy of leaving the gonorrhoea untreated o Small amounts of ceftriaxone and lidocaine may

	be excreted into the breast milk ○ The availability of alternative treatment options and can be referred to a prescriber if requested • Discuss with appropriate medical/independent non-medical prescriber 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. • Record reason for decline in the consultation record. • Explain the reasons for exclusion to the individual and document 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

Name, strength and formulation of drug	Ceftriaxone injection (dry powder vial) reconstituted with lidocaine 1% w/v injection. The 1g dose will be given from either 4x250mg vials or 1g vial as follows: **Using 4x250mg vials to administer 1g:** Each 250mg 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 1g to be administered. **Using 1g vial:** The 1g vial should be reconstituted with 3.5mL 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 of administration	• Deep intramuscular (IM) injection. • 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.
Dose and frequency of administration	1g administered as a single dose.
Off label use	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 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. 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.
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	All concurrent medications should be reviewed for interactions. 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.
Additional facilities and supplies	• Access to working telephone. • Suitable waste disposal facilities. • Immediate access to in-date anaphylaxis kit (IM adrenaline 1:1000).
Management of and reporting procedure for adverse reactions	• 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 DATIX reporting.
Written information and further advice to be given to individual	**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:** • Individuals diagnosed with gonorrhoea should be offered information (verbal, written and/or digital) about their diagnosis and management. • 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. • Warn of risk of re-infection and further transmission of infection, if sexual intercourse takes place within 7 days of treatment starting or with an untreated partner. • 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). • Where treatment not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services.
Follow up treatment	• 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 (or who did not have diagnosis made in a sexual health clinic) should be advised to attend an appropriate service for a full STI screen. • Individuals should be advised to re-attend (face to face or remotely) a sexual health clinic 2 weeks following treatment for: o test of cure o retaking the sexual history to explore the possibility of

	re-infection ○ pursuing partner notification and health promotion.
Records	**Record:** • 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. • Name of individual, address, date of birth. • GP contact details where appropriate. • Relevant past and present medical and sexual history, including medication history. • Examination including individual's weight (<50kg split dosing). • Microbiology finding/s where relevant. • Any known allergies and nature of reaction. • Name of registered health professional. • Name of medications administered. • Any administration outside the terms of the product marketing authorisation. • Date of administration. • Dose administered. • Site of injection. • Batch number and expiry date of administered injections in line with local procedures. • Details of any adverse drug reactions and actions taken. • Advice given, including advice given if excluded or declines treatment. • Advice given about the medication including side effects, benefits, and when and what to do if any concerns. • Any referral arrangements made. • Recorded that supplied via Patient Group Direction (PGD). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • NaSH – Sexual Health Electronic Patient Record.

	• BadgerNet – Digital Maternity Notes. • HEPMA. • Individual's GP records if appropriate. • Individual service specific systems. 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. Key references

Key references (accessed January 2023)	• 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 • 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/ • NICE Clinical Knowledge Summaries - https://cks.nice.org.uk • 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.pdf • Medusa Guideline, ceftriaxone IM https://medusa.wales.nhs.uk/

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1 - Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction Administration Of Ceftriaxone Injection (Reconstituted With Lidocaine 1% W/V Injection) By Intramuscular (IM) Injection For The Treatment Of Uncomplicated *Neisseria Gonorrhoeae* Infection Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles – Version 2

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2 - Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administration, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the medicine(s) under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.
Patient Group Direction Administration Of Ceftriaxone Injection (Reconstituted With Lidocaine 1% W/V Injection) By Intramuscular (IM) Injection For The Treatment Of Uncomplicated *Neisseria Gonorrhoeae* Infection Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles – Version 2
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction Administration Of Ceftriaxone Injection (Reconstituted With Lidocaine 1% W/V Injection) By Intramuscular (IM) Injection For The Treatment Of Uncomplicated *Neisseria Gonorrhoeae* Infection Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles – Version 2					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**