Dear Colleague

This letter authorises the extended use of the following PGD until 1st May 2021:

**Patient Group Direction For The Administration Of Salbutamol Via A Spacer By Nurses and Pharmacists Working Within NHS Grampian For Post Bronchodilator Lung Function Assessment Or Reversibility Testing, Version 2**

This PGD has been granted an extension due to the unprecedented workload related to COVID-19 and the clinical content of this PGD remains valid. This letter provides permission to continue using the PGD to a new expiry date of 1st May 2021, and should be kept with the PGD records and brought to the attention of the individual nurses and pharmacists who operate under the PGD currently.

If you have any queries regarding this please do not hesitate to contact the Pharmacy and Medicines Directorate.

Yours sincerely

Lesley Coyle  
Chair Medicines Guidelines and Policies Group
Patient Group Direction For The Administration Of Salbutamol Via A Spacer By Nurses and Pharmacists Working Within NHS Grampian For Post Bronchodilator Lung Function Assessment Or Reversibility Testing

Lead Author:  
Primary Care Respiratory Nurse, Aberdeen City H&SCP

Consultation Group:  
See relevant page in the PGD

Approver:  
Medicine Guidelines and Policies Group

Identifier:  
NHSG/PGD/Sal_COPD/MGPG865

Review Date:  
May 2019

Expire Date:  
May 2020

Date Approved:  
May 2017

A Patient Group Direction is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by Doctors, Pharmacists and other appropriate professionals, approved by the employer and advised by the relevant professional advisory committees. In most cases, appropriate clinical care is provided on an individual basis by a specific prescriber to a specific individual patient. Patient Group Directions should only be considered where they offer a benefit to patient care without compromising patient safety in any way.

Uncontrolled when printed  
Version 2
Revision History:

<table>
<thead>
<tr>
<th>Date of change</th>
<th>Approval date of PGD that is being superseded</th>
<th>Summary of Changes</th>
<th>Section heading</th>
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<tbody>
<tr>
<td>November 2016</td>
<td>November 2014</td>
<td>2 yearly update to new PGD template.</td>
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<tr>
<td>March 2017</td>
<td>November 2014</td>
<td>Statement added regarding using professional judgement.</td>
<td>Precautions and Special Warnings</td>
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<tr>
<td>March 2017</td>
<td>November 2014</td>
<td>The spacer should be compatible with the pMDI being used added.</td>
<td>Route/Method of administration</td>
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<tr>
<td>March 2017</td>
<td>November 2014</td>
<td>Shake inhaler before use added.</td>
<td>Route/Method of administration</td>
</tr>
<tr>
<td>March 2017</td>
<td>November 2014</td>
<td>Additional information regarding dosing added in line with updated SIGN Guidance.</td>
<td>Dosage/Total Dose</td>
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<tr>
<td>March 2017</td>
<td>November 2014</td>
<td>Information regarding ethanol content of inhalers removed.</td>
<td>Concurrent Medications/Drug Interactions</td>
</tr>
<tr>
<td>March 2017</td>
<td>November 2014</td>
<td>Statement regarding single use for spacers added.</td>
<td>Storage requirements</td>
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Subject: Patient Group Direction
Identifier: NHSG/PGD/Sal_COPD/MGPG865
Replaces: NHSG/PGD/Sal_COPD/MGPG696, Version 1
Keyword(s): Patient Group Direction PGD salbutamol nurse pharmacist assessment testing via spacer post bronchodilator lung function assessment reversibility testing

Policy Statement: It is the responsibility of the individual nurse or pharmacist 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 patient, 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 patient safety. The expiry date should not be more than 3 years from the date the PGD was authorised.

**Document:**
- **Drafted:** October 2014
- **Completed:** November 2014
- **Approved:** November 2014, May 2017 (published – June 2017)
### Clinical indication to which this PGD applies

#### Definition of situation/condition

This Patient Group Direction (PGD) will authorise trained nurses and pharmacists working within NHS Grampian to administer salbutamol via a spacer to individuals aged 16 years and over for the purpose of assessing post bronchodilator lung function, or bronchodilator reversibility as part of the diagnostic process, when a diagnosis of Chronic Obstructive Pulmonary Disease (COPD) or Asthma is suspected.

This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF) and individual Summary of Product Characteristics (SPC).

#### Inclusion criteria

Salbutamol may be administered to adults over 16 years of age who require post bronchodilator lung function or bronchodilator reversibility assessment, as part of the diagnostic process when a new diagnosis of COPD or asthma is suspected.

