Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered nurses or midwives 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. Health professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version.

Patient Group Direction

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 or Midwives

in Sexual Health Clinics

in Powys Teaching Health Board

Version number: **PGD 0239A**

Reference number: PGD 0239A
Valid from: 05/06/2024
Review date: 01/02/2026
Expiry date: 30/06/2026

Change history

Version number	Change details	Date
PGD 0239	Initial issue produced using SPS template v2.0	28/12/2023
PGD 0239A	Updated according to SPS template version 2.1: 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. Minor updates to PTHB PGD template.	05/06/2024

This Powys Teaching Health Board (PTHB) PGD is based on a template developed on behalf of the Specialist Pharmacy Service, which had been peer reviewed by the Sexual Health PGDs Short Life Working Group in accordance with their Terms of Reference. It had been approved by the British Association for Sexual Health and HIV (BASHH)/BASHH Bacterial Special Interest Group (BSIG) in February 2023.

Acknowledgements:

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
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Sim Sesani	CASH Nurse Consultant, MSI Reproductive Choices
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Vicky Garner	British Pregnancy Advisory Service (BPAS)

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Richard Stratton**	Lead doctor for PTHB	DocuSigned by: A4AB87B5EE40479..	7/17/2024
Chief Pharmacist **Jacqui Seaton**	Chief Pharmacist for PTHB	DocuSigned by: 71E8089DE3634C4..	7/17/2024
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB- Assistant Director for Innovation and Improvement	DocuSigned by: 74A4E51A42E9473..	7/17/2024
Senior representative of professional group using the PGD **Marie Davies**	Deputy Director of Nursing for PTHB	DocuSigned by: 3B113D283631403..	7/17/2024

Appendix A provides a staff accreditation sheet. Individual practitioners must be authorised by name to work to this PGD.

Those using this PGD must ensure that it is organisationally authorised and signed by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

The final authorised copy of this PGD should be kept by PTHB for 25 years after the PGD expires.

[1] This includes any relevant amendments to legislation.

Characteristics of staff	
Qualifications and professional registration	Current contract of employment with Powys Teaching Health Board and providing Sexual Health Services. Practitioners must only work under this PGD where they are competent to do so. Practitioners working under this PGD must also be a registered healthcare professional with the following body: • nurse or midwife currently registered with the Nursing and Midwifery Council (NMC) The practitioners must also fulfil the training and additional requirements detailed below. Check Appendix A: Staff accredited to use the Patient Group Direction to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
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, HEIW, RCN or a university or advised in the RCN Sexual Health Education directory. Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme, PTHB staff to access via ESR. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or a minimum of level 2 safeguarding or the equivalent. The healthcare professional must ensure that they have an up to date certificate for Basic Life Support (BLS)

	and anaphylaxis, and be competent in the administration of adrenaline. Additionally, practitioners: • must have access to the Patient Group Direction and associated online resources • must be familiar with Ceftriaxone injection (dry powder vial) reconstituted with lidocaine 1% w/v injection and knowledge of its uses, contraindications and adverse effects • must be alert to changes in the BNF and Summary of Product Characteristics • must be competent in the recognition, management and reporting of adverse drug reactions, including anaphylaxis **THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A). The individual must complete a self-declaration of competence for *Neisseria gonorrhoeae* infection testing and/or treatment in their Personal Appraisal and Development Review (PADR) – the **personal development plan** (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions. • A minimum of Level 2 safeguarding passport • Evidence of ongoing PGD training to be submitted to Line Manager annually- this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. • Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. • Evidence of training in BLS and anaphylaxis.

