NHS
Somerset
Integrated Care Board

Patient Group Direction: For the supply of FOLIC ACID 5mg TABLETS by Community Pharmacists in Somerset before conception and during pregnancy to reduce the risk of neural tube defect or to compensate for the increased demand for folate during pregnancy (PGD MAS 8 Version 1.0)

Staff involved in the development of this PGD:

	Name	Signature	Date
Physician	Dr Andrew Tresidder NHS Somerset ICB Prescribing and Medicines Management Group Chair		16.11.2022
Pharmacist	Hels Bennett Medicines Manager, NHS Somerset ICB		16.11.2022

Name of original authors:
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Authorised for use across NHS Somerset ICB by:

Shelagh Meldrum, Chief Nursing Officer for NHS Somerset ICB (Acting as Clinical Governance Lead)

Signed: Shelagh Meldrum Date: 23.11.22

Date of implementation: 1 December 2022
Expiry Date: 30 November 2024

TO BE COMPLETED BY PHARMACY AUTHORISING MANAGER:

I, ……, as authorising manager for …… pharmacy, have read and approved this PGD for use by appropriate healthcare professionals working at my pharmacy. I understand that I am responsible for ensuring that pharmacy staff have adequate training to ensure that FOLIC ACID 5mg TABLETS is supplied to patients in strict accordance with this PGD.

Signed…… Dated……

NHS Somerset Integrated Care Board

Patient Group Direction: For the supply of FOLIC ACID 5mg TABLETS by Community Pharmacists in Somerset before conception and during pregnancy to reduce the risk of neural tube defect or to compensate for the increased demand for folate during pregnancy (PGD MAS 8 Version 1.0)

This Patient Group Direction is operational from 1 December 2022 and expires 30 November 2024

The healthcare professionals named below are authorised to supply FOLIC ACID 5mg TABLETS as specified under this Patient Group Direction, while working at:

…… …… (INSERT PHARMACY NAME)

In signing this document, I confirm the following:

- I have read and understood the above mentioned PGD.
- I agree to practice only within the bounds of my own competence and in accordance with my Code of Professional Conduct.
- I have the qualifications required under the staff characteristics detailed in the PGD
- I am competent to operate under this PGD.
- I will provide the service in accordance with the PGD

NAME *(please print)*	TITLE	SIGNATURE	AUTHORISING MANAGER *(please print)*	MANAGER'S SIGNATURE	DATE

- **Complete additional pages as necessary.**
- **Retain original signed pages (1) and (2) with authorising manager.**

Patient Group Direction: For the supply of FOLIC ACID 5mg TABLETS by Community Pharmacists in Somerset before conception and during pregnancy to reduce the risk of neural tube defect or to compensate for the increased demand for folate during pregnancy (PGD MAS 8 Version 1.0)

N.B. You must be authorised by name, under the current version of this PGD before you attempt to work in accordance with it.

1. Clinical Condition

Definition of condition/situation	• 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 their pregnancy
Criteria for inclusion	• Informed consent given. • 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: o BMI ≥ 30kg/m^2 o Previous pregnancy affected by neural tube defect o Either partner has a neural tube defect o Family history of neural tube defect o Diabetes type 1 or 2 o Individuals taking anti-epilepsy medication o Individuals taking sulfasalazine • 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 entire pregnancy: o Individuals with sickle cell disease, thalassaemia or thalassaemia trait. • For individuals in the following groups – to be taken if pregnancy occurs and continued up to 12 weeks of pregnancy: o Individuals taking low dose methotrexate (≤25mg/week)* o Individuals treated with low dose methotrexate within one month prior to conception. *Individuals who become pregnant whilst taking low dose methotrexate should be advised to stop the drug immediately and contact their specialist for urgent review **Off label use** Best practice advice is given by the RCOG, NICE and BSR and is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). Where a medicine is recommended off-label consider, as part of the consent process, informing the individual that the medicine is being offered in accordance with national guidance but that this is outside the product licence.

	Other considerations Consider whether patient may also be eligible for treatment under *PGD MAS 7: For the supply of ASPIRIN 75MG DISPERSIBLE TABLETS by Community Pharmacists in Somerset to pregnant patients considered to be at high risk of pre-eclampsia*
Exclusion criteria	• Informed consent not obtained (if capacity is a problem, refer to GP) • 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 known untreated vitamin B12 deficiency • Malignant disease or individuals undergoing chemotherapy • Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. • Individuals already being treated with folic acid 5mg daily or higher • Clinically significant drug interactions which are not specifically covered in the 'Caution' section of this PGD. Refer to current British National Formulary (BNF) www.bnf.org or individual product SmPC http://www.medicines.org.uk

