



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

Folic acid 5mg tablets

by registered midwives

to reduce the risk of neural tube defect

or to compensate for the increased demand for folate

during pregnancy

in Powys Teaching Health Board (PTHB)

Version number: PGD 0095E

Change history

| Version number | Change details | Date |
|----------------|--|------------|
| PGD 0095 | Initial Issue | 07/03/2017 |
| PGD 0095-A | Review Issue- and new PTHB PGD template | 31/05/2019 |
| PGD0095-B | Review issue – to include SPS Pharmacy Service PGD template adoption | May 2022 |
| PGD 0095C | Updated according to SPS template version number 2.0: Planned review. Updated exclusion criteria in line with SmPC. SLWG membership updated. Minor formatting changes and updates to PTHB PGD template. Updated cautions section. Supply arrangements updated. | 01/02/2025 |
| PGD 0095D | Updated according to SPS template version number 2.1: Updated information around BMI and bariatric surgery to reflect latest NICE and CKS guidance | 22/07/2025 |
| PGD 0095E | Updated according to SPS template version number 2.2: Removed reference to extended duration of treatment for individuals taking dolutegravir to reflect updated BHIVA guidance. Removed reference to individuals with BMI $\geq 25\text{kg/m}^2$. Reworded statement on individuals who have had bariatric surgery. | 17/12/2025 |




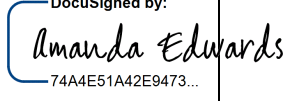
This Powys Teaching Health Board (PTHB) PGD is based on template v2.2 developed on behalf of the Specialist Pharmacy Service, which had been peer reviewed by the Preventative Medicines in Pregnancy PGDs Short Life Working Group (SLWG) in accordance with their Terms of Reference. It had been reviewed by the Royal College of Obstetrics and Gynaecology (RCOG) and had been endorsed by Professor Donald Peebles, National Clinical Director for Maternity NHS England.

Note the working group and approving organisation(s) agreement to the content only applies to the national template and does not extend to any local adaptations made to any of the content which are solely the responsibility of the organisation authorising the PGD. The most up to date version of the template is available from the [SPS national PGD template webpage](#).

Acknowledgements:

| Name or Role | Position |
|---|---|
| Amy Moore | Pharmacist HIV, Sexual and Reproductive Health Kingston Hospital NHS Foundation 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 |
| 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... | 12/16/2025 |
| Chief Pharmacist Jonathan Boyd | Chief Pharmacist for PTHB |  Signed by: Jon Boyd 6D8ECFE8C9EB423... | 12/16/2025 |
| Senior representative of professional group using the PGD Paul Hooton | Executive Director of Nursing and Midwifery for PTHB |  Signed by: Paul Hooton EEABC83AC83F4B9... | 12/17/2025 |
| Clinical Governance Lead Amanda Edwards | Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement |  DocuSigned by: Amanda Edwards 74A4E51A42E9473... | 12/17/2025 |

[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 (e.g. [2013 No.235](#), [2015 No.178](#), [2015 No.323](#) and [2024 No.729](#)).

Characteristics of staff

The decision to administer or supply any medicine rests with the individual registered practitioner who must abide by the PGD and any associated organisation policies.

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| <p>Qualifications and professional registration</p> | <p>Current contract of employment with Powys Teaching Health Board (PTHB). 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 listed in the legislation as able to practice under Patient Group Directions, and registered with the following body:</p> <ul style="list-style-type: none"> • Midwives currently registered with the Nursing and Midwifery Council (NMC) <p>Practitioners must also fulfil the Additional requirements listed below.</p> <p>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.</p> |
| <p>Initial training</p> | <p>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.</p> <p>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.</p> <p>Practitioner 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.</p> <p>Additionally, practitioners:</p> <ul style="list-style-type: none"> • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions) • must have knowledge of the uses of 5mg folic acid tablets, be familiar with its contraindications and adverse effects, and be alert to changes in the BNF and Summary of Product Characteristics |

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| | <ul style="list-style-type: none"> • must have undertaken training appropriate to this PGD as required by local policy • 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 PGD and associated online resources <p>THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.</p> |
| <p>Competency assessment</p> | <p>Registered healthcare professionals (HCPs) operating under this PGD must be assessed as competent (see Appendix A). The registered HCP must complete an appropriate 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.</p> <p>Registered HCPs operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions.</p> <p>Practitioners must recognise their own limitations and personal accountability and act accordingly.</p> |

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| <p>Ongoing training and competency</p> | <p>Registered HCPs operating under this PGD are personally responsible for ensuring they remain up to date with the use of the medicine included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising staff to act under the PGD and further training provided as required.</p> <p>Practitioners must ensure they are up to date with relevant clinical skills and appropriate Continued Professional Development (CPD) must be maintained and made available on request.</p> <p>Compliance with all mandatory NHS training.</p> <p>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.</p> <p>It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.</p> |
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Clinical condition or situation to which this PGD applies.