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. • Annual PGD training. • Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis, Life Support Skills, with evidence of appropriate Continued Professional Development (CPD). • Updating at least every 2 years on Ceftriaxone injection (dry powder vial) reconstituted with lidocaine 1% w/v injection. • Compliance with all mandatory NHS training including a minimum of safeguarding level 2. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.**
The decision to administer any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

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. **It is the responsibility of the administering healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice.**
Criteria for inclusion	• Individuals who present with mucopurulent penile or cervical discharge where there is no access to microscopy facilities to diagnose Gram-negative diplococci (GND). 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 intercourse within 7 days of receiving treatment or who have had sexual contact with an untreated partner. Cultures should be obtained. **NB. Cultures should be taken prior to commencing treatment** • Informed consent given. Refer to PTHB Consent to Treatment and Examination Policy. The individual should be informed they are being treated using a PGD. • Medical and drug history taken, no reason for exclusion.
Criteria for exclusion	**Personal characteristics** • Informed consent not given. Individuals for whom valid consent, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received. Refer to sections "Action to be taken if the individual is excluded or declines treatment". • Individuals under 13 years of age. If a child is under 13 years of age and is known to have engaged in sexual activity this must be referred to Powys Children Service or CEOP Safety Centre, advice from the local safeguarding lead should be sought and the local safeguarding policy should be followed. See Action to be taken if individual is excluded for further information. • 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 or to any constituent of the product - see Summary of Product Characteristics, 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 or to any constituent of the product - see Summary of Product Characteristics. • 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 • Less than 3 days before receiving, or within 3 days after receiving, oral typhoid vaccine

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:
	  ○ 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 pregnancy of leaving the gonorrhoea untreated
	  ○ 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.
	
	Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP.
	
	Any safeguarding concerns need to be directed to Safeguarding Hub:
	• To generic email address: PowysTHB.Safeguarding@wales.nhs.uk
	And
	• Central Safeguarding number: 01686 252806
	• Out of hours: 0345 0544847
	Advice can also be sought from local Safeguarding leads

Arrangements for referral for medical advice	Contact GP via the surgery or the emergency on-call service, document advice given. Where required, refer the individual to gynaecologist/ GUM consultant /level 3 Sexual Health services for advice, if applicable.
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 and any action taken 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 (GP/ gynaecologist/ GUM consultant/ level 3 Sexual Health services) if appropriate and/or provide them with information about further options. • Document any action taken in the consultation record. • If a child under 13 years of age is known to have engaged in sexual activity this must be referred to Powys Children Service and the PTHB Safeguarding Team notified.

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 4x250 mg 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 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	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 https://bnf.nice.org.uk 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	• 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 https://bnf.nice.org.uk • 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. For established medicines, serious adverse events in adults or all suspected adverse reactions in children that may be attributable to the medication/ vaccine should be reported. Guidance on the yellow card system is available at the back of the BNF, or using the above link. • Record all adverse drug reactions (ADRs) in the patient's medical record and inform their GP. • All significant adverse drug reactions and any administration errors must be recorded. Report via Datix Once for Wales Reporting system.

	In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone. In the case of anaphylaxis: • Refer to adrenaline (epinephrine) PGD 0017 and anaphylaxis policy • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in individual's notes • Ensure all individual's records are marked **ALLERGIC TO Ceftriaxone injection (dry powder vial) reconstituted with lidocaine 1% w/v injection.** • The individual may be advised to wear a MedicAlert or similar device to alert other healthcare providers
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) • 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 o pursuing partner notification and health promotion
Records to be kept	Record consultation details as required by local procedures. In addition, record: • The consent of the individual and o If individual is under 13 years of age record action taken o If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken. o 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 administered via Patient Group Direction (PGD), record PGD title, number and version 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.

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://medusaimg.nhs.uk/

Appendix A Staff accredited to use the Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board for the named healthcare professionals below who have signed the PGD to work under it. *The authorising manager must use the competency checklist (below).*

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

Printed name of registered health professional	Signature of registered health professional	Printed name of senior representative authorising health professional	Signature of senior representative authorising health professional	Date

The authorising manager should retain a copy of the list, which will be required for audit purposes. This list should be kept by PTHB for 25 years after the PGD expires.

The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N) Specify in	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number)_____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager and to the staff member, in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.