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

Patient Group Direction For The Administration Of Paracetamol 120mg/5mL Oral Suspension, At The Time Of Administration Of Meningococcal Group B Conjugate (Bexsero®) Vaccine, By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Medicines Management Specialist Nurse NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/ParaBexsero/ MGPG1284	**Review Date:** August 2024 **Expiry Date:** August 2025	**Date Approved:** August 2022

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 2.1 (Amended August 2022)

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD supersedes NoS/PGD/Para_MenB/MGPG1017.	
Date of change	**Summary of Changes**	**Section heading**
May 2022	PGD Review	
May 2022	Additional statement added regarding infants less than 8 weeks presenting for immunisation.	Inclusion criteria
August 2022	Error where 12 weeks was stated in inclusion criteria replaced with 16 weeks.	Inclusion criteria

NoS Identifier: NoS/PGD/ParaBexsero/MGPG1284 Version 2.1
Keyword(s): PGD oral suspension paracetamol bexsero approved healthcare professionals

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:	November 2021 (Protocol), March 2022, May 2022
	Completed:	July 2022
	Approved:	August 2022 (published – August 2022, September 2022)
	Amended & reauthorised:	August 2022

Organisational Authorisations

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

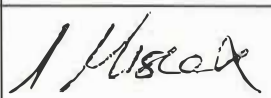
PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Louise Wilson **Health Board:** NHSO **Title:** Consultant in Public Health Medicine **Contact email:** louise.wilson2@nhs.scot **Signature** ..... L Wilson ..... **Date:** 31/08/2022
Senior representative of the professional group who will provide care under the direction	**Name:** Jacki Donachie **Health Board:** NHST **Title:** Vaccination Programmes Manager **Contact email:** jacqueline.donachie2@nhs.scot **Signature** ..... J Donachie ..... **Date:** 05/09/2022
Lead author	**Name:** Frances Adamson **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** frances.adamson@nhs.scot **Signature** ..... F Adamson ..... **Date:** 31/08/2022
Pharmacist	**Name:** Mary McFarlane **Health Board:** NHSS **Title :** Principle Pharmacist **Contact email:** mary.mcfarlane@nhs.scot **Signature** ..... Mary J M Farlane ..... **Date:** 01/09/2022

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		31/08/2022

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		08/09/2022

Management and Monitoring of Patient Group Direction

PGD Consultative Group

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

Name:	Title:
Frances Adamson	**Lead Author:** Medicines Management Specialist Nurse NHSG
Dr Louise Wilson	**Medic representative:** Consultant in Public Health Medicine NHSO
Jacki Donachie	**Staff Group representative:** Vaccination Programme Manager NHST
Fiona Browning	Health Protection Nurse Specialist NHSG
Lynda Davidson	Health Protection Nurse Specialist NHSH
Mary McFarlane	**Pharmacist:** Principal Pharmacist NHSS
Alistair Brand	Lead Locality Pharmacist NHST
Russell Mackay	Specialist Clinical Pharmacist NHSO
Liam Callaghan	Chief Pharmacist NHSWI

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Clinical indication to which this PGD applies

Definition of situation/ Condition	This PGD will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer paracetamol suspension to infants under 12 months of age for the prevention of post immunisation fever following administration of meningococcal group B conjugate (Bexsero®) vaccine. 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 from 6 weeks***** of age to under 12 months of age receiving Bexsero® for primary vaccination as part of the routine immunisation schedule at the same time as other routine vaccines. *****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, provided they are over 6 weeks of age these infants are to be included and paracetamol can be administered. Bexsero® vaccine is recommended with other routine childhood vaccines at age 8 weeks and 16 weeks. Prior to the supply/administration 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 aged 12 months or over • Are less than 6 weeks of age • Are receiving Bexsero® vaccine at 12 month booster dose • Have had an anaphylactic reaction to previous dose of the medicine or to any of its excipients • 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 known to have taken paracetamol containing products within the previous four hours

	• Are known to have taken four or more doses of paracetamol in the previous 24 hours • Are Infants weighing less than 4kg, advice should be sought from hospital neonatologist • Are infants <32 weeks corrected gestational age at the time of vaccination, advice should be sought from hospital neonatologist • Have current febrile illness. Individuals for whom no valid consent has been received.
Precautions and special warnings	Where there is any uncertainty over suitability of the infant to be given paracetamol the healthcare professional should contact their local immunisation team/coordinator.
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	Inform/refer to the relevant medical practitioner if parent/carer declines treatment. Document that the administration was declined, the reason and advice given in appropriate clinical records.

