NHS Grampian

Patient Group Direction For The Administration Of Salbutamol Unit Dose Vials Via Nebuliser By Nurses Working Within NHS Grampian

Lead Author: Medicines Management Specialist Nurse NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** Medicines Guidelines and Policies Group **Authorisation:** NHS Grampian
Signature: 		**Signature:** 
NHSG Identifier: MGPG/PGD/Salbutamol Neb/1574	**Review Date:** November 2026 **Expiry Date:** November 2027	**Date Approved:** November 2024

NHS Grampian 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 Board. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 10

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD supersedes NHSG/PGD/sal_UDVs/MGPG1225, Version 9	
Date of change	**Summary of Changes**	**Section heading**
August 2024	PGD review and transferred onto new template.	
August 2024	Updated.	Identifying and managing possible adverse reactions
August 2024	Website addresses updated.	References

NHGS Identifier: MGPG/PGD/SalbutamolNeb/1574
Keyword(s): Patient Group Direction PGD salbutamol unit dose vials nebuliser

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:	August 2024
	Completed:	October 2024
	Approved:	November 2024 (published – November 2024)
	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:** Dr Kris Mclaughlin **Title:** GP and Respiratory MCN Clinical Lead **Contact email:** kris.mclaughlin@nhs.scot **Signature:** ..... **Date:** 25/11/2024
Senior representative of the professional group who will provide care under the direction	**Name:** Susan Gowen **Title:** Senior Charge Nurse Peterhead Hospital **Contact email:** susan.gowan@nhs.scot **Signature:** ..... **Date:** 18/11/2024
Lead author	**Name:** Jodie Allan **Title :** Medicines Management Specialist Nurse **Contact email:** jodie.alllan@nhs.scot **Signature:** ..... **Date:** 18/11/2024
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Approved and authorised for use within NHSG by;

Medicines Guidelines and Policies Group Chair	Signature	Date Signed
Lesley Coyle		15/11/2024

Management and Monitoring of Patient Group Direction

PGD Consultative Group

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

Name:	Title:
Jodie Allan	**Lead Author:** Medicines Management Specialist Nurse
Birgit Teismann	**Pharmacist:** Lead Pharmacist Aberdeenshire HSCP
Dr Kris Mclaughlin	**Medical Practitioner:** GP and Respiratory MCN Clinical Lead
Susan Gowan	**Senior Representative:** Senior Charge Nurse Peterhead
Jackie Leggat	Senior Charge Nurse Fraserburgh

Patient Group Direction For The Administration Of Salbutamol Unit Dose Vials Via Nebuliser By Nurses Working Within NHS Grampian

Clinical indication to which this PGD applies

Definition of situation/ Condition	This Patient Group Direction (PGD) will authorise nurses to administer salbutamol unit dose vials (UDVs) via nebuliser to individuals for the relief of acute onset reversible airways obstruction, for example an acute asthma attack. **Note:** For children with acute asthma a metered dose salbutamol inhaler via a spacer is the optimal drug delivery route of first choice. Refer to PGD For The Administration Of Salbutamol Via A Spacer By Nurses And Midwives Working Within Primary Care and Community Hospitals in NHS Grampian. This PGD should be used in conjunction with the recommendations in SIGN guideline 158 British guideline on the management of asthma, the current British National Formulary (BNF), British National Formulary for Children (BNFC), and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	Nebulised salbutamol may be administered to adults or children 2 years of age or over (in accordance with SIGN guideline 158, July 2019) presenting with acute onset reversible airways obstruction, for example an acute asthma attack. (Prior consideration should be given to the use of the patient's own bronchodilator inhaler via a spacer device as this has been shown to be effective for many patients). See PGD For The Administration Of Salbutamol Via A Spacer By Nurses And Midwives Working Within Primary Care and Community Hospitals in NHS Grampian. Where possible, patients with acute asthma should have their peak expiratory flow (PEF) measured prior to the commencement of therapy, but this should not delay urgent treatment in life threatening situations. If it is not possible to measure PEF, it should be noted as 'un-recordable'. In children under 5 years, peak flow measurements should not be undertaken. 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 NHSG consent policy.