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| <p>Clinical condition or situation to which this PGD applies</p> | <p>Individuals where there is an increased risk of neural tube defect or where there is a requirement to compensate for the increased demand for folate during pregnancy.</p> <p>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.</p> |
| <p>Criteria for inclusion</p> | <ul style="list-style-type: none"> • Informed consent given. Refer to PTHB Consent to Treatment and Examination Policy. The individual should be informed they are being treated using a PGD. • For individuals in the following groups to be taken prior to conception (recommended for 3 months prior to conception where possible) and continued throughout the first 12 weeks of pregnancy: <ul style="list-style-type: none"> ○ Previous pregnancy affected by neural tube defect ○ Pregnant individual or baby’s biological father has a neural tube defect |

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| | <ul style="list-style-type: none"> ○ Family history of neural tube defect ○ Diabetes type 1 or 2 ○ Individuals taking anti-epilepsy medication ● For individuals in the following group to be taken prior to conception (recommended for 3 months prior to conception where possible) and continued throughout the entire pregnancy: <ul style="list-style-type: none"> ○ Individuals with sickle cell disease, thalassaemia or thalassaemia trait. ● Medical and drug history taken, no reason for exclusion <p>Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed, where appropriate. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults, POVA) advice from the local Safeguarding team should be sought (see below).</p> |
| <p>Criteria for exclusion</p> | <ul style="list-style-type: none"> ● Conditions outside of the clinical situations criteria. ● 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 "Actions to be taken if the individual is excluded or declines treatment". ● Individuals aged under 16 years of age who are assessed as not competent to consent using Fraser Guidelines. ● Hypersensitivity/allergy to the active ingredient or any of the product excipients. ● Individuals with malignant disease, unless megaloblastic anaemia due to folic acid deficiency. ● Individuals with known untreated vitamin B12 deficiency. ● Individuals with malabsorption states (e.g. coeliac disease, short bowel syndrome, lactase deficiency, pancreatic insufficiencies or liver disease) or those on sulfasalazine. ● 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 SmPC which can be accessed on the EMC website before supplying. ● Individuals who have had bariatric surgery. Individuals who have had bariatric surgery – advise them to contact the bariatric surgery unit for additional specialist advice. ● Clinically significant drug interaction/s – see interactions section of this PGD and also refer to current British National Formulary (BNF) or SmPC which can be accessed on the EMC website. |

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| <p>Cautions including any relevant action to be taken</p> | <p>Discuss with appropriate medical/independent non-medical prescriber any medical condition or drug interaction of which the healthcare professional is unsure or uncertain.</p> <ul style="list-style-type: none"> • Folic acid is removed by haemodialysis. • Folate should not be routinely used in individuals receiving coronary stents. • Caution should be exercised when administering folic acid to individuals who may have folate dependent tumours. • Individuals with complex multiple pathologies, polypharmacy or multiple allergies. • Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products (Refer to BNF/SPC for full list). <p>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 PTHB safeguarding policies followed. Consider discussing with GP.</p> <p>Any safeguarding concerns need to be directed to Safeguarding Hub:</p> <ul style="list-style-type: none"> • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk <p>and</p> <ul style="list-style-type: none"> • Central Safeguarding number: 01686 252806. • Out of hours: 0345 0544847. <p>Advice can also be sought from local Safeguarding Leads.</p> |
| <p>Actions to be taken if the individual is excluded or declines treatment</p> | <ul style="list-style-type: none"> • Explain the reasons for exclusion to the individual and document in the consultation record. • If applicable, explain consequences of refusing treatment – the patient information leaflet should be available to inform consent. Record reason for declining in the consultation record. • Where required refer the individual to a suitable health service provider if appropriate (GP/Consultant Obstetrician) and/or provide them with information about further options. • Document advice given and record any actions taken. |

Description of treatment

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| Name, form and strength of medicine | Folic acid 5mg tablets |
| Legal category | POM |
| Route or method of administration | Oral |
| Off label use | <p>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) which can be accessed on the EMC website.</p> <p>This PGD includes inclusion criteria, exclusion criteria and dosage regimens which are outside the market authorisation for many of the available products.</p> <p>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.</p> <p>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.</p> |
| Dose and frequency of administration | 5mg once daily |

