NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction For The Supply Of Paracetamol Oral Suspension 120mg/5mL By Pharmacists To Babies Between 6 And 8 Weeks Of Age For Prevention Of Post Immunisation Fever Following Administration Of Meningococcal Group B Conjugate Vaccine (Bexsero®) Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Vaccine Pharmacist, NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature: 		**Signature:** 
NoS Identifier: NoS/PGD/Paracetamol/ U8w/1611	**Review Date:** January 2027 **Expiry Date:** January 2028	**Date Approved:** 23rd May 2025

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 1

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	New PGD	
Date of change	**Summary of Changes**	**Section heading**
	N/A – New PGD	

NoS Identifier: NoS/PGD/Paracetamol_U8w/1611
Keyword(s): PGD Patient Group Direction paracetamol oral suspension meningococcal MenB (Bexsero®▼) vaccination

Policy Statement: It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	February 2024
	Completed:	September 2024
	Approved:	January 2025 (published – May 2025)
	Amended and re-authorised:	

Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Clare-Louise Walker **Health Board:** NHS Grampian **Title:** Consultant in Public Health **Contact email:** clare-louise.walker@nhs.scot **Signature:** Clare Walker **Date:** 06/03/2025
Senior representative of the professional group who will provide care under the direction	**Name** Gayle MacDonald **Health Board:** NHS Highland **Title:** Vaccine Pharmacist **Contact email:** gayle.macdonald@nhs.scot **Signature:** G MacD **Date:** 07/03/2025
Lead author	**Name:** Fiona Marion **Health Board:** NHS Grampian **Title :** Vaccine Pharmacist **Contact email:** fiona.marion@nhs.scot **Signature:** FMarion **Date:** 06/03/2025
Pharmacist	**Name:** Bethany Carstairs **Health Board:** NHS Grampian **Title :** Community Pharmacist **Contact email:** bethany.carstairs@nhs.scot **Signature:** **Date:** 20/03/2025

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		22/05/2025

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Adam Coldwells – Interim Chief Executive		23/05/2025

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and best practice to have a representative of the professional group who will provide care under the direction.

Name:	Title:
Fiona Marion	**Lead Author:** Vaccine Pharmacist NHSG
Bethany Carstairs	**Pharmacist:** Community Pharmacy NHSG
Clare-Louise Walker	**Medical Practitioner:** Consultant in Public Health NHSG
Gayle MacDonald	**Senior Representative:** Vaccine Pharmacist NHSH
Jodie Allan	Medicines Management Specialist Nurse NHSG
Pauline Merchant	Clinical Lead Nurse Vaccination Programme NHSG

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Clinical indication to which this PGD applies

Definition of situation/ Condition	This Patient Group Direction (PGD) will authorise the supply of Paracetamol 120mg/5mL by community pharmacists to individuals for the prevention of post immunisation fever following administration of Meningococcal Group B conjugate (MenB) vaccine (Bexsero®). This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	Infants between 6 and 8 weeks of age who are receiving primary doses of MenB vaccine as part of the routine immunisation schedule. MenB vaccine will usually be given with other routine childhood immunisations at age 8 weeks. Most infants will be greater than 8 weeks of age when presenting for first dose, but a small number may be under 8 weeks old. This PGD is to facilitate a supply of paracetamol to infants over 6 weeks of age in these circumstances prior to the supply of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	Individuals who: • Are less than 6 weeks of age or over 8 weeks of age. • Infants known to have hypersensitivity to paracetamol or any ingredient in the product. Pharmacists must check the marketing authorisation holder's Summary of Product Characteristics (SPC) for details of a particular brand's ingredients. • Are known to have rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency. • Have known impaired liver or kidney function. • Are Infants weighing less than 3kg. • Are infants <32 weeks corrected gestational age at the time of vaccination. • Have current febrile illness. Individuals for whom no valid consent has been received.

Precautions and special warnings	Pharmacists should refer patients to their GP when there is any uncertainty over the suitability of the infant to be given paracetamol.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Advise about the risk of fever following vaccination with MenB and how to manage this – see advice section. Inform/refer to the relevant medical practitioner if parent/carer declines treatment. Document that the supply was declined, the reason and advice given in appropriate clinical records, e.g. a patient's PMR.