Caution	• For a full list of special warnings, precautions for use & interactions consult the SmPC available at: https://www.medicines.org.uk/emc and the BNF
	• Antacids containing aluminium or magnesium - may reduce folic acid absorption. Patients should be advised to take antacids at least two hours after administration of folic acid.
	• Colestyramine - concurrent administration may interfere with folic acid absorption. Patients on prolonged colestyramine therapy should take folic acid 1 hour before or 4 to 6 hours after receiving colestyramine.
	• **Urgently refer** to patient's GP or specialist if taking any drug which requires urgent review in pregnancy. Including (but not exhaustive):
	  ○ Valproates
	  ○ Antiepileptic medication
	  ○ Chronic pain medication
	  ○ DMARDs
	  ○ Lithium
	  ○ Any other drug (OTC, illicit or prescribed) the patient tells the pharmacist they are taking which pharmacist identifies may need GP or specialist review in pregnancy
	
	Use the most up to date monograph from the UKTIS website to review the need for referral to GP http://www.uktis.org/
	
	Folic acid 5mg can be supplied against this PGD (1 x 28 tablets ONLY) in the following circumstances; however, patients must be referred to their GP or specialist for urgent review:
	
	Patients taking:
	• **Valproates**
	• **Phenytoin, phenobarbital and primidone** – serum levels of the anticonvulsant may be reduced by administration of folic acid and therefore patients should be carefully monitored by their specialist and the anticonvulsant drug dose adjusted as necessary.
	• **Other antiepileptic medication**
	• **Methotrexate**
	• **Sulfasalazine** - sulfasalazine reduces the absorption of folic acid - these patients may need closer monitoring by their specialists.
	• **Lithium** - folate supplements enhance the efficacy of lithium therapy.
	
	Patients with:
	• **Malabsorption states** (e.g. coeliac disease, short bowel syndrome, lactase deficiency, pancreatic insufficiencies or liver disease, weight loss surgery) https://www.nhs.uk/conditions/malnutrition/causes/ - these patients may need higher doses

Action if excluded	• Document reason for exclusion and any action taken or advice given in the clinical records. • Refer to appropriate medical practitioner or for urgent medical attention as appropriate to avoid delay in treatment. • If no valid consent or if child not Fraser competent then refer the individual to a suitable health service provider as appropriate and/or provide them with information about further options. • Patients not clinically indicated to take folic acid 5mg should be advised to take folic acid 400micrograms daily and to discuss with their GP if they believe they should take a higher dose but are not included within this PGD. https://www.nhs.uk/pregnancy/trying-for-a-baby/planning-your-pregnancy/
Action if patient refuses medication	• Suggest patient discusses with their medical practitioner or signpost them for urgent medical attention as appropriate. • Signpost patient to NHS website for further information on folic acid in pregnancy if appropriate: Vitamins, minerals and supplements in pregnancy - NHS (www.nhs.uk)

2. Characteristics of Staff

Professional qualification to be held by staff working under this Patient Group Direction	Pharmacist registered with the General Pharmaceutical Council (GPhC) and competent to work with this patient group direction (PGD), including familiarity with NICE guidance on PGDs (see references).
Additional requirements	• Must have completed initial training and/or be familiar with the current service level agreement • Must access RCOG, NICE and BSR guidance on folic acid and pregnancy when necessary or if not familiar with the topic (see references). • Must have access to a current copy of the BNF (electronic access is most appropriate.) • Consultation room available for discussion • The individual pharmacist's competence with respect to their practice under this PGD will be assessed by their mentor/manager on a regular basis • It is the responsibility of the pharmacist to keep up to date with their continued professional development, in line with GPhC requirements • The pharmacist must be alert to changes in Summaries of Product Characteristics, and Drug Safety Updates from the MHRA • CPPE level 2 Safeguarding children and vulnerable adults, or equivalent

3. Description of Treatment

Name of Medicine	• Folic acid 5mg tablets
Legal Class	• POM (Prescription Only Medicine)
Storage	• Do not store above 25°C • Keep the product in the original container in order to protect from light and moisture
Method or route of administration	• Oral
Dose to be used	• 5mg once daily
Frequency	• To be taken as defined in the inclusion criteria.
Total dose and number of times drug to be given. Details of supply (if supply made)	• An initial supply of 2 x 28 tablets • It is intended that the GP will continue to supply the medication thereafter • However, further supplies of 28 days duration may be supplied against this PGD if required • **For patients referred for urgent review – only 1 x 28 tablets can be supplied, with no further supplies allowed against this PGD.**

