Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

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

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. Healthcare 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 (PGD)

for the supply of

aspirin tablets

by registered midwives

for individuals at high risk of pre-eclampsia; and/or at risk of placental dysfunction

in Powys Teaching Health Board

Version number: PGD 0171C

Reference Number: PGD 0171C
Valid from: 01/02/2025
Review date: 01/08/2027
Expiry date: 31/01/2028

Change history

Version number	Change details	Date
PGD0171	Initial version	01/03/2021
PGD0171A	Review version to include SPS template	15/06/2022
PGD0171B	Review version to change duration of supply. Review for consistency with SPS template version 1.0. Review of inclusion criteria to add pregnant individuals, starting from 12 weeks of pregnancy to at least 36 weeks, identified at risk of placental dysfunction in accordance with Green-top guideline no.31. Removal of health visitors from working to the PGD. Minor updates to PTHB PGD template.	12/07/2024
PGD0171C	Updated according to SPS template version number 2.0: Planned review. Updated SLWG membership. Minor formatting changes. Watermark removed.	01/02/2025

This Powys Teaching Health Board (PTHB) PGD is based on template v2.0 developed on behalf of the Specialist Pharmacy Service, which had been peer reviewed by the Preventative Medicines in Pregnancy PGDs Short Life Working Group in accordance with their Terms of Reference. It had been endorsed by Professor Donald Peebles, National Clinical Director for Maternity NHS England.

Acknowledgements:

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 Workforce Chief 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 Midwife NHS 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	

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	12/23/2024
Chief Pharmacist **Jacqui Seaton**	Chief Pharmacist for PTHB	Signed by: Jacqui Seaton 71E8089DE3634C4...	12/30/2024
Senior representative of professional group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche F07413E114E04B1...	12/23/2024
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	1/7/2025

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.

1. Characteristics of staff

Qualifications and professional registration	Current contract of employment with Powys Teaching Health Board. Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions -practitioners working under this PGD must be a registered professional with the following body: • Midwives currently registered with the Nursing and Midwifery Council (NMC) Practitioners must also fulfil the Additional requirements listed below. Check Appendix A – Staff Accredited to use this Patient Group Direction to confirm whether all practitioners listed above have organisational authorisation to work under this PGD. Practitioners must only work under this PGD where they are competent to do so.
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. Additionally, practitioners: • must have undertaken appropriate training for working under PGDs for supply/administration of medicines. Recommended PGD training - eLfH PGD elearning programme, PTHB staff to access via ESR. • must have knowledge of the uses of aspirin 75mg tablets, be familiar with its contraindications and adverse effects, and be alert to changes in the BNF and Summary of Product Characteristics • must have undertaken and completed at least level 3 Safeguarding of Children, Young People and Vulnerable Adults - Training and Competency Passport, as applicable to the role • must have access to the Patient Group Direction and associated online resources

	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 to operate under this PGD 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.
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. Appropriate Continued Professional Development (CPD) must be maintained and made available on request. • Compliance with all mandatory NHS training. • Annual PGD training- 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. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.**
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

2. 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; and/or individuals at risk of placental dysfunction. **It is the responsibility of the supplying 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	• Informed consent given. Refer to PTHB Consent to Treatment and Examination Policy. The individual should be informed they are being treated using a PGD. • Individuals aged 16 years and over. • Medical and drug history taken, no reason for exclusion. • Pregnant individuals starting from 12 weeks of pregnancy to delivery identified at moderate and high risk of pre-eclampsia using the guidance outlined in Hypertension in pregnancy: diagnosis and management NICE guideline [NG133] 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) **OR** **Having two or more moderate risk factors:** ○ Nulliparous individuals ○ Age 40 years or older ○ Pregnancy interval more than 10 years ○ BMI of ≥35kg/m^2 at first visit ○ Family history of pre-eclampsia ○ Multiple pregnancy **OR** Pregnant individuals, starting from 12 weeks of pregnancy to at least 36 weeks, identified at risk of placental dysfunction in accordance with Green-top guideline no.31 **NB** Aspirin may be supplied to individuals within the inclusion criteria prior to 12 weeks of pregnancy, but the individual must be advised not to commence treatment until they are 12 weeks pregnant.

