Insert logo of [authorising body](https://www.nice.org.uk/guidance/mpg2/chapter/Recommendations#terms-used-in-the-guideline)

|  |
| --- |
| This Patient Group Direction (PGD) must only be used by registered healthcare professionals 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. |

**PATIENT GROUP DIRECTION (PGD)**

**Intrapartum administration of benzylpenicillin for prevention of early-onset Group B Streptococcus (GBS) infection in neonates in location/service/organisation**

Version Number 1.0

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| --- |
| **Change History** |
| **Version and Date** | **Change details** |
| Version 1January 2023 | New template |

Each organisation using this PGD must ensure that it is formally signed by a senior pharmacist, a senior doctor and any other professional group representatives involved in its review and that it is reviewed in line with the organisations’ PGD governance system. The organisation’s governance lead must sign to authorise the PGD on behalf of the authorising organisation to ensure that this document meets legal requirements for a PGD

**PGD DEVELOPMENT GROUP**

|  |  |
| --- | --- |
| Date PGD template comes into effect:  | January 2023 |
| Review date | June 2025 |
| Expiry date:  | December 2025 |

This PGD template has been peer reviewed by the NHSEI Preventative Medicines in Pregnancy Programme PGDs Short Life Working Group in accordance with their Terms of Reference. It has been reviewed by the Royal College of Obstetrics and Gynaecology (RCOG) and endorsed by Dr Matthew Jolly, National Clinical Director for Maternity and Women's Health NHS England and NHS Improvement.

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

|  |  |
| --- | --- |
| **Name** | **Designation** |
| Andrew Radley | Consultant in Public Health Pharmacy, NHS Tayside |
| Barbara Strawbridge | Lead Midwife Northern Health and Social Care Trust |
| Christina Nurmahi\* | Women & Newborn Care Group Lead Pharmacist, University Hospital Southampton NHS Foundation Trust |
| Emma Luhr\* | Director of Midwifery, Frimley Health NHS Foundation Trust |
| George Attilakos\* | Consultant in Fetal Medicine and Obstetrics in UCLH, Clinical Lead for Obstetrics and RCOG Council member |
| Jacqueline Lambert | Professional Advisor Midwifery & Perinatal Care, Chief Nursing Office’s Directorate (CNOD) & Directorate for Children and Families (DCAF), Scottish Government |
| Jo Jenkins\* (Working and core Group Co-ordinator) | Specialist Pharmacist PGDs Specialist Pharmacy Service |
| Karen Todd | Head of Maternity and Neonatal NHS Quality, Safety and Investigations, Department of Health and Social Care |
| Katherine Oldridge\*  | GP Clinical Lead for Bath, Swindon and Wiltshire-NHS Bath and North East Somerset, Swindon and Wiltshire CCG |
| Lisa Byers\*  | Pharmaceutical Officer, Medicines Regulatory Group, Department of Health, Northern Ireland |
| Richard Goodman | Regional Chief Pharmacist, NHS England & NHS Improvement (London Region) |
| Sandra Richards\* | BSW Local Maternity System Midwife, NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group |

\*Core group member

The SLWG gratefully acknowledge the specialist advice provided by Dr. Monsey McLeod AMR Research Translation Lead, NHS England & NHS Improvement and Dr Mariyam Mirfenderesky, Consultant in Infectious Diseases and Medical Microbiology IPC, Outbreaks and Antimicrobial Stewardship (IOS) Team, HCAI, Fungal, AMR, AMU & Sepsis Division, UK Health Security Agency

**The PGD template is not legally valid until it has had the relevant organisational approval - see below.**

**ORGANISATIONAL AUTHORISATIONS AND OTHER LEGAL REQUIREMENTS**

**This page may be deleted if replaced with a format agreed according to local PGD policy with relevant approvals and authorisation.**

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

To ensure compliance with the law, organisations must add local authorisation details i.e. clinical authorisations and the person signing on behalf of the authorising organisation. You may either complete details below or delete and use a format agreed according to local PGD policy which complies with PGD legislation and [NICE MPG2 PGD 2017](https://www.nice.org.uk/Guidance/MPG2).

|  |  |  |  |
| --- | --- | --- | --- |
| **Name**  | **Job title and organisation**  | **Signature** | **Date** |
| **Senior doctor**  |  |  |  |
| **Senior pharmacist** |  |  |  |
| **Senior representative of professional group using the PGD**  |  |  |  |
| **Microbiology specialist**  |  |  |  |
| **Person signing on behalf of** [**authorising body**](http://publications.nice.org.uk/patient-group-directions-gpg2/appendix-a-glossary#authorising-body) |  |  |  |

It is the responsibility of the provider organisation to ensure that all legal and governance requirements for using the PGD are met.