Patients must be able to use an inhaler via a spacer device and also a peak flow meter and/or a spirometer.

#### Exclusion criteria

Patients may receive the administration of salbutamol via a spacer under this PGD unless they have:

- Known anaphylactic hypersensitivity to any of the components.
- Known contraindications to performing a spirometry test (only if spirometry is being used as the test to assess lung function).
**Precautions and special warnings**

- Salbutamol via a spacer device should be used with caution in patients who have the following conditions; however it should be noted that these conditions do not exclude patients from receiving therapy. Nurses and pharmacists should exercise their professional judgement with regard to administering salbutamol. If there is any doubt as to the patient’s suitability they should be discussed with a GP:
  - Hyperthyroidism
  - Cardiovascular disease
  - Arrhythmias
  - Susceptibility to QT-interval prolongation
  - Hypertension
  - Thyrotoxicosis
  - Diabetes.

- In addition the administration of salbutamol via a spacer should be restricted during pregnancy or breast-feeding to situations where the benefit to the mother is likely to outweigh any potential risk to the foetus/neonate.

- Patients should not have used other bronchodilators within the time periods given below as this would affect the outcome of the lung function test results.
  - Short acting beta₂ agonists within 4 - 6 hours.
  - Long acting beta₂ agonists within 12 hours.
  - Long acting muscarinic or long acting oral theophylline preparations within 24 hours.

- Salbutamol inhalation may rarely cause paradoxical bronchospasm with an immediate increase in wheezing after administration. Medical advice should be sought immediately if this occurs.

- Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse are very rare. Refer to Patient Group Direction for the administration of adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals.

**Referral criteria**

Patients who fall into the categories detailed in the exclusion criteria.
| **Action if excluded from treatment** | If a patient is excluded from this PGD because of life threatening asthma, then the PGD for administering salbutamol nebulised through oxygen should be immediately used, and medical support sought.  
If a patient is excluded from treatment under this PGD because of reasons other than life threatening asthma, medical advice should be sought – refer to a doctor.  
The reason why the patient was excluded under the PGD will be documented in the patient’s medical notes. |
| **Action if patient declines treatment** | Patient should be advised of the risks and consequences of not receiving treatment.  
Record outcome in Patient Medication Record if appropriate and refer the patient to their General Practitioner/Consultant (relevant medical practitioner). |
| **Consent** | Prior to the administration of the drug, valid consent must be obtained. Consent must be in line with current NHSG “Staff Policy for Obtaining Consent for Clinical Procedures and Healthcare Interventions”. See link below.  
| **Description of treatment available under the PGD** | **Name of medicine** | Salbutamol 100 microgram pressurised metered dose inhaler (pMDI) |
| **Legal status** | Salbutamol 100 microgram pMDI is a Prescription-only Medicine (PoM). |
| **Form/Strength** | Pressurised inhalation, suspension. Each metered dose contains 100 micrograms salbutamol (as sulphate). |
| **Route/Method of administration** | Salbutamol should be administered via a spacer which should be compatible with the pMDI being used. |
Always shake inhaler before use.

The clinician must ensure the patient does not touch the pMDI during the test and to minimise any risk of cross infection, ensure that between patients, the mouthpiece and casing of the device are cleaned as per manufacturer’s instructions. Most salbutamol pMDIs contain 200 doses of 100mcg and subsequently should last for up to 50 tests but expiry dates and any damage to the pMDI should always be checked prior to use.

The salbutamol pMDI does not need to be single patient use, **but only if used for the purpose of this PGD.** It can be re-used in future tests if stored as described in storage section.

<table>
<thead>
<tr>
<th>Dosage/Total Dose</th>
<th>Adults 16 years of age and older:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dose</strong></td>
<td>400 micrograms (4 puffs or actuations) - This should be administered as one actuation of 100mcg at a time into the spacer. Each actuation should be followed by 5 tidal breaths by the patient using the spacer. After each cycle of actuation and 5 tidal breathes, wait 30 seconds and repeat again shaking the inhaler between each actuation. Do this a total of 4 times.</td>
</tr>
<tr>
<td>Frequency of administration</td>
<td>4 puffs or actuations, once only</td>
</tr>
<tr>
<td>Maximum effect of medication</td>
<td>15 Minutes</td>
</tr>
</tbody>
</table>

