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)**

**Supply of aspirin tablets for individuals at high risk of pre-eclampsia in location/service/organisation**

Version Number 2.0

|  |
| --- |
| **Change History** |
| **Version and Date** | **Change details** |
| Version 1February 2022 | New template |
| Version 2October 2024 | Planned review. Updated SLWG membership.Minor formatting changes. Watermark removed. |

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.

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

**PGD DEVELOPMENT GROUP**

|  |  |
| --- | --- |
| Date PGD template comes into effect:  | 1st February 2025 |
| Review date | August 2027 |
| Expiry date:  | 31st January 2028 |

This PGD template has been peer reviewed by the Preventative Medicines in Pregnancy PGDs Short Life Working Group in accordance with their Terms of Reference. It has been endorsed by Professor Donald Peebles, National Clinical Director for Maternity NHS England.

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

|  |  |  |
| --- | --- | --- |
| **Name** | **Designation** | **DATE** |
| Amy Moore | Pharmacist HIV, Sexual and Reproductive Health Kingston Hospital NHS Foundation Trust | October 2024 |
| Christina Nurmahi | Women & Newborn Care Group Lead Pharmacist, University Hospital Southampton NHS Foundation Trust |
| Emma Luhr  | Director of Midwifery, Frimley Health NHS Foundation Trust |
| Felipe Castro Cardona | Head of Midwifery Clinical WorkforceChief Midwifery Office, NHS England |
| George Attilakos | Consultant in Fetal Medicine and Obstetrics in UCLH, Clinical Lead for Obstetrics and RCOG Council member |
| Hannah Putley | Policy Manager - Maternity and Neonatal, NHS Quality, Safety and Investigations, Department of Health and Social Care |
| Jo Jenkins  | Associate Director Medicines Governance Specialist Pharmacy Service |
| Rosie Furner (Working Group Co-ordinator) | Advanced Specialist Pharmacist - Patient Group Directions and Medicines Mechanisms, Specialist Pharmacy Service |
| Sandy Richards | BSW LMNS MidwifeNHS Bath and North East Somerset, Swindon and Wiltshire Integrated Care Board (ICB) |
| Trixie McAree | National Midwifery Lead for Continuity of Carer, National Clinical Advisor, (Midwifery), Choice and Personalisation. |
| Verena Wallace | Senior Midwifery Adviser (Policy), Nursing and Midwifery Council |
| William Rial | Regional Chief Pharmacist for East of England, NHS England |
| Zoë van Zuylen  | Lead Women and Neonatal Pharmacist, Imperial College Healthcare NHS Trust  |

**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**  |  |  |  |
| **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.[Registered healthcare professional listed in the legislation](https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them) as able to practice under Patient Group Directions.  |
| **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.  |
| **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 pregnant individuals at risk of pre-eclampsia. |
| **Criteria for inclusion** | * Informed consent given.
* Individuals aged 16 years and over.
* Pregnant individuals starting from 12 weeks of pregnancy to 36 weeks/delivery (delete as applicable to local policy) identified at moderate and high risk of pre-eclampsia using the guidance outlined in [Hypertension in pregnancy: diagnosis and management NICE guideline [NG133]](https://www.nice.org.uk/guidance/ng133/resources/hypertension-in-pregnancy-diagnosis-and-management-pdf-66141717671365) which is assessed as:
* **Having any of the following high risk factors:**
* Hypertensive disease during a previous pregnancy (pre-eclampsia or pregnancy induced hypertension).
* Chronic kidney disease
* Auto-immune disease such as systemic lupus erythematosus or antiphospholipid syndrome
* Type 1 or 2 diabetes
* Chronic hypertension outside of pregnancy requiring antihypertensive treatment (as defined by [NICE](https://bnf.nice.org.uk/treatment-summary/hypertension.html))

**OR** * **Having two or more moderate risk factors:**
* Nulliparous individuals
* Age 40 years or older
* Pregnancy interval more than 10 years
* BMI of ≥35kg/m2 at first visit
* Family history of pre-eclampsia
* Multiple pregnancy