Authorising organisations must retain an Individual Practitioner Authorisation sheet, List of Authorised Practitioners or equivalent record of those authorised to operate under this PGD. This varies according to local policy and how the service is managed – it can be maintained physically or electronically according to local policy. An example is given in Appendix A.

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medication(s) listed only in accordance with the PGD.

**ORGANISATIONS MAY ALSO ADD:**

* Local training and competency assessment documentation
* Other supporting local guidance or information
* Links to local PGD Policy and other supporting guidance
* Audit requirements.

Any reference to a Trust protocol (either clinical to be followed as part of the administration of a medication with the PGD or for any other purpose) must be referenced and hyperlinked to ensure the practitioner acting under the PGD has direct access to the protocol for reference.

1. **Characteristics of staff**

|  |  |
| --- | --- |
| **Qualifications and professional registration** | Current contract of employment within an NHS commissioned service or an NHS Trust/Health Board/NHS organisation.Midwives registered with 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 patients ensuring safe provision of the medicines listed in accordance with local policy.
* Recommended requirement for training would be:
* Successful completion of a relevant module/course accredited or endorsed by a university, Royal College of Midwives (RCM) accredited learning, or locally developed training.
* Completion of the [eLfH PGD elearning module](https://www.e-lfh.org.uk/programmes/patient-group-directions/)
 |
| **Competency assessment** | * Individuals operating under this PGD must be assessed as competent or complete a self-declaration of competence to operate under this PGD (see an example authorisation record sheet in Appendix A).
* Staff operating under this PGD are encouraged to review their competency using the [NICE Competency Framework for health professionals using patient group directions](https://www.nice.org.uk/guidance/mpg2/resources)
 |
| **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 addressed and further training provided as required.
* Organisational PGD and/or medication training as required by employing Trust/organisation.
 |
| The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.  |

1. **Clinical condition or situation to which this PGD applies**

|  |  |
| --- | --- |
| **Clinical condition or situation to which this PGD applies** | For administration to individuals in labour where there has been an identified risk of early onset Group B Streptococcal (GBS) infection developing in the neonate (detailed below)  |
| **Criteria for inclusion** | * Informed consent gained (include explanation of GBS risk factors and additional information supplied as requested – adapted to include local resources)
* Individual in established labour at > 37 weeks gestation and one or more of the following:
	+ Previous baby diagnosed with early or late onset Group B Streptococcal infection
	+ Group B streptococcus colonisation, bacteriuria or infection during the current pregnancy
	+ Unknown Group B streptococcus status at onset of labour and prolonged rupture of membranes (exact timing of initiation of treatment subject to local guidance)
 |
| **Criteria for exclusion** | * Informed consent not given
* Known hypersensitivity to benzylpenicillin or any of its excipients (seek input from an appropriate clinician/microbiology specialist for alternative antibiotic treatment)
* Known penicillin or cephalosporin allergy (seek input from an appropriate clinician/microbiology specialist for alternative antibiotic treatment)
* Pre-term labour (<37 weeks gestation)
* Pyrexia in labour (body temperature >38.0°C) – follow local guidance
* Known renal impairment – all stages
* Known heart failure
* Diagnosed or suspected sepsis or infection
* Currently prescribed methotrexate, acenocoumarol, phenindione or warfarin (see interactions section)
 |
| **Cautions including any relevant action to be taken** | * Discuss with appropriate clinician any medical condition or drug interaction of which the healthcare professional is unsure or uncertain.
 |
| **Action to be taken if the individual is excluded or declines treatment**  | **Exclusion to treatment:****Refer immediately to an appropriate clinician/microbiology specialist where clinical exclusion to treatment is identified** (e.g. penicillin allergy).Explain the reasons for exclusion to the individual and document in the consultation record.**Treatment declined:** Where informed consent to treatment is not given record reason for the individual declining treatment in the clinical record including subsequent advice offered and, where appropriate, alternative management options discussed. Where requested by individual, or clinically appropriate for consideration of further management options, refer to an appropriate clinician. |

1. **Description of treatment**

|  |  |
| --- | --- |
| **Name, strength & formulation of drug** | * Benzylpenicillin 600mg powder for solution for injection vials
* Benzylpenicillin 1200mg powder for solution for injection vials
 |
| **Legal category** | Prescription Only Medicine (POM) |
| **Route of administration** | Intravenous infusion or injection  |
| **Off label use** | 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 medicines 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 medicine is being offered in accordance with national guidance but that this is outside the product licence. |
| **Dose and frequency of administration** | **Loading dose** of 3g:* as soon as possible after onset of labour OR rupture of membranes where known GBS positive individual or previous affected baby
* Unknown Group B streptococcus status at onset of labour and prolonged rupture of membranes (exact timing of initiation of treatment subject to local guidance)

**Follow up doses**: a dose of 1.5g (or 1.2g as per local policy) repeated every 4 hours until delivery of the neonate. **Instructions for reconstitution and administration** **IV INJECTION:****Reconstitution:** * reconstitute each 600mg vial with 4mL water for injections or sodium chloride 0.9%. It is recommended to further dilute the contents of the reconstituted vial to a final volume of 10mL to avoid vein irritation.
* reconstitute each 1.2g vials with at least 8mL water for injection or sodium chloride 0.9%. It is recommended to further dilute the contents of the reconstituted vial to a final volume of 20mL to avoid vein irritation.