Exclusion criteria	• Individuals under 2 years of age • Individuals with known anaphylactic hypersensitivity to salbutamol, beta-adrenoceptor agonists or any constituent of the product • Individuals who are sedated • Individuals where the possibility of a pneumothorax is considered. **Note:** Contraindications are relative as this product is intended for use in life-threatening emergencies. In the context of the clinical scenario described in this PGD the individual being treated may not be able to make an informed choice nor consent to treatment. Therefore, the clinician should act in the best interests of the individual at all times and within their professional competency and code of conduct.

Precautions and special warnings	• Nebulised salbutamol should be used with caution in patients who have thyrotoxicosis.
	• Salbutamol nebuliser solution should be used with care in patients known to have received large doses of other sympathomimetic drugs.
	• Salbutamol should be administered cautiously to patients suffering from severe heart disease including;
	  o ischaemic heart disease
	  o arrhythmia
	  o severe heart failure
	• Should be used with caution in pregnancy or when breastfeeding.
	• An oxygen driven nebuliser should not be used in cases of chronic bronchitis and hypercapnia when the nebuliser should be air driven.
	• Salbutamol can cause a reversible increase in blood glucose levels. Care should be taken when administering nebulised salbutamol to diabetics who may develop ketoacidosis. Concurrent administration of corticosteroids, such as prednisolone, can exaggerate this effect.
	• Rarely, potentially serious hypokalaemia may result from nebulised administration of salbutamol. Particular caution is advised in acute severe asthma as this effect may be potentiated by hypoxia and by concomitant treatment with xanthine derivatives, steroids and diuretics.
	• Nebulised salbutamol may rarely cause paradoxical bronchospasm, with an immediate increase in wheezing after the dose has been given. Medical advice should be sought immediately if this occurs.
	
	A small number of cases of acute angle-closure glaucoma have been reported in patients treated with a combination of nebulised salbutamol and ipratropium bromide.

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 individual/parents/carers of the risks of not receiving the treatment and refer to the relevant medical practitioner if individual/parent/carers declines treatment immediately. 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	Salbutamol 2.5mg/2.5mL and 5mg/2.5mL Nebuliser Solution. A clear, colourless to pale yellow solution in a clear, plastic single dose ampoule. Each 2.5mg/2.5mL ampoule contains 2.5mg salbutamol (as sulfate). Each 5mg/2.5mL ampoule contains 5mg salbutamol (as sulfate).
Legal status	Salbutamol 2.5mg/2.5mL and 5mg/2.5mL Nebuliser Solution are a Prescription-only Medicine (POM). **Note:** Administration of nebulised salbutamol to children over 2 years but under 4 years of age is out with the licensed indication for salbutamol UDVs, but may be used under this PGD and in accordance with the SIGN guideline 158, July 2019 and the current BNF. The individual or the individual/parents/carers should be informed prior to the administration that the use is off-label.
Is the use out with the SmPC?	Salbutamol 2.5mg/2.5mL and 5mg/2.5mL Nebuliser Solution are a Prescription-only Medicine (POM). **Note:** Administration of nebulised salbutamol to children over 2 years but under 4 years of age is out with the licensed indication for salbutamol UDVs, but may be used under this PGD and in accordance with the SIGN guideline 158, July 2019 and the current BNF. The individual or the individual/parents/carers should be informed prior to the administration that the use is off-label.