Description of treatment available under the PGD

Name form and strength of medicine	Paracetamol 120mg/5mL oral suspension.
Legal status	Paracetamol 120mg/5mL oral suspension is a General Sales List Medicine (GSL) for pack size 100mL. In accordance with the MHRA all medicines **supplied** under a PGD **must** either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply.
Is the use out with the SmPC?	Yes This PGD authorises prophylactic use of paracetamol at the time of MenB immunisation. The SmPC for paracetamol 120mg/5mL oral suspension is licensed for mild to moderate pain and the reduction of a fever, including post immunisation pyrexia. JCVI have recommended that paracetamol should be given prophylactically when MenB is given with the routine vaccines in infants under one year of age. A 2.5mL dose of liquid paracetamol (infant paracetamol 120mg/5mL) should be given orally as soon as possible after vaccination, followed by a second 2.5mL dose after 4 to 6 hours and a third 2.5mL dose 4 to 6 hours after the second dose.

	Should fever persist following the third dose and provided that the child appears otherwise well, additional doses of paracetamol may be administered at intervals of four to six hours for up to 48 hours. (Do not give more than 3 doses in any 24 hour period). Parents should be advised to seek medical advice if their child is noticeably unwell with a fever present, or if the fever occurs at other times. The administration of paracetamol 120mg/5mL oral suspension to infants less than 8 weeks old is outside the terms of the marketing authorisation and constitutes an off-label use of the medicine. The parent/carer should be informed prior to the administration that the use is off-label.
Dosage/Maximum total dose	60mg (2.5mL of 120mg/5mL oral suspension). Maximum of 3 doses in 24 hours.
Frequency of dose/Duration of treatment	Frequency of doses is every 4 to 6 hours. Three doses of paracetamol are required: 60mg (2.5mL of 120mg/5mL) at time of vaccination with Men B vaccine. A second 60mg dose after 4 to 6 hours. A third 60mg dose after a further 4 to 6 hours. Further doses at intervals appropriate to the age of the child may be administered in the period of up to 48 hours post vaccination if pyrexia persists.
Maximum or minimum treatment period	48 hours
Route/Method of administration	Oral
Quantity to be supplied	Supply 100mL of sugar free paracetamol oral suspension 120mg/5mL. Provide a 2.5mL oral syringe.
Storage requirements	Do not store above 25°C. Store in the original container.

Additional Information	Advise parent/person with parental responsibility/carer of recommended paracetamol dosing post MenB vaccination: First dose of 60mg (2.5mL paracetamol suspension 120mg/5mL) administered at time of MenB vaccination. A second dose of 60mg (2.5mL paracetamol suspension 120mg/5mL) should be administered 4 to 6 hours after the initial dose. A third dose of 60mg (2.5mL paracetamol suspension 120mg/5mL) should be administered 4 to 6 hours after the second dose. After the third paracetamol dose some babies may still develop a fever or continue to be febrile. Fever in the 48 hours after vaccination can be managed with paracetamol at home if the infant is otherwise well. If the infant remains febrile 48 hours after immunisation medical advice should be sought to exclude other causes. If a fever develops parents/persons with parental responsibility/carers should keep the infant cool by making sure they don't have too many layers of clothes or blankets and give them lots of fluids. If the baby is breast-fed, the best fluid to give is breast milk. Paracetamol may mask a fever due to other underlying causes such as systemic bacterial infection. Therefore parents/persons with parental responsibility/carers should not delay in seeking medical advice if they are concerned that their infant is otherwise unwell. Parents should be advised that these dosing recommendations are specific to paracetamol use in the 48 hours post MenB vaccination. • Do not give more than 3 doses in any 24 hour period. • Leave at least 4 hours between doses. • Do not give anything else containing paracetamol while giving this medicine. • The parent/person with parental responsibility/carer should be advised to seek medical advice in the event of an adverse reaction.

