NHS
Somerset
Integrated Care Board

Patient Group Direction: 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 (PGD MAS 7 Version 2.0)

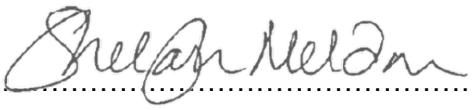
Staff involved in the development of this PGD:

	Name	Signature	Date
Physician	Dr Andrew Tresidder NHS Somerset Medicines Programme Board Chair		2.11.23
Pharmacist	Hels Bennett Medicines Manager, NHS Somerset ICB		01/11/2023

Name of original authors:
Hels Bennett, Medicines Manager, NHS Somerset ICB
Sam Morris, Medicines Manager, NHS Somerset ICB

Authorised for use across NHS Somerset ICB by:

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

Signed:  Date: 03.11.23

Date of Implementation: 8th December 2023
Expiry Date: 7th December 2025

TO BE COMPLETED BY PHARMACY AUTHORISING MANAGER:

I, ……, as authorising manager for ……. pharmacy, have read and approved this PGD for use by appropriate registered pharmacists working at my pharmacy. I understand that I am responsible for ensuring that pharmacy staff have adequate training to ensure that ASPIRIN 75MG DISPERSIBLE TABLETS is supplied to patients in strict accordance with this PGD.

Signed…… Dated……

Patient Group Direction: 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 (PGD MAS 7 Version 2.0)

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The registered pharmacists named below are authorised to supply ASPIRIN 75MG DISPERSIBLE 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 this 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 ASPIRIN 75MG DISPERSIBLE TABLETS by Community Pharmacists in Somerset to pregnant patients considered to be at high risk of pre-eclampsia (PGD MAS 7 Version 2.0)

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	• Pregnant patients considered to be at high risk of pre-eclampsia who are advised to take low dose aspirin as per NICE guidelines (NG133). • For the purposes of this document, the word patient(s) will be used to refer to women and people assigned female at birth.
Criteria for inclusion	• Aged 16 years or over • Valid informed consent given • Pregnant patients at high risk of pre-eclampsia. Patients at high risk are those with **any** of the following: ➢ hypertensive disease during a previous pregnancy (pre-eclampsia or pregnancy induced hypertension) ➢ chronic kidney disease ➢ autoimmune disease such as systemic lupus erythematosus or antiphospholipid syndrome ➢ type 1 or type 2 diabetes ➢ chronic hypertension outside of pregnancy requiring antihypertensive treatment (as defined by NICE) **Or:** Pregnant patients with **two or more** moderate risk factors for pre-eclampsia. Factors indicating moderate risk are: ➢ Nulliparity (never previously given birth) ➢ age 40 years or older ➢ pregnancy interval of more than 10 years ➢ body mass index (BMI) of 35kg/m² or more at first visit ➢ family history of pre-eclampsia ➢ multiple pregnancy **Off-label use** **The use of aspirin is off-label for this indication. Its use is in accordance with NICE guideline NG133 Hypertension in pregnancy: diagnosis and management. Patients should be made aware of this off-label use in order to give informed consent.**

Exclusion criteria	• Consent not obtained (if capacity is a problem, refer to GP) • Known hypersensitivity to aspirin, salicylic acid compounds, NSAIDs or prostaglandin synthetase inhibitors or to any of the excipients – see SPC for full details (link in references). • Asthma triggered by aspirin or NSAIDs • Peptic ulceration or history of peptic ulceration and/or gastric/intestinal haemorrhage, or other kinds of bleeding e.g. cerebrovascular haemorrhages • Known or suspected severe hepatic impairment • Known or suspected severe renal impairment • Active or history of gout • Patients under 16 years old • Current COVID-19 infection • Haemorrhagic diathesis; coagulation disorders such as haemophilia and thrombocytopenia. • Patients with Glucose-6-phosphate dehydrogenase deficiency • Patients currently prescribed any of the following: – Anti-coagulants – Anti-platelet agents – Methotrexate – NSAIDs – Oral steroids – Selective serotonin-reuptake inhibitors (SSRIs) – Uricosuric agents e.g. probenecid, sulfinpyrazone – Digoxin – Lithium – Carbonic anhydrase inhibitors e.g. acetazolamide – Ciclosporin or tacrolimus – Valproate – Phenytoin – Antihypertensives – Diuretics – Retinoids
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 • Current uncontrolled or severe asthma • Breastfeeding – refer to Specialist Pharmacy Service for further guidance https://www.sps.nhs.uk/articles/using-antiplatelet-medicines-during-breastfeeding/ • Urgently refer to patient's GP if prescribed any regular medications which require urgent review in pregnancy. Including (but not exhaustive): – Valproates – Antiepileptic medication – Chronic pain medication – DMARDs