Advice and information to patient/carer including follow-up	• Ensure that the Patient Information Leaflet (PIL) is provided and advise the patient to read the leaflet before using the medicine and that the pharmacy can be contacted if any queries arise • Provide full explanation of the risks and benefits to the patient (including the off-label use of the medicine in order to obtain informed consent). • Provide information on possible side-effects and management. The following possible adverse effects are rarely reported with folic acid (but may not reflect all reported adverse effects): o Abdominal distension o Decreased appetite o Flatulence o Nausea o Vitamin B12 deficiency exacerbated o Skin reaction – erythema, rash, pruritis, urticaria 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.org • The individual should be advised to seek medical advice in the event of an adverse reaction. • Advise patient to discuss with their midwife, so they are aware that they have initiated folic acid • Folic acid is safe to take while breastfeeding. Further information on pregnancy, breastfeeding and fertility while taking folic acid can be found on the NHS website https://www.nhs.uk/medicines/folic-acid/pregnancy-breastfeeding-and-fertility-while-taking-folic-acid/#:~:text=Folic%20acid%20and%20breastfeeding,small%20to%20harm%20your%20baby • RCOG Patient information – Sickle cell disease and pregnancy https://www.rcog.org.uk/media/ycrfqcva/pi-sickle-cell-disease-and-pregnancy.pdf **Adverse effects:** Any serious adverse reaction should be documented e.g. in the consent forms, patient's medical record and the GP should also be informed. Unusual /persistent side effects should be followed up with a medical practitioner. Any **serious** adverse events that may be attributable to folic acid should be reported to the MHRA using the yellow card system https://yellowcard.mhra.gov.uk/ and also follow the local incident reporting procedure.

Specify method of recording supply /administration including audit trail	It is a legal requirement to keep auditable records of administration and supply of medication via a PGD.
	
	Information entered into a patient clinical record should include:
	
	• Patient's name, address and date of birth
	• Informed consent of the individual and
	  ○ 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
	• Indication including risk factor (s)
	• Name, strength, form and pack size of medication supplied
	• Date supplied
	• Information and advice given to the patient.
	• Signature/name and GPhC number of pharmacist who supplied the medication, and name and address of pharmacy
	• Details of any drug interactions experienced
	• Details of any adverse reactions experienced
	• Any patient decline or reason for exclusion
	• Record that medicine supplied via Patient Group Direction
	
	A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes within each pharmacy. Check with employer which method of recording is to be used.
	
	The GP practice should be informed of the consultation and supply of medication. Data must be stored in accordance with Caldicott guidance and the Data Protection Act.

References used in the development of this PGD:	• Summary of Product Characteristics (SPC) www.medicines.org.uk • Current edition of British National Formulary (BNF) • General Pharmaceutical Council standards • 'National Institute for Health and Care Excellence. Medicines Practice Guidelines, 'Patient Group Directions' last updated March 2017. https://www.nice.org.uk/Guidance/MPG2 • Shared decision making NICE guideline [NG197] 12.08.2021 Overview | Shared decision making | Guidance | NICE • Specialist Pharmacy Service - Supply of folic acid 5mg tablets to reduce the risk of neural tube defect or to compensate for the increased demand for folate during pregnancy: PGD template https://www.sps.nhs.uk/articles/supply-of-folic-acid-5mg-tablets-to-reduce-the-risk-of-neural-tube-defect-or-to-compensate-for-the-increased-demand-for-folate-during-pregnancy-pgd-template/ • CMACE/RCOG (2018) Management of women with obesity in pregnancy. Available from: https://www.rcog.org.uk/guidance/browse-all-guidance/green-top-guidelines/care-of-women-with-obesity-in-pregnancy-green-top-guideline-no-72/ • NICE (2019) Pre-conception – advice and management. Available from: https://cks.nice.org.uk/topics/pre-conception-advice-management/management/advice-for-all-women/ • Diabetes in pregnancy: management from preconception to the postnatal period NICE guideline [NG3] Published date: February 2015 Last updated: August 2015 https://www.nice.org.uk/guidance/ng3 • FSRH Clinical Guideline: SRH for Individuals with Inflammatory Bowel Disease (IBD) October 2016 https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-srh-ibd/ • NHS Somerset Shared Care Protocol DMARDs available at: https://nhssomerset.nhs.uk/prescribing-and-medicines-management/shared-care/ • Use of sulfasalazine in pregnancy (medicinesinpregnancy.org) https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-SULFASALAZINE-IN-PREGNANCY/ • NHS Medicines A-Z Sulfasalazine https://www.nhs.uk/medicines/sulfasalazine/ (Section 7: Pregnancy & breastfeeding) • British Society for Rheumatology (BSR) guidelines on prescribing drugs in pregnancy and breastfeeding: immunomodulatory anti-rheumatic drugs and corticosteroids Updated November 2022 https://academic.oup.com/rheumatology/advance-article/doi/10.1093/rheumatology/keac551/6783012

Please refer to the summary of product characteristics for full information

This Patient Group Direction is operational from 1 December 2022 and expires 30 November 2024

Version History

Version	Date	Brief Summary of Change	Owner's Name
0.6	29.09.2022	**New PGD created**	Hels Bennett, Medicines Manager, NHS Somerset ICB
1.0	04.11.2022	**PGD updated following comments from YDH & SFT, and publication of updated BSR guidelines. PGD approved for use by Prescribing & Medicines Management committee**	Hels Bennett, Medicines Manager, NHS Somerset ICB