Criteria for exclusion	• Conditions outside of the clinical situations criteria • 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 section "Action to be taken if the individual is excluded or declines treatment". • Individuals aged under 16 years of age • Pregnancy prior to 12 weeks. **NB** Aspirin may be supplied to individuals within the inclusion criteria prior to 12 weeks of pregnancy, but the individual must be advised not to commence treatment until they are 12 weeks pregnant. • Hypersensitivity/allergy to aspirin or other Non-Steroidal Anti-inflammatory Drugs (NSAIDs) or to any of the product excipients • 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/1.73m^2 • 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 before supplying. • Clinically significant drug interaction/s – see relevant section of this PGD and also refer to current British National Formulary (BNF) www.bnf.nice.org.uk 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. • Check for any other medications that the patient is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. (Refer to BNF/SPC for full list)

	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.
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. • If applicable, explain consequences of refusing treatment and 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. • If appropriate refer to GP/Consultant Obstetrician, offer alternative management if appropriate. • Record any actions taken.

3. Description of treatment

Name, strength and formulation of drug	Aspirin 75 mg dispersible tablets
Legal category	POM/P
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	150mg (2 x 75 mg tablets) once daily.
Duration of treatment	For Pregnant individuals identified at moderate and high risk of pre-eclampsia using the guidance outlined in Hypertension in pregnancy: diagnosis and management NICE guideline [NG133]: • from 12 weeks of pregnancy to delivery. For pregnant individuals identified at risk of placental dysfunction in accordance with Green-top guideline no.31: • from 12 weeks of pregnancy to at least 36 weeks.
Quantity to be supplied	Supply of appropriate labelled packs of 28 x 75mg tablets can be made up to a maximum of 14 x 28 tablet packs (equivalent to a maximum of 28 weeks supply). NB. The registered healthcare professional may have a reason to issue the supply in instalments. If this is the case, only whole packs of aspirin 75mg may be issued, up to a maximum total of fourteen packs. Each subsequent supply is defined as a discrete episode of care, requiring the registered healthcare professional to re-assess the individual against the PGD criteria and document accordingly in line with the requirements of the PGD. A clear record of the quantity of tablets issued on each date must be kept in the individual's hand held maternity records. The registered healthcare professional supplying each instalment must ensure that a suitable appointment has been made for the individual to receive their next instalment. The service will keep a tracer documenting the date and quantity of aspirin supplied, to allow midwives to ensure identification and follow up of any patients who don't access treatment.

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 and the BNF www.bnf.nice.org.uk Where a clinically significant interaction is identified discuss with appropriate medical/independent non-medical prescriber and document advice given.
Identification and 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 and BNF www.bnf.nice.org.uk 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, via Datix Once for Wales Reporting system.

Written information and further advice to be given to individual	• Provide patient information leaflet (PIL) provided with the original pack. • Write the patients name and the date of supply onto the medication label(s). • Write the number of tablets to be taken daily (TWO) in the space on the label • Explain mode of action, dose, 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. • 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. • For pregnant individuals identified at moderate and high risk of pre-eclampsia using the guidance outlined in Hypertension in pregnancy: diagnosis and management NICE guideline [NG133], the aspirin should be continued until delivery; for pregnant individuals identified at risk of placental dysfunction in accordance with Green-top guideline no.31, the aspirin should be continued until at least 36 weeks. • 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. If the individual has received less than the full supply of aspirin, a record of the quantity of tablets issued on each date must be kept in the individual's hand held maternity records. The registered healthcare professional supplying each instalment must ensure that a suitable appointment has been made for the individual to receive their next instalment. The individual must be advised to contact the midwives via switchboard on 01874 622443 if she is likely to run out of aspirin. The service will keep a tracer documenting the date and quantity of aspirin supplied, to allow midwives to ensure identification and follow up of any patients who don't access treatment.

Records	Record consultation details as required by local procedures. In addition, record: • The consent of the individual and if the individual is over 16 years of age and not competent to consent, record action taken. Record name of representative who gave consent, if appropriate. • Name of individual, address, date of birth • GP contact details where appropriate • Relevant past and present medical history, including medication and family history. • Any reasons for exclusion or referral, including actions taken. • Examination finding/s where relevant. • Any known allergies or previous adverse events and nature of reaction. • Printed name and signature of registered health professional. • Name, form, and strength of medication supplied • Date of supply • Dose supplied • Quantity supplied. NB. If the medication is to be supplied in instalments, the healthcare professional must record the date of the next appointment and the individual must be given contact details for the service, along with advice to ensure she collects the next instalment. • Expiry date of medicine 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), record PGD title and version number 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 (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 Staff accredited to use this 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"	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.