Description of treatment available under the PGD

Name form and strength of medicine	Paracetamol Oral suspension 120mg/5mL.
Legal status	Paracetamol is a General Sales List medicine (GSL) for pack size 100mL and a Pharmacy medicine (P) for pack size 200mL.
Is the use out with the SmPC?	The administration of paracetamol 120mg/5mL 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	2.5mL (60mg) of 120mg/5mL oral suspension single dose.

Frequency of dose/Duration of treatment	Once only dose administered at the same appointment at which Bexsero® vaccine is administered.
Maximum or minimum treatment period	N/A
Route/Method of administration	Suspension for oral administration. It is important to **shake the bottle** for at least 10 seconds before use and to use an oral syringe if available.
Quantity to be administered	Single Dose of 2.5mL (60mg).
Storage requirements	Store in a locked cupboard: Do not store above 25°C. At first use of a new bottle add the date that it was opened. Ensure appropriate disposal of any unused paracetamol suspension three months after pack was opened for the first time.
Follow-up (if applicable)	The parent/carer should not leave if they have any concerns that the medicine recipient is unwell without speaking to the healthcare professional who administered the medicine first. If necessary a doctor or the medicine recipients GP should be contacted for advice. Advise the parent/carer about the use and timing of the subsequent two recommended paracetamol doses to reduce the risk, intensity and duration of fever.
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

	• The parent/carer 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	Adverse reactions are rare but rashes have been reported. For full details/information on possible side effects, refer to the marketing authorisation holder's SmPC 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 administered: • Appropriate storage facilities • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • 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 administer medicine(s) under PGD

Professional qualifications	The following classes of registered healthcare professionals are permitted to administer paracetamol at the time of Bexsero® vaccine as identified and included in individual Board immunisation delivery plans: • Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • Pharmacists currently registered with the General Pharmaceutical Council (GPhC) • Chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC) • Dental hygienists and dental therapists registered with the General Dental Council • Optometrists registered with the General Optical Council.
Specialist competencies	**Approved by the organisation as:** • Competent to assess the parent's/carer's capacity to understand the nature and purpose of the medicine administration in order to give or refuse consent. • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual. • 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 administration of the medicine. • 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. • Have attended basic life support training either face to face or online and updated in-line with individual Board requirements. • Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis in-line with individual Board requirements. • 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 administered 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 administer the medicine(s) specified in this direction.

Documentation

Authorisation of administration	Qualified registered healthcare professionals working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles listed and approved in legislation as able to operate under PGD can be authorised to administer the medicine specified in this PGD in accordance with local delivery plans and by agreement at individual Board level as per the following: Nurses, midwives and health visitors can be authorised by their line manager. Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to

	administer the medicine(s) specified in this PGD when they have completed local Board requirements for service registration. The following list of healthcare professionals can be authorised by their Line Manager, Head of Service or Vaccine Coordinator: Chiropodists, dental hygienists, dental therapists, dieticians, occupational therapists, optometrists, orthoptists, orthotist/prosthetists, paramedics, physiotherapists, podiatrists, radiographers and speech and language therapists. All authorised staff are required to read the PGD and sign the Agreement to Administer 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 administration	An electronic or paper record must be completed to allow audit of practice. An electronic/ Hospital Electronic Prescribing and Medicines Administration (HEPMA) record of the screening and subsequent administration, or not of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes. If a paper record is used for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD, it should include as a minimum: • Date and time of administration • Individuals name and CHI • Exclusion criteria, record why the medicine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, dose, form, route of the medicine administered • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who administered the medicine, and who undertook the assessment of the individual's clinical suitability for the administration of the medicine • Record of any adverse effects and the actions taken (advise individuals' GP/relevant medical practitioner).

	Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • Child Health Information Services if appropriate • Hand–held records such as red book if appropriate • Individual's GP records if appropriate • HEPMA • Individual service specific systems. Local policy should be followed with respect to sharing information with the individual's General Practitioner. 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 administered under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk Paracetamol 120mg/5mL Oral Suspension (Rosemont Pharmaceuticals) – Date of revision of text 30/05/2022 accessed 14/06/2022. British National Formulary for Children https://www.bnf.org accessed 14/06/2022. Department of Health (2006): Immunisation against Infectious Disease [Green Book]

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

Appendix 1

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

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer 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 administer 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 Administer 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 administer 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 administer 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 administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
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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**