Dosage/Maximum total dose	**Children under 2 years of age (Excluded under this PGD)** For acute asthma, a metered dose salbutamol inhaler via a spacer is the recommended drug delivery device. Refer to PGD For The Administration Of Salbutamol Via A Spacer By Nurses And Midwives Working Within Primary Care and Community Hospitals in NHS Grampian. **Children aged 2 years of age and over:** The patient's own salbutamol inhaler where available should be used first line for acute asthma. Using a metered dose inhaler via a spacer is less likely to produce tachycardia and hypoxia than when the same drug is given via a nebuliser, although there will be times when nebuliser therapy is clearly required, such as when a spacer as above has already been used at home prior to presentation at an NHS service. Children with acute asthma who have not improved after receiving up to 10 puffs via a spacer should be urgently referred to hospital. (Refer to PGD For The Administration Of Salbutamol Via A Spacer By Nurses And Midwives Working Within Primary Care and Community Hospitals in NHS Grampian). These patients can then receive a single dose (2.5mg dose for those under 5 years and 5mg dose for those aged 5 to 12 years) of salbutamol given via a suitable nebuliser and the vapour inhaled by the patient over 5 to 10 minutes. **Adults (including children aged 12 years and older plus the elderly):** Use the patient's own inhaler first line in acute asthma and administer as early as possible. In acute asthma with life threatening features the nebulised route (oxygen-driven) is recommended. A single 5mg dose of salbutamol should be nebulised and the vapour inhaled by the patient over 5 to 10 minutes. **For all age groups:** The onset of action is rapid, improvement should be seen within 5 minutes of starting treatment and last for four to six hours. If no improvement or a worsening of condition is apparent within the first 5 minutes of treatment, medical advice should be sought immediately. If there is a delay in medical support arriving and the patient's condition is deteriorating then an emergency ambulance must be called. A second dose of salbutamol may be given after 20 – 30 minutes if help is delayed.

	The contents of the UDV should not be diluted. Ideally, the nebuliser should use oxygen unless contraindicated or unavailable, in which case air may be used. The vapour should be inhaled via a suitably sized close-fitting facemask (this is particularly important in children), or via a T piece or an endotracheal tube. **Maximum doses allowed under this PGD are;** • Children aged 2 years and over and up to 5 years of age **5mg.** • Children aged 5 years and up to 12 years of age **10mg.** • Adults (including children aged 12 years and older plus the elderly) **10mg**.
Frequency of dose/Duration of treatment	Initial dose at onset of symptoms followed by a second dose given after 20 – 30 minutes if no improvement is seen and help is delayed.
Maximum or minimum treatment period	N/A
Route/Method of administration	Salbutamol Nebuliser Solution should be administered by a suitable nebuliser, via a face mask or T piece or via an endotracheal tube. To open the plastic ampoule, take a strip of ampoules from the foil pack, remove one ampoule, replacing the rest back in the foil pack, and replace the foil pack back in the carton. Hold the ampoule upright and open it by twisting off the top. Squeeze the liquid into the solution holder of the machine. Clinical features for assessment of severity can be found in Appendix 3. The following clinical features should be observed and recorded in the patient's case notes at the earliest opportunity and reviewed at each subsequent stage: • Pulse rate • Respiratory rate and degree of breathlessness • Use of accessory muscles of respiration • Amount of wheezing • Degree of agitation and level of consciousness. **Note:** Clinical signs correlate poorly with the severity of airways obstruction. Some children with acute asthma do not appear distressed.