	Pharmacists should advise that if the infant has received paracetamol containing products within the last four hours before attending for vaccination then they should wait 4 to 6 hours before administering further doses of paracetamol. Pharmacists should instruct the parent/person with parental responsibility/carer to shake the bottle well before use and measure the dose with the provided oral syringe.
Follow-up (if applicable)	Contact GP if fever persists as detailed in Additional Information.
Advice (Verbal)	• Advise parent/carer what to expect and of the possible side effects and their management. • Advise parent/carer about the risks of developing a temperature following Bexsero® vaccination. • Inform parent/carer that further doses (60mg) of paracetamol should be given 4 to 6 hours after the first dose and a further dose 4 to 6 hours after the second dose. **Note:** The recommendation for three doses of paracetamol to be given to infants under 1 year attending for Bexsero® vaccination is aligned with Scottish Government policy which is based on recommendations in the Green Book. The recommendation for three doses is also supported by the Commission for Human Medicines. • If serious adverse or persistent effects occur, the parent/carer should be advised to contact their GP/Accident and Emergency department/NHS24. • Parent/carers should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme.
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the parent/carer. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.
Identifying and managing possible adverse reactions	In the event of a severe adverse reaction parent/carer should be advised to seek medical advice. Adverse effects of paracetamol are rare but hypersensitivity or anaphylactic reactions including skin rash may occur. Very rare cases of serious skin reactions have been reported. Parent/carer should be informed about the signs of serious skin reactions, and use of the paracetamol should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

	For full details/information on possible side effects, refer to the marketing authorisation holder's SPC or current BNF for children.
	This list is not exhaustive. Please also refer to current BNFC and manufacturers SmPC for details of all potential adverse reactions. **BNFC:** BNF for Children British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Document in accordance with locally agreed procedures in the individual's record. Report any suspected adverse reactions using the Yellow Card System. Yellow Card Scheme - MHRA.
Facilities and supplies required	The following are to be available at sites where the medicine is to be supplied: • Appropriate storage facilities or pharmaceutical refrigerator • An acceptable level of privacy to respect individual's right to confidentiality and safety • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this current PGD in print or electronically.

Characteristics of staff authorised to supply medicine(s) under PGD

Professional qualifications	Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles and currently registered with the General Pharmaceutical Council (GPhC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the parents/carers capacity to understand the nature and purpose of the medicine supply in order to give or refuse consent • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the parent/carer • Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD • Competent to undertake supply of the medicine • Competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • Competent to work under this PGD and authorised by name as an approved person to work under the terms of the PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken NoS PGD module training on TURAS Learn • Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct. **Note:** All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the medicine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD. • Have knowledge and familiarity of the following; ○ SmPC for the medicine(s) to be supplied in accordance with this PGD.
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to supply the medicine(s) specified in this direction.

Documentation

Authorisation of supply	Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to supply the medicine(s) specified in this PGD when they have completed local Board requirements for service registration. All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.
Record of supply	An electronic or paper record must be completed to allow audit of practice. An electronic record of the screening and subsequent supply, or not, of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic recording processes. If a paper record is used for recording the screening of individuals and the subsequent supply, or not, of the medicine(s) specified in this PGD, it should include as a minimum: • Date and time of supply • Individuals name and CHI • Exclusion criteria, record why the medicine was not supplied (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, dose, form, route of the medicine(s) • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who supplied the medicine, and who undertook the assessment of the individual's clinical suitability for the supply of the medicine • Record of any adverse effects and the actions taken (advise individuals' GP/relevant medical practitioner).

	Depending on the clinical setting where supply is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • Individual's GP records if appropriate • Individual service specific systems, e.g. Community Pharmacy Public Health screen. All records should be clear, legible and contemporaneous and in an easily retrievable format.
Audit	All records of the medicine(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines supplied under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk Paracetamol 120mg/5mL Oral Suspension (Rosemont Pharmaceuticals) – Date of revision of text 11/10/22, accessed 05/03/24. British National Formulary for Children https://www.bnf.org/products/bnf-online/ accessed 05/03/24. Department of Health (2006): Immunisation against Infectious Disease [Green Book] Meningococcal: the green book, chapter 22 - GOV.UK (www.gov.uk)

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1

Healthcare Professional Agreement to Supply Medicine(s) Under Patient Group Direction

I:

_____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to supply the medicine(s) contained within the following Patient Group Direction:

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I have completed the appropriate training to my professional standards enabling me to supply the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2

Healthcare Professionals Authorisation to Supply Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to supply the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to supply the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction For The Supply Of Paracetamol Oral Suspension 120mg/5mL By Pharmacists To Babies Between 6 And 8 Weeks Of Age For Prevention Of Post Immunisation Fever Following Administration Of Meningococcal Group B Conjugate Vaccine (Bexsero®) Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 1
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date