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. • Refer to medical practitioner if patient excluded or if no valid consent.
Action if patient refuses medication	• Refer to medical practitioner or for urgent medical attention as appropriate.

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)
Additional requirements	• Must have undertaken appropriate education and training and declared themselves competent to undertake clinical assessment of patient leading to diagnosis of the condition(s) listed in this PGD. • Must be familiar with NICE guidance 'Hypertension in pregnancy: diagnosis and management NICE guideline [NG133]: https://www.nice.org.uk/guidance/ng133/chapter/Recommendations • Must be familiar with NICE guidance on PGDs and competent in the use of PGDs (see NICE competency framework for health professionals using PGDs). Suggested recommended training - eLfH PGD elearning programme • Must have access to the PGD and associated online resources relating to the use of the PGD • Must have access to current BNF (BNF online is recommended) • Consultation room available for discussion • CPPE level 2 Safeguarding children and vulnerable adults (including updates), or equivalent • Must have completed initial training and/or be familiar with the current service level agreement. • Individuals operating under this PGD must be assessed as competent or complete a self-declaration of competence to operate under this PGD • Staff operating under this PGD should review their competency using the NICE Competency Framework for health professionals using patient group directions • 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 MHRA.

3. Description of Treatment

Name of Medicine	• Aspirin 75mg dispersible 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	• 150mg (Two 75mg tablets)
Frequency	• 150mg (Two 75mg tablets) ONCE daily at night, with or after food. To be taken from 12 weeks gestation until birth of the baby.
Total dose and number of times drug to be given. Details of supply (if supply made)	• An initial supply of 112 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 **Off-label use** **The use of aspirin is off-label for this indication. Its use is in accordance with NICE guideline NG133 Hypertension in pregnancy: diagnosis and management. Patients should be made aware of this off-label use in order to give informed consent.**

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 patient with the leaflet '*Taking aspirin to reduce the risk of pre-eclampsia*', available from https://nhssomerset.nhs.uk/prescribing-and-medicines-management/shared-care/ • 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). • Advise patient that the tablet should be dispersed in water and taken with or after food - aspirin should not be taken on an empty stomach. • Drinking alcohol with aspirin may increase the risk of gastrointestinal bleeding and prolong bleeding time. It is recommended not to drink alcohol at all while pregnant. • No other NSAID or aspirin containing products including over the counter analgesic preparations should be taken • Provide information on possible side-effects and management. The following are well known side-effects of aspirin; see the Summary of Product Characteristics (SmPC) http://www.medicines.org.uk/emc/ and the current edition of the BNF for full details and updates – indigestion, nausea, vomiting, diarrhoea and gastrointestinal bleeding which can lead to haemorrhage and perforation – bruising or bleeding more easily e.g. cuts may take longer than normal to stop – aspirin may precipitate bronchospasm and induce asthma attacks or other hypersensitivity reactions in susceptible individuals • The patient should be advised to stop aspirin and seek emergency advice and assistance if they notice any of the following serious side effects: – Sudden wheezing, swelling of the lips, face or body, rash, fainting or difficulties swallowing (severe allergic reaction) – Reddening of the skin with blisters or peeling which may be associated with a high fever and joint pains. This could be erythema multiforme, Stevens-Johnson syndrome or Lyell's syndrome. – Unusual bleeding, such as coughing up blood, blood in vomit or urine, or black stools • Advise patient to discuss with their midwife, so they are aware that they have initiated or will initiate aspirin at 12 weeks. • Advise patient that COVID-19 can be associated with thrombocytopenia. When aspirin is being taken as prophylaxis for pre-eclampsia, it should be discontinued for the duration of the infection as this may increase the bleeding risk in women with thrombocytopenia. 2021-11-02-coronavirus-covid-19-infection-in-pregnancy-v14.1.pdf (rcog.org.uk) Advise patient to contact their midwife, consultant or GP if they have symptoms of COVID-19.