Quantity to be administered	See Dosage/Maximum total dose section.
Storage requirements	Store in a locked cupboard. Store below 25°C. Protect UDVs from light after removal from the foil tray.
Additional Information	Once a foil strip has been opened, the time before the contents should be discarded may vary, check individual SmPCs. UDVs unused after this time must be discarded in the appropriate pharmaceutical waste.
Follow-up (if applicable)	Recipients of nebulised salbutamol should remain under observation until they have been seen to recover from the episode of airways obstruction, they must then wait to be reviewed by medical staff. If no benefit is seen within 5 minutes of starting nebulised salbutamol, medical advice should be sought immediately. **Note:** Medical staff must review the patient after an episode of acute onset reversible airways obstruction as this may indicate deterioration in chronic illness. The patient should be advised not to leave the premises until seen by an appropriate professional.
Advice (Verbal)	Advise individual/parents/carers what to expect and what to do for minor and major reactions. Provide appropriate worsening advice describing the range of signs and symptoms to monitor for and the action to take if they occur. Ensure individual has supply of inhaled beta-2 agonist, any preventative therapies and that inhaler technique is correct. • 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/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	• Fine tremor of skeletal muscle, most noticeably the hands, occurs commonly. The effect is dose related. • Headaches are common. • Rash. • Nasopharyngitis • Oropharyngeal pain. • Tachycardia, increase in heart rate above normal, with or without peripheral vasodilatation commonly occurs. Cardiac arrhythmias, including atrial fibrillation, supraventricular tachycardia, and extrasystoles, have been reported very rarely in susceptible patients after use of salbutamol. • Hypersensitivity reactions such as angioedema, urticaria, paradoxical bronchospasm, hypotension and collapse are very rare. • Potentially serious hypokalaemia (low blood potassium levels) may result from nebulised salbutamol therapy. Particular caution is required in acute severe asthma because this effect may be potentiated by concomitant treatment with theophylline and its derivatives, corticosteroids, diuretics and by hypoxia. Serum potassium concentration should be monitored in severe asthma. • Lactic acidosis has been reported in association with high therapeutic doses of nebulised short-acting beta-agonist therapy, mainly in patients being treated for an acute asthma exacerbation. Increase in lactate levels may lead to dyspnoea and compensatory hyperventilation, which could be misinterpreted as a sign of asthma treatment failure and lead to inappropriate intensification of short-acting beta-agonist treatment. • Muscle cramps, mouth and throat irritation are uncommon. • Hyperactivity and paradoxical bronchospasm have been reported very rarely. • Salbutamol is antagonised by non-selective β-blocking drugs (such as propranolol) and may therefore be less effective in patients on long term β-blocker therapy. • Salbutamol may increase the risk of hypokalaemia with corticosteroids, acetazolamide, xanthine derivatives, loop diuretics or thiazides and theophylline. • Salbutamol may possibly reduce the plasma concentration of digoxin. **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 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) • Nebuliser equipment • Monitoring equipment (NEWS including BP, SpO2, HR and PEF if appropriate • 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	Registered Nurses as recognised by the Nursing and Midwifery Council (NMC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's/parents/carers 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 in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • Competent to undertake administration 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 • Have attended basic life support training either face to face or online and updated in-line with Board requirements • 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 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	Nurses working within NHS Grampian 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 locally.
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(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. This 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(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: • Individual's GP records if appropriate • Secondary Care Medical 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	Accord UK Ltd Home | Accord-UK Products | Accord-UK Products (accord-healthcare-products.co.uk) Salbutamol 2.5mg/2.5mL Nebuliser Solution (Arrow) – Date of revision of text 04/07/24 accessed 22/08/24. British National Formulary and British National Formulary BNF (British National Formulary) | NICE 22/08/24. British National Formulary and British National Formulary for Children BNFC (British National Formulary) | NICE 22/08/24. SIGN Guideline 158 July 2019 British guideline on the management of asthma. Accessed 22/08/24.

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 The Administration Of Salbutamol Unit Dose Vials Via Nebuliser By Nurses Working Within NHS Grampian, Version 10

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: _____

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 The Administration Of Salbutamol Unit Dose Vials Via Nebuliser By Nurses Working Within NHS Grampian, Version 10
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

Patient Group Direction For The Administration Of Salbutamol Unit Dose Vials Via Nebuliser By Nurses Working Within NHS Grampian, Version 10					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**

Appendix 3

Table 1. Clinical features for assessment of severity in children aged 1 year and over. Reference SIGN 158, revised July 2019, British Guideline on the management of asthma.

Life threatening asthma	**Any one of the following in a child with severe asthma:**	
	Clinical signs	**Measurements**
	Silent chest	SpO_2<92%
	Cyanosis	PEF <33% best or predicted
	Poor respiratory effort	
	Hypotension	
	Exhaustion	
	Confusion	
Acute severe asthma	Cannot complete sentences in one breath or too breathless to talk or feed SpO_2<92% PEF 33-50% best or predicted Pulse >140 in children aged 1-5 years >125 in children aged >5 years Respiration >40 breaths/min aged 1-5 years >30 breaths/min aged >5 years	

Table 2. Levels of severity of acute asthma exacerbations in adults. Reference SIGN 158, revised July 2019, British Guideline on the management of asthma.

Life threatening asthma	**Any one of the following in a patient with severe asthma:**	
	Clinical signs	**Measurements**
	Altered conscious level	PEF <33% best or predicted
	Exhaustion	SpO_2<92%
	Arrhythmia	PaO_2 <8 kPa
	Hypotension	"normal" $PaCO_2$ (4.6–6.0 kPa)
	Cyanosis	
	Silent chest	
	Poor respiratory effort	
Acute severe asthma	Any one of: - PEF 33-50% best or predicted - respiratory rate ≥25/min - heart rate ≥110/min - inability to complete sentences in one breath	