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

Patient Group Direction For The Administration of Sterile Water For Injection For Continuous Back Pain In Labour By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Katie Farnworth - Midwife	**Consultation Group:** See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian

Signature:		**Signature:**

NoS Identifier: NoS/PGD/Water_Inj/1741	**Review Date:** December 2027 **Expiry Date:** December 2028	**Date Approved:**

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Reference and approval date of PGD that has been adapted and/or superseded	New PGD	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**
	New PGD Developed	

NoS Identifier: NoS/PGD/Water_Inj/1741
Keyword(s): PGD Patient Group Direction

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:	23/04/24
	Completed:	19/03/25
	Approved:	19/12/25 (published – Dec 2025)
	Amended and re-authorised:	

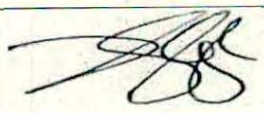
Organisational Authorisations

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

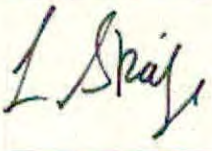
PGD Developed/Reviewed by;

Medical practitioner	**Name:** Priti Nagdeve **Health Board:** NHSG **Title:** Consultant Obstetrician **Contact email:** priti.nagdeve@nhs.scot **Signature:** ..... Priti ..... **Date:** 11/12/2025
Senior representative of the professional group who will provide care under the direction	**Name:** Linda Stewart **Health Board:** NHSG **Title:** Inpatient Midwifery Manager **Contact email:** linda.stewart2@nhs.scot **Signature:** ..... LStewart ..... **Date:** 11/12/2025
Lead author	**Name:** Katie Farnworth **Health Board:** NHSG **Title :** Interim Lead Midwife **Contact email:** katie.farnworth2@nhs.scot **Signature:** ..... KFarnworth ..... **Date:** 11/12/2025
Pharmacist	**Name:** Charlotte Morrison **Health Board:** NHSG **Title :** Pharmacist **Contact email:** charlotte.morrison@nhs.scot **Signature:** ..... CMorrison ..... **Date:** 11/12/2025

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		16/12/2025

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Laura Skaife-Knight		19/12/2025

Management and Monitoring of Patient Group Direction

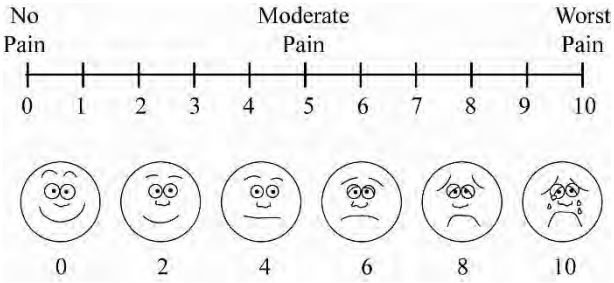
PGD Consultative Group

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:
Katie Farnworth	**Lead Author:** Interim Lead Midwife, NHS Grampian
Charlotte Morrison	**Pharmacist:** Specialist Clinical Pharmacist, NHS Grampian
Priti Nagdeve	**Medical Practitioner:** Consultant Obstetrician, NHS Grampian
Linda Stewart	**Senior Representative:** Interim Midwifery Manager, NHS Grampian
Mairead Black	Consultant Obstetrician, NHS Grampian
Catherine Macdonald	Chief Midwife, NHS Western Isles

Patient Group Direction For Administration of Sterile Water For Injection For Continuous Back Pain In Labour By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Clinical indication to which this PGD applies

Definition of situation/Condition	This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD, to administer sterile water for injections, intracutaneously or subcutaneously into the Rhombus of Michaelis for back pain in labour to individuals. 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	Prior to the 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. Women of 37-42 weeks' gestation in early or active labour experiencing continuous lower back pain with a Visual Analogue Score For Pain (VAS) >6.  (VAS SCORE FOR PAIN)
Exclusion criteria	• Women in labour with continuous back pain but with a VAS <6. • Women in labour who are not experiencing continuous back pain. • Women with visible rash/lesion on skin prior to injection. • Women who decline the offer of sterile water injections. There is no current evidence to support an exclusion criteria, other than the above. The primary care giver at the point of care should assess each individual case. Individuals for whom no valid consent has been received.

Precautions and special warnings	• Water is a non-pharmacological treatment therefore side effects are rare. • Skin inflammation will occur at the injection site, which should quickly disappear. • Explain to the woman that there will be an intense burning/stinging sensation following the procedure, which wears off. Pain relief should take effect from 10 minutes after the injection for up to 3 hours. No other reported reactions have been found in the evidence base that has been reviewed.
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 individual 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	Sterile Water for Injection. 2mL, 5mL, 10mL or 20mL ampoules can be used to withdraw desired volume.
Legal status	Sterile Water For Injection is a Prescription-only Medicine (POM).
Is the use out with the SmPC?	Indicate any off-label use (if relevant) or if medicine is (▼ or ▼*) Sterile Water for Injections is indicated to be used as a solvent for dilution and reconstitution of suitable medicinal products for parenteral administration. Use without addition of a medicinal product is outside the terms of the marketing authorisation and constitutes an off-label use of the medicine. The individual/parent/carer should be informed prior to the administration that the use is off-label.