*Note – local guidance may also include low dose aspirin for additional indications.*  |
| **Criteria for exclusion** | * Consent not given.
* Individuals aged under 16 years of age
* Pregnancy prior to 12 weeks
* Hypersensitivity/allergy to aspirin or other Non-Steroidal Anti-inflammatory Drugs (NSAIDs)
* Known history of asthma deterioration when taking NSAIDs or aspirin – if any doubt discuss with specialist clinician before initiating
* Active or history of recurrent peptic ulcer and/or gastric/intestinal haemorrhage or other types of bleeding such as cerebrovascular haemorrhages.
* Known bleeding disorder e.g. Von Willebrand’s disease
* Known coagulation disorder e.g. haemophilia and thrombocytopenia.
* Active or history of gout
* Known history of decompensated liver disease or markers suggestive of liver disease such as ascites and jaundice.
* Severe renal impairment i.e. eGFR < 30ml/min/1.73m2
* Individuals with rare hereditary problems of galactosaemia, galactose intolerance, total lactase deficiency, glucose-galactose malabsorption, sucrase-isomaltase deficiency, fructose-1,6-bisphosphatase deficiency (also known as hereditary fructose intolerance): check the individual list of excipients available in the [SPC](https://www.medicines.org.uk/emc) before supplying.
* Clinically significant drug interaction/s – see relevant section of this PGD and also refer to current British National Formulary (BNF) [www.bnf.org](http://www.bnf.org) or individual product SPC <http://www.medicines.org.uk>
 |
| **Cautions including any relevant action to be taken** | * Current uncontrolled or severe asthma – if any doubt discuss with specialist clinician before initiating
* Discuss with appropriate medical/independent non-medical prescriber 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**  | * Explain the reasons for exclusion to the individual and document in the consultation record.
* Record reason for decline 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.
 |

1. **Description of treatment**

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| **Name, strength & formulation of drug** | * Aspirin 75mg dispersible tablets
* Aspirin 75mg tablets
* Aspirin 75mg enteric coated tablets

Amend locally to reflect formulation supplied |
| **Legal category** | POM/P (legal status dependent of formulation and pack size supplied – amend locally to reflect formulation supplied) |
| **Route of administration** | Oral |
| **Off label use** | Best practice advice is given by the RCOG and NICE and is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC).This PGD includes inclusion criteria, exclusion criteria and dosage regimens which are outside the market authorisation for many of the available products.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** | 75mg/150mg once daily (delete as applicable to reflect dosing recommendations of local policy) |
| **Duration of treatment** | From 12 weeks of pregnancy to 36 weeks/delivery (delete as applicable to local policy) |
| **Quantity to be supplied**  | * Supply of appropriate labelled packs of 28x75mg tablets can be made up to a maximum of 14x28 tablet packs (equivalent to a maximum of 28 weeks supply).
* Supply of appropriate labelled packs of 56x75mg tablets can be made up to a maximum of 7x56 tablet packs (equivalent to a maximum of 28 weeks supply).
* Supply of appropriate labelled packs of 100x75mg tablets can be made up to a maximum of 4x100 tablet packs (equivalent to a maximum of 28 weeks supply).
* Amend to reflect local supply agreement.
 |
| **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 www.medicines.org.uk the BNF [www.bnf.org](http://www.bnf.org) Where a 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 are commonly reported with aspirin (but may not reflect all reported adverse effects):* Dyspepsia
* Haemorrhage
* Dyspnoea
* Rhinitis
* Skin reactions
* Bronchospasm / asthma attack
 |
| **Management of and reporting procedure for adverse reactions** | * Any individual experiencing mild side effects should contact their community midwife in the first instance for advice – where clinically necessary the midwife should advise on any need for immediate discontinuation and refer to a specialist clinician for further advice.
* 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 organisation incident policy.
 |
| **Written information and further advice to be given to individual**  | * Provide patient information leaflet (PIL) provided with the original pack.
* Explain mode of action, side effects, and benefits of the medicine
* Advise that aspirin is best taken in the evening, with food.
* Advise that dispersible forms should be dispersed in a small amount of water; enteric and standard tablet forms should be swallowed whole.
* There is no evidence to suggest that low dose aspirin increases the risk of bleeding during pregnancy or at the time of birth.
* No other NSAID or aspirin containing products including over the counter analgesic preparations should be taken.
* The aspirin should be continued until 36 weeks/delivery (delete as applicable to local policy)
* Any remaining tablets not taken by the end of the pregnancy should be returned to a community pharmacy for disposal.
 |
| **Advice / follow up treatment** | * The individual should be advised to seek medical advice in the event of an adverse reaction.
* Individual to seek further advice if she has any concerns
* Follow up appointments should be arranged as per local policy.
 |
| **Records** | **Record:** * The consent of the individual and if the individual over 16 years of age and 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 supplied
* Date of supply
* Dose supplied
* Quantity supplied
* 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 July 2024)** | * 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>
* Hypertension in pregnancy: diagnosis and management <https://www.nice.org.uk/guidance/ng133/resources/hypertension-in-pregnancy-diagnosis-and-management-pdf-66141717671365>
* Maternal, Newborn and Infant Clinical Outcome Review Programme Saving Lives, Improving Mothers’ Care Lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2015-17 MBRRACE Report <https://www.npeu.ox.ac.uk/assets/downloads/mbrrace-uk/reports/MBRRACE-UK%20Maternal%20Report%202019%20-%20WEB%20VERSION.pdf>
* Royal College of Obsetricians and Gynaecologists The Investigation and Management of the Small–for–Gestational–Age Fetus Green–top Guideline No. 31 2nd Edition | February 2013 | Minor revisions – January 2014 <https://www.rcog.org.uk/globalassets/documents/guidelines/gtg_31.pdf>
 |

**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.

|  |
| --- |
| **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.