**Administration:** Administer slowly over 5 minutes at a maximum rate of 300mg per minute.**IV INFUSION:** **Reconstitution:*** reconstitute each 600mg vial with 4ml water for injections or sodium chloride 0.9%.
* reconstitute each 1.2g vials with at least 8ml water for injection or sodium chloride 0.9%.

**Infusion preparation:**Dilute required dose to a suggested volume of 100ml with sodium chloride 0.9% or glucose 5% (in line with local policy) **Administration:** Infuse over 30-60 minutes. |
| **Duration of treatment** | Until delivery of the neonate. |
| **Storage** | Medicines must be stored securely according to national guidelines. |
| **Drug interactions** | **All concurrent medications must be checked for interactions.** A detailed list of drug interactions is available in the individual product SPC, which is available from the [electronic Medicines Compendium website](http://www.medicines.org.uk) and the [BNF](http://www.bnf.org) **Note specifically:*** Reduced excretion of methotrexate results increased risk of methotrexate toxicity when used with benzylpenicillin sodium. See exclusion section.
* Potential increased risk of bleeding events when benzylpenicillin is concurrently administered with acenocoumarol, phenindione or warfarin. See exclusion section.

Where a potentially clinically significant interaction is identified discuss with appropriate medical/independent non-medical prescriber. |
| **Identification & management of 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](http://www.medicines.org.uk) and BNF [www.bnf.org](http://www.bnf.org) The following possible adverse effects stated in the current BNF/SPC as **very commonly/commonly** reported with benzylpenicillin injection (note this list does not reflect all reported adverse effects):* Diarrhoea
* Hypersensitivity;
* Nausea
* Skin reactions/rashes
* Thrombocytopenia
* Vomiting
 |
| **Management of and reporting procedure for adverse reactions** | * Any individual experiencing mild side effects should be assessed by a midwife in the first instance – where clinically necessary the midwife should refer to a specialist clinician for further advice.
* If allergic reaction suspected refer immediately to a specialist clinician for further advice.
* Healthcare professionals and individuals/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 organisation incident policy.
 |
| **Advice/follow up treatment** | * Explain mode of action, side effects, and benefits of the medicine. This information may be provided in the form of a local information leaflet pack if available/manufacturer’s patient information leaflet (PIL) provided with the original pack.
 |
| **Records** | **Record:** * The consent of the individual and if the individual is not competent to consent, record action taken
* Name of individual, address, date of birth
* GP contact details where appropriate
* Relevant past and present medical history, including medication and family history.
* Examination finding where relevant
* Any known allergies
* Name of registered health professional
* Name of medication administered
* Dose administered
* Advice given, including advice given if excluded or declines treatment
* Details of any adverse drug reactions and actions taken
* Advice given about the medication including side effects, benefits, and when and what to do if any concerns
* Any referral arrangements made
* Any supply outside the terms of the product marketing authorisation
* Recorded that supply is via Patient Group Direction (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. |

1. **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>
* Royal College of Obstetrics and Gynecology Group B Streptococcal Disease, Early-onset (Green-top Guideline No. 36) 2017 <https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg36/>
* Neonatal infection: antibiotics for prevention and treatment NICE NG195 2021 Neonatal infection: antibiotics for prevention and treatment <https://www.nice.org.uk/guidance/ng195>
* Medusa IV monograph for benzylpenicillin <https://medusa.wales.nhs.uk/medusamyth.asp>
* UptoDate® Prevention of early onset group B streptococcal disease in neonates March 2022 <https://www.uptodate.com/contents/prevention-of-early-onset-group-b-streptococcal-disease-in-neonates>
 |

**Appendix A - Registered health professional authorisation sheet (example – local versions/electronic systems may be used)**

**PGD Name/Version Valid from: Expiry:**

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

**Registered health professional**

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

Patient group directions 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.

|  |
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| **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.** |
| **Name** | **Designation** | **Signature** | **Date** |
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**Authorising manager**

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| **I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of organisation for the above named health care professionals who have signed the PGD to work under it.** |
| **Name** | **Designation** | **Signature** | **Date** |
|  |  |  |  |

**Note to authorising manager**

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

Add details on how this information is to be retained according to organisation PGD policy.