| Duration of treatment | Single dose of 400 micrograms. |

<table>
<thead>
<tr>
<th>Storage requirements</th>
<th>The salbutamol inhaler should be stored in a locked cupboard below 30°C, protected from frost and direct sunlight.</th>
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<tbody>
<tr>
<td></td>
<td>As with most inhaled medications in aerosol canisters, the therapeutic effect of this medication may decrease when the canister is cold. The canister should not be broken, punctured or burnt, even when apparently empty.</td>
</tr>
<tr>
<td></td>
<td>Spacers are intended for single patient use only and after the test should be either given to the patient for home use (if the presence of respiratory disease is confirmed) or discarded.</td>
</tr>
<tr>
<td>Follow-up (if applicable)</td>
<td>Patients should not leave if they are feeling at all unwell without speaking to the nurse or pharmacist first. If necessary a doctor or the patient’s GP should be contacted for advice. The test results should be documented and the patient asked to see their GP or practice nurse to discuss the results or any possible new diagnosis in greater detail.</td>
</tr>
<tr>
<td>--------------------------</td>
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</tr>
<tr>
<td>Advice to patient (Verbal)</td>
<td>Advice should be given on what to expect and what to do for major and minor reactions.</td>
</tr>
</tbody>
</table>
| Advice to patient (Written) | The Patient Information Leaflet (PIL) contained in the medicine(s) should be made accessible to the patient, parent, guardian, or person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.  

Copies of PIL and SPCs for all medicines can be found at [http://www.medicines.org.uk](http://www.medicines.org.uk) or [http://www.mhra.gov.uk/spc-pil/index.htm](http://www.mhra.gov.uk/spc-pil/index.htm) |
| Concurrent Medications/Drug Interactions | Propranolol and other non-cardioselective β-adrenoceptor blocking agents antagonise the effects of salbutamol and should not usually be prescribed together. Salbutamol may therefore be less effective in patients on long term β-blocking therapy.  

Monoamine oxidase inhibitors, tricyclic antidepressants and digoxin increase the risk of cardiovascular effects.  

Hypokalaemia occurring with β2 agonist therapy may be exacerbated by treatment with xanthines, steroids, diuretics and long-term laxatives. |
| Identifying and managing possible adverse reactions | Common side effects include headache, dizziness, fine tremor (particularly in hands) and tachycardia.  

As with other inhalation therapy, paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with an alternative presentation or a different fast-acting inhaled bronchodilator. Salbutamol via large volume spacer should be discontinued immediately, the patient assessed, and, if necessary, alternative therapy instituted. |
This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SPC for details of all potential adverse reactions.

**BNF:**  
[https://www.medicinescomplete.com/mc/bnf/current/](https://www.medicinescomplete.com/mc/bnf/current/)  
[https://www.medicinescomplete.com/mc/bnfc/current/](https://www.medicinescomplete.com/mc/bnfc/current/)

**SPCs/PILs:**  
[https://www.medicines.org.uk/emc/](https://www.medicines.org.uk/emc/)  

If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.

Report the reaction to the MHRA using the Yellow Card System.  
[https://yellowcard.mhra.gov.uk/](https://yellowcard.mhra.gov.uk/)

### Medical advice in cases of anaphylaxis

Injections of IM adrenaline/epinephrine 1:1000 must be available to treat an anaphylactic reaction should this occur. Medical advice must be sought as soon as possible from a doctor if any patient develops any signs of hypersensitivity. If there is a delay in medical support arriving and the condition of the patient is deteriorating then an emergency ambulance must be called on 999 or direct via ambulance control or dial 2222 (hospital internal) according to local procedure, or seek urgent medical advice. (Refer to Patient Group Direction for the administration of adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals)


### Facilities and supplies required

The following should be available at sites where the medication is to be administered:

- Appropriate storage facilities.
- An acceptable level of privacy to respect patient’s right to confidentiality and safety.
- Resuscitation equipment.
- 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.
- Copies of the current PGD for the medicine specified in the PGD.
- PGD for the administration of Adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals.

### Characteristics of staff authorised to supply/administer medicine under PGD

<table>
<thead>
<tr>
<th>Professional qualifications</th>
<th>Registered Nurses as recognised by the Nursing and Midwifery Council (NMC) and Pharmacists whose name is currently on the register held by the General Pharmaceutical Council (GPhC).</th>
</tr>
</thead>
</table>
| Specialist competencies    | Be competent to assess the patient’s capacity to understand the nature and purpose of the administration in order for the patient to give or refuse consent.  
Has undertaken appropriate training to carry out clinical assessment of patients leading to a diagnosis that requires treatment according to the indications listed in the PGD. 
Be aware of current treatment recommendations and be competent to discuss issues about the drug with the patient. 
Have been trained and assessed as being competent in the administration of the drug. |
| Ongoing training and competency | Have attended basic life support training which is required to be updated annually.  
Have undertaken the NHS e-anaphylaxis training session (and annual updates) which covers all aspects of the identification and management of anaphylaxis. This can be accessed via eKSF, or the AT Learning® tool.  
Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.  
The practitioner must be familiar with the SPC for all medicines supplied in accordance with this PGD. |
| Professional managers/Lead Nurses will be responsible for | Ensuring that the current PGD is available to 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 drug specified in PGD. |
| --- | --- |