Dosage/Maximum total dose	Sterile Water for Injection 0.1mL intracutaneously x 4 injections Or 0.5mL subcutaneously x 4 injections
Frequency of dose/Duration of treatment	Minimum period between doses should be at least 30 minutes apart.
Maximum or minimum treatment period	Sterile water injections can be given up to every 30 minutes as requested by the woman for the treatment of lower back pain.
Route/Method of administration	Intra-dermal injections to the skin surrounding the Michaelis's Rhomboid over the sacral area. Two healthcare professionals perform two injections simultaneously. Administer as quickly as possible to reduce the time and effect of the burning/stinging sensation. Aim to raise a small bleb at least 0.5cm diameter at each of the four injection sites.
Quantity to be administered	0.1mL intracutaneously x 4 injections Or 0.5mL subcutaneously x 4 injections
Storage requirements	Store below 25C.
Additional Information	• Avoid rubbing touching or massaging or any other counter pressure to the injection site for 30 minutes following procedure. Bleb formation on the skin is vital for effectiveness. • Procedure is effective in relieving moderate to severe back pain only. Can be used alongside any form of pharmacological or non-pharmacological pain relief. • Sterile water injection has no reported negative effect on mode of delivery.
Follow-up (if applicable)	If any signs of adverse effect, seek medical assistance.
Advice (Verbal)	• Advise individual what to expect and of the possible side effects and their management. If serious adverse or persistent effects occur, the individual/parent/carer should be advised to contact their GP/Accident and Emergency department/NHS24

	• Individuals/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 individual Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.
Identifying and managing possible adverse reactions	Water is a non-pharmacological treatment therefore side effects are rare. Skin inflammation will occur at the injection site, which quickly disappears. Intense burning/stinging will occur following the procedure. **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF/BNFC**: BNF 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	Midwives and Nurses as recognised by the Nursing and Midwifery Council (NMC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the woman's capacity to understand the nature and purpose of the administration of water for injection 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 sterile water for injections in labour training package regarding the administration, as determined by local board guidance. • Caregiver to carry out clinical assessment of women identifying that treatment is required according to the indications listed in the PGD. • Competent to undertake administration of sterile water for injection • 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 • Have undertaken appropriate training in administration of Sterile Water Injections and will ensure practice is kept up to date. • Obtains and documents informed consent prior to the Administration of Intradermal Sterile Water Injections. • Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis in-line with 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; o 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	Midwives' and Nurses working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD by their Professional Line Manager/Consultant/Practice GPs. 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/HEPMA record of the screening and subsequent administration, or not of the medicine 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 (batch number, expiry date and anatomical site where appropriate for injectable medicines) of the medicine(s) 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/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 administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • BadgerNet – Digital Maternity Notes • 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 Almassinokiani, F., Ahani, N., Akbari, P., Rahimzadeh, P., Akbari, H. and Sharifzadeh, F. (2020) 'Comparative Analgesic Effects of Intradermal and Subdermal Injection of Sterile Water on Active Labor Pain', *Anesthesiology and Pain Medicine,* 10 (2). Derry, S., Straube, S., Moore, R., Hancock, H. And Collins, S. (2012) *Sterile water injections for the relief of pain in labour.* Available at: https://www.cochrane.org/CD009107/PREG_sterile-water-injections-for-the-relief-of-pain-in-labour *(*Accessed: 23 November 2023). Hutton, E., Kasperink, M., Rutten, M., Reitsma, A. and Wainman, B. (2009). Sterile water injection for labour pain: a systematic review and meta-analysis of randomised controlled trials. *BJOG: An International Journal of Obstetrics & Gynaecology*, 116(9), pp.1158–1166. Available at: https://doi.org/10.1111/j.1471-0528.2009.02221.x Lee, N., Gao, Y., Collins, S., Martensson, L., Randall, W., Rowe, T. and Kildea, S. (2020) 'Caesarean delivery rates and analgesia effectiveness following injections of sterile water for back pain in labour: A multicentre, randomised placebo controlled trial', *E Clinical Medicine,* 25 pp. 100447. Available at: https://doi.org/10.1016/j.eclinm.2020.100447 Mårtensson, L., Hutton, E., Leed, N., Kildea, S,. Gao, Y. and Bergh, I. (2018) 'Sterile water injections for childbirth pain: An evidenced based guide to practice', *Women and Birth,* 31(5), pp.380-385. Insert Available at: https://doi.org/10.1016/j.wombi.2017.12.001 National Institute for Health and Care Excellence (2023) (Updated November 2025) *Intrapartum care for healthy women and babies.* Available at: Intrapartum care (nice.org.uk) (Accessed: 02 December 2025).

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:

Patient Group Direction For Administration of Sterile Water For Injection For Continuous Back Pain In Labour By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 1

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.
Patient Group Direction For Administration of Sterile Water For Injection For Continuous Back Pain In Labour By Approved Healthcare Professionals Working 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**