Other considerations

Consider whether patient may also be eligible for treatment under *PGD MAS 8: 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*

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 aspirin 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. All records should be clear, legible and contemporaneous. All records should be kept in line with national guidance. This includes individual data, master copies of the PGD and lists of authorised practitioners. Information entered into a patient clinical record should include: • Patient's name, address and date of birth • Informed consent given • Specify how the individual has/has not met the criteria of the PGD, including risk factors • Name, strength, form and pack size of medication supplied • Date of supply • 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 • Any referral arrangements • Record that medicine supplied via Patient Group Direction • Recording of any prescription charges / exemptions • Consultation details to be recorded on PharmOutcomes (ideally at time of consultation but must be within 48 hours) The GP practice should be informed of the consultation and supply of medication (this will be done automatically via PharmOutcomes). 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. Data must be stored in accordance with Caldicott guidance and the Data Protection Act.

References used in the development of this PGD:	• PMP Aspirin National PGD template Feb 2022 https://www.sps.nhs.uk/articles/aspirin-tablets-for-use-within-antenatal-and-maternity-services/ • Summary of Product Characteristics (SPC) www.medicines.org.uk • Current edition of BNF (British National Formulary) | NICE • 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 • Hypertension in pregnancy: diagnosis and management NICE guideline [NG133] Published: 25 June 2019 Last updated: 17 April 2023 https://www.nice.org.uk/guidance/ng133/chapter/Recommendations • Drugs & Lactation Database (LactMed) accessed 18.10.2023 https://www.ncbi.nlm.nih.gov/books/NBK501196/ • The Breastfeeding Network accessed 18.10.2023 Low dose aspirin and breastfeeding – Breastfeeding and Medication (breastfeeding-and-medication.co.uk) • USE OF ASPIRIN AND ASPIRIN OVERDOSE IN PREGNANCY – UKTIS • Specialist Pharmacy Service accessed 18.10.2023 https://www.sps.nhs.uk/articles/using-antiplatelet-medicines-during-breastfeeding/ • Shared decision making NICE guideline [NG197] 12.08.2021 Overview | Shared decision making | Guidance | NICE • Coronavirus (COVID-19) Infection in Pregnancy Version 14.1 RCOG Published 02.11.2021 https://www.rcog.org.uk/globalassets/documents/guidelines/2021-11-02-coronavirus-covid-19-infection-in-pregnancy-v14.1.pdf

Please refer to the summary of product characteristics for full information

This Patient Group Direction is operational from 8th December 2023 and expires 7th December 2025

Version History

Version	Date	Brief Summary of Change	Owner's Name
0.1	09.08.2021	**New PGD created**	Hels Bennett, Medicines Manager, Somerset CCG
0.2	06.10.2021	**Minor updates following comments from Somerset FT, LPC & LMC**	Hels Bennett, Medicines Manager, Somerset CCG
1.0	01.12.2021	**Minor updates following comments from Somerset CCG Prescribing & Medicines Management committee**	Hels Bennett, Medicines Manager, Somerset CCG
1.1	08.12.2021	**PGD updated with RCOG guidance: Coronavirus (COVID-19) infection in pregnancy. Current COVID-19 infection added to Exclusion Criteria, advice to patient added**	Hels Bennett, Medicines Manager, Somerset CCG
2.0	18.10.2023	**Reviewed against national aspirin PGD template published Feb 2022. Inclusion criteria updated from 17+ to 16+ years. 'First pregnancy' changed to 'nulliparity'. Reference to Folic acid PGD added. Current uncontrolled or severe asthma added as Caution. Minor updates & formatting changes. Approved at Somerset Medicines Programme Board October 2023.**	Hels Bennett, Medicines Manager, NHS Somerset ICB