**Documentation**

| Authorisation of administration | Nurses working within NHS Grampian can be authorised to administer the drug specified in this PGD by their Nurse Manager/Consultant/practice GPs. Pharmacists working within NHS Grampian can be authorised to administer the drug specified in this PGD by the Director of Pharmacy.  
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 doctor/manager should be supplied. This should be held in the individual practitioners records, or as agreed locally. |
| --- | --- |

| Record of administration/supply | An electronic or paper record for recording the screening of patients and the subsequent administration of the drug specified in this PGD must be completed in order to allow audit of practice. This should include:  
- Name and address of patient  
- Patient CHI No and date of birth  
- Details of parent/guardian, or person with parental responsibility where applicable  
- Consultant/General Practitioner details  
- Risk group, if appropriate  
- Findings of physical examination, if appropriate  
- Exclusion criteria, record why the drug was not administered  
- Reason for giving  
- Consent to the administration (if not obtained elsewhere)  
- Signature and name in capital letters of practitioner who administered the drug  
- Date drug given  
- Record of any adverse effects (advise patient’s doctor). |
| --- | --- |
These records should be retained:

**For children and young people**, retain until the patient's 25th birthday or 26th if the young person was 17 at the conclusion of treatment.

**For 17 years and over** retain for 6 years after last date of entry, for 3 years after death, or in accordance with local policy, where this is greater than above.

**Audit**

All records of the drug specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each H&SCP/practice/service will be responsible for auditing completion of drug forms and collation of data.

**References**

Medicines and Healthcare products Regulatory Agency

http://www.mhra.gov.uk/spc-pil/index.htm

Salbutamol Sulphate 100 micrograms Inhaler—Date of revision of text 23/03/16, accessed 02/11/16

British National Formulary

https://www.medicinescomplete.com/mc/bnf/current/ accessed 02/11/16

**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

Frances Adamson  Medicines Management Specialist Nurse  
Susan Allan  Practice Nurse, Peterhead Health Centre  
Anne Casson  Long Term Conditions, Anticipatory Care Nurse Specialist  
Alison Davie  Pharmacist: Lead Pharmacist Aberdeen City H&SCP  
Kris McLaughlin  GP, Stonehaven Health Centre  
Morag Reilly  Lead Author: Respiratory Lead Aberdeen City H&SCP
Authorising Managers

Dr Nick Fluck
Medical Director, NHS Grampian

Mr David Pfleger
Director of Pharmacy and Medicines Management, NHS Grampian

Professor Amanda Croft
Director of Nursing, Midwifery and AHPs, NHS Grampian
Appendix 1

Health Care Professional Agreement to Administer Medicines Under Patient Group Direction

I: _________________________________ (Insert name)

Working within: _________________________________ e.g. H&SCP, Practice

Agree to administer medicines under the direction contained within the following Patient Group Direction

**Patient Group Direction For The Administration Of Salbutamol Via A Spacer By Nurses and Pharmacists Working Within NHS Grampian For Post Bronchodilator Lung Function Assessment Or Reversibility Testing**

I have completed the appropriate training to my professional standards enabling me to administer medicines under the above Patient Group Direction. I agree not to act beyond my professional competence nor outwith the recommendations of the Patient Group Direction.

Signed: _________________________________

Print Name: _________________________________

Date: _________________________________

Professional Registration No: _________________________________
Certificate Of Authorisation To Administer Medicines Under Patient Group Direction

This authorises: __________________________

Working within: __________________________ e.g. H&SCP, Practice

To administer medicines under the following Patient Group Direction

Patient Group Direction For The Administration Of Salbutamol Via A Spacer By Nurses and Pharmacists Working Within NHS Grampian For Post Bronchodilator Lung Function Assessment Or Reversibility Testing

The above named person has satisfied the training requirements and is authorised to administer medicines under the above Patient Group Direction. The above named person has agreed not to act beyond their professional competence nor outwith the recommendations of the Patient Group Direction

Signed: __________________________ Authorising Manager/Doctor

Print Name: __________________________

Date: __________________________