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| <p>Quantity to be supplied</p> | <p>Supply of appropriate number of labelled packs of 28 x 5mg tablets (up to a maximum of 10 packs) as defined in the inclusion criteria.</p> <p>NB. The registered healthcare professional may have a reason to issue the supply in instalments. If this is the case, only whole packs of folic acid 5mg tablets may be issued, up to a maximum total of 10 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 (NB. this may be an appointment made for the individual to attend their GP, following appropriate notification). The service will keep a tracer documenting the date and quantity of medication supplied, to allow midwives to ensure identification and follow up of any individuals who don't access treatment.</p> |
| <p>Duration of treatment</p> | <p>To be taken prior to conception (where possible) and continued throughout the first 12 weeks of pregnancy or continued throughout the entire pregnancy as defined in the inclusion criteria.</p> |
| <p>Storage</p> | <p>Medicines must be stored securely according to national guidelines and in accordance with the Summary of Product Characteristics (SmPC) which can be accessed on the EMC website.</p> |
| <p>Drug interactions</p> | <p>All concurrent medications must be checked for interactions. A detailed list of drug interactions is included in the Summary of Product Characteristics (SmPC) which can be accessed on the EMC website or the BNF.</p> <p>Where a clinically significant interaction is identified discuss with appropriate prescriber and document advice given.</p> |

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| <p>Identification and management of adverse reactions</p> | <p>A detailed list of adverse reactions is included in the Summary of Product Characteristics (SmPC) which can be accessed on the EMC website or the BNF.</p> <p>The following possible adverse effects are rarely reported with folic acid (but may not reflect all reported adverse effects):</p> <ul style="list-style-type: none"> ○ Abdominal distension ○ Decreased appetite ○ Flatulence ○ Nausea ○ Vitamin B12 deficiency exacerbated ○ Skin reaction – erythema, rash, pruritis, urticaria |
| <p>Management of and reporting procedures for adverse reactions</p> | <ul style="list-style-type: none"> • Any individual experiencing mild side effects should contact their community midwife in the first instance for advice – where, if clinically necessary, the midwife should advise on any need for immediate discontinuation and refer to a specialist clinician for further advice. • Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the MHRA's Yellow Card Scheme. For established medicines, serious adverse events in adults or all suspected adverse reactions in children that may be attributable to the medication should be reported. • Record all adverse drug reactions (ADRs) in the individual’s clinical record. • Report via organisation incident policy, via Datix Once for Wales Reporting system. |
| <p>Written information and further advice to be given to individual or carer</p> | <ul style="list-style-type: none"> • Provide patient information leaflet (PIL) provided with the original pack. • Write the individual’s name and the date of supply onto the medication label(s). • Explain mode of action, side effects, and benefits of the medicine. • Any remaining tablets not taken by the end of the pregnancy should be returned to a community pharmacy for disposal. |

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| <p>Advice/ Follow-up treatment</p> | <ul style="list-style-type: none"> • The individual should be advised to seek medical advice in the event of an adverse reaction. • Individual to seek further advice if they have any concerns. • Contact GP via surgery or emergency on call service. • Follow up appointments should be arranged as per local policy. If the individual has received less than the full supply of folic acid 5mg, 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 the next instalment (NB. this may be an appointment made for the individual to attend their GP, following appropriate notification). The individual must be advised to contact the midwives via switchboard on 01874 622443 if she is likely to run out of folic acid. |
| <p>Records to be kept</p> | <p>Record consultation details as required by local procedures. In addition, record:</p> <ul style="list-style-type: none"> • The consent of the individual and <ul style="list-style-type: none"> ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken ○ If individual over 16 years of age and not competent, record action taken. 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 history and relevant family history • Examination finding where relevant e.g. weight • Any known medication allergies or previous adverse events and nature of reaction • Printed name and signature of registered health professional operating under the PGD • Name, form and strength of medication supplied • Date of supply • Dose supplied • Quantity supplied including batch number and expiry date in line with local procedures. 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 • Advice given and actions taken, including advice given if excluded or declines treatment (also document reasons for exclusion or referral) |

- 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, including referral arrangements to GP to prescribe a further supply, if appropriate
- Any advice received from medical cover and advice given to individual / carer
- Any supply outside the terms of the product marketing authorisation
- Record that supplied via Patient Group Direction (PGD), record PGD title and version number

Records should be signed and dated (or 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 July 2024, March 2025 and July 2025)

- [SmPC on EMC website](#)
- [Current edition of British National Formulary](#)
- [NICE Medicines practice guideline MPG2 - Patient Group Directions - Last Updated 27 March 2017](#)
- [CMACE/RCOG \(2018\) Management of women with obesity in pregnancy.](#)
- [NICE \(2025\) Pre-conception – advice and management](#)
- [NICE \(2025\) Maternal and child nutrition: nutrition and weight management in pregnancy, and nutrition in children up to 5 years](#)
- [Diabetes in pregnancy: management from preconception to the postnatal period NICE guideline \[NG3\] Published date: February 2015 Last updated: December 2020](#)
- [BHIVA guidelines on the management of HIV in pregnancy and the postpartum period 2025](#)

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 |
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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 |
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| 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 | | | |

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| 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.